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UNIVERSITY OF OKLAHOMA

GRADUATE COLLEGE

INSTITUTIONAL REVIEW BOARDS: POLITICS, POWER, PURPOSE AND PROCESS IN A REGULATORY ORGANIZATION

A Dissertation

SUBMITTED TO THE GRADUATE FACULTY

in partial fulfillment of the requirements for the

degree of

Doctor of Philosophy

By
ANN FOLSOM HAMILTON
Norman, Oklahoma
2002

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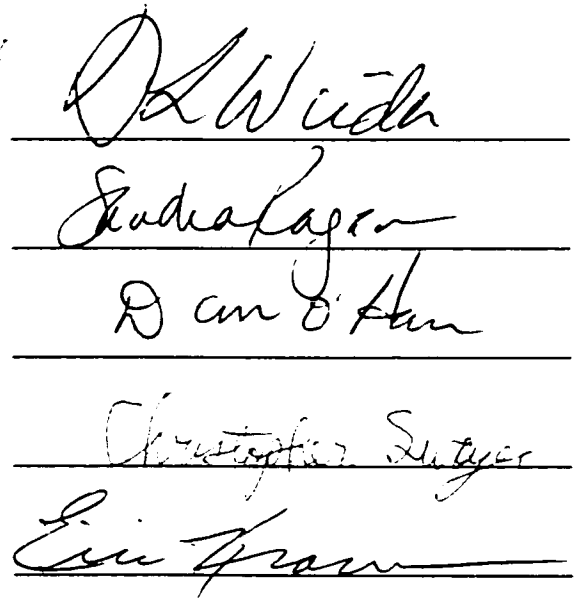
A Dissertation APPROVED FOR THE

DEPARTMENT OF COMMUNICATION

BY



Acknowledgments

I am thankful for my roots: Linnie, Frank, Dorothea, Sara, Kelly, Kerry, Betsy, Michele, Brooke, Mark, Emily, Dylan, Aaron, Sean, and Jennifer.

And for my advisors and friends: Ken, Angie, Sandy, Amir, Yuri, Mitchell, Eric, Dan, Chris, and EdLee.

I am especially grateful for my advisor, D. L. Wieder.

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Abstract

This organizational communication study involves critical analysis/ideology critique of regulation, and deconstruction and resistance readings of texts produced by the human subjects regulation system in the U.S. This regulatory organization includes federal government agencies and local entities called Institutional Review Boards (IRBs). Information related to the historical development of the IRB system is provided, along with analyses of federal and local systems and the relationships among the regulators, researchers, and the researched. Textual data include IRB application forms, the Human Research Subject Protection Act of 1997, and several reports from executive, legislative, and administrative entities.

Underlying theoretical support is found in Marx, Horkheimer, Adorno, Schutz, and Baudrillard. The work of constructionists is also employed, including Goffman, Mead, Berger and Luckmann. Additionally, the ideas of Foucault, Habermas, Derrida, and Lyotard are utilized, in particular discursive formations and relationships of power (Foucault), cultural reproduction and instrumental technical reasoning (Habermas), deconstruction, particularly language (Derrida), and performativity (Lyotard). More recent applications of ideas in this vein are found in the critical management studies of Deetz, Alvesson, Manning, and others; these works serve as models for the present study.

An analytical device, (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS, was developed. Through utilization of (SINS), each term or portion of text can be viewed as a social *Structure* at various levels of operation (from widely held beliefs to regional, local, and individual ones), and/or as an *Institutionalization* of Structures, or ways these Institutionalizations become *Naturalized* in the lives of individuals, or, finally, in the *Simulations* created with increased detachment of structures (regulations) from the lifeworld (the research environment).

Alternatives are offered for consideration: 1) use of more precise terms, for example, distinctions between participant/patient, doctor/researcher, and therapy/research); 2) developing different rules for social research, particularly qualitative methods involving no treatment and/or "minimal risk"; 3) insisting regulators focus on treatment when making decisions and contemplating rules; 4) developing realistic attitudes about what regulation of any kind can do; and 5) engaging in and encouraging passive rebellion, i.e., rejecting local systems in favor of federal standards for exemption from IRB processes when studies involve only "minimal risk."

Chapter One: Introduction

> *"But here let me say that no one should suppose it could ever be possible to devise a set of rules or laws to provide us with the answer to every ethical dilemma ... such a formulaic approach could never hope to capture the richness and diversity of human experience. It would also give grounds for arguing that we are responsible only to the letter of those laws, rather than for our actions."* The Dalai Lama, *Ethics for The New Millennium*, p. 27.

Regulation of human subjects research is tricky and important business, occurring in social, political, academic, and economic environments. It affects individuals not only as regulators, researchers, and participants in research, but as members of society, politicians and the political, academics and intellectuals outside the academy, and people with a variety of economic interests.

Institutional Review Boards (IRBs), charged with approving, revising, and/or rejecting research proposals, regulate researchers most directly (although researcher self-regulation may be more prominent, as discussed later in this chapter, p. 33-34; also see Alvesson & Deetz, 1996, especially p. 205). IRBs—not too indirectly—affect which research projects will or won't be undertaken as researchers become conditioned, entrenched within (often invisible) unquestioned boundaries set by the regulatory system in the larger social context.

The present work may best be described as a critical organizational communication study, or a critical study of regulatory "management" (as described by Alvesson & Deetz, 1996 and 2000; Alvesson & Willmott, 1992; Alvesson & Sköldberg,

2000; see also Redding & Tompkins, 1988). Texts produced within and around the IRB system are utilized as data, and methods include Foucauldian analyses (Foucault, 1972; also see Manning, 1989, in his examination of the Nuclear Installations Inspectorate, especially p. 217-233) and resistance readings of the texts, as well as other critical methods. The Institutional Review Board regulatory system, especially as it applies to certain qualitative and survey methods (methodological distinctions are described in more detail below), is in need of scrutiny (see DHHS OIG 1998b, 2000b; GAO, 2001). The purpose of the study, ultimately, is to make an effort to change this system. This will require, as I argue herein, changing the view of individuals toward the system. This study is designed to enhance understanding of the ways texts work to produce negative effects and an overly restrictive regulatory situation in social science. As described by Redding and Tompkins (1988), the critical perspective within the field of communication involves issues of emancipation and empowerment, material interests and who possesses them, conflict and struggle over meaning, domination, instruments of oppression, power relationships, distorted communication, infinite realities, ideology, and hegemony (see also Alvesson & Willmott, 1992, and Alvesson & Deetz, 2000).

"To a greater or lesser extent, politics suffuses all social scientific research (Guba & Lincoln, 1989, p. 125; see also Forester, 1989, p. 3-4). The bureaucratic suffusion of politics into research and some of its consequences is illustrated by the problems created by the Bush administration's efforts to regulate the quality of scientific information released by federal agencies. This is an effort to hold federal agencies more accountable for the money they receive (*i.e.*, the guidelines are not

necessarily purported to have anything to do with science directly, though it is likely the rules will affect scientists, and therefore, science) according to sources reported in Brainard (2002, Mar 29b). An example is Bush administration standards "to govern the quality and objectivity of scientific information released by federal agencies" (Brainard, 2001, Sep 28, Daily News) released in 2001 (Office of Management and Budget, [OMB], 2001, Oct 1). A number of difficulties (such as defining "quality," "utility," "objectivity," "integrity," "influential" findings, and even "affected party") and typical problems associated with attempts to standardize exist with the rules. (If scientists at the National Weather Service deliver a "low quality" forecast, are they to re-issue a "quality" forecast after the fact? And, as will be discussed at several points herein, the likelihood of finding definitions that hold across the broad spectrum of research types is slim. For example, what constitutes "quality" varies among clinical, social, and critical research methods, as does the role of "objectivity" and perhaps most significantly, the types of treatments, risks, or lack of them.) Of particular concern is the requirement that research findings released by federal agencies be "capable of being substantially reproduced," suggesting the agencies could somehow "ensure the results could be verified independently" according to Brainard (2001, Sep 28, Daily News). The Office of Management and Budget (OMB) states that peer review may not be sufficient (OMB, 2001, Oct 1), at least indirectly suggesting that bureaucrats/regulators might somehow be better suited to assess the quality of research. Finally, OMB statements indicate a recognition that problems are inherent in "developing detailed, prescriptive, 'one-size-fits-all' government-wide guidelines" yet the agency proceeds to offer guidelines

anyway, stating the guidelines were designed "to be generic enough to fit all media, be they printed, electronic, or in other form" implying the form of the *dissemination* of information rather than the gathering and analysis of information (or as mentioned, the treatment to be used) is the reason one size doesn't fit all. It also appears inherently problematic (probably impossible) to make meaningful guidelines "generic enough to fit all." These statements are, I argue, offered to meet political ends more than practical ones.

Most research is conducted in universities (Walker, 1996, Nov 8), and these activities are subsequently used as baselines by government to devise regulations. Government rules, in effect, supercede individual researcher's desires, under the premise that researchers must be at least indirectly supervised, can't be left to their own devices, *i.e.*, they can't be trusted, and this view is reinforced by the OMB statement devaluing peer-review quoted in the previous paragraph. If Bush's recommendations are implemented, it will not necessarily be scientists who judge science, but regulators (who may or may not be researchers, *i.e.*, no provisions are made for ensuring experienced researchers are selected as regulators, nor are there rules/guidelines requiring/suggesting that various methodologies be represented in the regulatory apparatus) will judge the "quality and objectivity" of studies and results. As I will show, regulators already do have more to do with what kind of "science" is conducted and in what ways than any other group.

It is not the *purpose*, but the *process* of human subjects regulation (particularly as it is applied to many social scientific methods) that is absurd. Re-opening these

processes to scrutiny (via critical analysis) more readily leads to identifying and remedying problems (see Alvesson & Willmott, 1992; Alvesson & Deetz, 2000; Horkheimer, 1937/1976; Adorno, 1989a; Horkheimer & Adorno, 1944/1972). Some of the most controversial leading edge projects (gene therapy, stem cell research, and genetic engineering in agriculture are current examples)[1] are difficult for regulators to categorize, consider, or control. Yet, the common regulatory response to new areas of research (or atrocities) is to make more rules (see Office of Protection from Research Risks [OPRR, 1999], especially the section entitled "An opportunity for federal leadership," p. 13). These rules often have unintended effects (and do not meet the intended purpose). We stay mired where we never should have walked, bogged in what Baudrillard (1983) calls a cultural simulation—substituting signs (rules, words) for reality, making no distinction between the process and reality, normalizing

[1] Regarding gene therapy in general, see Robertson, 1993, Nov 24; and Walker, 1996, Nov 8. For developments during the Clinton administration, see Andrews, 1999, Jan 29; Brainard, 1999, Dec 13; Wheelwright, 2001, Jan; Southwick, 2000, May 12; and Southwick, 2000, Aug 24. George W. Bush's policies are covered in Bash, 2001, Jul 18; and Southwick, 2001, Aug 10. Related issues and views are discussed in Schmidt, 2001, Apr 6; Frontline's "Organ Farm," a two-part report that aired Mar 27 and Apr 3, 2001, on PBS, see http://www.pbs.org/wgbh/pages/frontline/shows/organfarm/, accessed May 25, 2002; Kahn, 1998, Jan 26; Kahn, 1999, Jun 1 and 2000, Aug 22; CNN.com, 2000, Aug 24; and CNN.com, 2000, Sep 14. Regarding the use of stem cells, particularly controversial because of the relationship to the abortion debate, has celebrity and political endorsements, see Kiely & Hall, 2001, Aug 8; and in particular, Mary Tyler Moore's comments in E. Berger, 2001, Jul 11; Christopher Reeve's in Cohen, 2001, Mar 8; Orrin Hatch's in CNN.com, 2001, Jul 17; and Arlen Specter's comments in Healy, 2000, May 12. On the other side of the debate, and speaking to the notion that science *and* religion are politics, see Pope John Paul's position statement in CNN.com, 2000, Aug 29, and finally for an outgrowth of the debate, *i.e.*, the lifting of the moratorium on stem cell research, see NIH, 2000, Aug 24. See also Patagonia's corporate publication (2002, Spring) for a summary of thoughts about genetic engineering of crops, and *Atlantic Monthly* (Weinberg, 2002, Jun) for an *actual molecular biologist's* view of cloning and important distinctions among various types, in particular reproductive cloning versus therapeutic cloning. Note that these "new" areas of research have been debated, as indicated in this list of citations, for at least 10 years by diverse groups in diverse publications.

meaninglessness (see Baudrillard, 1983, p. 4).[2] Attempting to predict disasters and control the research world with one set of rules for all treatments—spanning at least from observations of the natural environment (too often contaminated when regulatory requirements are followed, as I will argue) near one end of a continuum to installation of devices and drugs into (often desperately sick and vulnerable) peoples' bodies (near the other extreme)—is fallible, dubious (and ludicrous) behavior.

Other considerations make the IRB system an interesting site for study, and a timely one. Developments in the world, particularly in the economic domain, affect research. Medical research is becoming more and more a commercial enterprise (Schmidt, 2002, Mar 29; DHHS OIG 2000a; Blumenstyk & Wheeler, 1998, Mar 20); lines between academia and *commercialia* are blurrier than they have been previously[3] and many administrators (and legislators and governors[4]) applaud this.[5] It is also

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[2] Also, Bormann (1972) contends, "the events may not be the things or 'reality' but the words ... are the social reality and to try to distinguish one symbolic reality from another is a [widespread] fallacy," p. 401).

[3] See Blumenstyk, 2002, May 17, re: the (lack of) rights of researchers to their own ideas.

[4] About the moves by several states to commercialize research, Schmidt (2002, Mar 29), writes that most of the efforts "have been politically popular" (as they have been positioned as economic development incentives and even by Gov. George Pataki of New York as "for the emerging homeland-security industry," as quoted by Schmidt, p. A26), and Schmidt adds, "have met little organized resistance on campuses or elsewhere" (p. A26).

[5] Lyotard (1984) suggests "The games of scientific language become the games of the rich, in which whoever is wealthiest has the best chance of being right. An equation between wealth, efficiency, and truth is thus established" (p. 45). Mary Faith Marshall, director of the bioethics program at the Medical University of South Carolina, states "What you see is a fear by administrators and researchers that if the public's confidence in their research and ethics is undermined, [scientists] will in the future no longer be able to support their research, because they depend on tax money" ... "And I think that's appropriate," she concluded (quoted in Brainard, 2000, Mar 17, p. A31). Cho (1997, Aug 1) reported that in a 1996 study of journal articles, in one-third of the articles sampled the first author listed had a financial conflict of interest, *i.e.*, being a patent holder or shareholder, and that evidence indicated that not only was the potential for financial gain leading to changes in researchers' behavior, but also that industry made attempts to alter the timing and content of scientific research reports. (See also Mangan, 2000, May 26; Blumenstyk & Wheeler, 1998, Mar 20; Blumenstyk, 1999, Apr 9; DHHS OIG 2000a.)

reasonably apparent that conflict of interest issues become more prominent when money is involved (and when researchers are invested in their findings[6]).

Academics serve business.[7] According to Kenneth Getz, Director of Center Watch in a telephone conversation cited May 26, 1998, and reported by the Department of Health and Human Services, Office of Inspector General (DHHS OIG, 1998d), "The clinical research market is roughly a $4 billion market. It is estimated that about 75 percent of clinical research is industry-sponsored" (p. A-1)[8]. And, of course, independent social scientists conduct large amounts of market research, product development research, and other studies directly sponsored by industry. "The amount of interest in encouraging the commercialization of university-developed technology has just exploded," said Dan Berglund, the president of the State Science and Technology Institute (as quoted in Schmidt, 2002, Mar 29, p. A26), and Berglund indicated he thinks there is no question that the view of the role of universities in most states is

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[6] See Choudhry, et al. (2002, Feb 6) re: doctor's self-reported influence from drug companies; Boseley (2002, Feb 7) re: scientists to take money for papers ghostwritten by drug companies; and Deetz (1995) who says "Economic inequalities become political inequalities; without a means of contestation, such conflicts are suppressed. All rationality is reduced to economic rationality" (p. 133). I suggest that the decisions (on the part of universities) to allow drug companies (with their obvious interests) to have so much control in the research environment, as well as journals that allow results to be published when researchers are financially invested in the product they are testing are evidence that Deetz is right. I have described this elsewhere as the-right-to-make-a-profit-at-any-cost mentality. Finally, Adorno (1989b) states, "Profit comes first. A humanity fashioned into a vast network of consumers ...behind the reduction of men to agents and bearers of exchange value lies the domination of men over men" (p. 271). Doctors and researchers are dominated by drug company stockholders.

[7] "Academics, particularly those in management studies, are often viewed as ideologists. They serve dominant groups through socialization in business schools, support managers with ideas and vocabularies for cultural-ideological control at the workplace level, and provide the aura of science to support the introduction and use of managerial domination techniques" (Alvesson & Deetz, 1996, p. 199; Giroux, 1988, presents an alternate view, see footnote # 74, p. 65, herein).

[8] The tendency is toward more infusion of capitol. President Clinton issued an executive memorandum in June 2000 directing the Medicare program to "revise its payment policy and immediately begin to explicitly reimburse providers for the cost of routine patient care associated with participation in clinical trials, and to take additional action to promote the participation of Medicare beneficiaries in clinical trials for all diseases" (The White House, Office of the Press Secretary, 2000, Jun 7, p. 1).

changing. And in summarizing a corporate movement against genetic engineering of crops, Patagonia points out one of the rather obvious conflict-of-interest issues in this situation. "The underwriting of science by corporations (through university grants) certainly influences the studies agricultural scientists pursue, or don't" (Patagonia, 2002, Spring; see also Tacio, 2002).

From personal relations within, between, and among researchers across several communication genres and related areas of study, to complex university research environments, and further, to the powers and policies of the federal government research entities, these contexts and their attendant constraints substantially influence research design, implementation, and, consequently, outcomes (see Gubrium & Silverman, 1989).

Issues surrounding the roles of Institutional Review Boards (IRBs) are of critical importance in academia, and central to the functioning of the research environment. To test and adopt methods, procedures, boundaries for claims, and to make discoveries have existed as the primary goals of science since The Enlightenment. And since that time, with more and more frequency, these tests involve the use of human subjects. Further, from the apodictic to the assertoric, a persistent temptation exists to apply procedures, methods, claims, and more recently, regulation developed for the medical sciences to social sciences.

The IRB regulatory system is nonsensical as it relates (or fails to relate) to many social science methods; the rules are often not right or wrong, but ill fitting and irrelevant. For example, federal and local regulators describe their rules as "minimal

standards," the "basement" or "foundation" for the regulation of research (as is expressed in many of the Office of Human Research Protections (OHRP) documents cited herein, and these descriptions are based, in part, on the notion that the federal government should operate in a way that creates the least restrictive environment for those regulated, especially in matters related to public health and safety, areas of rule-making generally reserved to the states.) For some proposed treatments, (and particularly non-treatment observation) federal regulation alone is hardly a foundation. It is inapplicable or unduly restricting, though substantially less so than layers of "more rigorous" standards (often perceived as virtuous) imposed proudly[9] by local IRBs.

In this attempt (even presumption) that one-rule-fits-all-methods, it is perhaps clear that both the rules and the methods are well established. It does not follow however that the rules and the methods work well together. The regulatory system and many qualitative methods are and have always been incompatible. Qualitative researchers have acquiesced, conceded, and have become involved in this regulatory

[9] Because of restrictions a news reporter would not encounter, I cannot use—as data—information from an open forum I attended during 2001. However, references to statements made in this forum and those made during conversations I have been a part of during the years are presented as "loose" recollections, (although few in number are contained in this document) appearing perhaps weakly worded, lacking in detail, or vague. I do have field notes of these encounters, which include much detail: names (coded), dates, times, and places. Further, I have permission from the people with whom I have spoken to use their comments (except in the cases involving public officials, when such permission is not necessary to obtain). Under the local (and I will argue, unlawful) interpretation of IRB rules, however, I am restricted in the use of this data. I *will* say (under what I consider to be rightful ownership and subsequent right to the use of my own life experiences) that I recall a time in an open forum conducted by local and federal regulators when the local regulators repeatedly, as a matter of arguing their virtues, indicated the local restrictions were "more rigorous" than the federal ones, and the federal regulators in attendance, again, just in my recollection, echoed the comments of their local counterparts by describing federal regulations as the "basement" or "foundation" of the system. I will argue this is not the case, particularly for many social scientific approaches, especially where no treatment is involved; that federal and local rules contribute to restriction (in terms of topic and method) and represent debilitating intrusion rather than a "minimal foundation." I will argue, further, that local interpretations are to a very great extent uninterpretable and, therefore, greatly meaningless.

process against their will and sensibility (see O'Connor, 1979; Klockars, 1979; Wilkins, 1979; Whyte, 1987; Punch, 1998; Flyvbjerg, 2001).

Human Subjects Regulation Issues for Consideration

Several questions should be re-opened with respect to the IRB system, including this positivistic bias described by Knights.[10] And Agar (1980) suggests that the intent[11] behind the "bureaucratic feeding frenzy" is a good one, "but the procedures[12] are becoming an annoyance that may or may not have anything to do with insuring that the intent is realized" (p. 183). Not only is there a lack of whying[13] on the part of researchers, but also researchers (and regulators) are asking "wrong" questions about the IRB process. For example, qualitative researchers find themselves asking "How do I make a successful application?" or "When might I know whether my protocol is approved?" rather than "Why should I ask for approval?" And IRB and other regulators are asking questions of researchers that many perceive to be beyond the scope of the regulators' interests (see Brainard, 2000, Mar 17; 2001, Mar 9; and Campbell, 1998, Apr 3).

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[10] Another example of this bias comes from a GAO report (1991b) that makes the assumption "given the need to collect uniform data from numerous persons or organizations..." (p. 10) when describing ways to evaluate or choose interview methods. I would suggest "uniform" data is often contrary to the goals of much interviewing, and is not in the interest of "thick" ethnographic descriptions, as described by Geertz. Further, the use of the term "many" is meaningless across methods, and even within them, as there is and has been traditionally much debate about what constitutes "adequate" samples and sample size.

[11] *i.e.*, purpose

[12] *i.e.*, processes

[13] Adorno (1989a) speaks about "unquestioned, unanalyzed, and undialectically presupposed" perpetuation of processes (p. 133), and in 1989b, he says "Situation[s] are unreconciled, contemplated without theory, in a kind of mental asceticism, and what is accepted thus ultimately comes to be glorified: society as a mechanism of collective constraint" (p. 270). Foucault's genealogy analyzes practices that "were instituted in the name of reason but that threaten to harden into unquestioned but oppressive

It seems the regulatory system may have abundant form but inadequate, if even existent, substance. Atrocities and infractions happen that rules, *i.e.*, administrative law in the case of IRBs, are in place to prevent. Conversely, many people who have no knowledge of the rules often "follow" them. There are rules that are ignored and therefore do not work; there are rules that cannot be understood and therefore do not work; there are rules that are unknown and therefore do not work; and there are rules that are unlawful themselves that may or may not, and maybe should not work; there are rules that allow unsafe or exploitative behaviors and certainly should not work[14]; there are interpretations of rules and therefore they do not work consistently, and so on. The inherent fallacy that rules are doing what they call for on the surface has perhaps even deeper roots in criminal law.

Regarding form, if a research study proposal is standardized, "normal," has been done before, or "contributes to the body of knowledge," it is perceived to be safe, *i.e.*, less risky in a legal sense. It appears these pseudo-qualities take considerable priority over saying anything important, significant, risky, difficult, or interesting. This is not to imply that a research project can't both conform to IRB regulations (or other rules such as those presented in stylebooks) and render interesting results, but that occurrence is as likely to be by coincidence as by design.

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necessity" (Hoy & McCarthy, 1994, p. 148). This is what I mean by whying. I use this term (rather than "questioning") because of its euphonic resonance with whining.

[14] See Shogan & Ford, 2000, for an example involving doping in competitive sports.

Regulators have demonstrated their concern, and appear frustrated and confused (see DHHS OIG, 1998b-e, 2000b; GAO, 2001) [15]. Federal regulators and members of local IRBs find themselves in a somewhat common bureaucratic situation of administering rules that no longer fit the affairs they are to control as evidenced by the steady stream of calls for and actual issuances of "updates" in virtually every regulatory system one could imagine and also evidenced by the steady pressure on the regulatory organization from inside and out (see Brainard, 1999, Nov 18; 1999, Dec 13; 2000, Feb 4; and 2000, Sep 13; AAUP, 2001; Ellis testimony, U.S. House, 1998, Jun 11, and others cited later) to acknowledge deficiencies in the rules, particularly as the deficiencies pertain (or not) to new areas of research, as mentioned above (*i.e.*, stem cell and gene therapy research, as examples).

"Real" unregulate-able life keeps appearing. Reactionary responses to media "heat" lead to rule quagmires, for example the Bush administration's guidelines mentioned early in this chapter. Defining terms related just to these regulations has taken more than a year, and may never be "finished." Another example is the case of oral history: older people who are most often the participants in historical research constitute a protected class under IRB rules. Difficulties in getting these studies approved have increased according to the Association of Oral Historians (see American Association of University Professors, AAUP, 2001). (Far from being harmed, many of these elderly participants are eager to share their stories; interaction and attention of this

[15] Puglisi, former director of human subject protections in the OHRP/OPRR and having 20 years of experience in the protection of human research subjects, also states, "If no one at your institution has the expertise [to answer questions about IRB expectations or requirements] call OHRP or email me..." (Puglisi, 2001, p.3).

kind has been shown to have positive benefits (see intergenerational literature, particularly Baumhover & Beall, 1996, and this situation, I would suggest, is an example of the Hawthorne effect, *i.e.*, attention and being asked about oneself is positive, often enhancing the self esteem of people.) Even the idea that these researchers are required to make application to an IRB is unknown to many of these historians and unreasonable to many more (see Brainard, 2001, Mar 9).

Bureaucracies are often ill equipped to handle the issues of the day (or the volume of the week). Rules are outpaced by "real" life, with which we must eventually contend. "Real" life is dynamic, and, by definition, ambiguous. It is a liquid target, and a local phenomenon. While a variety of thresholds exist for various participants' suggestions about the dysfunctional aspects of the IRB (or any) system, eventually nearly all participants will describe some aspect of the system as deficient, absurd, frustrating, unreasonable, etc., whether they are regulators, regulatees, or regulatands. For example, regulators, often politically appointed and motivated, point out the "problems" (deficiencies) with the former administration's regulatory efforts, or regulators themselves indicating they don't understand how to apply a rule, or even how to explain it to regulatees. In turn, regulatees often criticize the system as unreasonable and vague (deficient). These criticisms are justifiable: The system *is* deficient, unreasonable, and absurd if regulators can't explain rules to researchers, and neither group can explain adequately the rules to participants in research. Actual observation of the informed consent process as it occurs between researchers and participants is rare. One of the only occasions for close scrutiny of this process occurs when an

investigation of an infraction occurs. In many cases the participants indicated they did not even understand the basic difference between research and treatment (see Advisory Committee on Human Radiation Experiments [ACHRE], 1995; DHHS OIG, 1998b, 2000b). This of course is perhaps the most important "minimum standard" and is frequently not met in part *because* of the complexity and interpretation and execution of the rules.

In other cases, researchers are sometimes confused, according to IRBs interviewed by Department of Health and Human Services (DHHS) investigators (DHHS OIG, 1998b), about what types of research need to be submitted to the IRB. New objects of study and new methods to address questions emerge continually (and thankfully) and, while emerging ideas often contribute to better understandings, they also contribute to regulatory confusion (emerging ideas are, by definition, non-standard). However, researchers don't call into question (often enough, loud enough, or with a broad enough scope) the limitations of the regulatory process itself (*i.e.*, what regulations *can* do, or prevent), and the limitations imposed on researchers (what regulations *prevent* us from doing). Such is the nature of intellectual captivity, of bars[16]—we fail to acknowledge regulation as a matter of choice; we seem to view it (when we see it at all) as something inevitable and unchangeable. We "confine" ourselves, build our own bars, and stay within them.

A second area of confusion exists in the ways that IRBs are inconsistent, as is the nature of any localized (and temporally located, therefore, every) system (see DHHS

[16] See quote at beginning of Chapter 2, p. 44 and also J. Buffett reference, p. 94.

OIG, 1998b, p. 3 for description of the basic structure of this system, and the General Accounting Office [GAO, 2001, p. 3] for description of OHRP role; for a discussion of the inconsistencies at the federal level generally, see GAO, 2001, p. 3 and 11[17]; for more specific inconsistencies between the Food and Drug Administration [FDA] and the National Institutes of Health [NIH], see Burd, 1994, Jul 13; at the researcher level, Sobal, 1984). I maintain that all "real" systems are local, and in the case of IRBs, there was a (perhaps rare) convergence of the desire for the regulation system to be local and the local nature of the "real" world. This situation, coupled with the transient nature of scholars' lives, (*i.e.*, not often does a scholar study and subsequently work at that same institution for an entire career), creates the potential for more confusion on the part of the scholar/researcher.

Further confusion is produced because IRBs are inconsistent on at least two vortices. First, they establish local rules, so there is variance across IRBs (OHRP, 2002, Apr 2; ACHRE, 1995; DHHS OIG, 1998b, 1998c, 1998d, and 2000b; also variance across federal agencies, see Burd, 1994, Jul 13; GAO, 2001, p. 3; see also Appendix B, Legal citations section, p. 350). Second, and more problematic, IRB decisions are

[17] The GAO (2001) states, "FDA officials told us they are revising all of the agency's Information Sheets for investigators and IRBs, including the guidance on informed consent" which increases the likelihood of confusion on the part of investigators and IRBs and the FDA itself, in the first place, and these "revisions" may produce little toward enhancing human subjects protections or efficiency in the system. The GAO (2001) also states "beginning in 1999, NIH has funded 12 studies on informed consent and research ethics. The studies include an evaluation of the cognitive ability required to comprehend different aspects of a research project and an analysis of how potential participants weigh risks and benefits; the results are not yet available" (p. 11). Even the GAO (2001) seems to acknowledge, at least indirectly, that all the "activity" hasn't resulted in substantial differences in the system, "Although problems with the oversight of human subjects protection have received increasing attention since the 1990s, it is only recently that DHHS has made a concerted effort to address these issues" (p. 12). Of course, this rhetoric still begs the question of "problems," (especially in social science) failing to distinguish where the "problems" may be, what evidence of the problems exists, etc., as well as begging the question about the effectiveness of past, current, or new rules.

internally inconsistent, making it impossible for a researcher to adjust, *i.e.*, to know how to make a successful application. Nearly identical applications may be treated differently by the same IRB.[18] And, it appears not all departments within universities adopt the process of IRB approval (see findings of DHHS OIG and GAO reports, among others). One graduate student told me that when he[19] asked about the IRB in the English and cultural geography departments, only one professor seemed to know what he was talking about. When I asked students from other departments (long before I recognized any of these conversations as potential data) they seemed nearly obsessed with the IRB and its requirements and impact on their research, or attempts at research. Regardless of the "accuracy" of the comments from any of these and other students, if accuracy is discernable or distinguishable at all in this instance, the fact that students make such comments indicates confusion about the process. Students and faculty members have, in numerous conversations of which I have been a part, expressed an understanding and acceptance of the purpose for regulation, and often suggest that the process and the purpose appear unrelated to each other.

It is perhaps no surprise, then, given the confusion of regulators and researchers, that the researched—the very people who should be informed before giving consent —

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[18] During my time as a graduate student, I have heard several stories from other students about their having submitted similar applications, one within a year or so of another. In several instances students expressed puzzlement that one application passed with no problems or revisions required, and a later one, modeled on the first, failed evaluation of the same IRB. Further, an evaluative study of NIH commissioned by the National Bioethics Advisory Commission (NBAC) found that research proposals are not generally rejected outright by IRBs, but that fewer than twenty percent are approved as submitted. In an exploration of the revisions requested by IRBs, Brainard (2000, Mar 17) suggest wordsmithing consent forms occupies much of the time in IRB meetings. He and others offer reason why this is the case which I will take up in Chapter Six, especially p. 212 and p. 222.

[19] Throughout this study, with respect to personal recollections, I have used gender references alternately. I use "he" in this instance and "she" in the next, etc., rendering the gender references meaningless, used as syntactic placeholders only.

are confused. Perhaps "confused consent" is a more apt label (and is considered in more detail below, see p. 114, and p. 222; see also ACHRE, 1995, Discussion of part 3, http://tis.eh.doe.gov/ohre/roadmap/achre/dispart3.html, accessed May 25, 2002).

Official regulators (federal or institutional) are not the only forces working to create rules. Qualitative researchers themselves continue working to establish a set of ethical standards to guide their research, according to Deyle, Hess, and LeCompte (1992). I would argue that a set of ethical standards is already guiding (individual, local) qualitative researchers, and that what Deyle, et al., are actually talking about is a *written*, (and thereby more legitimate in the view of some) formalized statement of *purpose* or a set of *procedures* (the kind of interference Klockars, 1979, warned against, see p. 35 herein). Regardless of who is writing rules, or whether they are called guidelines or rules, many qualitative and survey researchers are being squeezed into an ill-fitting regulatory space.

Changes in the "real" research world, the lack of change in "real" regulation, and "real" escalation in litigiousness have created difficulties for everyone involved in this system. Regulators are unable to keep up with the needs of the research community, (DHHS OIG, 1998b, 1998c, 1998d, 2000b; ACHRE, 1995) and researchers find themselves lost in a paper maze-to-nowhere. Participants in research are at least as misguided and confused as they have ever been, and probably more so as research becomes more specialized, complex, and costly (or profitable). Somewhat ironically, the participants—the very people for whom informed consent and other provisions exist — are those least affected by them. While regulators and researchers focus intently on

informed consent documents, research participants, as described in the various reports cited, sign them, but often they don't understand or even read them thoroughly.[20] One must ask what difference it "really" makes. If informed consent documents read more like the fine print of contracts (this being a prime example of legal issues, specifically fear of litigation, driving the system), it stands to reason that participants would treat the two documents in much the same way, *i.e.*, mostly ignoring the fine print. On the other hand, in qualitative and survey research, informed consent documents state the obvious (you are being interviewed, you are completing a survey, and so on), so participants remain confused. In this latter case, participants may be puzzled about why they are being asked to sign a form that states the obvious. This might make even the most unsuspecting of participants at least a little suspicious. (The form creates in my way of thinking an unsettling "real life redundancy.") Informed consent forms for these research activities are mostly meaningless; the *purpose* is important, but the *process* is impotent.

The proliferation of research studies, stresses created by growth in both volume and diversity, along with the rise in the number of private and academic IRBs, the intensifying of commercial interests (DHHS OIG 2000a; Blumenstyk & Wheeler, 1998, Mar 20; Andrews, 2000, Mar 10, and 1999, Jan 29; Amos, 2000, Apr 26), and structural

[20] Similar to the proliferation of professional tax preparers since the dawn of income tax, private companies are emerging to offer assistance to researchers in writing informed consent documents. One such company is Consentwrite; the owner Sandra Philipson suggests "Protocols are often complex, and writing a readable and comprehensible document may be time consuming and difficult for the researcher since most physician writers have had little or no training in writing for varying levels of reading comprehension (Philipson, et al., 1995; Philipson, et al., 1999). This is precarious; writers generally have little or no training in medicine. Besides, the main concern of physicians appears to be a legally defensible consent document, not necessarily readable or comprehensible (see American Medical Association, AMA, 1998).

changes at the federal level combine to make this a very good time for taking a snapshot (implying "natural setting" and "unposed") of the IRB regulatory system. In the face of continuing political, moral, and scientific debates about anthrax vaccine administration to troops during Desert Storm (see CNN.com, 2001, May 2; 2000, Oct 11), the debates surrounding gene therapy and stem cell legislation (see references listed, footnote # 1, p. 5; see also *Time's* cover story, "At your own risk," Lemonick & Goldstein, 2002, Apr 22 [released two days before the defense of this dissertation], which includes many of the cases presented here), and other issues suggest a study such as this one is appropriate and timely. (And Alvesson & Willmott, 1992, Horkheimer, Adorno, and others would argue that anytime is a good time to scrutinize "managerial" or regulatory ideologies.[21]) With the infiltration of technology into every aspect of our lives, the consideration of managerial motives is particularly important today. "These technologies for information distribution provide sensory as well as behavioral domination" (Deetz, 1995, p. 165). And Lyotard (1984) says, "In the computer age, the question of knowledge is now more than ever a question of government" (p. 9).

In 1995, the Advisory Committee on Human Radiation Experiments (ACHRE) called for more direct oversight of the informed consent process. In June 1998, the DHHS OIG (1998d) made the explicit suggestion that more direct oversight of the informed consent process is needed; this was reiterated three years later in a General Accounting Office (GAO) report (2001). DHHS OIG (1998e), issued in October 1998,

[21] "Critical theory never aims simply at an increase in knowledge as such. Its goal is [our] emancipation from slavery" (Horkheimer, 1937/1976, p. 224). "Studies of management that take little or no account of such struggles [such as whose purpose or interest (owner, manager, producer, or consumer) is to be

indicated the federal oversight process should be reengineered. This talk has added momentum to my efforts.

Rules proliferate in a litigious social system. Rules are, in litigious societies, often made in attempts to avoid (or create an environment for the proliferation of) lawsuits[22]. The casualties of this system as mentioned are scientists, doctors, faculty, researchers, and other members of the intelligentsia. Eventually, rules restrict behavior until nearly nothing can be done (including taking a critical look at the University of Oklahoma's IRB, as will be explained).

It appears, for example, that a review of IRB minutes might be a rich source of data.[23] Federal regulators, in enumerating the problems they found at Johns Hopkins University in July 2001 (and seemingly supporting my contention about the "richness" of them), wrote "minutes of IRB meetings do not yet exist for 18 of the last 21 meetings dating back to October 2000," that "the minutes of meetings for all IRBs often failed to document the basis for requiring changes in research," and that "IRB actions were not documented separately for each individual protocol" (from the letter declaring sanctions, issued by the Office of Human Research Protections [OHRP, 2001, Jul 19, p. 6], available http://ohrp.osophs.dhhs.gov/detrm_letrs/jul01a.pdf, accessed May 25, 2002). These comments speak not only to the activities, focus, and priorities of regulators, but also to the ways IRBs are conducting various aspects of their business (see also http://www.uab.edu/lister/hopkins.htm for information about this case,

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served by work, or struggles about how work is organized, *i.e.*, autocratically, bureaucratically, democratically] are intellectually shallow and politically naïve" (Alvesson & Willmott, 1992, p. 7).

[22] See Blumenstyk, 2002, Jan 11, as an example of this proliferation.

[23] I requested minutes from board meetings from my university, but my request was "discouraged."

accessed May 25, 2002, and to read Hopkins officials' statement in which they say they believe the OHRP action to be "an unwarranted, unnecessary, paralyzing, and precipitous," see http://www.hopkinsmedicine.org/ohrpsuspends.html, accessed May 25, 2002, [Johns Hopkins, 2001, Jul 19, p. 1]).

Call for Overhaul

The IRB system is in flux, and this, I perceive, is typical of social structures in general. At the risk of replacing existing dogma with new and just as impotent dogma, it appears this regulatory system must be updated or eliminated to allow certain qualitative researchers to work in the natural world. It seems very clear that, for all the time and effort devoted to making, maintaining, and enforcing universal rules, these attempts (and the rules) have made little difference. Universals are problematic for many reasons (see Whyte, 1987; Goffman, 1971; Gardner, 2001, Mar 9, and others re: similar efforts in positivism). Lyotard (1984) states, " ... we are all stuck in the positivism of this or that discipline of learning, the learned scholars have turned into scientists, the diminished tasks of research have become compartmentalized and no one can master them all" (p. 41).[24]

Within the public and (fueled by the) mass media, distrust in the system—the entire research enterprise—persists, and seems justified. Examination and analysis about how atrocities have occurred and how they are viewed (ACHRE, 1995;

[24] Lyotard (1984) draws on the work of de Solla Price (1963), who "emphasizes the split between a small number of highly productive researchers (evaluated in terms of publication) and a large mass of researchers with low productivity. The number of the latter grows as the square of the former, so that the number of high productivity researchers only really increases every twenty years. Price concludes that

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1981), consideration of the potential for lasting effects (ACHRE, 1995; DHHS OIG 1998b, 1998e), and acknowledgement about the very limited role administrative rules actually play in affecting the behavior of any of the participants (Greenberg, 2001, Jan. 19; AAUP, 2001; Brainard, 2001, Mar. 9; Campbell, 1998, Apr. 3, Brainard, 1999, Nov 12, Manning, 1978, and others) may yield useful information about the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS[25] in operation.

When existent administrative rules don't work, why is it that we make more of them?[26] Why is it our knee-jerk response to do so? How did we get like this? [27] Was it in the same/a similar way we contributed to (by not resisting or whying) the entrenchment of a pro-positivism bias, *i.e.*, trusting statistics more than our lived

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science considered as a social entity is "undemocratic" (p. 59) and that "the eminent scientist" is a hundred years ahead of "the minimal one" (p. 56).

[25] I have found this acronym useful (as an analytical device) when considering specific texts for analysis; it has helped me to see more of the ways objects operate in the lifeworld. "Structures" I associate with the organization-in-society level of analysis, specifically the ideology critique of Marx. "Institutionalizations" I have used to describe organizations and ideologies in and of themselves. "Naturalizations" have to do with the individual-in-organization and self-regulatory behaviors, as described by Alvesson & Deetz, 1996, p. 199. "Simulations," as described by Baudrillard (1983, and described in more detail elsewhere), are used to consider the hyperreal aspects of regulation, *i.e.*, the detachment of the regulatory processes and managers from the "real" research world. I use this acronym to remind myself and the reader that any data contained herein (and beyond), regardless of the issue being addressed at any particular point, can also be analyzed via any of the other constructs (SINS) and can be thought of in (any of) those terms. (See further explanations of each component of the acronym, p. 58-64.)

[26] It may be that rules matter in this way: that our natural bias toward "more rules" when problems arise should be reversed *completely*, *i.e.*, when problems arise, we should look for the rule that *contributed to* the problem. Additionally, an argument could be made that fewer rules may contribute to a better understanding of and more compliance with the rules that *are* in place, *i.e.*, Fewer Rules = Better Compliance, or simpler (sets of) rules are more likely to be understood at all. Perhaps the more beneficial behavior would be (nearly automatic) proposals to *eliminate* rules when a problem arises.

[27] Rules are like alcohol. One takes a few drinks and feels great, and, while under the influence decides that if three drinks worked so well, think of what six will do! So it goes with rules. Of course, as we learn we eventually realize more is not better.

experience?[28] (See Goffman, 1971.) Deviation is inherent (and desirable) in (life and) rules, so attempts to standardize life via rules is delusional (and undesirable, too). It seems that standardization is inherently "expected" of rules, and attempts to standardize experience (*i.e.*, the lifeworld) in terms of the ideals of "uniform application of law," "blind justice," "(separate but) equal education," and other myths, proliferate in numerous levels of society[29].

Even with provisions of the Nuremberg Code (1949), the Declaration of Helsinki (1964, and amended in 1975, 1983,1989, 1996, and 2000), the Belmont Report (1979), regulations, and the history of research atrocities, abuses persist. Thalidomide distribution, the administration of cancer cells to chronically ill and senile patients, the Tuskegee syphilis study, uranium miners studied without their knowledge or consent,[30] and even more recent events[31] have occurred though considerable regulation was in place, designed to prevent them. What rationale supports the need for more rules? Rules don't work. (Manning, 1978, states: "... rules can only function as resources for organizing and rationalizing a given contingency," p. 77.) From this one might imply, and I do, that rules serve to create and maintain standards by which actions are justified

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[28] Alvesson and Deetz (1996) state, "to the extent that technical reasoning dominates, it lays claim to the entire concept of rationality and alternative forms of reason appear irrational" (p. 200).

[29] Adorno (1989b) points out, "It is well known that the formal possibility of equal education does not correspond in the least to the actual proportion of working class children in the schools and universities" (p. 272).

[30] According to Brainard (2001, Mar. 9), such research "falls under a set of federal regulations that have evolved during the past 50 years in response to abuses like Nazi experiments on prisoners during World War II, and the Tuskegee Syphilis Study (1932-1972) in which the U.S. government was found to have deliberately and deceptively withheld treatment from poor black men in order to study the progression of the disease" (p. A21).

[31] For example, in hearings before the U.S. House, testimony about non-therapeutic, non-beneficial, medical experiments that involved only African-American and Hispanic male children was presented. (See U.S. House, 1998, Jun 11, p. 5.) See also *Time* magazine's cover story, "At your own risk," (Lemonick & Goldstein, 2002, Apr 22) and Onion (2002, Mar 13).

(or not), and are related to issues such as social desirability, political correctness, and legal liabilities. Rules may guide behavior when people are aware of and accept the idea of their usefulness, but rules do not "ensure" anything.

Regardless of what rules may actually do, rules don't prevent atrocities (Brainard, 2000, Apr 14). Even the "ultimate" rules, *i.e.*, constitutional and near-ultimate federal statutes don't work. Extended arguments to support these assertions have been made. Alcohol prohibition didn't work (see Amendment 21 of the U.S. Constitution, Repeal of Prohibition). Marijuana prohibition isn't working (U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services, Administration Office of Applied Studies, Preliminary Estimates from the 1995 National Household Survey on Drug Abuse; Becker, 1953, 1963; National Organization for the Reform of Marijuana Laws (NORML), 1999; Novak, 1980). Laws prohibiting certain sexual and social conduct don't work, hence creating "criminals." (See Associate Press and other news stories related to the Boston and numerous other archdioceses, and Utah polygamists, as examples.) And, rules to prevent atrocities in research don't work. Solomon (1985), who conducted an analysis of journal articles produced by the Tuskegee researchers, for example, argues that "journal reports of the Tuskegee syphilis study ... employ rhetorical conventions which can obscure and de-emphasize any ethical, non-scientific perspective" and discussed "the role that rhetoric played in the study's continuation" (p. 233). Much of the rhetoric employed in journal articles is similar to that employed in regulations, by design. (The rhetoric then becomes part of the "fine print" we block and move without reading, sign without understanding,

etc.; we often listen to what the people who prepared or are presenting a document say, we choose to believe what people say or follow along with what others are doing, signing documents without reading the "fine print." Examples are ignoring the fine print on the back of credit applications, loan contracts, or admission tickets.)[32] This would indicate that rules (and the automatic following without questioning, *i.e.*, the bias toward and default to make and comply with administrative rules) worked to the detriment of the Tuskegee "participants."

Proposals for new rules proliferate when there is a failure, and often the proposed rules are remote to the original problem (See Agar, 1980, p. 183; for specific criticisms of the IRB system regarding the lack-of-fit of administrative rules, see ACHRE, 1995; DHHS OIG, 2001b; OHRP, 2001, Jul 19. See also the Littleton argument, below, footnote # 40, p. 29.) We're swinging in the dark at an unknown target when the first thing we think about is "what went wrong with the rules" and/or "we must need more rules" and second, since we don't know what we're doing, we make irrelevant and ill fitting regulations. We then keep them around for eons and, unfortunately, "build" on them, spin webs of them.[33] This of course is a cycle that can be broken only with near-endless dissention and intense, perpetual whying in every kind

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[32] Contracts are relatively new. In my memory, I recall Indian people "going to the stick." This was a ceremony conducted when a cooperative effort (a marriage, a farming venture, land partnership, etc.) was to be made. The parties to the agreement stood opposite each other and held onto the bonding stick (the first person's left hand, the other person's right hand, the first person's right hand and the second person's left hand, knuckles facing opposite directions) and said what it was they intended to do, in front of many/all tribal members. This was the way contracts were conducted well after the tribal members learned to read and write English; even after many tribal members had become lawyers, agreements were still made in this way.

[33] Among numerous examples is the new accountability initiative of the Bush administration (discussed on p. 2-3), built on the Government Performance and Results Act that took effect in 2000 (see Brainard, 2002, Mar 29b). Of course, we could start earlier: The Nuremberg Code begat the Declaration of Helsinki, begat the National Research Act of 1974, begat the Belmont Report, and so on.

of meeting for eons to "unbuild" (deconstruct) the web of regulation, and as I hope to make clear, that starts with changing our minds about administrative rules and their value.[34] Adding to the woes, new rules often have unintended effects. For example, in the Littleton tragedy, the talk about instituting new rules about the selling of guns is removed from the issue of what 17-year-olds can bring to school. In the IRB system, rules related to informed consent, and mostly designed to protect patients by making clear distinctions between therapy and research, are irrelevant to the needs (or the lack of them) that might exist for interview participants or survey respondents who undergo no treatment.[35] It may be helpful at this point to explain that it is this lack of treatment (and lack of any substantial risk) that is the most common reason for highlighting differences between qualitative and quantitative methods. Later, other distinctions are mentioned such as the difference in qualitative and quantitative methods with respect to *a priori* hypotheses and the lack of them. I also explore the distinction between the role of researchers' values and objectivity in quantitative and qualitative methods *in general.* In making these distinctions, I do not imply that qualitative and quantitative research methods are somehow "opposite." I argue simply that in a general way, qualitative and quantitative research methods are different in some important ways that (I suggest should) affect the ways they are regulated (or not regulated). See also Becker's (1993) views discussed on p. 94 herein, for more about qualitative/quantitative distinctions.

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[34] This dissertation is a case about rules in *administrative law* and the ways they are perceived, created, valued, etc. While I use a variety of lifeworld examples in various places in the dissertation, it should be noted that only similar but not identical problems are presented by rules of basketball, speed limits, and the prohibition of marijuana.

[35] And even certain clinical trials are exempt from the informed consent process. For example, the FDA allows the use of devices and drugs in life-threatening situations where patients are unconscious and there is no time to contact relatives (see FDA, 1995; Campbell, 1997, Oct 24; Burd, 1995, Nov 3).

Flowing from the position that rules don't work (in the way they are intended or perceived to work, if at all) is argument surrounding the placement of values in human conduct. Many hold, as I do, that people "prevent" atrocities by virtue of their own virtues (*i.e.*, values).[36]

"Prevention" has little if anything to do with written codes, rules, and regulations.[37] Lyotard (1984) states, and others support his notion, "Most people have lost the nostalgia for the lost narrative. It in no way follows that they are reduced to barbarity. What saves them from it is their knowledge that legitimation can only spring from their own linguistic practice and communicational interaction" (p. 41). Morley and Shockley-Zalabak (1991) suggest "proponents of the 'strong culture' perspective view the construction of social realities, which contribute to shared values, as the very core of culture and central to high organizational performance" (p. 422; see also Deal & Kennedy, 1982) and "the more an individual values what the organization values, the more likely the individual is satisfied with communication activities and has positive expectations about the organization" (p. 427). Morley and Shockley-Zalabak (1991) state, with respect to the evolution of organizations (relying on the work of Schein,

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[36] "It doesn't matter how many checks you have in the system if you don't have a scrupulous provider," says Susan Winckler, group director of policy and advocacy for the American Pharmaceutical Association (see Sealey, 2001, Aug 17; see also Cassell, 1982, p. 155; and Frieden, 2001, Aug 24 re: a Kansas City pharmacist who watered down chemotherapy drugs, alleged to have affected thousands of patients.

[37] In the Advisory Committee on Human Radiation Experiments (ACHRE) report, issued in 1995, the Commission concluded that current policies do not safeguard against the recurrence of atrocities, particularly the lack of informed consent for studies involving very high risk to participants. And Gary Ellis, former director of Office for Protection from Research Risks (OPRR), in testimony before the U.S. House stated "I talked about a non-zero possibility of catastrophic failure and that's just what it is. It's not zero, and I'm not saying there's no problem...I'm talking about the numerator of a ratio and in the denominator is a huge, huge volume of research activity as we pursue new knowledge in biomedical and behavioral research" (U.S. House, 1998, Jun 11, p. 49). See also, Campbell, 1998, Dec 18 and GAO,

1985), "organizational maturity brings cultural constraint on innovation with an emphasis on preservation of the past" (p. 425). I will demonstrate this entrenchment of habits, *i.e.*, the ways we do things, is present in the IRB system. The behaviors of participants demonstrate the tendency to avoid thinking, to follow without question. Also ideas such as "the letter of the law" implies a single and "correct" interpretation exists, *i.e.*, an example of inherently futile absolutism. These behaviors greatly affect the research environment, as I will also show.

I am arguing that ossification, while maybe not part of the problem directly, (because the problem is a lack of whying), is the by-product of the problem of not thinking, defaulting to rules, etc., and this ossified mass is big, heavy, and hard to move out of the way. An even more stubborn mass than calcareous deposits. Solid. Heavy. Stuck. Inertial. To add further complication, this mass is invisible/we are blind.[38]

Strong "real life" evidence suggests most people don't want to commit inhumane acts,[39] don't even wish to see them, and those who are inhumane are not

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2001. Personally, I wonder how much behavioral research boosts the ratio, to the benefit of much riskier, sometimes horrifying medical trials. See also footnote # 253, p. 251, herein.

[38] "It is like a pair of glasses on our nose through which we see whatever we look at ... it never occurs to us to take them off" (Wittgenstein, quoted in Trachtman, 2002 Apr, p. 125). I will argue that we often don't even realize that we need glasses (or that we are wearing them, whichever the case).

[39] About torture for example, Rose (1986, Oct) argued that "torture is most often associated with commitment to an overarching ideology ... you have to convince people that they are working for a great goal in order to get them to overcome their repugnance to the task of causing physical pain to another person," and "[torture] is not always private and perverse but sometimes social and institutional, vetted by the government and, of course, the Church" (p. 1). She adds "there have been few bigger fans of torture than Christianity and Islam ... Righteousness, as much as viciousness, produces torture" (p. 1). Rose suggests an antidote to societies' inclination to use torture may be a matter of prioritizing the immediate and material (as I call it, the liquid and the local) over the abstract, to refuse to "allow the nobly abstract to seduce us from the sweetness of the concrete" (p. 39; see also Baudrillard, 1983 and 1988, re: seductions). I also will argue that the first step in reforming the IRB system is recognition on the part of the regulators and the researchers that oversight of the "liquid and local" research environment is impossible and, therefore, *all* compliance to administrative rules is "really" voluntary, and further, that this situation is adequate, *i.e.*, it works just fine. Also I argue that researchers don't hurt participants

stopped by administrative rules. Why not? Because those who commit inhumane acts have no regard for *people*, why would anyone expect respect for *rules* from such a person? To think otherwise is, I suggest, social-level delusion. Individuals' morals and values rather than rules are the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS protecting the human subjects of research (and most other humans).[40] Individuals' morals and values are the SINS because what we accept as natural (normal[41]) and reasonable creates the simulation that we live in. My point is that our acceptance, our creation of "normal" or "natural" is often by default rather than conscious consideration of choice.[42]

Contemporary developments in the federal regulatory structure create an interest for study. The Office of Protection from Research Risks (OPRR) was moved from the National Institutes of Health (NIH) where it had been since 1972, to the Secretary of Health and Human Services' office (a move "up" the bureaucratic ladder), "in order to

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because the researchers' personal (local) values prohibit it, making administrative rules redundant at best, particularly in social science research involving no treatment and no protected classes.

[40] A strong but rather complex case could be built on the basis of the following examples. The first situation surrounds the 1999 school shooting tragedy in Littleton, Colorado. What happened there (specifically carrying guns to school and killing classmates and teachers with them) was against the law already, yet people talked then, and continue to talk as if more gun control would have prevented it. The War on Drugs is another example. The use of drugs has increased in spite of more laws, enforcement efforts, and huge expenditures. It appears to be a war on people who use drugs, as incarceration rates have also increased substantially during the "war" years. Rules are not only impotent, but worse. Rules increase complacency, creating the illusion that as a society we are doing something about a problem. And, as Rose (1986, Oct) alluded, rules *made to support values* (often implicitly) can be used to encourage people to kill each other (military and religious rules as examples, the upholding of values such as freedom, democracy, justice, various issues related to morality, etc.) supporting the contention that values are more potent than rules.

[41] Throughout this document, (and especially in the SINS device), I employ the term used by Alvesson and Deetz (1996), "naturalization" in a way similar to some uses of the word "normalization" in social science, *i.e.*, what seems normal or natural to us, things we do not (at least often) question, things perceived as "self-evident."

[42] Consider the plight of Mennonites who are sometimes forced to buy insurance to comply with a rule. Mennonites see "insurance" as *contrary* to being responsible. That we may think Mennonites are

enhance the office's power," according to a statement made by the Department of Health and Human Services (DHHS) Secretary (see Healy, 1999, Jul 30). The office is now known as the Office of Human Research Protection (OHRP), changed effective June 18, 2000 (see Federal Register, 2000, Jun 13; see also GAO, 2001, p. 3), and mostly notable as it relates to who has the right to name and re-name, and the timing of the event, as noted in the *Chronicle of Higher Education* (see Brainard, 2001, Jan 5; Federal Register, 2000, Jun 13), *i.e.*, the changes came less than a year after the September 1999 death of research patient 18-year-old Jesse Gelsinger in a gene therapy trial at the University of Pennsylvania[43] (Brainard, 1999, Dec 17; see also Gelsinger, P., 2000) and recommendations of the OPRR in June 3, 1999 (see Wheeler, 1999, Oct 8; OPRR 1999), and amidst the revealing reports of the DHHS OIG (particularly 1998b, 1998d, 1998e, 2000b) and the GAO (1996; see also 2001, for argument that "problems" still exist), the new OHRP director's own statements about the need for reform (Brainard, 2000, Sep 13), and introduction of a bill in the Senate (see Human Research Subjects Protection Act, S. 193, 1997).

Whether the entity is called the Office of Protection from Research Risks or the Office of Human Research Protections is not particularly significant. The power to

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"strange" in this regard is an example of "naturalization," *i.e.*, the reification of insurance and rules requiring it.

[43] It was believed that Gelsinger's was the first gene-therapy trial death, but it was later found to be the seventh death (see Brainard, 1999, Dec 17). The reason for this is the prior deaths were reported to the FDA that "does not publicly disclose reports of deaths unless the therapy is eventually approved or the sponsor of the research gives permission" (p. A40). For reasons unapparent to me, this never became a big story. I would suggest it *is* the story. (Also see Brainard, 2001, Jan 5, regarding an NIH proposal to *relax* guidelines "that require researchers to promptly report deaths and complications among patients in gene-therapy studies," p. A33). Not only is the reporting of deaths and harm among if not the most important activity one could do to prevent more harm, to *not require* such reporting is dangerous *and* absurd. Further, I believe it is a clear illustration of at least one serious and negative effect of commercialization on the integrity of the human subjects protection system.

name (and re-name) the office is of interest, however. Also of interest is the change in the enforcement effort (based on the increased number of sanctions issued during 1999 to mid-2000), immediately followed by a dismantling and restructuring of a big part of the enforcement system. And, as mentioned, government reports have suggested more direct oversight of the informed consent process is "needed," and that the federal oversight process should be "reengineered" (see DHHS, OIG, 1998b, p. *iii* and *xi*; GAO, 2001). As of mid-2001, the OHRP initiated an elaborate IRB registration (see http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/faq.htm, accessed May 25, 2002). This registration system itself it could be argued is an outgrowth of the congressional realization that one did not exist; Ellis couldn't tell the representatives how many IRBs function in the U.S. (see U.S. House, 1998, Jun 11).[44] For some reason this seemed important to them, *i.e.*, that the legislators seemed to think that knowing the (exact, or close to it) number of IRBs was indicative of "doing a good job" as an administrator, or something akin to that assessment. The number of IRBs overall doesn't seem particularly important or relevant to designing the way an individual IRB is to operate to adequately protect human subjects of research.

Purpose of Study

It appears the IRB system (including federal regulation, institutional renditions, and self-regulatory behavior) that has existed for at least 25 years in the U.S. is in a

[44] The registry is available at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/inum.htm, accessed May 25, 2002. The GAO (2001) reported as part of the new assurance process (details available, and changing frequently, at OHRP website) "Registration will enable DHHS to build an IRB database, which

somewhat common situation of administering, imposing rules and regulations that no longer fit important aspects of the "real" world they are meant to constrain (and, as time goes by, often have less to do with the intended purpose, *i.e.*, protecting human subjects). The IRB regulatory system may be described as a simulation (Baudrillard, 1983),[45] a discursive formation (Foucault, 1972) that will be made more visible in the interest of critique (and perhaps deconstructing and abandoning). This system is in need of scrutiny, for the benefit of regulators, researchers, and the researched. Management, and regulatory entities, should be openly and regularly questioned and challenged, for the benefit of management and the managed. "Management [is] a social phenomenon meriting serious critical examination" as "established management discourse and practice tends to incorporate and 'swallow up' larger and larger domains of social and personal life, such as culture, conflict, and even pleasure" (Alvesson & Willmott, 1992, p. 3; see also Burrell, 1992).

The system of regulation for human subjects research in both social and medical science has reached a point of diminishing returns, even detrimental effects. This is the essential problem of concern for the present study. The "grand narrative" and other

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will facilitate the identification of and communication with officials who actively review projects using human subjects" (p. 6).

[45] Baudrillard's notions will be covered in the description of SINS, below, p. 58-64. However, his words may be useful here. "The real is produced from miniaturized units, from matrices, memory banks, and command models – with these it can be reproduced an indefinite number of times (and across spans of time and places, I would mention by way of extending to my topic). It no longer has to be rational (as is often the case that regulation is irrational) ... it is nothing more than operational (process over purpose)" (1983, p. 3). And with respect to regulators themselves, I would apply Baudrillard's comment, "For it is with [the same] Imperialism that present-day simulators try to make the real, all the real, coincide with their simulation models. (These formations are positioned as things we *must* do to make the world "work" or "function," *i.e.*, the idea that [administrative] rules must be in place or chaos [or abuse] will [inevitably] result.)

institutionalized structures surrounding (particularly social) science regulation must be re-opened, questioned, and revised or eliminated. First they have to be exposed.[46]

Fundamental debates continue about the very soul of research, including the tensions among the goals of social science and research ethics, bureaucratic protection and secrecy, political control and individual rights and obligations (Whyte, 1987; Garfinkel, 1967; Bantz, 1981; Greenberg, 2001, Jan 19; Pence, 2001, Jan 12; ACHRE, 1995).

Much IRB regulation, for example, is designed to protect the privacy of participants of research. But, what is public and what is private? (See O'Connor, 1979, p. 249; Kelman, 1982; Caplan, 1982; Denzin & Lincoln, 2000, and others.) When can research be said to be "harming" people? Who has the right to decide? In what ways are ethical norms institutionalized? Or are they? How do respect, beneficence, and justice work? Accountability? Responsibility? To what extent do deception, invasion of privacy, or other "harms" occur? And to what extent do those rare cases damage field relationships, contribute to researchers becoming cynical and devious, and/or enrage participants? How many times is the greatest harm damage to the reputation of social scientific inquiry-at-large? And, how many potential benefits are lost (not to mention the rights of researchers in a more general way) because researchers give up trying to get a study proposal, or a type of study proposal (e.g., covert yet treatment-less studies) "past the IRB?"

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[46] Working to be sensitive to the operation of these multi-level structures is somewhat like hearing voices—a rather prominent din. And, I'm only "hearing" a few structures relative to the number likely operating. (This is one reason I have found the SINS device functional for this analysis.)

"Management is too potent in its effects upon the lives of employees, consumers and citizens to be guided by a narrow, instrumental form of rationality" (Alvesson & Willmott, 1992, p. 1). I suggest this is especially true in terms of researchers and regulators who often know little about the type of research they are "regulating" at any given moment. And this overly narrow and often uninformed "guidance" for social science researchers in particular (*i.e.*, those who employ methods without treatments such as observation, survey research, etc.) is combined with the problem of researchers' consenting to this frequently absurd system through their very participation in it.

Hamilton (1998) in arguing that participatory research is emerging, points out that Habermas has focused on the deconstruction of science (p. 126). Habermas (1971) suggests that Cartesian absolutism be replaced with mutual understanding, and that social research is "an interactive rather than a controlling process," (Hamilton, p. 126). Habermas (1971) states "objectivism deludes the sciences with the image of a self-subsistent world of facts structured in a law-like manner; it thus conceals the *a priori* constitution of these facts" (p. 69; see also Sunwolf & Seibold, 1998, p. 287). "Participants aim for mutual understanding over the coordination of their subsequent actions. Applied research, therefore, is not about social conformity but about social justice" Hamilton (1998, p. 126) concludes. Finally in this vein, Derrida (1978) states that deconstruction brings down the "unities" of meaning, theory, and self, and Cooper and Burrell (1988) state, "It is [such] legitimizing meta-positions to which postmodernism objects" (p. 98). (See Figure 2, p. 87; X-axis designed to aid and/or imply conformity [marketing research is an X-axis phenomenon, for example]; Y-axis

designed to study effects of structures on people [workplace features and their effects on workers, for example].)

And how would those who would try to institutionalize ethics answer critical theorists and postmodernists who would likely say that institutionalization is domination? That respect, beneficence, justice, accountability, and responsibility are entirely local phenomena[47] and cannot be given a general or universal definition in any meaningful, standardized way. Attempts to control them amount to attempts to control thinking. (I use the many wags who have uttered, "you just can't legislate morality" as further evidence of the futility in this.) These questions address ethical, moral, legal, professional, theoretical, and practical problems and positions – and the answers, along with the view none exist – that continue to reverberate in classrooms, boardrooms, and conferences, in all parts of the academy and beyond. As mentioned, the focus of this study is how regulation affects social science, and in particular qualitative researchers.

> The implication for fieldwork is to be most wary of any and all attempts to fashion rules and regulations, general guidelines, rules of ethics, or standards of professional conduct, which would allow well-meaning bureaucrats and concerned colleagues to mobilize punishments for morally dubious behavior. Doing so, will, I think, only have the effect of forcing decent fieldworkers to lie, deceive, wear masks, misrepresent themselves, hide the methods of their work, and otherwise dirty their hands more than their vocation now makes morally necessary. (Klockars, 1979, p. 279-80)

"It is time to get on with the multidisciplinary project called qualitative research. Too much critique will stifle this project" (Denzin & Lincoln, 1998a, p. 410).

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[47] In my theoretical approach, all rules are local, as all interpretations and "real" actions are local, and occur only in the "lifeworld" as described by Husserl, Schutz and Luckmann, Dilthey, and others, *i.e.*, the region of reality in which people are engaged and where people can change while operating in it. At the same time, though, the objects and events (such as regulations) that are already found in this realm (*i.e.*, the bars, see p. 14 and 44) limit free possibilities of action.

And, I would add, too much regulation has had the same affect. Durkheim (1933, pp. 65-110; 1951, pp. 335-392, as quoted in Grabe, 1999) argues "the ritualization of crime is a powerful means to draw publicly the line between good and evil, thereby constructing morality" (Grabe, 1999, p .156). I will argue that regulation works much the same way, in that "rules" imply notions about what is right and wrong. There are many arguments against this notion, *i.e.*, that many rules aren't strict enough to prevent wrongs, others are overly restrictive, disallowing what many might call "right," "good," or at least "reasonable" in any given liquid and local situation, *i.e.*, the lifeworld, and still other rules are required but unnecessary, irrelevant, and/or ill-fitting. (See footnote # 93, p. 81, re: "liquid and local.")

Tensions between bureaucratic protection and political control; necessity (or lack of it) for covert activity (O'Connor, 1979, p. 250), secrecy or deception (a clinical example is the use of placebos, which involves all of these things, however, *i.e.*, blind participation, not knowing whether a patient takes "real" medicine, not to mention issues related to the *right* to receive "real" medicine, etc.); individual rights and common good; and between therapy and research perpetuate debate about the use of human subjects.

Simply, the most significant reason for doing this study this way is to open authority to questioning, a theme I find to be of enduring value. To reveal (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS involved in the construction and operation of the IRB system is a primary goal for this study (see Alvesson& Willmott, 1992; Alvesson & Deetz, 2000;

Horkheimer, 1937/1976, 1972, and 1989; Adorno, 1989a). And, ultimately (and consistent with the goals of critical management/regulatory study), I hope to contribute to efforts to reform the IRB process, specifically to create true and complete exemptions for social researchers who deliver no treatment to participants—to emancipate these researchers employing unobtrusive methods from local interpretations of federal rules, as I will explain in the next several chapters.

"Through obscuring the construction process, institutional arrangements are no longer seen as choices but as natural and self-evident ... [this] protects them from examination" (Alvesson & Deetz, 1996, p. 199). Adorno (1989a) describes mass media in a way that is relevant: It is not "a question of primary concern for the masses, nor of the techniques of communication as such, but of the spirit which sufflates them, their master's voice. The culture industry misuses its concern for the masses in order to duplicate, reinforce, and strengthen their mentality, which it presumes is given and unchangeable" (p. 129).

I call for renewed questioning of the IRB system (i.e. whying to regulators, each other, and ourselves, and about regulations and the "management" of them), with specific emphasis on the relationship between qualitative methods and regulation. I call for the widespread de-regulation of social science research restrictions when no treatment and no protected classes are involved, the acknowledgement of the "real world" lack of direct oversight and lack of reasonability of attempting or possibility of attaining it[48]. It is already the case that researcher compliance is "really" only voluntary

[48] Deetz (1995) says, "Even if they wanted to, government cannot micromanage companies" (p. 25). (I suggest the same is true of institutions and processes related to the IRB system.) Deetz uses the savings

(without oversight, it can be nothing but). We, as researchers, cannot be watched every minute, and even if we could who would do the watching? What do they know? Would they say what they know or would they say what they are "supposed" to say according to the "script" of the rules and policies? Would they know what they were doing, *i.e.*, would they think they were saying what they mean, when they might "really" be saying what they think others wish to hear? It is this kind of whying that should be more prevalent in the face of regulators/regulation.

I believe we have allowed too much control to be taken by "the process," too much control about what we have to "obtain consent" to do ourselves. For example, first-hand direct experience belongs to the experience-er, thus no "consent" *can* be required.[49] Are we to sign our own informed consent forms before we ask ourselves to "describe" our own(ed) experiences? Whether considered to be in non-protected classes or not, (the categories themselves are in no way determinate, definitive, or "real") adults participate moment-to-moment in their own lives. As researchers/people, we ask questions, scientifically and socially, formally and informally. When we are asking as scientists, we act as scientists. We often use tape recorders and notebooks, making them obvious to participants/conversants. We ask whether or not the person (participant) wishes to be anonymous in our reports, if in fact we even know the identity of the person with whom we may be speaking or about whom we may have recollections.

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and loan fiasco as support for his statement, saying "Bad decisions were made, the companies failed, the pubic paid the bill, and the managers walked away with bundles of money" (p. 25). Of course, there is now another rich example in the Enron debacle.

[49] When do we know that an encounter will become relevant as an example (as data, rather than "fact") of a construct we're presenting in a scholarly work? Or a story we're telling in life? (See footnote # 9, p. 9 re: the use of recollection herein.

Based on this "real world" description, I assert that social researchers as I have described embrace the *purpose* of regulation, but abandon the local *processes*. It is often the case in what I have seen in local IRB interpretations, that the federal government is in a better position to make viable rules than are local boards. First, the federal government in making administrative rules only has two higher levels of law to consider, and to avoid contradicting: the U.S. Constitution and federal statutes. The local IRB must contend with both of those legal levels, as well as a state constitution (or in the case of multiple site studies, numerous state constitutions), state statutes, and often a university handbook (or, again, several in the case of multiple site studies). Additionally, the local IRB, which in theory given the larger legal "maze" would need *more* legal expertise to write rules that would stand up to court or other procedural challenges, has *less* legal expertise at its disposal than do federal agencies, traditionally.

Agar (1980) writes about IRB regulation, "there are hundreds of problems here" (p. 183) for ethnographers and social scientists. "If minors are involved, how do you get parental consent, especially if the study is of some behavior of the minor that s/he does not want the parents to know about?[50] Or what if it is an experiment in which you cannot tell the subjects exactly what is going on because it would bias the results?[51] Or what if the sample is drawn from an institution where it is questionable that the subject has any "choice?" (p. 183-84). Agar (1980) continues, "An ethnographer would not

[50] This can, of course be some "really" important work.
[51] Further, following the rules most often alters the natural environment, the lifeworld, rendering it useless for research purposes (*i.e.*, one might *enjoy* the day in the particular environment, but cannot *study* it).

object to the spirit of protecting human subjects – it is just that the *written* form can be a problem" (p. 184). Several documents cited herein support the idea that the written informed consent form has little to do with actual process of consent (see US Agency for International Development [USAID, 1999]; ACHRE, 1995; and others). These administrative rules can be difficult in any kind of research (qualitative or quantitative, social or medical, treatment and non-treatment methods) because much research is conducted to develop new knowledge and is therefore unpredictable (see Brainard, 2002, Mar 29b). "There are too many cases in science where you can't measure relevance in 5, 10, 15, or 20 years," said Irwin Feller, a professor of economics at Pennsylvania State University at University Park, and quoted by Brainard (2002, Mar 29b, p. A25).

I suggest, assuming the risk inherent in any dogma, the present system be replaced with a "blanket assurance." (See Lofland's idea of a "certificate of competency" for field researchers, as mentioned in Punch, 1998, p. 157; and see the University of Oklahoma, IRB policy and procedure [http://research.ou.edu/policy/IRB_Human_Subjects_Policy.html, accessed May 25, 2002], specifically the provision for student researchers under Section 5.) Lofland's idea represents a "professional guideline" outcome, whereas blanket assurance is a "self-regulatory" outcome, to be adopted by researchers in lieu of countless contrived applications and other mute parts of the process. This is taken up in Chapter Eight.

Among the benefits of deregulation may be the preservation and expansion in the diversity of research approaches, the enhancements that diversity brings, the

enhanced view of diversity itself, and the raising of the "actual" social capital of diversity, not just the discourse surrounding it. To show respect for the unorthodox, the non-traditional, the non-standard, the strange and the weird is beneficial, I contend. To demonstrate the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS associated with, and the folly of, "being normal" or even attempts to define what that may be is useful.

Outline of Contents

Forester (1993) suggests the importance of linking control structures to daily experience in forming what he terms a "structural phenomenology" (p. 140; see also p. 73 herein). Further, Forester holds that the organizing of attention is a central feature of administrative and organizational processes of social reproduction. As Forester advocates, I will present an illustration (what Forester calls a map) of the "formal mandates, informal routines, and various precedents [that] frame participants' attention" (Forester, 1989, p. 159), viewing both the staging and framing of social (in this case regulatory) interaction. The data for this study is written communication, i.e. "discursive formations" (Foucault, 1972, pp. 31-49) along with a few of the author's recollections, presented at (I'm told minor) risk of breaking (local interpretations of) rules about the use of one's own direct personal experience. The risk is in the potential of having one's direct first hand experience "swallowed up" in the interpretations of some local IRB as constituting human subjects data although no human subjects were subjected to treatment and none are identified in these recollections.

Employing Foucault's position that discourse *constitutes* organizations, and the value he and others place on ordinary texts, *i.e.*, the written products of ordinary, local, day-to-day existence of regular people doing regular things, the data for this study, as described, is predominately these forms of texts. With respect to organization of the present study, and consistent with Habermas's (1984) model explained in the next few paragraphs, Foucault suggests the rationalities of government are, among other things, associated with discipline and the "shepherd flock" model (see Hindess, 1996, p. 20). Foucault presents each of these rationalities as present at a number of levels, from external supervision to self-regulation and personality modification (see Hindess, 1996). Chapter Two contains epistemological/theoretical considerations and Chapter Three, the data and methods employed here.

Habermas's (1984, 1987, p. 107) model of reproduction includes three areas that work well to explain some of the chapter divisions in this study. First in Habermas's model is "cultural reproduction of worldviews," including ideas, knowledge, beliefs, etc. In Chapter Four, the development of the IRB system of regulation is discussed, how it came about and parts of the "original" (and ever-evolving) system that have been rather consistent in the discourse, and remain apparent. Chapter Five includes Foucauldian analyses and resistance readings of various documents produced within the system, including government reports, local application forms, and documents designed to provide guidance to compliance.

The second part of Habermas's (1987) model is "social integration," during which norms and other patterns of social membership are reproduced. This corresponds

to the focus of analysis for Chapter Six, *i.e.*, the institutional reproductions of federal regulations. An example of this level of analysis is scrutiny of the "translation" of the Code of Federal Regulations and similar texts to university research policy handbooks. Renditions of events in the press, and comments of university officials and researchers also provide insight about IRB system operations.

Third in Habermas's (1987) model is "socialization" which includes the development and alteration of social identities, motives, and expressions of self. Chapter Seven includes an analysis of the affects on the identities, motives and self-expression of researchers.

Finally, two appendices are included. Appendix A offers a few samples of the Foucauldian analysis conducted herein. Appendix B contains a resource/bibliography of congressional hearings, government reports, and other documents related to human subjects protection in the U.S.

Chapter Two: Epistemological and Theoretical Considerations

"*Modern society has subjugated the populace to the point that it no longer even sees the bars of its cage.*" Anarchism-as-sensible-resistance-to-our-subjugation proponent and WTO protester John Zerzan, as reported by Derrick Jensen, *Alternative Press Review*, reprinted in *Utne Reader*, May-June 2001, p. 49.

Alvesson and Deetz (1996) suggest that critical theory and postmodern thought oppose objectivists with their goals of prediction and control of nature and people, as well as humanists who set forth a "naïve version of human freedom" (p. 205) by privileging certain individual points of view. "Both critical theory and postmodern thought share the view that domination is aided, and both people and organizations lose much, if we overlook social constructions by treating the existing world as natural, rational, and neutral" (p. 211). Even with these shared aspects, critical theory without postmodern themes "easily becomes unreflective in regard to cultural elitism and modern conditions of power" and without critical theory, postmodernism becomes "esoteric" (p. 211; see also Huspek, 1991).

Hegemony is a process of "pervading common sense and becoming part of the ordinary way of seeing the world, understanding one's self, and experiencing needs" (Alvesson & Deetz, 1996, p. 201; see also Gramsci, 1971; Angus, 1992; Trachtman, 2002, Apr). Schutz and Luckmann (1973) suggest, "In contrast to specific experiences, [these] fundamental structures do not enter into the grip of consciousness in the natural attitude" but they are "a condition of every experience of the lifeworld (p. 103). These experiences enter "the horizon of experience ... each experience 'obviously' or 'self-

evidently' has an unchangeable spatial, temporal, and social arrangement" (p. 103; see also Sunwolf & Seibold, 1998, p. 287, and Giddens, 1979, re: structuration). An example is "science" about which Baudrillard (1983) says "science never sacrifices itself; it is always murderous" (p. 14).

How does this IRB (or any) regulatory enterprise maintain itself (each of its parts) if the participants – the rule makers themselves – don't support (parts of) it? Perhaps this is a component of reform. What will constitute "critical mass" for change? Who will be the Hundredth Monkey? (Schell, 1982)[52]

Historically and currently, with respect to regulation of all kinds, the (hegemonic) opinion that more direct oversight, more rules, more enforcement, more penalties are needed is pervasive. In the case of human subjects regulation, direct oversight is "needed" because of concerns about rules being followed (DHHS OIG, 1998b, 1998c, 1998d, 2000b; GAO, 2001) not necessarily, nor centrally, concerns about the protection of people. (This situation is an example of detachment from the lifeworld of research, as described in the "Simulations" section, below, p. 62.) These rules themselves, much less more direct oversight, are especially unnecessary in social science research studies in which no treatment and/or "minimal risk" are involved, *as defined by the federal government*. What are we "protecting" people who participate in "minimal risk" studies *from*? (The federal definition of "minimal risk" implies we would be protecting people from life's risks.) We have developed an unwarranted belief

[52] The anti-nuclear movement in the early 1980s was stalled. Schell, in *The Fate of the Earth* (1982), employed the "Hundredth Monkey" fable in an attempt to increase the level of individual activism by convincing people their work as activists was worthwhile. Schell argued that a single individual would eventually tilt the balance toward change, making every individual of, at least potentially, "critical"

that rules plus compliance equals protection. They do not, and the belief that they do is SINSful (see National Bioethics Advisory Commission, [NBAC, 2001]; and Brainard, 2001, Jan 12).

The Entrenchment of Enlightenment Ideology

I have chosen to highlight the distinctions between qualitative and quantitative research, including aspects of their historical development. This distinction, while not perfect, is best suited for the purposes here. Some notes about the distinction are appropriate, however. First, this analysis does not require nor suggest that qualitative and quantitative research methods are "opposites" or even totally exclusive of each other. For many portions of this study, the main distinction is not the particular method *per se*, but the treatments (or lack of them) associated most generally with certain methods. An overwhelming majority of clinical studies are quantitative in nature, and most studies involving no treatment are qualitative. In other parts of this study, the important distinction between qualitative and quantitative research is related to the nature of what is assumed by researchers to be the end product of the method they employ. For example, in completing application forms (most often designed by and for clinicians, or derived from forms originally designed for clinical researchers), qualitative researchers (who don't often employ hypotheses) often find the questions and requirements of the process and forms absurd. For example, many qualitative researchers have very little idea about the "outcome" of their research, or even what

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importance to the movement. See O'Leary (1988), for a copy of the fable and analysis of its use. Also see Habermas' (1975) "legitimation crisis," *i.e.*, failure to maintain mass loyalty (footnote # 75, p. 66).

data might be useful in a "final" analysis (see Van Maanen quote, p. 48; Agar quote, p. 49; and Feller quote, p. 40).

The positivistic, naturalistic bias is very much with us (O'Connor, 1979; Klockars, 1979; Whyte, 1987; Knights, 1992; Flyvbjerg, 2001, just to highlight a 32-year micro-slice of the debate). Too often, qualitative researchers are required to spend considerable time justifying their existence.[53] Yet, prediction is highly problematic even when/if we don't acknowledge that is the case. Whyte (1987) suggests " ... the history of recent failures in [quantitative] social research points to the need for an anthropological orientation to research," to researchers with "the ability to conceptualize human behavior into systems of interpersonal, intergroup, and interorganizational relations, to relate the structure and functioning of the organization to the structure and functioning of the community, and finally, to integrate economic and technological with social data" (p. 161; see also Sunwolf & Seibold, 1998, p. 286, re: "boundary spanners;" Vidich & Lyman, 2000; and Jones, 1999, Feb 18, re: the usefulness and popularity of those holding anthropology degrees with businesses). With respect to organizational theory, Mumby (1987) states, "several authors have sought to question the legitimacy of organizational models based on the notion that organizations are intrinsically rational in their *modus operandi*" (p. 115).

I suggest it is time for (renewed) vigorous whying on the part of researchers, organizational and otherwise. The IRB system appears to be unreasonable in many

[53] "Qualitative research has a long and distinguished history in the human disciplines. In sociology the work of the "Chicago school" in the 1920s and 1930s established the importance of qualitative research for the study of human group life. In anthropology, during the same period, the work of Boas, Mead,

respects, and critical reviews of the processes may be useful in reforming the system. At (at least) one institution, though, rules constituting the process have prohibited observation of the process.[54] Obviously if this interpretation of the rules is employed (*i.e.*, IRBs refusing to approve studies designed to study IRBs), the system remains beyond the scope of open critique and discourse that would perhaps enhance understanding of the system (and even the system itself) for all involved parties: regulators, researchers, and participants of research.

In some ways IRB regulations have always been inappropriate. It is time to acknowledge the absurdity of some IRB requirements (and pursuant interpretations), particularly in social science research, *i.e.*, observational, non-treatment, minimal risk (*i.e.*, no risk beyond that found in life in general) studies. These characteristics of qualitative research make preparing IRB application forms, as they exist now, hardly possible (as unreasonable, irrelevant, contrived, required but unnecessary texts-as-ritual rather than meaningful texts).

> Qualitative research is endlessly creative and interpretive; the interpretations are constructed from field texts, *i.e.*, notes and documents. The writer-as-interpreter moves from this text to a research text: notes and interpretations based on the field text. This text is then transformed to a working interpretive document, containing the writer's early attempts to make sense out of what s/he has learned. Finally the writer produces the public text that comes to the reader. This final tale of the field may assume several forms: confessional, realist, impressionistic, critical, formal, literary, analytic, grounded theory, and so on. (Van Maanen, 1988, p. 29-30.)

Benedict, Bateson, Evans-Pritchard, Radcliffe-Brown, and Malinowski established "fieldwork" as a method (see Denzin & Lincoln, 1998a, p. 1). See also Geertz (1973, 1983).

[54] I submitted four applications to the IRB at my university in April 2001, one of which included a request for interviews with IRB members for the purpose of gathering data for this dissertation. While there has been activity *about* my applications, there has been no action *on* them. The board as of June 2002, more than one year later, has not approved nor denied any of my applications.

What is the researcher, particularly the qualitative researcher, to do? A dilemma is inherent: A qualitative researcher cannot know the future and therefore cannot gain advance approval for data that presents itself, often on-the-spot (*i.e.*, in the lifeworld) or at later times (*i.e.*, recollections of the lifeworld), in the mind of the writer, *i.e.*, a connection is made from life's experiences, and becomes, in a *post hoc* fashion, relevant data, hardly something for which advance approval can be sought. (And, this differs considerably from hypothesis-driven approaches.) Agar (1980) suggests "You can't specify the questions you're going to ask when you move into the community; you don't know how to ask questions yet. You can't define a sample; you don't know what the range of social types is and which ones are relevant to the topics you're interested in. None of this goes over well with hypothesis testing fanatics" (p.70). Even the National Institute on Drug Abuse (NIDA, 1995) states, "There is now a much greater demand for creativity and resourcefulness on the part of behavioral and social science researchers to expand and integrate traditional research methods and develop new approaches" (p. 1). Regulations and applications do not contribute to or accommodate "creativity" (unless perhaps in developing circumvention tactics)[55] but to sameness. Detailed advance planning snuffs out the opportunity to do much expanding or integrating or development-in-the-moment. The federal rules are apparently in conflict with the federal goals in this instance. The NIDA also admits, "Despite the increased receptivity toward qualitative research methods, however, there is still some lack of clarity in what qualitative methodologists do" (p. 6; see also Vidich & Lyman, 2000).

[55] See section about researcher circumvention, p. 260

Qualitative research holds to no single methodology or set of methods, doesn't privilege one over others, has no theory or paradigm that is distinctly its own, and is used in many disciplines including education, communication, psychology, history, organizational studies, medical science, anthropology, sociology, and others (Denzin & Lincoln, 2000)[56]. Qualitative researchers use semiotics, narrative, content, discourse, archival, and phonemic analysis, even statistics.[57] They also utilize various aspects and

Search 1
Date: 4/22/00, 2:56 and 2:58 pm
A. Institutional Review Boards: 99 matches; 73 on *Chronicle* pages; 26 in Daily news releases
B. Institutional Review Boards and Social Science: 6 matches, 5 on *Chronicle* pages; 1 in Daily news releases

Search 2
Date: 7/26/01, 7:49 and 8:11 pm
A. Institutional Review Boards: 136 matches; 93 on *Chronicle* pages; 43 in Daily news "headline" releases
B. Institutional Review Boards and Social Science: 8 matches, 7 on *Chronicle* pages; 1 in Daily news "headline" releases

The comparison shows a 37 % increase in 15 months in overall matches for A, and a 33% increase for B. Twenty more stories appeared on the *Chronicle* pages, averaging more than 3 stories every two months, while in Search condition B, only two new stories appeared during the entire 15-month interval. The ratio of A:B is 99:6 (6.06 % for social science) for Search 1 and 136:8 (5.88%) for Search 2.

Figure 1

applications of ethnomethodology, phenomenology, hermeneutics, feminism, deconstructionism, ethnographies, interviews,[58] psychoanalysis, cultural studies, survey

[56] I suggest that some amount of qualitative research is present in many quantitative studies but is simply not labeled as research, see "exempt by label" section, p. 269-272
[57] Strauss and Corbin (1990) broaden the definition: "By qualitative research we mean any kind of research that produces findings not arrived at by means of statistical procedures or other means of quantification" (p. 17-18). And, some researchers utilize qualitative techniques; the data gathered are subsequently coded and analyzed statistically. These researchers, in effect, quantify qualitative data, as explained by Denzin and Lincoln (2000, p. 8). See also footnote # 53, p. 47.
[58] In qualitative interviews alone, techniques range substantially in the form they take, from informal to semistructured interviews and life histories (Agar 1980; Fontana & Frey, 1994; Glaser & Strauss, 1967;

research, participant observation, and others (Denzin & Lincoln, 2000, p. 6). Diaries, and diaries in combination with interviews, are also useful (see Zimmerman & Wieder, 1977).[59] Qualitative research is, therefore, according to Denzin and Lincoln (2000, p. 8) "interdisciplinary, transdisciplinary," and sometimes a "counterdisciplinary" field, it is "multiparadigmatic" and researchers in this field value "the multimethod approach" to answering questions. Qualitative researchers are committed to the "naturalistic perspective" and "interpretive understanding of human experience" (Denzin & Lincoln (2000, p. 8).

Social Science Regulatory Observations and Considerations

In a search of the *Chronicle of Higher Education* for ten years' time, 73 stories were found under the heading "Institutional Review Boards" overall, but only five of those were social scientific in nature (see Figure 1, p. 50).[60]

Pelto & Pelto, 1978; Holstein & Gubrium, 1995). The main unifying feature is the collection of textual data through tape recording and note taking. Open-ended interviews are allowed to flow freely, other interview situations are more restrictive. Both require preparation and skill on the part of the qualitative researcher to encourage individuals to talk about themselves. And, of course, a huge variance in interview approaches is required given the range of possible topics. (Also see Gottschalk, 1995, for example of the use of unstructured interviews in a postmodern vein.)

[59] Minutes of meetings (and results of audits and annual reports) constitute what might be viewed as a diary of an organization, for example.

[60] A similar search of the NIH website (http://search.nih.gov/advanced.html, accessed May 25, 2002) conducted September 2, 2001, yielded the following results:

1) Your search for "Human subjects" matched 5842 documents out of 147002.
2) Your search for "human subjects" and title <CONTAINS> "behavioral research" or title <CONTAINS> "social research" matched 25 documents out of 147002.
3) Your search for "human subjects" and title <CONTAINS> "clinical research" or title <CONTAINS> "medical research" matched 176 documents out of 147002.
4) Your search for "human subjects" and keywords <CONTAINS> "behavioral science" or keywords <CONTAINS> "social science" matched 12 documents out of 147002.
5) Your search for "human subjects" and keywords <CONTAINS> "clinical research" or keywords <CONTAINS> "medical research" matched 1839 documents out of 147002.

This would also indicate that in general, the focus of government funding organizations, such as the "umbrella" NIH, is on clinical and medical trials rather than behavioral or social research. In Search

In the qualitative research arena, the questions surrounding the protection of human subjects of research shrink in volume and narrow in focus: What is public and what is private? What distinctions (*i.e.*, interpretations) are made between "confidential" and "anonymous" and when do they (*i.e.*, are they interpreted to) apply? When does the distinction matter, in terms of regulation? When does it matter in "real" life? And, what can the researcher promise the participant anyway? Does a researcher who refuses to break a promise of confidentiality or anonymity have immunity from formal/legal, professional, academic, or other forms of prosecution?

What is "harmful" research? What is "minimal risk?" "Greater than minimal risk?" "Somewhat greater than minimal risk?"[61] "Only slightly greater than minimal" risk?[62] Who labels it so?[63] Who has the right to distinguish? Who has the ability? When

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2, only *one* document pertained to rules for social scientists; the rest were announcements of research and all appeared to be quantitative in nature. A title search for the term "ethno" yielded one match in 147002 documents, for example. Finally, OHRP Director Koski (see Brainard, 2001, Mar 9) indicates that social scientists' concerns are a priority of a DHHS advisory committee that met for the first time in December 2000. However, Brainard (2001, Mar 9) reports only one social scientist is on the 17-member panel. (NOTE: Wildcards were used to broaden the search, *i.e.*, medical to include "biomedical" and ethno to include ethnographic, ethnography, etc.)

[61] According to the Common Rule (45 CFR § 46.102 (i), minimal risk means "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Local IRB interpretations often imply (in their failure to exempt certain kinds of research exempted under federal law) that being observed at a shopping mall, or interviewed in a park is more dangerous than driving to the mall, park, or elsewhere. A related issue is weapons testing; can we not assume weapons are dangerous, and that would include the testing of them? (See CNN.com, 2001, Jan 15.)

[62] See Charo (1999, Mar 26) who says "Many boards already struggle with the difference between 'minimal' and 'greater than minimal' risk, despite regulatory definitions of those categories. Boards evaluating research on children have not found a third category of risk – 'only slightly greater than minimal' – any easier to define with precision" (p. B9).

[63] The answer to this question is rather obvious. Based on the Common Rule definitions provided in the previous two footnotes, it is the federal government in this case that has the power to define. The answer to the next question about who has the ability to define is of course uncertain and mostly unasked.

is covert research activity justified? When is regulation justified? What *is* the role of regulation in all of this? And, how does it *work*?

How *does* it work? Not only in terms of efficiency, *i.e.*, how *well* it works, but also more basically how it *operates*. These are important local questions, even if no absolute or comprehensive answers exist. And certainly, an understanding of how something operates is a logical prerequisite to understanding how to evaluate, reform, or improve it. (For examples of analysis, see Appendix A, p. 344)

Epistemological Position

Evaluations of the "true" effectiveness of regulatory efforts may not be comprehensive, conclusive, possible, useful, or advisable. High degrees of intersubjective agreement are not likely to exist, especially in regulatory situations. However, observations and subsequent descriptions of regulatory activity, in an attempt to understand how the system works (*i.e.*, operates) seems a reasonable pursuit.

From the position that the regulatory system is substantially detached from the research system (in a sense, hyperreal, as described by Baudrillard, 1983, and also by Russell, 1972), "this passage into a space whose curvature is no longer that of the real, nor of truth" (p. 3-4) is the onset of "the age of simulation" which "begins with a liquidation of all referentials," (*i.e.*, things corresponding with the lifeworld, p. 4), and made "worse," by "their artificial resurrection in the form of signs" (p. 4). It involves the "substituting signs of the real for the real itself, an operation to deter every real process by its operational double" (Baudrillard, 1983, p. 4). Epistemologically, then it is

important to critically analyze the "curvature" of the regulatory world without, to the extent possible, making "flat earth" assumptions. Deetz (1995) says, "The management of work must be reintegrated with the doing of work" (p. 170).

Simulationally, then, much of the science of human communication relies upon the optimistic assumption that behavior can be both understood and improved through systematic study. Further, it assumes that improvement must be based upon understanding, which converges on the primary goal of science. Some communication scientists "positivistically" assume that they can find important patterns in social behavior through observations of many similar actions. Positivists believe they can devise and support general laws about behavior (Skinner, 1938; and more recently in the communication field, C. Berger, 1991; Berger & Calabrese, 1975; Burgoon & LePoire, 1992; nearly anything coming from the McCroskey Machine or the grinding of Gudykunst's Gears). Some communication theorists want to understand and interpret, and to know the affects and meanings communication holds for the participants themselves in every conceivable context (interpersonal, group, organizational, societal, etc.). And still other theorists want to take up the issues of change, emancipation, and critique (Alvesson & Willmott, 1992; Alvesson & Deetz, 2000; and predecessors Marx, Horkheimer, Adorno, and later Foucault, Habermas, Derrida, and others).

For example, Redding and Tompkins (1988; see also Tompkins & Cheney, 1985), from a postmodern viewpoint (though not explicitly stated as such) suggest that communication distortion does not mean the same thing to a critical scholar that it might mean to a traditionalist. Following their argument, when communication

traditionalists[64] talk about distortion, they focus on (in)accuracies or errors in (in)formation that lead to (in)efficiency and (in)effectiveness (mal-formation) in communication or some such conjecture. Traditionalists might observe and measure managers' communicative behaviors in order to classify them in degree of "openness" or some other notion, or purport to measure the levels of job satisfaction among employees or managers, or perform statistical analyses related, they would contend, to whether employee job satisfaction is greater under "high-openness" or low, etc.[65] These terms (operationalizations, or what might be described as "real" world detachments, or Baudriesque simulations), *i.e.*, "measure," "openness," "high-openness," "job satisfaction," etc. point out language that dominates thinking about jobs, happiness, the desirability of whatever "openness" is defined as, what an adequate sample size is, what efficiency is, and even what science is. This thinking is SINSful (see next section, p. 58-64), specifically assumptions that these processes, definitions, observations, measurements, observations, and conclusions are relevant, or fit, or are fit to describe more than a tiny sliver of "reality." These same processes, definitions, observations, measurements, and conclusions are too many steps removed from the "real" world to be used alone or authoritatively about what life is like, yet we accept them as institutions, as natural, normal, as preferable, as "science." In my way of thinking Baudrillard's "simulation" (the second "S" in SINS) is very close in meaning to "operationalization"

[64] I find the term "traditionalist" a further indication of the reification of positivism. For an example of a similar situation, re: use of the term "critic," see p. 160.

[65] Generally speaking, traditionalists might examine communication processes and some perceived relationship to organizational effectiveness. This trend toward "managerial" interests in communication departments is troublesome, see Mumby & Stohl (1996).

(see footnote # 108, p. 92, re: Schutz comments about lost relationships to meaning in the natural sciences). Jackson (1989) says that the "impersonal idioms" we use in talking about our "unsystematic, unstructured nature of our experiences" helps us "create illusory word-worlds which we can more or less easily manager because they are cut off from the stream of life" (p. 4). Jackson concludes, "In this sense, objectivity becomes a synonym for estrangement and neutrality a euphemism for indifference" (p. 4).

"In a postmodern approach ... language which is produced by the empirical process does not equate with an increasingly accurate correspondence with reality. Instead it represents a process of professional self-justification" according to Hassard (1993, p. 12). Further, the inherently impossible value-free position of positivists contributes to this "distance from reality" (*i.e.*, detachment) problem. In turn, these departures from reality create a layer (or several layers) of what might be called "buried superficiality," *i.e.*, we know something we do does not work, and is not based on "reality," but we keep doing it, burying our concerns in some kind of un- or de-being process. (See Schutz & Luckmann, 1973, and/or footnote # 247, p. 241 re: use of rules as simplifying.)

Analytical Framework

> Each person is born into ongoing discourses that have a material and continuing presence ... Available discourse positions the person in the world in a particular way prior to the individual having any sense of choice. [This discourse] structures the person's subjectivity, providing a particular social identity and way of being in the world. The person, *contra*

> humanism, is always social first and only mistakenly claims the personal self as the origin of experience. (Alvesson & Deetz, 1996, p. 205)

Schutz and Luckmann (1973) use the term "historizations" (in describing a phenomenon similar to "discourse structures") saying they "originate from socially conditioned motives" (p. 283-84; see also Sunwolf & Seibold, 1998, p. 286-87).

Language is inherently limiting; it hides important alternatives. (See Poole, et al., 1985, for discussion about boundary establishment and identity maintenance within structured environments.) Once we subscribe to the patterned system, we begin talking "at" or past" each other, role-to-role (*i.e.*, detached) rather than "with," (real-to-real) in a sort of pseudo-engagement. This notion of pseudo-engagement is particularly relevant to the issue of regulation, *i.e.*, we rarely have face-to-face encounters with regulators. Our conversations with them, if they occur at all, are focused on the *fulfillment* of rules rather than the reasons for them (Baudrillard, 1983, 1988; Foucault, 1972, 1980; Habermas, 1975, 1984, and others).[66] For example, most regulators would likely be "offended" by and probably unable to answer "why" questions; they are accustomed to answering "how" questions (even if/when unable).

Individuals arrange for—and often direct the flow of—activities (talk) within settings (Goffman, 1974; Austin, 1962; Searle, 1969; Chomsky, 1965; Garfinkel, 1967; Sacks, Schegloff, & Jefferson, 1974; Foucault, 1972, and others). Asking questions that others must answer, and making requests and issuing directives to which others must—

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[66] In this case, I cite Baudrillard for his discussions about simulations. He might say something like what we do at the office is deal with how to do things at the office rather than why we have an office, for example. Foucault I bring for his comments about discursive formations, specifically, though he doesn't use this phrase, that "texts drive activity." And, I cite Habermas for his ideas about legitimation and the rather interesting and somewhat terrifying process of tethering activity and beliefs to other activity, ideas,

at least are expected to—respond (and to respond in specific ways) are examples. People create rules, specialized vocabularies, and certain forms of argument. They form hierarchies, rituals, and routines via this discourse. Individuals *produce* (or more accurately, co-produce) control and power, then, through discursive dominance, *i.e.*, making some resources (including ways of knowing, *i.e.*, what is considered fact, what is considered logical, what is considered risky [or less than risky, or somewhat less than risky], what is public and private, and perpetuating the myth of a singular truth, justice, beneficence, etc.) available to themselves and others, and acting to make other resources less available. And people do this through talk. In the case of regulatory bodies, most of the talk results in written documents, *i.e.*, rules and reports.

SINS (Structures, Institutionalizations, Naturalizations, Simulations)

In the present study, the works of the classical theorists–Weber (1947), Fayol, (1916/1949), and Taylor (1919/1947)–are useful for understanding the roots of the IRB system and may provide glimpses of the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS operating in the system. SINS may be described as "unacknowledged" knowledge. SINS are neutral but powerful. (See Foucault, 1980; 1977/1995, p. 297, re: "carceral continuum," "carceral net," and "carceral circles" underlying morality, power relations, and order; and Durkheim, 1933, p. 79, re: "common consciousness" creation.)

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expectations, etc. rather than the tethering of activity and beliefs to reality (*i.e.*, the use of instrumental reasoning).

> The power of any position has been traditionally gathered from its grounding. This grounding could be to either a metaphysical foundation – such as an external world in empiricism, mental structures in rationalism, or human nature in humanism – or a narrative, a story of history, such as Marxism's class struggle, social Darwinism's survival of the fittest, or market economy's invisible hand. With such groundings, positions are made to seem secure and inevitable and not opportunistic or driven by advantage. (Alvesson & Deetz, 1996, p. 208)

Structures. Marx offered the earliest ideological critiques of the workplace in 1844 and 1867 (Alvesson & Deetz, 1996). Marx focused on economic exploitation practices, direct coercion, and structural social differences, but he also described ways exploitation is disguised and comes to be legitimized (see also Lefebvre, 1969, p. 7 and 10). The focus of study shifted to scrutiny of active consent, and the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS (and concessions) that make the need for coercion rare. In this view, a worker's *self*-understanding of experiences became, and remains, important to understand.

Similar to Adorno (1989a), Hall (1986) offers the example that marketing research operates with the ideology that capitalism is good, similar to the contention that science and regulation continue to operate with a bias toward positivism (see also Whyte, 1987; Agar, 1980; Goffman, 1971).

I believe this is consistent with Marx' economics-as-deep-structure premise, and this perspective may be useful in gaining more understanding of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS affecting the IRB system. For example, the notions that rules are

perceived by many individuals as desirable or as constituting protection. There appears to be a bias toward compliance, perhaps in part because of this notion of protection, and because it is easier, safer, and substantially more "appropriate" to conform than to rebel[67]. (Re: rules perceived as desirable, following rules as good, and rules as protective, see Schutz & Luckmann, 1973; re: maintenance of status quo, see Adorno, 1989a and Horkheimer & Adorno, 1944/1972; also see Brainard, 2001, Jan 12; NBAC, 2001; Sunwolf & Seibold, 1998). The (mythical) ideas that rules are good, and even that following rules is good,[68] are obvious, particularly on the part of federal and institutional regulators, as I will show.

(SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS are operating in the IRB system, even when the rules (often symptoms of even deeper structures) are being (at least occasionally) criticized. It may be that the IRB (or other) system remains in place (and is expanding in some local interpretations to include film makers, journalists, historians, cultural geographers, and others previously not affected) even though it is considered abusive and unnecessary by many (see, in particular, AAUP, 2001 and others cited herein), because the oppressed allow it (see Adorno, 1989b, footnote # 67, below), and then contribute to entrenching the system of rules by the SINSful assumptions that the system is unavoidable, cannot be deconstructed, has a "higher purpose" of which an individual researcher is unaware, etc.

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[67] Adorno (1989b) states, "The whole [system] survives only through the unity of the functions which its members fulfill. Each individual without exception must take [on] some function ... order to prolong ... existence; indeed, while [his] function lasts, he is taught to express his gratitude for it" (p. 268).

[68] See also Sunwolf & Seibold (1998), for a similar argument about juries and nested values, specifically they state, "the rule that 'the law should be followed' interpenetrates with the social rule that 'people should not report the transgressions of a friend'" (p. 303). In our own experiences we may recall times

Institutionalizations. More or less following Marx, Giddens (1979) defines ideology as a set of assumptions and beliefs comprising a system of thought. Ideology provides the structure of an organization's "mode of rationality," and is essential to an organization's deep structure. Ideology, in Giddens' (1979) view, serves to privilege certain groups. Members of dominated groups participate in their own oppression (they concede) by identifying with and consenting to the system preferred by the dominators. In organizational settings, according to Williams (1977), such dominance occurs when a group in power (managers, for example, or regulators) convinces an oppressed group to adopt the interests of the dominant group (the we're-all-on-the-same-team pitch, loyalty, patriotism, and corporate cultism are examples), or makes some reality *claims* more available than others (Foucault, 1977/1995). Hall (1986), in the context of mass communication, suggests that the media do not reflect the status quo ideology, but the media actually reinforce it. (See also Grabe, 1999, particularly the last sentence, "This study's results support the notion that television mass disseminates messages to nurture the survival of the existing social order," p. 168.)

Naturalizations. According to Alvesson & Deetz (1996) naturalization involves social formations that are abstracted from the "historical conflictual site" of their origins and treated as fixed entities. These reifications "become the reality rather than life processes" and these "institutional arrangements are no longer seen as choices but as natural and self-evident" (p. 199). Adorno (1989a) states that "conformity has replaced

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when we have felt the law was been followed but justice was not served, or that certain rules are not fair or not fairly followed, etc.

consciousness" (via models in the media of how to dress, think, behave, etc.) and "the concepts of order which [the culture industry] hammers into human beings are always those of the status quo. They remain unquestioned, unanalyzed, and undialectically presupposed, even if they no longer have any substance for those who accept them" (p. 133; see also Mumby, 1987, p. 51). And Derrida (1981) says that normative[69] social structures are products of systems privileging unity and identity over separation and difference. This work has relevance to the "invisible functioning" of the IRB regulatory system, the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS, at work. "Nothing offers a more striking symbol for the fact that people's lives, what they hold for the closest to them and the greatest reality, personal, maintained in being by them, actually receive their concrete content in large measure from above" (Adorno, 1989b, p. 273).

Simulations. To further explain Baudrillard's (1983) ideas about simulations, I'll first present a descriptive example he offers, and then a brief discussion of the "phases of the image" as he outlines. Baudrillard (1983) presents feigning versus simulating an illness in illustrating his idea. When feigning an illness, a person "can simply go to bed and make believe [he] is ill" (p. 5); when someone simulates an illness, though, the person produces in him/herself some of the symptoms of the illness. Therefore, "feigning or dissimulation leaves the reality principle intact: the difference is always

[69] The term "normalization" might have been used in this SINS device, though it has been used in other ways. I chose "naturalization" (the term used by Alvesson and Deetz) because it is a little more precise, more clearly attributable, and has fewer unintended connotations.

clear, it is only masked; whereas simulation threatens the difference between 'true' and 'false,' between 'real' and imaginary'" (p. 5).

Baudrillard's (1983) phases of the image include first a "good appearance," *i.e.*, a reflection of a basic reality. Next, characterized as a "bad appearance," is an image that masks and perverts a basic reality. Third, what Baudrillard terms sorcery, masks the *absence* of a basic reality. And finally, simulation, in which an image "bears no relation to any reality whatever; it is its own pure simulacrum" (p. 11). In the case of the IRB system, many examples of these phases can be seen. Application forms, completed by researchers for presentation to IRB members, "good appearances" (phase one). They are "good" in that they are produced by the person who will actually conduct or at least conduct a potion of the study, *i.e.*, will be in the liquid, local research environment. That these applications are accepted as accurate representations of what actually happens in any local situation is a masking/perversion (phase two) of that local reality (and especially perverted, perhaps, is an irrelevant/ill fitting regulatory structure). Researchers contribute to the sorcery (phase three) in "masking" the absence of reality in the system (regulators' acceptance of written documents as ensuring protection and/or compliance to rules, or the assumptions that rules, if followed, provide protection and/or that researchers know and comply with rules). An argument could be made, with respect to phase four, that the entire IRB system (and indeed many regulatory systems) is a "simulation." Examples of evidence of this image phase might be the (rather prevalent) idea that regulatory systems are needed and/or are accomplishing their goals,

or that regulators and the regulated often perceive regulations to be "mandatory" (when, without direct oversight, the system can only be in a "real" sense voluntary).[70]

Bringing SINS into View: Foucault's Archeology

Critical theorists, with a focus on communicative and symbolic approaches to power, argue that assumptions within a group that things are or should be a particular way is most powerful. "Domination involves getting people to organize their behavior around a particular rules system" (Mumby, 1987, p. 115). Foucault, it seems, agrees when he advances the idea that power is a set of relationships that people hold with the texts[71] that constitute organizations to which they belong[72]. Further, Foucault's idea that the more invisible the power is, the more effective it is resonates with Mumby's

[70] For this study, I am not concerned with whether the *entire* IRB system is a simulation or not. I am, rather, concerned with the various ways in which specific *procedures* are simulated" in this way, i.e. the level of detachment among federal regulators, regulations, local interpretations of regulations, actual researchers, the researched, and their local environments.

[71] Derrida considers "text" in a way that indicates, for me, something more akin to "context," *i.e.*, Derrida says the text refers to both the interplay of discourses (political, social, etc.) and the "stage upon which the process of deconstruction is enacted" (as described by Hassard, 1993, p. 10). Thinking of texts in this way supplements the Foucauldian analytic approach (in my view).

[72] Dissertations are an example. Dissertations, I would assert, are "non-authored" texts produced by texts (see Foucault, 1972, re: discursive formations). Every dissertation ever written provides a frame for every dissertation that will be written. Previous dissertations, read by scholars who serve on committees and as chairs, work to formulate the view of what the dissertation text should be. Texts (including guidelines and stylebooks, as examples) are used to disseminate rules, which in turn dictate what dissertations must look like (at least to a very great extent). IRB regulations dictate what the dissertation can and cannot contain. And the dissertation "writer" creates a new text, based on previous and related texts, and the prospectus, rough draft, and (mostly written) critiques of chairs and committee members. Therefore, there is no single "writer" of a dissertation; the dissertation is a text produced by texts. In this example, who is on the committee, who writes the rules, or who punches the keys to actually create the text doesn't matter. Dissertations are framed and produced in this same way, regardless of who the student is, who the chair is, which institution the "dissertation production entity" involves, or who writes rules. Somewhat ironically, the document bears the student's name although often the student had the least to do with the "writing." However, the student generally does the "word processing," and it is then this feat of word processing, rather than any true "authorship," that is used in the "final" evaluation of the student. The student must defend the document s/he has (not) authored. In this way, one might argue that dissertations are textually dictated (rather than "authored") typing tests. (See also Hassard, 1993, "Research proceeds on the basis of discourses which are already shared within a particular scientific community," p. 12.)

statement about assumptions, as well as the views expressed by Hall, Gramsci, and others.[1]

Deetz (1982) suggests the goals of critical scholarship are to gain a richer understanding of naturally occurring events, to criticize systematically distorted communication and false consensus (the result of insufficient whying; see Adorno, 1989a, p. 133), and to work to expand the intellectual, cognitive horizon from which organizational members think and work. In order to do this, I suggest the "horizon" must be made more apparent than it often is, and expanded to better accommodate (maybe someday even welcome) those with atypical or unorthodox (*i.e.*, strange, weird, etc.) approaches.

In a departure from those critical theorists who focus almost entirely on issues of domination and oppression, Foucault (1980) examined the codes and theories of order by which societies operate (see Manning, 1989, p. 213 and 232), and suggested that power is not domination, rather Foucault made a distinction between the two.[73] In the Foucauldian scheme, power is viewed not simply as a pervasive force, but also a productive, creative one. Foucault asks, "If power were never anything but repressive, if it never did anything but to say no, do you really think one would be brought to obey it?" (1980, p. 119).[74] In attempting to describe the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS in place in the

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[73] And Hall (1989) states that hegemony is "not the old notion of determinism in a new disguise, for it refuses to ascribe the positions of power, whether in discourse or across the whole social formation, permanently to anybody" (p. 51-52), and he further states that hegemony isn't total, a plot, and is not force. (See also Hall, 1996.)

[74] Similarly, Giroux (1988) suggests schools can become institutions where ideas, values, and social relations are taught for the purpose of students' critical empowerment rather than subjugation.

IRB regulatory system, I will utilize questions set forth by Foucault in 1972 (see Table 1, Appendix A, p. 345) to assist in the exploration of IRB discourse related to regulations, guidance documents, sanctions, evaluations, and other discursive formations within the system.

Loss of Foundations (Habermas' Legitimation Crisis).[75] In the first of two views about the loss of foundations and grand narratives described by Alvesson and Deetz (1996), they suggest some analysts hold that foundations and narratives have always been a hoax. They have been used (often unknowingly and in ways that are unacknowledged and unarticulated, *i.e.*, mindlessly) to support a dominant worldview. The second position focuses on "growing social incredulity" (p. 211) toward foundations and grand narratives; Lyotard (1984), for example, demonstrated the decline of grand narratives of spirit, emancipation, patriotism, etc.

Growing public skepticism (or astuteness) added to the proliferation of the profit motive in research and the record of atrocities in (almost exclusively medical or military/medical) research, can be associated with what Habermas (1975) termed "legitimation crises." Deetz (1985) suggests legitimation appears "in the rationalization of decisions and practices through the invocation of higher-order explanatory devices " (p. 127; see also NIH, 2001, p. 1, regarding "Decision Trees") and argues Habermas (1975) has "convincingly" demonstrated motivation and high productivity have been sustained in the Western world more by the Protestant work ethic (*i.e.*, the belief that

[75] Habermas (1975) states that legitimation crisis occurs when "the legitimizing system does not succeed in maintaining the requisite level of mass loyalty" (p. 46).

work is preferable or more valuable or virtuous than play, that leisure and family time are expendable in the face of work, or adages about idle hands and devil's work)[76] than by intrinsic work experiences (see also Weber, 1930, who shows how one group's set of social norms can become infused into the wider socio-cultural context). Lyotard's (1984) view suggests only local narratives exist, leading to explorations of how stories in organizations connect to legitimizing narratives and how some are more local, situational in nature (see Martin 1990; Deetz, 1997, 1998). Others have used this position to illustrate the false certainty in management narratives (Jehenson, 1984; Ingersoll & Adams, 1986; Carter & Jackson 1987). The rise of "performativity"[77] occurs when measures of means toward social ends become ends in themselves and when new forms of control arise, directed not by a desire for social good but simply by more production and consumption, according to Alvesson and Deetz (1996, p. 209). I believe the IRB system has clearly arrived at this point, *i.e.*, means overshadow ends, process has supplanted purpose.

Proliferation of private free enterprise (as an activity and as a value) encroaches on other realms of "real" life, including politics (PACs, for example), education (we now teach "marketable skills" in the continuation of the "vo-teching" of the university),

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[76] It may be possible, eventually, to change the compliance bias. If/when rules are bad (*i.e.*, ineffective, ill-fitting, irrelevant, debilitating) it could be argued that they *should* be ignored. But, rather obviously, the SINSful idea that following rules is good contributes mightily to the pervasive tendency to follow bad rules rather than ignore them.

[77] "Performativity," according to Lyotard (1984) rose to the greatest prominence, catapulting convenience and efficiency, productivity, profitability and other measures of "return on investment" ahead of everything else in importance. In Habermasian terms, these values are cultural reproductions, and an example of instrumental reasoning privileging the means over the ends, aiding dominant groups' (positivists and regulators, for example) ability to accomplish their goals invisibly. (See also the concepts of "glocalization" and "globalization," Kraidy, 1999.) My local point is that perpetuating the *process* is privileged over accomplishing the *purpose* in the IRB system, and that compliance takes precedence over critique.

and on even deeper levels, including the human consumption of animals and their habitat, and our own habitat including air, water, earth, and space. According to Mumford, (1970), "Western society has accepted as unquestionable a technological imperative that is quite as arbitrary as the most primitive taboo: not merely the duty to foster invention and constantly to create technological novelties, but equally the duty to surrender to these novelties unconditionally, just because they are offered, without respect to their human consequences" (p.185-186). The right-to-make-a-profit-at-any-cost mentality is prevalent.

With respect to the IRB regulatory system, it seems, when these are in conflict, that we favor process over purpose, maintaining the status quo over development and implementation of new ideas, and compliance over critique. We are conforming to (at best) a pointless system of protection (and in some cases a potentially debilitating system) rather than rebelling against it. Why don't we ignore it? Engage in passive rebellion? Encourage our colleagues and students to ignore (certain ill-fitting and meaningless parts of) the system? Insist that our professional organizations endorse the ignoring of these (selected) rules? Why don't we act as if this is possible?[78]

Because the IRB system is highly political (as will also be shown), I suspect federal regulators, (once the momentum of the rebellion is apparent)[79], would perhaps

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[78] Deetz (1995) suggests that "the production of particular oppositions and conflicts" would be as much a part of [compliance] "as the production of integration and order ... the dialectic of control ... delimits and limits dominant groups ..." (p. 166). He continues, "Communication researchers in looking at such constitutive processes are not so interested in the production of a dominant culture as in the cultural fragmentation and dispersion that function to control and make productive resistance difficult" (p. 166). And Adorno (1989b) states, "When details come to seem the strongest reality of all, on account of their tangible immediacy, they blind the eye to genuine perception" (p. 269).

[79] See Schell (1982), re: the Hundredth Monkey, and Habermas (1975) re: legitimation crisis as a consequence of failure to maintain mass loyalty (footnote # 75, p. 66, herein).

move quickly to dismantle the system (as it pertains to "minimal risk" studies, as described and defined by the federal government) and claim credit for what might be spun as a system "innovation."

Chapter Three: Data and Method

"Against positivism, which halts at phenomena – 'There are only facts*' – I would say: No, facts is precisely what there is not, only interpretations. We cannot establish any fact 'in itself:' perhaps it is folly to want to do such a thing.* Friedrich Nietzsche, *The Will to Power*, p. 267, (emphasis in original).

Data

"Discourse is the way we do things ... discourse becomes social structure" (Loseke, 1993, quoted in Miller, 1997, p. 170). Social settings and institutional discourses create possibilities for reality construction (see Hindess, 1996, especially p. 19; Sunwolf & Seibold, 1998). "Reality" construction is not so precisely determinate that participants may predict the exact ways issues will be interpreted, but reality construction occurs under conditions, *i.e.*, (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS, that make some reality *claims* more available than others, as Foucault (1977/1995) suggests.

Foucault's methodology (as discussed in 1972, especially p. 6-8) is characterized by the kinds of data he chose to utilize. Rather than documents of renown or merit produced by famous philosophers or texts surrounding extraordinary events, he most often employed common, generally unknown and/or disregarded documents, those considered by many to be insignificant. Examples include records kept by doctors, teachers, and priests; manuals; grant proposals; files kept by government agencies or other organizations; and personal diaries and journals of ordinary people doing ordinary things (see Sacks, 1970). Foucault wanted to address "a layer of material which hitherto

had no pertinence for history and which had not been recognized as having any moral, aesthetic, political or historical value" (Foucault, 1980, p. 50-51). Such documents are local, providing a look at the way a system *really* works (in a day-to-day sense, these documents providing nuts-and-bolts parts, an empirical way of observing the discourse which constitutes the system). Examples of such documents utilized in the present study are the rules written by regulators, with the various interpretations of those rules appearing in the handbooks and on the websites of research institutions. These texts provide insight as to the ways federal regulations are used by participants to produce new layers of institutional-level rules. Foucault's (1972) ideas about what constitutes data are not inconsistent with those set forth by Dilthey (1900/1969) and Kant (1781/1958). Dilthey (1900/1969) advocated the use of literature, art, social life, and "the course of history" as data. And Forester (1992) utilized (as data) twelve lines of text, a transcript from an "insignificant" city planning meeting (see footnote # 85, p. 74).

Based on these theoretical ideas, data for this analysis includes textual materials from the regulatory bodies holding (by virtue of being given) the power to make policy. These materials include transcripts of Congressional hearings; commission reports; journal articles; the Code of Federal Regulations (CFR, the codification of general and permanent agency rules published in the Federal Register); handbooks issued by federal regulators and those written by institutions; information user-lists featuring announcements about changes in and interpretations of regulations; press releases from government agencies; transcripts and reports from proceedings designed to stimulate

discussions about human subject research and regulation; articles from the *Chronicle of Higher Education* and other academic, research, news, and related publications; numerous websites of regulatory agencies and research institutions, and other materials.

This study will examine the talk,[80] the discourse produced by regulators, research institutions, and others related to the policy and rule making surrounding the use of human subjects. Deetz (1982) suggests this (kind of) discourse is of interest to interpretive researchers as data for analysis of the "processes by which the meanings of organizational events are produced and sustained through communication" (p. 132)[81]. Emphasis in the present study is placed on social science and qualitative methods (particularly the distinctions between these and clinical methods, as described earlier, see p. 26). Documents spanning approximately 60 years – from 1940 to the present time – are part of the analysis. The discourse, the "conversation" that constitutes this regulatory system involves 10s of organizations, 100s of regulators, 1000s of institutions (IRBs), 10s of 1000s of researchers[82] and 100s of 1000s of two-legged research participants (not to mention millions of feathered, finned, furred and four-

[80] "Talk" is implied by many words, including "accrediting," "examining," "a full accounting of," "to simply and clearly address," "interviews," "surveys," and two instances of talk about talk: "drawn on information," and "drawn on their comments." All of these examples are found on one page of one government report (DHHS OIG, 2000b, p. 7).

[81] Interpretations, better understanding, and/or thick descriptions are only part of this dissertation project. It is also part of the purpose of this work to change the system (via passive rebellion, *i.e.*, ignoring certain portions of the IRB system *en masse*). See Horkheimer statement in footnote # 21, p. 19 and also Chapter Eight, herein.

[82] In an evaluative report of National Institutes of Health (NIH) commissioned by the National Bioethics Advisory Commission (NBAC), it was reported that in 2000 in the U.S. approximately 4,000 IRBs operated and between 35,000 and 45,000 researchers conducted human-subject research in 1995. Southwick (2002, May 3) reports more than two million people participated in *clinical* trials in 2001.

legged participants). Specifically, the discourse among and between the regulators, the institutions, and researchers within the IRB system constitutes the data for this study.[83]

Somewhat extended analyses are done utilizing a federal government agency report (GAO, 1996), a presidential commission report (ACHRE, 1995), a guidance (*i.e.*, how to be in compliance) document (USAID, 1999), a Senate bill (the Human Research Subject Protection Act of 1997), and the University of Oklahoma's IRB application form.[84]

Method

In a way consistent with the mission of critical theory, proceeding with postmodern sensitivity and sensibility (see Lash & Urry, 1987, who place emphasis on disorganization, untidiness and flexibility), and utilizing the work of Foucault (particularly 1972), these qualitative, phenomenological, and critical methods, especially Foucauldian analysis, can be used to address the questions posed here. Forester (1993) says by linking control structures to daily experience, voice, and action, we form a structural phenomenology: "it is structural because it maps the systematic staging and framing of social action; it is phenomenology because it explores concrete

[83]And this is not unusual. According to Denzin, "except for the dissertation ethnography and for those anthropologists who choose to move in on the turf of the equally postmodern sociological ethnographers of urban and industrial settings, the ethnographic task of anthropology may become one devoted to reading texts and writing critiques. The 'field' may be located in one's library or one's study" (Denzin, 1989, p. 79). See also Foucault (1972).

[84] I had hoped to include "real" applications and consent forms as submitted and the attendant correspondence between the researchers and the OUIRB, as well as official minutes of meetings of review boards; interviews with faculty members, OUIRB members and members of other campus boards, and researchers; and ethnographic observation and tape recordings of OUIRB and similar meetings. None of these requests was approved by the OUIRB, or were they (technically) rejected. Indeed, none were even considered by the OUIRB, as they were "held up" by three administrators, and not "allowed" to go to the actual board.

social interactions (promises, threats, agreements, deals, conflicts) that are so staged" (p. 140).[85]

Postmodernism "primarily serves to attempt to open up the indeterminacy that modern social science, everyday conceptions, routines, and practices have closed off" (Alvesson & Deetz, 1996, p. 210). This is the purpose, as mentioned, of the present study, *i.e.*, to open questioning, to begin more active, more aggressive whying as social scientists, especially those researchers employing unobtrusive methods about unobtrusive topics. The result of such questioning and re-evaluation of the arrangement between purpose for the IRB (and other organizations) and the processes that have come to constitute them, is a kind of anti-positive knowledge (Knights, 1992; see also Alvesson & Deetz, 2000). Knights argues that conventional approaches to management and organizational study involve the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS of positivism, encouraging researchers to produce positive knowledge in the "form of representations of what they consider to be the real world of management" (p. 514; see Reyna, 2001, p. 10-11 for an example in anthropology; Agar, 1980, particularly Chapter 4; Mumby & Stohl, 1996, about the role of communication department in the study of management; and Goffman, 1971 on the failure of positivism to deliver) or the academy, as I have argued (see footnote # 72 regarding dissertation production, p. 64).

For Denzin (1989), traditional ethnographic concerns regarding the search for valid generalizations and substantive conclusions, are currently, perhaps temporarily,

[85] Forester (1992) studied a city staff planning meeting. His data was twelve lines of transcript from the meeting. From this, he explored ways social and political relations are established, reordered, and

set aside, replaced by "thick descriptions" (Geertz, 1973, 1983) that will in turn make possible "thick interpretations" – joining ethnography to both biography and lived experience (Denzin, 1989, p. 32-34). Postmodern, contemporary ethnographers are informed by the work of deconstructionists such as Derrida, Lyotard, and Baudrillard,[86] and make attempts to disprivilege "all received texts and establish discourses in behalf of an all-encompassing critical skepticism about knowledge" (Denzin, 1989, p. 78). Legitimate, important conflicts can occur about questions such as how we know what is "needed." Who says? Why do we do certain things certain ways at certain times? Why do we think these ways are The Way, that a certain way is any more "right" (*i.e.*, appropriate) than some other way(s)?

Changes in social, political, and research conditions provide new areas of application for postmodern and critical theory work, deconstruction, and resistance reading (see next paragraph) in organization studies. "Critical theory and postmodern writing have provided innovative and instructive analyses" (Alvesson & Deetz, 1996, p. 192). The IRB regulatory system provides an excellent area of application for this kind of scrutiny: The IRB is a useful "vehicle" for illustrating regulation functioning in general, and it is an organization particularly relevant in academia.

Two primary postmodern methods are deconstruction and resistance readings. Deconstruction involves the exploration of suppressed terms and the system that allows positive terms to become established. Resistance reading is a broader process in which

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reproduced as the staff talk and listen.

[86] Hassard (1993) writes, "Five key epistemological notions ... underpin the works of Baudrillard, Lyotard, and Derrida—representation, reflexivity, writing, *differance* [*sic*] and de-centring [*sic*] the subject" (p. 11).

the construction activity is demonstrated and indeterminacy illustrated. "The positive and the polar constructions are both displayed as acts of domination, subjectivity doing violence to the world and limiting itself in the process" (Alvesson & Deetz, 1996, p. 210). Conflicts that were suppressed by the emergence of positive terms are re-opened, brought back for creative redetermination – constant dedifferentiation and redifferentiation" (p. 210).

"Given the power of closure and the way it enters common sense and routines, especially in simulations, such rereadings require a particular form of rigor and imagination ... a keen sense of irony, a serious playfulness, and freedom from the dull compulsions of a world made too easy and too violent" (Alvesson & Deetz, 1996, p. 210; see also Cooper & Burrell, 1988, re: serious play). Virtually every piece of text analyzed in this dissertation utilizes these techniques.

Regulatory processes are the focus of much critical theory and postmodern writings.[87] These have "now found fertile ground in management studies[88] [in part because of] the decline and disillusionment of what is broadly referred to as modernist assumptions by both organizational theorists and practitioners" (Alvesson & Deetz, 1996, p. 191; see also Mumby & Stohl, 1996). As is generally understood by writers such as Alvesson and Deetz, who pointed out, a central feature of both critical and

[87] "[Critical theorists and postmodernists contend] something fundamental has gone awry and more technical instrumental solutions will not fix it ... Critical theorists see the modernists' project as sick and see hope for reconstruction in recovery of good parts and redirecting the future. Postmodernists pronounce its death and proclaim the absence of a thinkable future" (Alvesson & Deetz, 1996, p. 195). And Alvesson and Deetz (1996) consider postmodernism a "carnival of positionings and structurings" involving "a serious playfulness" (p. 210).

[88] In general, I'm equating "management activities" with "regulation activities" (and regulatory management activities for that matter) in theoretical applications.

postmodern studies are attacks on modernist traditions.[ii] "[Critical theory] tends to treat management as institutionalized and ideologies and practices of management as expressions of contemporary forms of domination" (Alvesson & Deetz, 1996, p. 198; see also Alvesson & Deetz, 2000).[89] Of course, critiques of the postmodern perspective (for example Hammersley, 1995), abound.

When "naturalization and freezing of contemporary social reality" (Alvesson & Deetz, 1996, p. 211) occur, opportunities for important conflicts, *i.e.*, open questioning of "authority" and, in this case regulatory systems (*i.e.*, the authorities and processes), are lost. Some groups of people and values (such as qualitative methodologies and researchers utilizing those methods) are marginalized.

A critical theory/postmodern approach to the study of management and regulations, and particularly analysis of the IRB system seems appropriate. Precedents exist, for example, Alvesson's (1987) study of constraining work conditions that lead to intrinsic work qualities such as creativity, variation, development, and meaningfulness being ignored or subordinated to instrumental values, and various studies concerning the development and reinforcement of asymmetrical social relations between experts and non-experts (or Marx's distinction between owners of capital and owners of labor, see Alvesson & Willmott, 1996; or Fischer, 1990, especially "politics of expertise, p. 28 and 106; Forester, 1989, re: the politics of planning, p. 3-4; and also Hollway, 1984). Additionally, there are precedents in studies of extensive control of employee mindsets

[89] Both critical theory and postmodernism proponents see organizations and the social sciences that support them as relying increasingly on a form of instrumental reasoning privileging the means over ends and aiding dominant groups' ability to invisibly accomplish their ends. Habermas describes this in terms

and a freezing of their social reality, more recently referred to as "culting,"[90] (Mumby, 1987; Arnott, 2000), and far-reaching control of employees, consumers, and the general political-ethical agenda in society, through mass media and advocating consumerism and the priority of the money code as a yardstick for values, perception of individual worth[91] and collective political decision-making – perhaps most relevant to the "commercialization" of research (Alvesson & Willmott, 1996; Deetz, 1992; DHHS OIG 2000a).

From their neo-Marxist, critical theoretical perspective, Alvesson and Deetz (1996) state, "In the guise of technocracy, instrumental rationality has pretenses to neutrality and freedom from the value-laden realms of self-interest and politics. It celebrates and 'hides' behind techniques and the false appearance of objectivity and impartiality of institutionalized sets of knowledge, bureaucracy and formal mandates" (p. 204). This is at once why it is difficult to locate the many techniques of domination

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of 'instrumental technical reasoning' and Lyotard in terms of 'performativity'" (Alvesson & Deetz, 1996, p. 211).

[90] "Culting," as Arnott (2000) describes, is developing an acceptance of the way things are done, and being part of a team or "corporate family." The use of the term here implies a deep sense of attachment to or an extravagant admiration or blind acceptance of certain principles, life styles, ways of doing things, habits, etc. "Culting" would involve taking on the goals of the organization (the organizational *cul*ture) as one's own, thinking of the workplace as a "home," colleagues as "family" and a "team," etc. One may be said to be "culted" when a certain way of doing something becomes sacrosanct.

[91] See Adorno, 1989a, with respect to "culture industry," particularly "the culture industry transfers the profit motive naked onto cultural forms" (p. 129) and "although the culture industry undeniably speculates on the conscious and unconscious state of the millions toward which it is directed, the masses are not primary, but secondary; they are an object of calculation, and appendage of the machinery. The customer is not king, as the culture industry would like to have us believe, not its subject, but its object" (p. 129). And Deetz (1995) states "Democracy is reduced to capitalism, and citizens are reduced to consumers ... free-market capitalism was never intended to present the public well; it was intended to describe how to make a return on financial investment" (p. 23). Deetz, who acknowledges the ideas of Polyani in this area (especially 1944), quotes Kelly (1993) who says, "Human beings and the natural environment became 'commodities,' with no intrinsic worth ... all people, all the Earth's resources were to be used by the market for one purpose only: to increase profits (p. 6 of Kelly). I will argue that regulation of human research often ignores the "masses" of research participants, *i.e.*, participants may be the objects of regulatory activity, but they are not, often, the subjects of it.

and a justification for attempting to do so. A form of technological determinism, *i.e.*, the view that if something is technically feasible then it is both desirable and bound to be realized in practice, exists even if we don't want it and even if it is likely to be socially, culturally, (or environmentally) harmful (Watson & Hill, 1997). As mentioned, we as researchers do things, we go along, in the name of *process* even when the *purpose* doesn't seem clear, important, useful, right, sensible, moral, or logical to us. (See also Adorno quote, footnote # 67, p. 60, herein.)

Chapter Four: Development of Federal Human Subjects Regulation

"I had no idea as to what don Juan wanted, and yet I did understand him to perfection." Carlos Castaneda, *The Active Side of Infinity*, p. 10.

In mapping the ideas, knowledge (and ideas about that), and worldviews at work in this regulatory system, I will offer observations about the development of science, the positivist/humanist split (and the distinctions between them that "really" matter in this analysis, see p. 26, herein) along with the regulatory system in general that is the focus of this study. By doing this, it is possible to show which terms, concepts, constructs, etc. that appeared in the discourse in the "beginning" still appear today, and how they may be operating. I will consider these cultural-level reproductions, as Habermas (1984) describes, along with views about the underlying moral/value and other structures (SINS) that can be seen working in the system through the text that produces it, as Foucault (1972, 1980) and Forester (1989) might suggest.

I am not providing a history of science or of the system to be relied upon as *the* story for *the* analysis (rather a story for an analysis), as I share the belief with Foucault and others[92] that a single, accurate, definitive history is impossible. Portraying one's own time as unique and a period of great importance, an important transition, etc., is an unfortunate tendency of many Western thinkers, Foucault remarked (1983).

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[92] For example, Alvesson and Deetz (1996) contend "Let us be clear at the start: all such social histories are types of fiction. They often serve present social purposes more than record the past" (p. 193). I contend that history should be treated the same way as truth, never a capital letter or used in the singular, *i.e.*, the only possible appropriate terms are "histories" and "truths."

What I intend to do alternatively is tell a creation story (what Foucault might describe as a genealogy, see Knights, 1992, p. 517; or what O'Connor, 1979, termed "interpretive investigation," p. 238; also see p. 51 herein) based on texts of laws and rules, events, the ways they were positioned, and by whom. I do not presume to know the way things "really" were or are, and it is not necessary nor possible to know that. A primary goal in doing this study is to find and reveal, to *describe* structures (SINS) operating in the system and the possible effects of abandoning these structures, rather than attempting to *explain* the roots or values of these (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS. To suggest ideas and offer an accounting of the time at which certain terms or ideas are *reported* to have first appeared in the discourse, not when they actually *did* appear will be useful to this analysis. To consider the views held by various participants does not claim absolute accuracy, nor is it nihilistic nothingness. It is for me simply an acknowledgement that life is liquid and local.[93] We react to interpretations rather than an absolute, objective "reality." Our eyes are not windows, but sensory receptors (see Kolak & Morgan, 2001, or http://www.wpunj.edu/cohss/philosophy/LOVERS/surprise.htm, accessed May 25, 2002. Besides, social structures are most often slippery (sometimes, for some, even slimy) and difficult to grasp. These structures are implicit and interpretable, liquid, and local. Timmermans (1999) studied CPR in emergency rooms and described survival rates as "part of a scientific story in which the assumptions, the interpretation, and the

[93] I don't know if anyone has used the exact phrase "life is liquid and local" before, but I think this way because of dozens of people, including Goffman (1974), Mead (1934), Garfinkel (1967), Sacks, Schegloff, & Jefferson (1974); Sacks (1970); Becker (1963); Geertz (1973, 1983, 1988); Schutz (1973); Berger & Luckmann, (1966), and others.

conclusion are predetermined" (as quoted in Wheeler, 1999, Oct 15, p. A21). Timmermans says if survival rates are low, CPR researchers recommend more training and technology; if they are high, CPR training is considered a success. This is not unlike regulation: if no problems are reported, the system is successful; when problems (often atrocities, in the case of human subjects regulation) do occur, more rules, oversight, and enforcement are "needed."

Creation stories about how "scientificity" became dominant have been told many times. This one is drawn predominantly from Polkinghorne (1983), Anderson (1996), Denzin & Lincoln (2000), and Hamilton (1998). Given Aristotle's enduring rules of rhetoric (Original SINS?), it wasn't until the 1600s—the time of Bacon (1620; introduction of the inductive-experimental method), Galileo (assertion that nature is ordered), and Newton (mathematization of observation)—that science began to rival and overtake philosophy and religion as the dominant paradigm. These ideas paved the way for positivism, and it was during this time (from the 1600s to the Enlightenment) that views of human phenomena (including communication phenomena) were changed significantly.

In the early days of the reign of science ("positivism" has become too synonymous with "science"),[iii] the Cartesian model was employed, *i.e.*, knowledge was held to the standard of absolute certainty. About pursuant developments, Anderson (1996) states, "From Hume (skepticism) to Kant (transcendental idealism, see below, and also footnote # 94, p. 83) to Husserl (transcendental phenomenology) to Peirce (semiotics), there have been lines of argument that sought to liberate the human mind

from Locke's empirical prison" (p. 20). Locke's blank-slate passivity paradigm was replaced by Kant's view that the knowledge is in the *knower*. This produced a knowledge that was nonhistorical, *i.e.*, a knowledge that did not change.[94] Dilthey (1900/1969) contradicted, asserting Kant's view did not account for the knowledge we have of human phenomena, our understanding of life and other persons. For Dilthey, and perhaps most relevant to issues in the present study, the study of life is a consideration of particular individuals living at a particular time in a particular place, *i.e.*, the study of life, and life itself, are *local* phenomena. It took some time for these views to infiltrate science significantly, if it can be said that they have.

As early as 1725, Vico had anticipated the growth of the positivistic approach to human phenomena and resisted the trend by asserting that we can gain a true knowledge of human phenomena through the study of history (see Croce, 1964, p. 19). This movement recognized the life experience of humans, the emotional and vital feeling of life, and the engagement that humans have with others and the lifeworld. Vico said what was wrong with positivism was that it neglected meaningful experience (the "real" world). (I think of these arguments as falling along a continuum, from absolutism

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[94] Hassard (1993) describes two types of modernism: systemic and critical. "Critical modernism stands against the programmatic absolutism of systemic modernism. The main contemporary advocate of this position is Habermas ... whose objective is to confront the increasing power of instrumental reason in social life and in so doing to recapture the spirit of enlightened rationalism for late modernism ... For Habermas it is through the 'language of the community' that we will rediscover that lost sense of enlightenment that Kant first revealed to us" (p. 5; see also Power, 1990). Regarding modernism in either form, Cooper and Burrell (1988) state that whether we are considering systemic modernism, *i.e.*, championing the mechanization of social order, or critical modernism, *i.e.*, seeking the emancipation of the lifeworld, both modernisms share a commitment to an inherently logical social world constituted by reason. In systemic modernism the rational subject is the system itself; in critical modernism, it is the knowing subject (see Hassard, 1993, p. 5)

[modernism], to a mid-ish point at relativism [interpretivism], to the polar extreme, fragmentation [postmodernism].)

Mill (1910/1972) and Comte (1910)[95], co-fathers of positivism, provided a philosophical and logical foundation for empiricism as the ground of knowledge. The preference for positive knowledge continues. (I would argue interpretivists [and other though not all other non-positivists] are more empirical than positivists in today's research environment, in large part due to the use of operationalizations by the latter group.)

"Science" (or the most prominent representation of it, as Habermas or Derrida might describe it[96]) was (and remains) deterministic, reductionistic, and in search of covering laws of cause-and-effect relationships. Researchers were—and are—held to a "value-free" standard. The purpose of positivistic science is to describe, predict, and control. Scientists—again the term "positivists" is unfortunately too synonymous—utilize experiments, sometimes administer surveys, and are to report with a (passionately dispassionate?) disinterested, disconnected (and de-valued) voice[97]. Positivists believe this is possible; only those statements free from metaphysical

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[95] Comte proposed (between 1830 and 1850) that the study of human phenomena should conform to the methods used in the natural sciences. All "fictitious" or "negative" philosophical speculation about the human realm should be given up, and the "positive" or scientific study of human beings should be undertaken. He coined the term "sociology" in 1839.

[96] For an explanation of the problem of representation as it is viewed postmodernistically, see Hassard, 1994, p. 11-12, who says, "Our knowledge of the world is constructed as a problem of 'representation' rather than one of factual accuracy ... attempts to discover the genuine order of things are both naïve and mistaken ... In particular, the modernist objective of determining factual relationships through the empirical method is considered problematic ... research proceeds on the basis of discourses which are already shared within a particular scientific community ... findings produced through empirical science reflect pre-existing intellectual categories" (p. 12). See also Denzin and Lincoln, 2000, p. 16-17.

[97] See Jackson (1989), quoted p. 56, herein, especially the comment about neutrality as euphemism for indifference.

overtones and personal bias can assure certainty. All sciences, in this paradigm, are to limit their assertions to these kinds of positive statements, including the sciences of human phenomena. Social life is considered to be rational and rule governed and the rules for rational conduct were to be derived from "scientific" (meaning, then and now in a very pervasive sense, *positivistic*) inquiry. [98] Positive science *became* knowledge, as described in Habermas's (1984)[99] model, replacing rhetoric, religion, and other enterprises claiming to know "The Truth." That this remains the case is demonstrated rather clearly in many documents. (See GAO, 1991a, p. 113-117, regarding criteria for evaluating case studies, and GAO, 1991b, regarding evaluation of structured interviewing.)[100] Further, Solomon (1985) states "The Tuskegee study reveals the hollowness of claims that scientific language is always neutral, objective, and value-free ... While all of us appreciate the importance of reason in human affairs, we also recognize the value of human emotion in tempering our behavior" (p. 244-45). She continues, "If allegiance to objectivity and detachment blinds us to other values, it produces neither humane behavior nor sound science" (p. 245). Allowing those who know less and care less about our work (*i.e.*, regulators or "jackasses," see footnote #

[98] That this remains the case was demonstrated when, in about 1999, at least one ordinarily affable "qualitative" member of a doctoral committee during a dissertation defense and after several exhausting and tedious discussions rather strongly asserted, "It's not that kind of study!" to a particularly dogmatic positivistic thinker.

[99] Habermas (1984) separates two historical learning processes and forms of rationality: the technological-scientific-strategic, associated with the system world, and the communicative-political-ethical, associated with the lifeworld, and, according to Alvesson and Deetz (1996), Habermas "tries to contribute to the latter" (p. 202). (See Figure 2, p. 87.)

[100] In this report, criteria for the evaluation of case studies are focused on issues of researcher impartiality, standardization of data gathering techniques, generalizability of findings, and, according to the GAO, include explicit statements of observations and whether "the identification of these factors was based on insight and recognition or on quantitative techniques" (p. 117).

238, p. 230) tell us how to go about doing our work produces work lacking in values and value, and bearing our names.

The functioning of the IRB system, especially with respect to qualitative methods often utilized in sociology, anthropology, education, and communication research, and to a lesser extent in political science and psychology departments, is an example of the institutionalization of a positive definition of science. The notion that all researchers should be treated the same way as a matter of "fairness," regardless of the treatment they plan to implement, is inherently unfair (see Forester, 1989, p. 3, re: planners, for example). We, as scientists, do not work in a neutral stage, in some ideal setting involving all affected interests; we work instead in political and social institutions. We are, at once, political, social, and scientific actors, and these "selves" are inextricably linked. Interpretivists for example sometimes seek (or are "forced" to seek) legitimization by having their study protocols subjected to the same scrutiny as positivists. This practice of treating all procedures as alike may be a contributing factor to over-regulation (AAUP, 2001; Brainard, 2000, Mar 17 and 2001, Mar 9; O'Connor, 1979) in the IRB system currently and historically, and especially in areas of social science research.

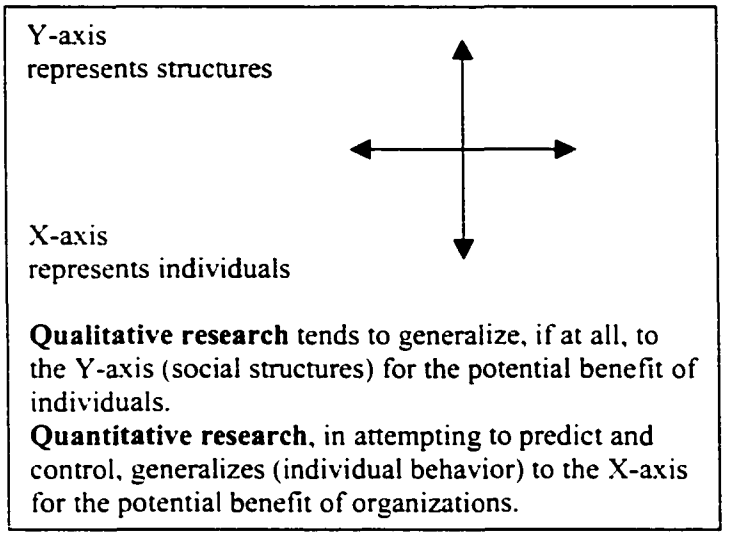

Figure 2

Analytic, reductionist, quantitative, particularistic, positivistic, nomothetic, etic, or micro- or individual-level analysis, and other terms are used to describe the science – and often positioned as the *only* science—that pursues universal laws to guide the study of human behaviors.[101] Simply, quantitative methods are used in the search for generalizations along the X-axis, as described in Figure 2 (above; see also footnotes # 98, 99, and 100, p. 85), while qualitative studies, if they seek to generalize at all, are more prone to do so along the Y-axis. When quantitative researchers (positivists) strive to "predict and control" individual behavior, they are often serving the interests of organizations (corporations, product manufacturers, and political candidates and causes,

[101] From the positivist perspective, social sciences don't have the success that physical sciences have, *i.e.*, a set of central principles about which all (or most) agree. Perhaps that is because it is easier to predict moon phases than mood phases. Or, perhaps social scientists are less optimistic—or more astute, or both—about what "science" is and what it *can* do. On the other hand, there are social theorists such as Gudykunst (1995); he sets forth 47 axioms contained in his Anxiety/Uncertainty Management Theory. These axioms represent "conclusions" for Gudykunst, whereas they represent "possibilities" for qualitative researchers.

as examples), while qualitative researchers attempt to generalize about organizations or how people operate within them, often with the idea of benefiting individuals (although that is not necessarily what prompts them). An example of qualitative, X-axis thinking is a researcher's interest, perhaps, in assisting individuals in the "negotiation" of the lifeworld within certain organizations, such as intercultural studies or studies of political movements.[iv] None of this suggests, however, that quantitative/positivists and qualitative/interpretivists cannot or do not work together to produce results that benefit both individuals and organizations. Nor is there any suggestion that positivism is *inherently* more moral or ethical than interpretivism, or visa versa. However, from a critical perspective, the desire to control and predict the behavior of individuals is of great interest for critique (see also Alvesson & Deetz, 1996, re: anti-positivism).

Postmodern traits, according to Alvesson and Deetz (1996, p. 205-210), include the centrality of discourse (textuality), fragmented identities (industrial, technical, and academic specializations, as examples), essentialistic understanding of people, a critique of philosophy of presence and representation (as found in Mead, 1934; Wittgenstein, 1953/1975; Heidegger, 1927/1962; and Habermas, 1975), the loss of foundations and power of grand narratives (Habermas, 1975; Lyotard, 1984; Derrida, 1981), abandonment of the notion that knowledge is innocent or neutral (Gadamer, 1960/1989; Heidegger. 1927/1962); hyperreality, simulacra replacement of the "real world" (Baudrillard, 1983), research aimed at resistance and indeterminacy (Marx, Horkheimer, Adorno, Deetz, S. Hall, and others), and a general preference for irony and play over rationality, predictability and order. Detachment, displacement, and a high

level of disengagement dominate deconstructive postmodernism. Groundlessness is the only constant. (Power, 1990, describes postmodernism as the death of reason; Hall, 1986, suggests it is Marxism with hope but without guarantees," p. 58.) Values, history, and ethics are considered arbitrary (*i.e.*, based on the liquid and local, the lifeworld). Deconstructive postmodernists hold that most all aspects of human existence are culturally created and developed in particular, localized circumstances. Generalizations are, therefore, not reasonable, possible, or desirable (except to dominators, perhaps, and then only for short-term benefits). This is not inconsistent with Dilthey's particular person, place, and time thesis. The fairly prevalent notions held by regulators, *i.e.*, that no distinctions between qualitative and quantitative methods (*i.e.*, between social and clinical research) need to be made in regulation[102] is an example of SINS that need to be re-opened for questioning.

The Sensibility of Different Regulatory Stances

Rorty (1979) comes down equally hard on scientists and humanists when either side claims a "lock" on truth. He says that there are some irreconcilable differences between the two groups. He argues that both groups are self-sealing language communities that don't—and really can't—talk to each other. The questions in one approach don't have answers in the other. At the risk of sounding like Punch[103] or Miss

[102] These notions are rather obvious in that no separate rules exist and that federal regulators rarely address purely qualitative methods in any of the literature they produce. Further, I recall several comments made by federal regulators during an open forum I attended.

[103] Punch (1998) asserts he would accept some field-related deception so long as the interests of subjects are protected. This comment demonstrates what I call the Miss America Posture, drawing an "ideal world" rather than "real world" picture. This is something akin to engaging in an epistemological debate,

America, we need to acknowledge and respect each other. In the view of rhetorician Nichols (1963) "the humanities without science are blind, but science without the humanities may be vicious." Similarly, Alvesson and Deetz (1996) point out that critical theory without postmodernism can be blind to its own elitism and power, and without critical theory, postmodernism becomes esoteric (p. 211). It would appear cooperation rather than competition produces better results, scientific or otherwise.

Technocracy as an outgrowth of positivism. A slogan used to publicize the 1933 Chicago World's Fair succinctly presents this technocratic tenet (demonstrating again the 1984 Habermas model) and provides testament to its tenacity: "Science Explores: Technology Executes: Mankind Conforms" Denzin & Lincoln, 1998a, p. 122). Goffman (1971), and others[104] long before and since, reject scientific claims of positivistic sociologists altogether:

> The work begins with the sentence, "We hypothesize that ... ," goes on from there to a full discussion of the biases and limits of the proposed design, reasons why these aren't nullifying, and culminates in an appreciable number of satisfyingly significant correlations tending to confirm some of the hypotheses as though the uncovering of pattern in social life were that simple. A sort of sympathetic magic seems to be involved, the assumption being that if you go through the motions attributable to science then science will result. But it hasn't. (p. *xvi*)

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getting backed against the wall, and bailing to an ontological "well it's all up to god anyway" default/surrender strategy.

[104] Gardner (2001, Mar 9) states, "Indeed, when it comes to questions of the human mind, consciousness, and experience, philosophers retain one powerful weapon ... a good many people—especially those who consider themselves humanists—still prefer to believe that there is something special about human beings, some properties that do not lend themselves to explanations in the same way that one can explain the structure of the universe or the anatomy of the cell or the food preferences of other animals" (p. B7).

Habermasian ideas about cultural reproduction[105] can be used to illuminate the underlying theme of positivism in both science and regulation. Texts will be offered (and analyzed in Chapters Five and Six) as evidence of beliefs such as the existence of absolute and/or universal truths, value-free science, the ability of humans to accurately predict and control each other and nature, to order the world, etc. (see Dreyfus, 1992).

Culturally Reproduced Positivism Operating in the IRB System

> Historically, there has been a heavy emphasis on quantification in science. Mathematics is often termed the 'queen of sciences,' and those sciences such as physics[106] and chemistry that lend themselves especially well to quantification are generally known as 'hard.' Less quantifiable arenas, such as biology (although that is rapidly changing) and particularly the social sciences are referred to as 'soft,' less with pejorative intent than to signal their putative imprecision and lack of dependability. Scientific maturity is commonly believed to emerge as the degree of quantification found within a given field increases. (Guba & Lincoln, 1998, p. 196)[107]

Cultural reproduction: Statistics are of more value than personal experience

Declaring that "hard data" are more reliable or revealing than personal experience doesn't make the declaration true. These notions (biases) are cultural

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[105] Cultural reproduction of worldview, according to Habermas (1987), involves the "transfer of cultural reproduction, social integration, and socialization from sacred foundations over to linguistic communication and action oriented to mutual understanding. To the extent that communicative action takes on central societal functions, the medium of language gets burdened with tasks of producing substantial consensus. In other words, language no longer serves merely to *transmit* and actualize prelinguistically guaranteed agreements, but more and more to *bring about* rationally motivated agreements as well" (p. 107, emphasis in original).

[106] See also Pellegrini, 2001, Aug 15, who reports that even physics is in need of overhaul.

[107] Critical theory is neutralized in a different way: via labeling it as non-scientific and (therefore) of no value in "real" scientific debate. I would counter "real" scientific debate has become political at the social level and is censored (self or otherwise) at the individual level. Science *reporters* offered commentary after President Bush spoke about stem cell funding August 9, 2001, rather than scientists themselves, for example.

reproductions; the ideas are commonly believed.[108] There is widespread agreement that quantification equals credibility (see next section); alternately, the idea that local experience is more credible than a national statistic is not as commonly believed. This is a product of the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS operating in the IRB system, and the academic enterprise at large. This bias affects IRB rules and downstream interpretations (as will be shown, especially in the next chapter) including application forms and the acceptance, revision or rejection of them, for example.

Cultural reproduction: Quantifying = credibility

Regarding the quantification bias, "That this is the case is hardly surprising," assert Guba and Lincoln (1998, p. 196). Positivists focus on efforts to verify positivistic science or falsify post-positivism (frequently debunking non-positive methods as non-scientific, ungeneralizable, unreliable, and biased, just for starters.) Formulaic precision is central when the aim of science is prediction and control of natural phenomena. Given that the tools are readily available, what is needed to perpetuate positivistic science is widespread belief in it. Sechrest (1992) argues such a widespread notion persists—that only quantitative data are valid or of high quality.[109] This is evidence of the structure within a structure—of what has become valid or true in science. As

[108] Schutz (1973) states "The natural sciences generally, and especially the natural sciences which use mathematics, have lost their relation to their basis of meaning, namely the lifeworld" (p. 127). Schutz surmises, "Physical science ... has to develop devices by which the thought objects of common-sense perception are superseded by the thought objects of science" (p. 4).

[109] "Even the fundamental laws of physics may be mere suggestions" (Pellegrini, 2001, Aug 15).

mathematization of the ideas of a science becomes possible, that science becomes more valid. Because mathematics can offer proofs, and derive an (positioned to be *the*) "answer," if a finding can be quantified, it represents "proof" whereas if we see or experience something, it proves nothing "scientifically" speaking, and regardless, it may be that neither the quantified or the experiential result passes the Grandmother Test.[110] A local example of this cultural reproduction is the clear preference for the words of others over the "reality" of personal experience in the graduate learning environment (the latter often referred to disparagingly as "merely anecdotal," implying immaturity and irrelevance).

How is one paradigm replaced by another? As geocentric cosmologies were replaced by heliocentric worldviews, as The Truth and History are replaced by provisional truths and personal histories (not assuming any of these conversions is complete or, for many, even possible), what is happening? Life *is* transition, moving, dynamic. Liquid. Local. One contemporary transition is not *from* positivism *to* postmodernism, rather toward the *inclusion* of postmodernism, a recognition of the need for deconstruction, and acknowledgement of ways life is liquid and local, and most relevant perhaps, not regulate-able. A minute-by-minute active negotiation, encumbered with the incredible (and often non-credible) weight of tradition.

"Realistic social scientists do not mention tradition," Shils remarks (1981, p. 7). Tradition, as described by Shils (1981) is much like Habermas's (1984) cultural

[110] The grandmother test was relayed to me by Professor Chris Swoyer, who attributes the idea to his mentor, Paul Meehl. Meehl "used the test to determine whether a piece of research was worth doing. Doing an experiment to show something that your grandmother knew all along fails the grandmother test" according to personal correspondence I received from Swoyer in March 2002.

reproductions. For example, one might catch a glimpse of the bars when considering the words "communication traditionalist." Reading "traditional" literature (for non- and anti-positivists) can be likened to watching the wheels (Lennon, 1980) or pacing the cage (Buffett, 1996).[111] The scholars I have brought to demonstrate "traditional" works in communication (see footnote # 111, p. 94, below) are those inextricably linked to positivistic science. Shils (1981) suggests the concept of tradition lost formative value in The Enlightenment. Knowledge accepted via authority was replaced by science (putting new "authorities" in place.). Science, and through it, knowledge, became the "experience of the senses and its rational criticism" (p. 4). Knowledge is (remains) tied to money, as well (see Lyotard, 1984, who stated "games of scientific language become the games of the rich ... whoever is wealthiest has the best chance of being right ... An equation between wealth, efficiency, and truth is thus established," p. 45). Deetz (1995) states, "Information [defined as codified knowledge] is only loosely connected with decisions, hence, political power struggles and processes of social control substitute for rationality" (p. 136), and quotes Lageza (1992) who says, "Information and decisions are linked by knowledge claims ... knowledge claims have an interactive and rhetorical dimension" (p. 7).

Becker (1993, as cited in Denzin & Lincoln, 1998a, p. 8) says qualitative and quantitative research methods differ in significant ways, because of differing ways of addressing the same set of issues (for example, the uses of positivism, acceptance of postmodernism, and the examination of constraints of everyday life). Each tradition is

[111] This statement is conservative from my anecdotal view. C. Berger, Burgoon, McCroskey, Gudykunst, and most other "traditionalists" actually *scare* me. This may have more to do with how their works are

governed by different structures: genres, their own classics, and their own preferred forms of representation, interpretation, and textual evaluation (see Becker, 1986b, p.134-35). The variance across qualitative methods is also relevant. Regulation is difficult enough *within* either the qualitative or the qualitative tradition, leading to no surprise that *across* traditions involving such diverse methods, it is very unlikely that one set of rules will ever fit all methods[112] (or, more precisely, treatments).

Emerging Alternative Methodologies

Postpositivists suggest there is no correct method to follow (see Richardson, 1994; Denzin & Lincoln, 1998a, 2000). As noted, Goffman (1971, p. *xvi*) argued that no authentic science is simply an activity of following methodological recipes that yield acceptable (and statistically significant) results. Along similar lines, Hall (1989) argues that critical theory rejects the "body counts" of survey research, "which consistently translate issues that have to do with signification, meaning, language, and symbols into crude behavioral indicators" (Hall, p. 42), an outgrowth of operationalism (see Bridgeman, 1927, as cited in Anderson, 1996, p. 19).

One effect of adopting these views (*i.e.*, broad acceptance of diverse methods) is the possible expansion of notions about what constitutes science and what science of any kind *can* do. With these postmodern, postpositive views emerging, the likelihood of science becoming a creative search designed to better understand the ways of things is enhanced, and scientists will be *allowed* to use a broader variety of sometimes

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(mis) used than the actual production of them, of course.

[112] See Rorty (1979) re: positivists and humanists and their inability to "talk" to each other.

improvisational approaches, responsive to, rather than the SINS in science-defining dogma, the particular questions and subject matters addressed (and will be called "scientist" even when not employing positivism).

The downside of these views is that the distinction between social science and other scholarly activities loses its edge. A postmodernist might answer, "Who cares?" I would agree. No distinction *can* exist. In other words, it is not the process (method) but the purpose (understanding) that matters.

Considering the differences in various research approaches is useful because it points us to the differences in treatments traditionally associated with various approaches. It is important to recognize that these basic philosophical orientations or worldviews are not mutually exclusive, exhaustive, nor totally contradictory. A dichotomy (between qualitative and quantitative research) has emerged for several reasons—some historical, and some practical (see Liska & Cronkhite, 1994). A recognition that a variety of philosophies are at work, to a greater or lesser extent, in many studies is important because the variety has a bearing on what sorts of standards IRB regulators may reasonably/properly enforce with respect to differing forms of research. These qualitative/quantitative, social science/medical science distinctions are relevant to the purpose herein, because "treatment" (and *only* treatment, as I have argued) is what should concern regulators.[113]

[113] Sometimes IRB regulators find themselves making judgments about the scientific adequacy of the proposed research as a concern that is affiliated with their interest in seeing that the benefits outweigh the risks (even when there are no evident risks nor immediately knowable effects/benefits). Given the variety of kinds of research that is submitted to an IRB on a campus like the University of Oklahoma, such judgments are likely to strain the resources of the board. Additionally these judgments are not authorized by federal regulations (see 45 CFR § 46.101[b]).

"Themes of the Enlightenment are deeply embedded in modernist management theory" (Alvesson & Deetz, 1996, p. 194). Three such Enlightenment leftovers, (*i.e.*, cultural reproductions, SINS) at work in this system (and all three beg the assumptions that life can and should be standardized) include blanket assurance provisions[114] (the "same page" the federal government requires all institutions receiving federal research dollars to be on[115]), the Common Rule (45 C.F.R. § 46, 1991), and informed consent (perpetuating/reifying the "positive" notion that if we can standardize the actual paper form, we can somehow standardize the "real" world; see Lincoln & Guba, 1989; Sobal, 1984).

Leftovers related to blanket assurance, the Common Rule (45 C.F.R. § 46, 1991), and informed consent include expertism/respect for authority, *i.e.*, who is given the power to name, establish criteria, and define terms.[116] In this case, "process" and "punishment" are examples[117] along with "adverse effects" and "timely reporting"[118] as

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[114] According to a written statement prepared for the U.S. House, (1998, Jun 11) by Ellis, former director of OPRR, "An Assurance statement is a formal, written commitment to: 1) widely held ethical principles; 2) the DHHS regulations for Protection of Human Subjects; and 3) institutional procedures adequate to safeguard the rights and welfare of human subjects. The terms of the institution's Assurance are negotiated with OPRR. The detailed written assurance statement becomes the instrument that OPRR [federal regulators] uses to gauge an institution's compliance with human subject protections if there is a problem" (see *Institutional review boards: A system in jeopardy*, 1998, p. 45).

[115] OHRP's (1999) instructions (sample language) for the assurance document are 24 pages long. See http://ohrp.osophs.dhhs.gov/humansubjects/assurance/mpa.htm, accessed May 25, 2002.

[116] See NIH, 2001, Jun 26, for a demonstration of the federal regulators' power to define both types of research and the role of research, and the power to set priorities and agendas for research. NOTE: Here, and throughout, I'm not (always) suggesting that the regulators *shouldn't* be doing this, or even that they do it poorly. I sometimes conclude both *personally*, but the point here is simply to identify who is allowed to name and define and what it may mean to others who are not allowed to name and define. I also wish to point out that when I speak of abandoning the system in passive rebellion (in upcoming chapters), I am limiting that suggestion to researchers who employ unobtrusive methods, administer no treatment, and involve no protected classes.

[117] Also see OHRP (2001, Jul 19) regarding right to name viable sources of information. On page 2 of that document, the OHRP in issuing sanctions against Johns Hopkins University stated that researchers "had failed to obtain published literature about the known association between hexamethonium and lung toxicity. Such data was readily available via routine MEDLINE and Internet database searches, as well as

reported by Brainard (2000, Apr 14 and 1999, Nov 12); hierarchical rigidity (for example, in which arenas discourse gains legitimacy); and absolutism/one-right-way-ness (demonstrated in the ways parts of the regulatory process have become entrenched as objects of discourse, especially in education/the academy and to great potential detriment, *i.e.*, if unorthodox approaches aren't accommodated/accepted/promoted at universities, then where? Few profiteers allow very much unorthodoxy). Finally, ways the notion that standardization is desirable or possible can be shown to be SINSfully operating within the system.

Power in the System

Power of federal system, effects on institutional system, and subsequent effects on researchers. Knights and Morgan (1991), using Foucault's discursive practices model, point to a number of power effects of corporate strategy discourse, including the sustaining and enhancement of the prerogatives of management, the generation of a sense of personal security for executives and managers, and the facilitation and legitimization of the exercise of power. These power effects are operating in the IRB system, for example, the withholding by regulators of federal funds for research (regulatory coercion, the exercising of legitimate power), the voluntary adoption of the

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recent textbooks on pathology of the lung" (p. 2). This is an example of not only the OHRP defining *terms* but also defining *legitimate* sources and thresholds for "adequacy."

[118] When asked about the lack of reporting about six gene therapy deaths, Ruth Macklin, a member of the NIH advisory committee and a bioethicist at the Albert Einstein College of Medicine at Yeshiva University asks "If death is not a serious adverse event, what is?" Considering the NIH regulations requiring "immediate" reporting of "adverse events," it seems reasonable that in spite of the liquidity of definitions (*i.e.*, lack of "unity" in meaning), disclosure of patient deaths seems reasonable by any interpretation including FDA, NIH, other sponsors, IRB, researchers and participants. It seems critical to anything we might label as "protection."

federal rules by institutions (sustaining and enhancing the prerogatives of regulators *without* coercion), the approval/disapproval of researchers' protocols (generating a sense of security and importance for regulators themselves, via control of researchers), and even the self-regulatory behavior of researchers themselves (facilitating and legitimizing the power of regulators). Adorno's (1989b) comments about internal (or self) coercion to maintain the status quo are fitting here: "The whole business keeps creaking and groaning on, at unspeakable human cost, only on account of the profit motive and the interiorization by individuals of the breach torn in society as a whole" (Adorno, 1989b, p. 272).

How Power is Derived

"Forester (1989) distinguishes between unavoidable and socially unnecessary disturbances, between socially *ad hoc* problems [liquid and local "reality" issues] and more socially systematic, structure-related sources of distortions [SINS]" (as quoted in Alvesson & Deetz, 1996, p. 204). Organizations may be understood as structures of systematically (nonaccidental, non-questioned, and possibly avoidable) distorted communication. Without regard to the extent to which distortions can be avoided in practice, knowledge and insight of these distorted communications are certainly of value. From a communication perspective, organizational power might be described based on the extent to which power is (perceived to be) gained/maintained through dogma (closed communication) or dialogue (open communication), for example.

Alvesson and Deetz (1996) suggest corporate visions and cultures are strategic local narratives that aid management's objectives (see X-axis description, Figure 2, p. 87). They also create and maintain the local hierarchies and "relationships of power" as Foucault (1972, 1980) describes (see also Clegg, 1989, re: "circuits" of power). These localized visions, sometimes manifested in grassroots movements, town hall meetings, quality circles, company picnics—and corporate and other cults—could be viewed (risking the oxymoron) as "grand local" narratives, *i.e.*, local stories including who is in charge, what to wear, when to talk, where to shop, why rituals are done and how they are done, and so on. And on.[119] And in the case of the IRB system, the instructions have become more and more detailed. More and more cumbersome, restricting, ambiguous, voluminous (as I show below, for example, see p. 166, re: consent forms; p. 282, re: assurance documents, and footnote # 139, p. 119, re: historical documents related to the system).

Power in the IRB System. Applying Forester's (1993, 1989) structural phenomenology idea yields the following formulation: In the IRB system, at both federal and institutional levels, the discursive activities constitute a dogmatic entity that defines terms and procedures without offering justification.[120] The system sometimes has the appearance of an open system, taking on the role of educator rather than enforcer (holding seminars, maintaining user-lists, and more recently providing $28.5

[119] These stories are defined as brainwashing and cult indoctrination when they involve unpopular people, positions, and organizations.
[120] And, justification is rarely requested.

million in grants to help research institutions improve their efforts to protect people who volunteer for medical research, see Brainard, 2002, Mar 29a; see also NIH, 2002, Mar 5, or http://grants2.nih.gov/grants/guide/rfa-files/RFA-OD-02-003.html, accessed May 25, 2002). At other times, the system is blatantly (and curiously) closed, for example, the OUIRB's due process and appeal provisions, or administrative rule changes done without input from more than a few people[121]. An applicant at OU may, under the rules, only request a hearing before the very board that disapproved the application. The OUIRB's written rules provide no other avenues of appeal.[122] Problems with a lack of specific written appeal procedures include the lack of standardization in the process (generally a highly valued goal of regulators), lack of clear access to the appeals process (leaving those who might wish to appeal wondering how and to whom), lack of written guidelines leave the process "optional" (increasing the potential for regulators and administrators to say in certain cases "there's not really anything that can be done" or "this situation appears normal, sorry you're frustrated") and, finally, the lack of written rules for appeal procedures leaves the process wide open to improvisation (an unusual

[121] I recall a time when a faculty member told me that the chair of an IRB, with great excitement, declared "we," [the IRB], have "redone the entire application system." It appears this particular regulator has no lack of confidence in her ability to devise a regulatory system without the input of those she is regulating.

[122] According to the OUIRB policy statement (http://research.ou.edu/policy/IRB_Human_Subjects_Policy.html, accessed May 25, 2002) at Section 10, Part 5, the authors state: "The IRB-NC shall notify each investigator in writing of its decision to approve or disapprove his/her proposed research activity, or of any modification required to secure IRB-NC approval of the activity. If the IRB-NC disapproves a research activity, the notification shall include a statement of the reasons for its decision and the investigator shall be given an opportunity to respond in writing or in person. The IRB-NC may, at its discretion, re-review and reconsider its decision to disapprove a research activity at any time. And at Section 6, Part 5: "The investigator shall abide by the decisions of the IRB-NC requiring changes (for approval) or disapproving the research. When the proposed research is to be funded by a federal agency, and that agency's regulations permit, an investigator may appeal an IRB-NC decision to the appropriate official (e.g., the Secretary of the DHHS) or section of that agency. However, for research activities not submitted to federal agencies for

accommodation to be given to those enforcing/making "rules" or "laws"). Collectively, this lack of written guidelines, then, contributes to the likelihood that more "uneven" application and administration of the rules will occur. It contributes to the condition that make appealing an action an option of the *IRB* rather than the *researcher* who is denied permission to conduct research. The lack of a written, specific appeal process is in apparent contradiction to obligatory due process and appeal provisions of law generally, and this particular absence of rules seems to benefit, overwhelmingly, those making (rather than those who may be attempting to understand or follow) the rules.

Historical Development of IRB System: Early, Middle, Later, and Contemporary Stages

Early stages. "The history of human subject protections follows a fitful journey between trust and tragedy, from the Hippocratic oath to the Holocaust, from the Nuremberg Code to Tuskegee, from the Common Rule (45 C.F.R. § 46, 1991) to the irresponsible administration of pyridostigmine bromide to U.S. troops in the Gulf War," said Rep. Christopher Shays, Chair of Congressional hearings about IRBs (*Institutional Review Boards: A system in jeopardy*, 1998; see also Campbell, 1998, Apr 3; Charo, 1999, Mar 26).

More than 50 years ago, judges of the Nuremberg court announced their verdict in the trial of 23 Nazi doctors for crimes against humanity (see ACHRE, 1995, particularly Chapter 2). The trial followed the discovery of gruesome medical "experiments" performed on prisoners of war. Since at least the time of the trials, and

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sponsorship, the decision of the IRB-NC shall be final." This finality appears to fly in the face of provisions of the U.S. Constitution and most administrative rule makers' sensitivities.

adoption of the Nuremberg Code in 1947, society has maintained skepticism about the nature of research and the inherent conflicts of interest present in all research.

Distrust seems justified. Even after the adoption of the Nuremberg Code, and the subsequent Declaration of Helsinki by the World Medical Association in 1964, abuses persist as noted (specifically Tuskegee, New York/Willowbrook, anthrax vaccination of military personnel,[123] etc.; see also Lemonick & Goldstein, 2002, Apr 22).

Also in 1947, the Atomic Energy Commission (AEC) was created in the U.S. The AEC was a major source of research funding, a major user of human subjects (for radiation experiments), and has been described as a major violator of human rights (see ACHRE, 1995, Chapter 1; see also CNN.com, 2001, Jan 15 for related contemporary issue re: uranium missile fears). So, the problems (atrocities) appeared in the U.S. consciousness and began to affect policy. However, because these government agencies operated in the name of national security, most of what the U.S. government researchers did to people wasn't made public until decades later.

A 1966 article by Harvard medical researcher Henry Beecher brought prominent attention to human research abuses within U.S. medical schools and hospitals (not insignificantly, this was one of the first times problems *outside* government research were publicly exposed), citing 22 cases involving highly questionable ethics. Atrocities (and lesser infractions), along with the eventual acknowledgement of them, contributed to passage of the National Research Act (1974) that set forth the formal requirements for establishing IRBs. Food and Drug Administration (FDA) regulations followed in

[123] Anthrax and vaccinations for it took on many more levels of meaning after September 11, 2001. My references are to pre-September 11 issues, specifically those related to military personnel's resistance to

1981. By 1991, 16 federal agencies had adopted the Federal Policy for the Protection of Human Subjects, known as the "Common Rule" making regulations applicable to all human subjects research these agencies conduct or sponsor.[v]

Beecher (1966) stated, "Ethical errors are increasing not only in numbers but in variety" (p. 1354) and offered as an example the "recently added problems arising in transplantation of organs" (p. 1354). Today, stem cell research and gene therapy, and intensifying conflict of interest issues are newer versions of the problems Beecher noticed.

Between 1944 and 1974 in the U.S., (enhanced by works such as Beecher's) tensions between the treatment of patients and clinical research (between humanitarian values and the pursuit of knowledge, *i.e.*, between therapy and research) emerged throughout the medical science community. This activity was a product, at least partly, of the times—the wartime atrocities revealed during the post-war years, and later the activism of the 1960s, sometimes militant, and often centered on human rights issues (including the rights to say and to know, self-determinism, individual rights and autonomy, etc., see particularly information about the Berkeley Free Speech Movement, 1964, http://home.att.net/~enfield/fsmhist1.html, accessed May 25, 2002). These developments contributed to the institutionalization of informed consent. (See p. 135 regarding the first known use of the term.) Federal sanctions occurring between 1999 and 2001, specifically those at Duke University, the University of Oklahoma, and Johns Hopkins University (see Andrews, 2000, Mar 10), indicate that ethical struggles to find the proper balance between the rights of patients and the rights of researchers, between

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taking anthrax vaccinations during the Gulf War era, before FDA had approved its use.

safety and discovery, and between over- and under-regulation continue in American society. Basic questions remain about what constitutes "advancing medical science" or the loftier "improving the quality of life" (which are nearly coterminous and often subsumed by "attempts to advance one's career" or "protecting the flow of funding;" see also Shilts, 1987). Just where does "protecting the rights and interests of patients" fit in with keeping one's job, avoiding litigation, playing the game, and covering one's ass? Arthur Beaudet, chairman of the department of molecular and human genetics at Baylor College of Medicine says, "Let's face it – we're all interested in our careers," and adds, "Investigators could be perceived as having a conflict of interest with their own desire to be successful" (as quoted in Brainard, 1999, Dec 17, p. A37; see also Blumenstyk, 1999, Apr 9; 2000, Nov 6 and 2001, Apr 26; Mangan, 2000, May 19 and 2000, Oct 30; and Schmidt, 2002, Mar 29, regarding various state legislative actions to commercialize research at state-run universities).

This is a rendition of the classic debate between the common good versus individual rights and freedom, and the neo-classic rendition in this regulatory system, specifically debates between what constitutes research (benefits for the masses) and what constitutes therapy (treatment for the individual). It is also indicative of a belief someone (or some "body") can know what the common good is (see O'Connor, 1979, especially p. 226; Nietzsche, 1968; and Rand, 1957/1992), or that such a condition exists. It follows that common good *and* individual freedom are (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS, *i.e.*, institutionalized, simulated, naturalized structures, just not "real"

(in an absolute sense), nor real(ly) just. Common good and individual freedom are social constructions similar to "average." None of these exist in the lifeworld. They are examples of the abstract being treated as concrete[124]. With respect to common good and individual freedom, we act as if they are good (always) and possible (ever); we treat them as "real," somewhat like promotions in the workplace, *i.e.*, promotions are perceived by employees as "always" beneficial; employees do not question (until later, perhaps) whether they themselves actually benefit or whether the promotion may benefit management most (and of course, this is often perceived as good management). It appears "really" there is (a condition that is) good for you, good for me, good for us, good for them, but there is no "common good." Yet we allude to it, respond to the "need" for it, and live in ways that are designed to accommodate it. Even when we can see in our immediate surroundings a workable solution to a current problem, we may restrict ourselves from doing what seems right in the situation, rationalizing "I can't do that for you, because everybody might then expect it." In other words, it wouldn't be in the interest of the (abstract) "common good" to do what makes sense for the (concrete) particular good (*i.e.*, one's life at the moment).

These questions and debates become more complex, often unanswerable, though answers may flow freely. Newer, narrower, and more specialized problems associated with developments in science, such as gene therapy trials, stem cell research, and their

[124] And even if there was such a thing as "common good," Deetz (1995, especially chapter two) suggests "neither the marketplace nor governmental action are likely to lead to more effectiveness and the fuller accomplishment of public good," p. *xvi*.

attendant ethical considerations have emerged.[125] American regulative bodies are not prepared for their arrival. As in the past, atrocities may serve as catalysts in the system, a system that is built primarily to offer a reactionary response.

Middle stages. In 1974, the Department of Health, Education, and Welfare (HEW) published regulations, pursuant to the National Research Act (1974), governing the protection of human subjects. The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the members of which authored the Belmont Report (published in 1979; for information about the Act and the text of the Belmont Report, see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm, accessed May 25, 2002), a guiding document in American research policy (see also O'Connor, 1979). Additionally, the Common Rule—the guiding tenet for contemporary researchers—has its roots here, although the Rule wasn't codified until 1991 (45 C.F.R. § 46, 1991). It took at least 17 years to write this one procedural contribution, the purpose of which was overwhelmingly being met without the Rule.[126] As another example, it took more than three years for the government regulators to define "scientific misconduct," according to Brainard (1999, Nov 19), much less to determine what the degrees of or

[125] These issues have surfaced in many places. For example, see CNN online archive for numerous stories about stem cell research especially during 2000-2001; Andrews, 1999, Jan 29; and Walker, 1996, Nov 8. See also GAO, 2000, for an example of the role government researchers play in the process of policy formation, especially labeling and defining criteria. See also footnote # 1, p. 5.

[126] A calculation based on the ratio between studies conducted and atrocities committed, or at least reported.

penalties for it may be (see also NIH, 2001, Jun 26, p. 4-6, regarding attempts to define behavioral and social sciences; and problems with the Bush administration proposals, p. 2-3 herein).

Later stages. The Common Rule (45 C.F.R. § 46, 1991, explained in detail below) is a guiding institutionalization, (actually an "institutionalization" within layers of other SINS) a construction that is an attempt to legislate not only integrity but also humanity. It can be argued that it is not feasible, not "enforceable" to act (because of an Act) as if we can control the hundreds of thousands of interactions between researchers and participants. It can be argued that the Common Rule (45 C.F.R. § 46, 1991) is an instance of social-level delusion, detached from reality, a Baudrillardian (1983) seduction into simulation.[127] We act as if the Act is protection.

Private research that is not supported by the government, or researchers who are not seeking FDA approval of a drug or medical device are not required to apply the Common Rule to research. Therefore, the government has little recourse (and even less direct knowledge because of lack of engagement in the process, commonly termed "oversight," but what might be more precisely described as "technological" or *textual*ogical oversight[128]) if "improper" research practices occur. Federal and institutional regulators define what is improper yet do not traditionally "see"

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[127] The Common Rule "seduces" us into believing (if we follow it), protection of participants in research is guaranteed, the "simulation" (see Baudrillard, 1983, 1988, especially p. 166-184). A similar seduction (Baudrillard, 1988, especially p. 149-165) is the idea that our protection on the highway is guaranteed by following safety rules such as wearing a safety belt, abiding by the speed limit, paying insurance premiums, etc.

[128] "Technology is the knack of so arranging the world that we do not experience it" (Frisch, 1977).

improprieties unless called to their attention by death, injury, complaint, lawsuit, or whistleblower, *i.e.*, until a problem/atrocity occurs and is reported.

The Common Rule, officially titled "Federal Policy for the Protection of Human Subjects," (45 C.F.R. § 46, 1991) is the result, as we can see, of regulations being slowly developed by various federal agencies throughout the 1980s, until the Rule was adopted in 1991. The Common Rule requires institutions receiving federal support and federal agencies sponsoring research to establish internal committees—IRBs—to review research proposals for their potential risk to human subjects.[129] The Rule also requires that "legally effective"[130] informed consent of the subject or legally authorized representative be obtained, and that researchers should maintain written documentation of the consent, *i.e.*, the signed consent forms (45 C.F.R. § 46.111). Further, DHHS regulations specify 14 elements of informed consent, eight of which are required, according to a written statement from Ellis, director of OPRR from 1993 to 2000, (and responsible for bringing more sanctions than any previous director), to the U.S. House 1998, Jun 11:

> The consent document must provide to the participant: 1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; 2) a description of any reasonably foreseeable risks or discomforts to the subject; 3) a description of any

[129] The Common Rule, however, does not apply to all human subjects. These regulations apply only to studies sponsored by one of the 17 agencies and departments following the Common Rule, and to studies of drugs, devices, and other items regulated by the FDA under interstate commerce regulatory provisions. At least two agencies that conduct research on human subjects—the Nuclear Regulatory Commission and the U.S. Department of Labor—have not adopted the Common Rule (Campbell, 1997, Sept. 12; also see Gary Ellis' testimony, *Institutional review boards: A system in jeopardy*, 1998, p. 51-52 and John Glenn's comments upon introduction of S.193, the Human Research Subjects Protection Act, 1997).

[130] The meaning of this term is not explicitly stated in the law (45 C.F.R. § 46.116), and is open to layers of interpretation besides.

> benefits to the subject or to others which may reasonably be expected from the research; 4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; 5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; 6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; 7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; 8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (U.S. House, 1998, Jun 11, p. 45-46)

Ellis' report states: "A researcher who seeks to recruit an individual for research without conveying these elements of information in language understandable to the potential subjects is not obtaining *informed* consent" (U.S. House, 1998, Jun 11, p. 6; emphasis in original). There are no separate informed consent provisions or guidelines for those researchers employing observational and other unobtrusive methods, *i.e.*, there is no accommodation for the substantial variance in treatments. In the interest of treating all researchers the same way, *i.e.*, being "fair," and based on both social desirability and legal interests, one set of rules to be equally applied to everyone is being culturally reproduced (naturalized, institutionalized) by the participants in the IRB system, contributing substantially to irrational, irrelevant, and ill-fitting regulation for much research activity (see Nelson quote, in Brainard, 2000, Apr 14; DHHS OIG 1998b, 1998d, 1998e; ACHRE, 1995; AAUP, 2001). Adorno (1989b) states, "Irrational

institutions are useful to the stubborn irrationality of a society which is rational in its means but not in its ends" (p. 273).

Federal regulatory bodies: Who makes rules and define terms. Bodies explicitly charged with establishing policy regarding some aspect or context of human subjects research include, in addition to the NIH and the FDA, the U.S. House and Senate, the judicial system, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Commission on Research Integrity, Applied Research Ethics National Association (ARENA), the executive branch: President Clinton in his 1997 apology for the Tuskegee tragedy, the National Bioethics Advisory Commission (NBAC), the Advisory Committee on Human Radiation Experiments (ACHRE), the Office of Protection from Research Risks (OPRR, now renamed the Office of Human Research Protection, OHRP), and others. These entities are "voices" in the discursive formation (Foucault), actors in the Burkian scene or Goffman's stage, perpetuators of Baudrillardian seduction and simulation. What is notable about this is that professional organizations, universities, researchers, or participants are marginalized, involved generally on an *ad hoc* basis, *i.e.*, they aren't integrated into the standing decision-making process, but only invited (allowed) to speak (usually briefly) in the press, at Congressional hearings, in commission meetings, etc., and often in situations that resemble indictments (see U.S. House, 1998, June 11, particularly Ellis testimony, as an example)[131]. This is not to say that professional organizations of

[131] See list effects of strategy discourse on power relations devised by Knights and Morgan (1991).

doctors and teachers and university administrators do not establish policy (see AAUP, 2001, and publications of professional organizations, particularly the Consortium of Social Science Associations, the American Anthropological Association, the American Sociological Association and others; see Appendix B, p. 349 for website addresses). These entities do establish policy, locally, as do researchers and the researched, via the use of unwritten and often informal conventions, as often, perhaps, as (their interpretations of) written or explicit rules (see Punch, 1998; Geertz, 1988; Hall, 1989). And individual researchers establish policy, as well, demonstrated in their personal behaviors, even if no one (a regulator, for example) is watching and even if the participants don't "see" it themselves. In other words, participants may feel they need the protection of regulation, when "really" they already know whether they should or wish to answer a certain question, or whether they feel comfortable filling out a survey questionnaire. People establish policy continually in their lives. Within the liquid-and-local reality frame, a participant chooses whether to show up for the scheduled interview or not, whether to answer any particular question or not, decides whether to answer honestly or not, etc. This may have something to do with social rules, but not IRB rules, I assert, because most of the rules are not even *known* to participants (see also Foucault's, 1980, comments about universal and specific intellectuals, p. 126).

To be "explicitly charged with establishing policy," as are the entities mentioned above, means these bodies (and individuals, see Shalala, 2000, Dec 21)[132] are allowed

[132] During the swearing in of the National Human Research Protections Advisory Committee December 21, 2000, Donna Shalala (as Secretary of Health and Human Services) spoke about those researchers seeking only to make a name for themselves, those seeking "only to unmask a discovery," or to secure "some kind of financial reward," are "researchers whose priorities are wrong, and who need to find

to label (see Campbell, 1999, Oct 22, and Brainard, 1999, Nov 18, as examples), impose procedures, sanctions, and fines (where federal dollars are involved this is explicit, but is voluntary or at least implicit otherwise, see Campbell, 1999, May 21; Brainard, 2000, Feb 4; OHRP, 2001, July 19; Andrews, 2000, Mar 10; and Brainard, 2000, June 2). These bodies may shut down research activities (before or after the onset of the activity), and/or withdraw, withhold, or deny funding (in virtually every announcement of grants available from the government, the standardized language covers the rules that must be followed, including the process, reporting, record keeping, etc. The penalty for breaking the rules in every case is the withdrawal of the funding; see also OHRP, 2001, Jul 19, letter to Johns Hopkins University). Technically this involves rescinding the MPA (Multiple Assurance Document) generally for only a few days (see Campbell, 1999, May 28, for example). Exceptions were the University of Illinois at Chicago and the University of Colorado Health Sciences Center in Denver (see Brainard, 1999, Oct 8 and Brainard, 1999, Oct 29). In seven sanctions issued prior to November 1996, only one suspension was enacted; the institutions, except the University of Virginia, were cited for violating rules, but allowed to continue conducting research involving human subjects under close government supervision (see Walker, 1996, Nov 8).

Governmental impact on the research environment extends beyond laws and rules, to include the reports of (mostly presidential and always political) commissions.

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another line of work" (see Shalala, 2000, Dec 21). Perhaps Shalala (and her successors) would agree with a similar argument, *i.e.*, that regulators who don't seem to know or follow the rules, or who are more concerned with power and process than with protection and purpose, also find other lines of work.

The ACHRE report (1995, Roadmap section), commenting mostly on human subjects in medical research, states:

> ... contemporary human subject research does not suffer from the same shortcomings witnessed in the 1940s and 1950s, but poses different issues that need to be addressed...We found that subjects needed protections to ensure their basic rights to consent to or to refuse participation in research. While this need to protect the right of consent continues, in the current period we found that subjects also need protections to ensure their interests are served in understanding the distinctions between research and therapy and the limits of the benefits research may offer. (p. 3)

The writers of the report conclude that written information provided to participants is often obscure, and ambiguities about crucial differences between research and medical care (therapy) are likely contributing to confusion between the two on the part of research participants (see also p. 17 herein, re: "confused consent" issues). In general, the ACHRE (1995) report states that consent forms over-promised what research could offer sick patients and downplayed the potentially negative research effects on patients' quality of life. Earlier, at a meeting organized by Public Responsibility in Medicine and Research, a Boston-based group that educates professionals and the general public about ethical, legal, and policy issues related to research, Jay Katz, professor of law, medicine, and psychiatry at Yale University, said physicians needed to be more careful not to exploit the trust that patients place in them and to draw a sharp line between what they propose as a treatment and what they propose as research (as quoted in Wheeler, 1991, Dec 4, p. A14; see also the organization's website: http://www.primr.org/, accessed May 25, 2002).

As is probably apparent, the federal system is difficult to discern. Texts are innumerable. Researchers face a daunting task in attempting to decipher the regulations, but also in determining who to listen to, *i.e.*, whose discourse applies to their own. Even federal regulators themselves acknowledge the convoluted nature of the system. According to Ellis in his testimony before the U.S. House 1998, Jun 11:

> The federal authorities over IRBs are partitioned in a most complex way ... the universe of involvement of human subjects research is broad, and the outer limits are actually unknown ... two statutes that are especially pertinent: first the Food, Drug and Cosmetic Act, and the Food and Drug Administration discharges its responsibility under that statute to protect human subjects when an investigational drug, device, or biologic is involved. Second, the Department of Health and Human Services, under the Public Health Service Act, discharges its responsibility when DHHS funds or support are involved. That's where my Office for Protection from Research Risks sits. And the jurisdiction of these two statutes overlap ... share congruent regulations on informed consent and Institutional Review Boards. The Food and Drug Administration conducts numerous IRB inspections. Our office conducts very few site visits... [DHHS] is formally yoked with 16 other departments and agencies. We are in lock-step. We share a common rule ... any change in regulation for the protection of human subjects ... at the federal level must be agreed upon by 17 departments and agencies. (U.S. House of Representatives, 1998, Jun 11, p. 51-52; see also GAO, 2001, p. 3)

In the community of regulators, NIH is one of eight health agencies that is part of the U.S. Department of Health and Human Services (DHHS). Within NIH, the Office of Extramural Research oversees the bulk of research funded by the NIH. Within the Office of Extramural Research was, until May 2000, the location of the Office of Protection from Research Risks (OPRR). The OPRR was the entity that, until the change in May 2000, had the most direct federal government contact with local IRBs.[133]

[133] This relationship between federal rules and institutional interpretations is the focus of the Chapter Six.

(For information about the past and current structure of DHHS, go to www.dhhs.gov and for NIH, www.nih.gov; see also GAO, 2001 for a "state of the system" report).

Contemporary stage. An estimated 3,000 to 5,000 IRBs operate in the U.S.[134] Federal regulations require that the boards have at least five members with varying backgrounds (45 C.F.R. § 46.107). At least one member must have primarily scientific interests, one must have primarily nonscientific interests, and one must be otherwise unaffiliated with the institution in which the IRB resides. A frequent feature of institutional compliance is to fill these latter two roles with a single individual.

Most IRBs remain in large teaching hospitals and medical centers (see Walker, 1996, Nov 8), but the addition of new commercial and hybrid settings (an example of such a hybrid organization is found at the University of Oklahoma: the H.A. Chapman Institute of Medical Genetics, a private research organization, is located on the OU Tulsa Schusterman campus) has created new research situations (DHHS OIG 2000a). Also, multi-site trials are much more common today and add to the difficulties of adapting the old regulatory system to the new world of research. At the time many of the rules were written, studies were typically conducted by a single researcher with a small number of subjects, much lower financial stakes, and far fewer conflict of interest concerns.

[134] Ellis, when head of the OPRR and during House testimony in 1998, estimated the number of IRBs operating at 3,700. The AAUP (2001) reports that approximately 4,000 IRBs were operating (in 2000) in the U.S., mainly at universities, teaching hospitals, and private research facilities.

Power shift. Ellis was named director of OPRR in January 1993 (see Brainard, 2000, May 30). He brought more suspensions in 20 months than in the 20 years prior to his appointment. Since October 1998, federal regulators have "imposed an unprecedented series of suspensions on campus research efforts involving human participants, after finding that some institutions were not following mandatory guidelines[135] meant to safeguard the safety and dignity of the participants" (Brainard, 2000, Feb 4). Notice that the accusations, indeed the sanctions, did not involve the *purpose* of regulation, *i.e.*, protection of participants from harm,[136] rather harm to the *process*, the regulatory structure, was the concern (see Brainard, 1999, Sep 10). The *process* was at risk. Papers weren't filed[137] in many of the sanction cases, the

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[135] It is unclear what distinction is to be made between "mandatory" guidelines and what might be called "the force of law."

[136] Brainard (2001, Mar 9) reports that "methods and ethics of social science and behavioral research were not at issue in the federal suspensions" (p. A 21). And Brainard (2000, Mar 17) states, concerning the sanctions at Duke University, "The [OPRR] voiced concern that Duke's board was overworked to the point it was no longer meeting its responsibilities" (A21). Even more seriously, the regulators said, the board had violated federal rules about how to conduct its deliberations. This was true in 1994 when the OPRR "in an unusual step" issued sanctions against the University of Virginia for failure to have on their Behavioral and Educational Sciences Institutional Review Board a member "whose primary concerns are in non-scientific areas" (Burd, 1995, Apr 14). Inconsistency is a problem as well. In 1999, two New York institutions were allowed to continue federally sponsored research in spite of having subjected children to "intravenous lines for multiple blood drawings, genetic testing, and the infusion of the banned flenfluramine" (Campbell, 1999, Jun 25, p. A43), yet the University of Virginia was sanctioned in 1994 for not meeting the composition standards for their IRB.

[137] The 1999 four-day shutdown of Duke's medical research was described as "all about procedure" (Brainard, 2000, Mar 17) and as "administrative lapses" (Duke officials, quoted in Campbell, 1999, May 21). The board had failed to review some continuing research projects at least once a year. Among other problems, the IRB lacked formal training for researchers and board members about regulations covering human volunteers. Duke was scolded as well for such seeming minutiae as failing to keep sufficiently detailed minutes of IRB meetings. Regulators did not allege that volunteers had been physically harmed in experiments by Duke researchers" (Brainard, 2000, Mar 17, p. A31). Chairman of the Yale University IRB and editor of IRB: A Review of Human Subjects Research says, "If you don't like the way an IRB is keeping minutes, you can say so, but you don't need to close an institution to bring about change of this sort" (quoted in Brainard, 2000, Feb 4). And in the letter delivered by the OHRP in July 2001 announcing sanctions at Johns Hopkins University, the regulators cited numerous paperwork infractions. (See OHRP, 2001, July 10.) With respect to social scientific studies, privacy concerns emerge occasionally, but damage suits, even in this litigious society, are rare. In my reading about this subject, I haven't

implication being that if the papers had been filed (that is, the *process* had remained intact) that the filing of paper would protect people (meeting the *purpose*). The *process* of paper filing has become institutionalized, *i.e.*, SINSful[138]; the paper forms are equated with *protection of research participants*, rather than with the much more tangible (*i.e.*, actual, "real") situation of *protection of the university/IRB personnel* from somewhat remote, yet potential problems with federal overseers, researchers, or (even) participants. This process is a manifestation of the "I" in SINS, specifically universities and regulatory agencies (institutions) have developed a pattern of paper filing, and have perpetuated it—an *institutionalization* organized by the texts that come before and after any given piece of paper being put into the process at any given moment (see also footnote # 72, p. 64). The result is that the institutional-level players (IRB members and administrators) fulfill the (paper, *textualogical*) process, without ever seeing an informed consent *process* in the lifeworld, without ever meeting a participant, without any contact (at least a very high probability of no contact) with the "real" research process at all. This also demonstrates the Baudrillardian idea of *simulation* (the second "S" in SINS). We are seduced by the "goodness" of the (stated purposes for) rules to create the paper process, and further seduced by the fulfillment of the paper process, which in turn, further contributes to the *simulation* of protection.

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encountered any information related to a "survey-gone-bad" or any lawsuits related to observational data gathering techniques.

[138] Brainard (2000, Mar 17) observed an IRB meeting at Duke University after sanctions were issued there in 1999. His observations "revealed a paperwork-driven process that places great faith in the precision of language, and in the careful review of documents that scientists submit to justify research projects. The process does not involve direct oversight by board members of the research itself. All of those features are typical of review boards at other universities" (p. A31).

SINS and paper processes: Further explanation. The paper process is accepted, institutionalized, as "the way we do things," and its acceptance is based on *structures* (*i.e.*, ideologies) such as "the way we do things is good" (*i.e.*, effective, meets the goal), and "these things are good for us" (the goal is worthy/possible). These are three stellar leaps of faith; the more faith we have, (I would add that I believe this is mostly passive defaulting rather than active faith) the deeper the SINS, *i.e.*, the more invisible the STRUCTURES; the more firmly entrenched the INSTITUTIONALIZATIONS become, accepted, not questioned even when they seem unreasonable or ineffective. NATURALIZATIONS occur as objects become "obvious," "normal," or "natural," this based on the sheer number of people who participate in the process, perpetuate it, mostly without question, without whying. NATURALIZATIONS support and perpetuate INSTITUTIONALIZATIONS; and we are more easily seduced into more complete SIMULATIONS (*i.e.*, situations involving processes ever more detached from "real" lifeworld events).

These phenomena would likely be observed in many regulatory entities and other organizations.[139] But situations vary in interesting ways. I'll give two somewhat contrasting examples. First, consider the probation process for criminal offenders. The probation process involves as a central feature a "real" world, a contact visit in the lifeworld, between the probation officer and the "real" parolee, a local *attached* "reality" (and realizing that not all such appointments are kept, of course.)

[139] IRBs seemed a good choice for a dissertation.

Alternatively, consider typical unemployment insurance procedures. An unemployed person goes to the Employment Office and completes a form that states s/he has solicited work at some number of places during the past few weeks or month. This form, in the organizational view, actually *constitutes* the process of "looking for work."

The unemployment paperwork is similar to the IRB assurance document process between the federal government and the institutions (described more fully below, footnote # 140, p. 121) though the employment example is more local, *i.e.*, the parties to the process (the unemployed person and an employment service employee) are directly involved in the making and accepting of the assurance. As pointed out above, the IRB assurance document is negotiated among people who often conduct no research at all and who rarely if never meet each other in person. The parties to the making of the assurance document are the federal regulators and institutional administrators, not, in the normal course of things, the researchers or research participants who actually "fulfill" the assurance, an assurance they didn't write, and often have never read. This paper-only process also adds to the detachment (*i.e.*, hyperreality) of the "assurance" from the research environment. Regulators and administrators particularly are seduced by the goodness of the ideas in the document and the faith in the overall bureaucratic process to believe such a document can be meaningful, will have an impact, will be followed, is possible to accomplish, etc.

In the employment paper process example, it is not significant (with respect to getting the unemployment check issued) whether the unemployed person *actually* sought employment or not. It is only significant that the person fill out the paperwork,

correctly and on time, etc. The unemployed person gets the check for doing the paperwork, not for "really" looking for work. It is a charade, a "just tell me what I must hear" presentation, and known to all parties as a charade, but as a "natural" (or at least "normal") charade, *i.e.*, it has come to be the "way we do things." This is unlike what happens if a parolee doesn't show up to fulfill the paperwork process ... s/he is declared to have absconded from parole, and a warrant is issued for his or her arrest, making running from parole much more than a paper process.

The assurance document. The assurance document is perhaps an important example of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS operating in the federal-institutional interface."[140] Regulators, both federal and institutional, function as if this document protects participants, *i.e.*, as "real" assurance. Yet, it would be nearly impossible for the regulators to know what effect, if any, the assurance document has. It is impossible for the regulators to know how the assurance document/process works because no "real world" oversight exists (nor can it practically, "real"-istically exist) to assure the assurance (see Brainard, 2000, Mar 17). In other words, without direct oversight or exposure to the process, assurance can *only* be voluntary (*i.e.*, self-controlled) rather

[140] The assurance document is negotiated between the regulatory agencies and the research institutions. The upfront assurance document specifies an institution's agreement to comply with the human subject protections required by federal regulations. The assurance document outlines the organization and purview of the IRB, along with processes for reviewing protocols and other procedural issues. (For details, see Appendix B of DHHS OIG, 1998e, which states: The assurance process is conducted "entirely through document transmittal and phone communication" (p. B-1). Also see U.S. House, 1998, Jun 11, particularly Ellis' testimony. For examples of assurance documents, see University of Utah, University of Louisville, and University of Texas multiple assurance documents (website addresses given in

than regulator/regulation-controlled, and is detached from reality, (hyper-real, simulated). The assurance process creates the illusion of assurance by containing promises that processes are and will remain in place according to federal rules to *ensure* the protection of research participants. When the "real" world crashes through, shatters the simulation with the occurrence of a research-related death or injury, a whistleblower, or a paper process failure (the latter, fortunately, being the most common), the focus of regulators and the regulated, often immediately and nearly always, turns to an assessment of what went wrong with the *process* that was in place to *ensure* such problems (or tragedies) were prevented. In this case, the *process* is an institutionalization (the "I" in SINS), the notion that the process can prevent problems is a structure (the first "S" in SINS) that underlies the simulation (the last "S" in SINS) that protection, based on the formulaic production and dissemination and even the occasional reading of texts, is somehow *ensured*. That we do all of this is natural, (the "N" in SINS) even if it seems unreasonable, illogical, pointless, etc.

The assurance document completes a portion of a socially constructed regulatory process. The institution provides a ceremonial document (the assurance) with words dictated by the regulators. The assurors (institutions, IRBs) make promises to the assured (federal regulators) that may or may not be kept (as is the nature of all promises) but that can provide a basis for various kinds of additional paperwork processes, from grant applications to sanctions, *i.e.*, an assurance must be on file to apply for grants. And the assurance document is often the "rope" used to hang research

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bibliography). Also see the OHRP website which outlines procedures for filing assurance documents: http://ohrp.osophs.dhhs.gov/irbasur.htm, accessed May 25, 2002.

institutions, *i.e.*, nearly always among the array of "charges" is violating the assurance document (see as an example the OHRP's letter to Johns Hopkins, http://ohrp.osophs.dhhs.gov/detrm_letrs/jul01a.pdf, accessed May 25, 2002). Further, it cannot be assumed that the assurance document directly addresses nor changes the research environment because the local participants in the assurance ceremony do little if any research, and the researchers and research participants who are directly involved in research overwhelmingly don't even know the document, process, or ceremony exist. To summarize, the "assurance" is an institutionalized process sustained by people who most often aren't involved in the research process they are making and accepting promises about, and this process seems natural (i.e. has been *normal* for many years). The assurance process is not tethered in (attached to) "reality," rather it occurs apart from the research environment, is detached from the research process and those conducting it. It is a process involving people making promises about things they don't do in their own lives and can't control in the lives of others. It is hyperreal in that very few "real" researchers know what an assurance document is, what it is for, what it says, who signed it, or who sent it. It has no direct meaning for the researcher, and less meaning for the research participants or patients in medical trials who, in overwhelmingly large numbers, do not even know it exists.

According to DHHS OIG (2000b), published in April 2000, NIH/OPRR had conducted an on-site investigation[141] at only one institution between April 1997 and

[141] A "site visit" is defined as a "visit by OHRP officials, representative, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research" (http://ohrp.osophs.dhhs.gov/irb/irb_glossary.htm, accessed May 25, 2002). In a report from OPRR to NIH in January 1999, it is stated that OPRR, now OHRP, has the

May 1998. However, between June 1998 and March 2000, it conducted ten on-site investigations. Similarly, FDA's number of routine on-site investigations of IRBs increased from 213 in FY1997 to 253 in FY1998, and to 336 in FY1999. Further, OPRR's reviews, which resulted in the suspension of federally funded research at eight institutions (beginning with sanctions at Duke in May 1999 to the most recent to be included in Brainard's comment, sanctions at the University of Oklahoma in June 2000)[142] have been particularly influential in drawing attention of the national research community to the (in)adequacy(ies) of IRB oversight and human-subject protections.[143] For more than a year after the "restructuring" of the federal system, described in the next paragraph, no sanctions were imposed until, prompted by the death of a healthy volunteer, Johns Hopkins University was sanctioned in July 2001.

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authority to "identify locations and agendas for site visits" (See http://ohrp.osophs.dhhs.gov/references/060399b.htm, accessed May 25, 2002.) The FDA has a lengthy Investigations Operations Manual (see http://www.fda.gov/ora/inspect_ref/iom/IOMforeword.html, accessed May 25, 2002) that outlines many procedures for various types of investigations such as vaccines, medical devices, food additives, etc. None of these concern social science issues. Also, in related news: In April 2001, the FDA solicited hospitals to participate in as volunteers for site visits, assuring potential participants that "activities of these facilities will be observed for instructional benefit. Again, the intent is not regulatory. We will look at the procedures followed and the records that are maintained to ascertain each hospital's 'state of compliance.' A special report will be provided to each hospital outlining the deficiencies identified in an effort to provide them with a better understanding of what must be done in order to comply with the applicable regulations" (see http://www.fda.gov/cdrh/reuse/042001_pilot.html, accessed May 25, 2002, for copy of solicitation letter).

[142] More than a year after the OU suspension, the government suspended all federally funded research on human subjects at Johns Hopkins University July 19, 2001, prompted by the death of 24-year-old Ellen Roche, a healthy research participant. (The term "participant" is appropriate rather than "patient:" Roche's death was "directly related to the study and not part of an underlying illness" according to Curry, 2001, June 29. See analysis regarding use of these terms, p. 132, herein.) The Hopkins suspension was the first under the newly organized OHRP and its director, Greg Koski. It is also notable that Hopkins traditionally receives more federal funds than any other institution, more than $770 million in 1999, and more than $301 million to the medical school in 2000, as reported by the *Chronicle of Higher Education*. On July 3, 2001, Johns Hopkins was awarded a 12-year, $600 million contract by NASA.

[143] Brainard (2001, Mar 9) reports "In the past two years, the federal government has ratcheted up pressure on all researchers studying people, urging them to do a better job of protecting the participants' safety and dignity. The push has followed some widely publicized lapses in review of medical experiments – especially the September 1999 death of Jesse Gelsinger in a gene-therapy trial at the

After the death of 18-year-old Jesse Gelsinger, a research patient at the University of Pennsylvania in 1999, and the discovery that six prior deaths had not been reported as required by federal law (see footnote # 43, p. 30, herein), the OPRR was criticized by legislators, members of the public, NIH officials, the FDA (in issuing sanctions), bioethicists and others for not doing enough to protect research volunteers (see Brainard, 1999, Nov 12 and legislative hearings transcripts, particularly in the questions raised by Reps. Towns and Shays in *Institutional Review Boards: A system in jeopardy*, 1998). In June 2000, Ellis was "reassigned," and the OPRR was moved (up the regulatory food chain) to the Office of the Secretary of DHHS (Brainard, 2000, May 30). This development can be interpreted in numerous ways, of course. Naming a new person at that particular time, *i.e.*, just as Ellis was enforcing the rules he was stripped of his responsibility to do so, and the changing of the structure, location, and name of the OPRR (to the not-so-different OHRP) may indicate a desire, on the part of regulators and researchers alike, for change in the role and/or boundaries of the system.[144] In other words, Ellis, while enforcing the provisions of law may have called attention to a lack of support for the law. It could also be argued that the overhaul/reorganization activities, including Ellis' reassignment, were at least in part political responses (see Brainard, 2000, May 26a, and 1999, Sep 10, as examples). In this case, it was socially desirable for the federal regulators to appear responsive and caring in the face of mounting pressures: the release of the concern-ridden ACHRE

University of Pennsylvania. Between October 1998 and July of last year, officials of the National Institutes of Health suspended federally financed research at eight institutions" (p. A21).

[144] Brainard (2000, May 30) states, "Some observers have concluded that [DHHS] wants to scale back the tougher enforcement of the research-risks office under Mr. Ellis's leadership over the past 20 months"

report (1995), the Executive Order forming the NBAC (see Clinton, William J., 1995, in bibliography), President Clinton's public apology in 1997 for the Tuskegee incident, the DHHS OIG reports (issued from 1998 to 2000), capped by the Gelsinger death in 1999, and other sanctions following. It could be argued that the federal regulators *had* to do *something*. (Also see Nelson, quoted in Brainard, 2000, Apr 14, p. A45.) And whatever the federal regulators do affects institutions and researchers with little or no regard to treatment, in large part because of federal regulators' (expressed) beliefs that consideration of the distinctions among treatments is not necessary.[145]

Avoiding litigation. Hayes, Hayes, and Dykstra (1995) suggest when IRBs make mistakes, thorough, periodic evaluations—particularly ones conducted externally—would serve to re-orient the groups to their missions and objectives. Hayes, et al., state the IRB process is too important not to include careful evaluation. They further suggest such procedures protect not only human subjects, but also institutions and investigators against liability.[146] These and other comments (numerous similar ones from government reports, DHHS OIG 1998b, 1998e, and 2000b; ACHRE, 1995; U.S.

(Daily News). That has, in turn, Brainard indicates "prompted criticism from some university officials, who have privately called Ellis's actions excessive and unwarranted."

[145] I have field notes from an OHRP open forum I attended in 2001to support this assertion, but I have no permission to use the data. If I were a reporter in this situation, I could write about it. But as a researcher, under the OUIRB administrators' interpretation of the rules, I cannot.

[146] An argument could be made that the latter takes precedence in today's "real" (and highly) litigious world and much of the activity of the IRB system is directed toward the avoidance of litigation. Consider the language of the Legal Issues for Physicians document prepared by the American Medical Association's Litigation Center: "To protect yourself in litigation, in addition to carrying adequate liability insurance, it is important that the communications process itself be documented. Good documentation can serve as evidence in a court of law that the process indeed took place. A timely and thorough documentation in the patients' chart by the physician providing the treatment and/or performing the procedure can be a strong piece of evidence that the physician engaged the patient in an appropriate

House of Representatives, 1998, Jun 11, for example) support the idea that, in addition to (or superceding) any motivation toward human subject protection, legal considerations drive the IRB system.

In comparing medical and social sciences, "in the past, particularly in medical research and psychological experimentation, there was a considerable amount of deception and, in some cases, a demonstrable element of harm" (Sieber, 1992, p. 4) including (in an example given by Sieber) distributing LSD to visitors at a brothel[147] and filming the incident with a hidden camera. "One person committed suicide while under the influence of the drug" (p. 68). Attempts to control this deception have also had an impact on social science in general, for example enhanced regulation and scrutiny of the informed consent form, and what some consider local IRB interference in areas exempted by the federal government (45 CFR § 46.101)[148]. Federally funded (and most other) research[149] in the U.S., as mentioned, must conform to the process described here including auditing by review boards. In addition, professional

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discussion" (AMA, 1998, available: http://www.ama-assn.org/ama/pub/category/4608.html, accessed May 25, 2002). Also see AAUP (2001, p. 7) re: pressure of possible litigation.

[147] The administration of a drug (LSD in the example above) would mean the study would be placed in the "medical" category, regardless of whether the researchers considered themselves "social scientists" or something else.

[148] The main complaint against the OPRR, according to Brainard (2000, Feb 4) is that "its suspensions have focused largely on universities' failure to document their oversight of experiments involving humans, and to follow federally mandated procedures" (p. A29). He continues, "Critics note that several of the OPRR's suspensions included no allegations that human participants had been injured by risky experiments or had not given informed consent" (p. A29). See also the argument made by the chairman of the Yale University IRB , footnote # 137, p. 117 about the severity of sanctions).

[149] Tropp (1982) extends civil rights precedents requiring the extension of civil rights statutes to all parts of a university campus, not only those receiving federal dollars, stating these precedents apply "exactly to the issues of protection of subjects in nonfederally funded research" (p. 395). Tropp maintains the precedent *requires* that IRBs assert their authority over all research, *campus-wide*, if that campus receives federal funds *at all*. George Annas, an ethicist and professor of Law and Public Health at Boston University states, "We can't tolerate having one rule for private firms to do research, out of the public view, and for public scientist not to be able to do research .. and that's the situation today" (as quoted in Amos 2000, Apr 26; see also Campbell, 1998, Dec 18).

associations have adopted and advocated/required the following of (*i.e.*, attempted to institutionalize) various codes of conduct.[150] To this end, there is disagreement about many things. As presented, regulators vacillate between positions of "stricter enforcement" and the "relaxing of rules," *i.e.*, between enforcer and educator personas (Brainard, 2000, Feb 4, and Mar 17; 2001, Mar 9) and professional organizations struggle with whether to attempt to establish "guidelines" and "policies," even "certification" schemes of their own (see AAUP, 2001; Punch, 1998).

Even though contradictory opinions exist (a seemingly healthy, desirable condition), attempts to stifle dissention are apparent. Approving of the effort to cooperate with federal authorities, Sieber (1992) says, "In essence, there is a strong argument, reinforced from disparate but powerful forces," that "sound ethics and sound methodology go hand in hand" (p. 4). Translation: Believe as we believe and do as we do and you will be sound (and heard). And protected from legal liability. And called a "good team player." And so on. The Grand Narrative produces The Grand Illusion (see Baum, 1900/1965).

Many voices, (AAUP, 2001; ACHRE, 1995; Brainard, 2000, Feb 4; Brainard, 2000, Mar 17; Brainard, 2000, May 30; Brainard, 2001, Mar 9; Campbell, 1997, Sep 12; Campbell, 1998, Apr 3; Campbell, 1998, Dec 18; Charo, 1999, Jun 25; Charo, 1999,

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[150] According to the AAUP (2001), the Oral History Association, the American Historical Association, and the Organization of American Historians in 1998 corresponded with approximately 700 IRBs to encourage them to take into account the standards of practice relevant to historical research in their evaluations of oral history projects. And, Professor Murray Wax, anthropologist from Washington University in St. Louis states, "The problems that emerge within anthropological research ... have to do with human beings, not just as physiological specimens, but as social creatures living in families, clans, groups, tribes, or nations ... the risks and benefits to the people [who anthropologists study] are very different from those faced by subjects of biomedical research" (as discussed in AAUP, 2001, p. 4).

Mar 26; DHHS OIG 1998b; DHHS OIG 1998d; DHHS OIG, 1998e; DHHS OIG, 2000b; GAO, 1996; GAO, 2001; Geertz, 1988; Gray, 1982; Greenberg, 2001, Jan 19; *Protecting human subjects: Status of recommendations, 2000*; *Institutional review boards: A system in jeopardy*, 1998; Hall, 1989; Hayes, Hayes & Dykstra, 1995; Healy, 1999, Jul 30; NBAC, 1997 and 2001; OHRP, 2001; Okie, 2001, Aug 6; Pence, 2001, Jan 12; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1981; Punch, 1998; Tropp, 1982; and Wheeler, 1991, Dec 4) are suggesting (and have been for more than 20 years now) that the system (especially as it pertains to the regulation of non-treatment, no risk approaches) doesn't work. I join the chorus. The purposes remain important, and the processes, impotent.

Fortunately, the process is text (Foucault, 1972). It can be rewritten.[151]

Additionally, the American Sociological Association and the American Anthropological Association and several other groups participated in the study conducted by the AAUP (2001).

[151] The AAUP (2001) argues " ... genuine threat[s] to academic freedom could be removed by rewriting the regulations so they do not sweep unnecessarily broadly or by better educating members of the IRBs" (p. 5-6). (I would add that educating those in charge of supervising IRBs, specifically deans and university legal counselors, also be better educated about unnecessarily or unlawfully sweeping researchers out of operation.) And Schutz and Luckmann (1973) state: "Subjective knowledge can be translated into the 'idealizing' and 'anonymous' interpretive matrices of a system of signs, and it can be again transformed into subjective knowledge by means of an appropriately meaningful retranslation" (p. 281).

Chapter Five: Foucauldian Analyses of Texts Constituting the IRB System

"The 'welfare of the individual' is just as imaginary as the 'welfare of the species ...'"
Friedrich Nietzsche, *The Will to Power*, p. 299.

This chapter includes analyses of several documents created within and for the maintenance of the IRB system. They include the Advisory Committee on Human Radiation Experiments, a 14-member body (one representative of the general public and thirteen experts in bioethics, radiation oncology and biology, nuclear medicine, epidemiology and biostatistics, public health, history of science and medicine, and law") appointed in 1994 by President Clinton "to investigate reports of possibly unethical experiments funded by the government decades ago" (ACHRE, 1995, Executive Summary, p. 1). The ACHRE released its report in 1995. This was one of the most well funded and accommodated commissions (*i.e.*, presidential instructions were to give this commission whatever documents it wanted in pursuit of its goals) ever to study human subjects of research (far and away the largest until the National Bioethics Advisory Commission [NBAC] in 2001).

In contrast to this broad, historically scoped, upper-executive level entity's report, other analyses are conducted on important but less comprehensive documents produced by federal administrators (who are not necessarily "representative of the general public" nor "experts.") One of these administrative texts is a "state of the system" report produced by the GAO (General Accounting Office) in 1996, which was used heavily by Sen. John Glenn in proposing the Human Research Subjects Protection

Act of 1997, an analysis of which is also offered in this chapter (see next paragraph). The other administrative text selected for analysis is a "guide" to the Common Rule (for use by researchers and IRB members, or their international equivalents). This guide was produced by the U.S. Agency for International Development (USAID) in 1999, and is described as a "companion" to the Common Rule.

Finally in this chapter, a proposed U.S. Senate bill is analyzed. The Human Research Subjects Protection Act of 1997 (S.193) was proposed by one of the most famous research subjects of all time (and U.S. Senator) John Glenn. The analysis includes not only the text of the Act itself, but the context surrounding and contributing to the text, *i.e.*, consideration about documents supplied by the administration used in constructing the Act, and the extent to which researchers or participants themselves were asked to contribute information or ideas about how to best design a "new program." (See also footnote # 121, p. 101 for a local example of this phenomenon.)

These documents were selected in order to focus this section of the analysis on federal-level operations and development, and for their diversity (specifically, executive, administrative, and legislative documents are represented, retrospective looks at the system [GAO and ACHRE documents] along with contemporary "guides" to it [the USAID text], and how these documents become "nested").

Advisory Committee on Human Radiation Experiments (ACHRE) Report: Analysis

In considering Foucault's questions (see Appendix A, p. 344; see also Manning, 1989) it becomes apparent that the ACHRE (1995), while not having the power to make

laws directly, does (substantially) define important terms, including "suffering," "shortcomings," "needs" (four references contained in parts of only two sentences; see introduction to part 3 of the ACHRE report), "protections," "basic rights," "the interests of subjects," "the distinction between research and therapy," "limits of the benefits of research," and what is "obscure" and "ambiguous" (see ACHRE, 1995, Executive Summary, Key Findings, or http://tis.eh.doe.gov/ohre/roadmap/achre/summary.html#findings, accessed May 25, 2002).

Another observation is that the ACHRE and other bodies refer to "subjects," "participants," and "patients" interchangeably, which is problematic (see DHHS OIG, 1998d, p. 21; researcher user-list from the University of Pittsburgh Medical Center, May 23, 2000). This cultural reproduction (*i.e.*, the term "participant" used in this way) has become an important point of confusion. That the term "participant" includes interviewees, survey respondents, the observed (who undergo no treatment), *and* clinical *patients* adds to the notion that there is no difference among these types of participation, and, following that, a single set of rules is adequate.[152] One term to describe all participants is not adequate, as it makes no distinction among diverse forms of treatment. And the same may be said about the rules. In other words, to fail to

[152] This "single set of rules" preference may be associated with ideas about fairness, *i.e.*, treating all participants the same in the name of being fair. Other fairness issues have been raised about the adequate protection of participants in non-federally funded studies (for example U.S. House, 1998, Jun 11, particularly then-director of OPRR Ellis's testimony; DHHS OIG, 1998b, 1998c; NBAC, 1997, 2001), the argument being there should be no distinction made between participants in federally funded studies and those not federally funded in terms of protections. This argument, *i.e.*, that funding source shouldn't matter in terms of protections that should be provided, I believe, is a more acceptable argument than the notion that participants, in the interests of standardization and fairness, need the same regulations regardless of treatment (or lack of it) or the level of risk involved.

distinguish among interviewing participants, observing people, drawing blood, giving people experimental medications, installing medical devices in peoples' bodies creates a lack of sensitivity to "treatment"—the very phenomenon that should be the *focus* of protecting human subjects, and therefore, must be the primary focus of regulators. A similar case can be made with respect to (mis)use of the term "doctor" rather than "researcher" or the more precise "research doctor."

Use of other terms is problematic for the qualitative researcher. Cassell (1982) points out that "Linguistic confusion appears when 'subject' is [used to] characterize ... someone studied by a wide range of research methods" (p. 145). Cassell suggests that by using the "familiar sociological concept of *role* to analyze the term *subject*" (p. 144), we can think of roles as coming in pairs, roles indicate relationships. Following this, "other reciprocal role relationships in social research are those between interviewer and respondent, ethnographer and informant, observer and observed. All involve particular relationships which differ significantly from one another" (p. 145). And, the group of methods described by Cassell (1982) and discussed above, differ even more significantly from medical (*i.e.*, drug and device) trials.

The lack of focus on the treatment particularly at the institutional level (discussed in the following chapters) is one of the primary ways social scientists are procedurally included, without much thought, into an ill-fitting system. According to the American Association University Professors (AAUP, 2001, p. 3), "social-science research was included almost from the outset in the system of regulatory oversight, although there was also recognition from the beginning that, in the words of the surgeon

general of the U.S. in 1966, "there is a large range of social and behavioral research in which no personal risk to the subject is involved" (Gray, 1982, p. 331). If *no personal risk* is involved, what procedures (to protect from risk) can logically be imposed?

Both federal regulations and local interpretations of them provide for expedited and exempted reviews when risks are "minimal" (see 45 CFR §46.101 and University of Oklahoma, IRB policy and procedure, Section 4, as examples). The OHRP states, "Institutions may elect to review all research under the auspices of the institution even if the research qualifies for exemption under 45 CFR §46.101(b)" (OHRP, 1995). Most institutions, it appears, do this (see below).

The meaning of "exempt" differs from federal to local institutional uses, and from IRB to IRB. Further, in the regulatory vernacular, "exempt" is far from the common meaning one might attribute to the word.[153] First, self-exemption is not typically allowed in university settings, though the process for studies that are exempt-able vary considerably. The University of Oklahoma's exemption policy is explicit (see OU Policy, Section 4), though the University of Utah and the University of Texas at Austin both have policies in place to "review" exempt studies. The University of Texas at Austin's policy appears to be the most like a "real" exemption, at least in terms of time taken for the review. The UT policy states that every effort will be made to process the exempt studies within 2-3 days. The applications/research protocols that must be

[153] This can create problems for students attempting to graduate, for example. Those students who read the (federal) regulations may assume the word "exempt" means "free from rule or obligation." In regulation-ese it hardly means "free from obligation," *i.e.*, the student must complete (in most places) a lengthy application document. If they do not go through the "exemption" procedure/process, they may later find themselves in an academic misconduct review and/or scrambling to get their data rendered "admissible" for their (often completed) dissertation/thesis.

submitted for exempt studies[154] must (generally) be read by at least one member of the IRB, and often two or more "reviewers" are involved in "exempting" a study.

With respect to expedited reviews, the OHRP policy states "An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110" (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm, especially the first footnote, accessed May 25, 2002).

Informed Consent Background.[155] In general, it is agreed that the term "informed consent" was first used in a landmark legal opinion in a medical malpractice case issued in the 1950s (see ACHRE, 1995, Introduction). However, "consent" was established as a requirement when the Atomic Energy Commission (AEC) was created in 1947 (ACHRE, 1995, Introduction). The concept was expressed in a letter from the chief of the AEC's Medical Division and two AEC lawyers, who summarized (ACHRE, 1995, Chapter 1, The First Wilson Letter[156]) "... it was most important that it be susceptible to proof that any individual patient, prior to treatment, was in an understanding state of mind and that the nature of the treatment and possible risk involved be explained very clearly and that the patient express [his] willingness to

[154] At the University of Utah, University of Texas at Austin, and the University of Oklahoma, and elsewhere, the application forms are the same for exempt, expedited, and full-board studies, see handbook/policy websites for each school).
[155] As outlined by the ACHRE (1995).
[156] Carroll Wilson was the general director of the Atomic Energy Commission at the time of its formation.

receive the treatment." (Also note the use of the term "patient.") Initially, the lawyers suggested a written release from the patient, however, it was agreed that at least two doctors' written certification would be sufficient (from the First Wilson Letter, as cited in the ACHRE Report, 1995, Chapter 1). So, even early on, (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS such as the bias toward believing a doctor's word ensures that the patient understands the procedure and is protected, more precisely (two) doctors' signatures stood for, *i.e., equaled* adequate protection.[157] Further, the AEC *legal* staff defined the terms, established the procedures, evaluated, and revised them. Just how the legal staff was authorized to take these steps is not entirely clear. The texts were produced "at least in part, [in a] straightforward effort to define the rules according to which the AEC would provide contractors with research funding" (ACHRE, 1995, Chapter 1, The First Wilson Letter). The chair of AEC's Interim Medical Advisory Committee in January 1947 requested that the AEC legal department determine the "financial and legal responsibility" of the AEC when "clinical investigations" using federal funds are conducted (ACHRE, 1995, Chapter1).

During the years, the process, (if not the purpose), of informed consent has changed. Written consent of actual participants was suggested in the First Wilson Letter in 1947 but later dropped at the request of the chair of the Interim Medical Advisory

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[157] Of course, given the commercialization of the research enterprise (Blumenstyk & Wheeler, 1998, Mar 20), this situation today many times represents a conflict of interest in that (research) doctors are often stockholders in the pharmaceutical companies whose products they are "researching." It has been argued by many that conflict of interest issues are being neglected by IRBs in part because of the IRB members' fairly evident preference for the less political focus on the wording of consent documents. (See Okie, 2001, Aug 6; Cho, 1997, Aug 1; Andrews, 2000, Mar 10; Brainard, 2000, Mar 17; and DHHS OIG 2000a.)

Committee (ACHRE, 1995, Chapter 1). With the implementation of the Common Rule in 1991, Wilson's suggestion was (re-)adopted more than 40 years later.

Historical Development Contributing to Complexity of the Federal System. As mentioned previously, the federal system is difficult to decipher for federal regulators themselves, and even more so for other participants in the system. For example, informed consent requirements, as outlined in the Common Rule (45 C.F.R. § 46, 1991), contain many of the same requirements for researchers as those first proposed in the 1940s, but today the requirements are more specific, more articulated (ACHRE, 1995; see also p. 166, herein). Rules are refined, even re-refined at the federal level. Next, rules are interpreted by the institutions (the focus of the following chapters). The IRB system has gained more detail in the 44-year interim between the 1947 AEC letters and the establishment of the Common Rule (see ACHRE, 1995, Chapter 14, History of the Common Rule since 1974, p. 1). For example, more specificity has been added to regulations regarding the use of fetuses, pregnant women, psychosurgical procedures, children, prisoners, the mentally infirmed (see the National Research Act, 1974, and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research between 1974 and 1978). The Belmont Report (1979, and also produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research) added more precise criteria for distinguishing research from medical treatment (see O'Connor, 1979). The sheer increase in the length of documents during this historical development is evidence of at

least the convolution of regulation today, if not actual increases in regulatory specificity, scope, and burden.[158]

Rule refinements (transformations) continue (and continue to beg the question of the need for many of them, and for any of them in many situations). The NBAC (1997, 2001) noted the dual standard of protection in the U.S.: one for subjects in federally regulated research and another for those in unregulated research, *i.e.*, not funded federally. [159] The NBAC (1997) called for a single standard of basic protections, and the provision that every person in the U.S. who participates in research should have the twin protections of informed consent and independent review of risks and benefits involved. If this suggestion is taken (and it was also discussed by Ellis in his testimony before the House, see U.S. House, 1998, Jun 11), these and subsequent policymakers (framers, shapers) will change the status of (quasi) voluntary compliance by universities for studies not involving federal funds to mandatory status, thereby broadening the (legal, federal) definition of "participant" substantially (yet changing nothing about the

[158] The 1947 Nuremberg Code is approximately one page long (contains 10 tenets; fewer than 500 words). The 1963 Declaration of Helsinki, produced by the World Medical Association, is approximately three pages long (1250 words), involving 22 tenets. The Belmont Report (1979) is approximately 11 pages in length, 4650 words, and each of the tenets presented is several paragraphs long, as opposed to the one or two sentences comprising the tenets in the Nuremberg and Helsinki documents. The Common Rule (1991) is not concise enough to be stated clearly in tenets, or even in one document. It must be "mined" from the federal code involving several areas of federal regulation (Titles 45 and 21, among others, see Appendix B, legal citations section) and, in another area that is problematic to the notion that all research participants should be treated the same way (and other notions), the Common Rule is not "really" common: it often differs from agency to agency. (The Common Rule is codified in Titles 7, 10, 14, 15, 16, 22, 24, 28, 32, 34, 38, 40, and 49, in addition to Titles 45 and 21 of the Code of Federal Regulations.)

[159] No provision of U.S. law explicitly requires that informed consent and independent review of research involving human subjects be obtained for research not sponsored by the federal government (see DHHS OIG 1998e, p. *i*; see also Ellis' testimony before U.S. House, 1998, Jun 11).

"real" participation). This NBAC (1997) suggestion has not become law, though laws were proposed in both the U.S. House and the Senate. (In the Senate, the Human Research Subject Protection Act of 1997, S. 193; and in the House, the Human Research Protection and Promotion Act of 2000, H.R. 3569.) However, the NBAC final report was issued in 2001, and while it is somewhat more specific, it is not inconsistent with the earlier draft. The NBAC (2001) concluded (as summarized by Brainard, 2001, Jan 12, p. A 24): Congress should create a new, independent office to oversee human-subjects research (exhibiting the more-is-better bias), and the office would develop and reinforce new, government-wide rules for such research. NBAC (2001) would require at least half the members of IRBs not be affiliated with the institution and at least half should not be scientists. Further, the NBAC (2001) stated Congress should pass legislation requiring that all human subjects of research be covered under federal regulations—even research sponsored by corporations without federal funds. Further, IRBs should directly monitor the informed-consent process when doing so would significantly enhance protection of human subjects, and that researchers and IRB members who approve research should be certified by independent organizations.[160] Another problem with understanding federal regulations, and speaking to the convoluted nature of them, may be the fairly large number of interpretations at the federal level (various agency "guides" to understanding the Common Rule, for

[160] Many of these rules or versions of them are being implemented, but as administrative rules rather than statutorily. Congressional action is not needed to adopt the rules, adding strength to the argument that Congressional involvement and bill-sponsoring activity was politically valuable perhaps, but unnecessary for any other purpose, including interest in human subjects of research or in changing rules. The argument is already supported by the existence of civil and criminal penalties for hurting people, and these penalties not only encompass all research, but myriad other behaviors.

example). An analysis of one of these "guides" (published by USAID) is included in this chapter.

Federal Politics and Power: Sounding Good: Saying Nothing. The IRB regulatory system is clearly affected by political maneuverings[161]. Perhaps commissions and Congress are similar to quantitative researchers—they have to find significance (numerically, in the case of quantitative researchers; politically in the case of commissions and Congress). More than a decade and a half after the Belmont Report (1979), the ACHRE (1995) issued their final report. From Chapter 15 of the ACHRE report:

> There is no evidence in this review that research in which human subjects are exposed to radiation is any more ethically problematic than other kinds of research involving human subjects; in fact, our results suggest that human subject protection may be more effective in radiation research than elsewhere, perhaps because some radiation research is reviewed by a radiation safety committee as well as an IRB. (Chapter 15, Discussion section, p. 1)

In considering this statement, several assumptions on the part of the ACHRE are apparent. The first part of this sentence (up to the semicolon) implies that all research is the same because radiation research does not differ from "other kinds of research," with respect to ethical concerns. The ACHRE declares this is the case based on "no evidence" to the contrary. The lack of specificity in the use of the term "other kinds" of

[161] The lack of agreement about who will head the FDA is one among hundreds of examples. With the (demonstration of) concern about protecting human subjects on the part of politicians, it seems the activity is more political than protecting. Drug companies lobbied against Bush's last candidate for the post; the commissioner's job, one important to protecting human subjects, has been vacant for more than a year (since Bush took office); see Zuckerbrod (2002, Feb 21). Deetz (1995) states "Even what governmental regulatory policy remains is largely influenced by corporations" (p. 27).

research implies the ACHRE knows about "other kinds" of research and can make comparative judgments about the ethical concerns in each. Readers (including most significantly policy makers) don't know how many "other kinds of research," or whether the ACHRE's implication is *all* other kinds or *any* other kind.

In the second part of the sentence, the ACHRE states that their "results suggest" protections may be "more effective in radiation research than elsewhere." The ambiguity of the term "elsewhere" broadens substantially the scope of the statement. Even more significant, perhaps, is the evidence offered for the justification of the view that radiation research protection is "more effective" because "some radiation research is reviewed by a radiation safety committee as well as an IRB." The authors of this part of the sentence, of course, beg the question (*i.e.*, make SINSful assumptions) that more review (*i.e.*, review by both IRB and committees) automatically increases effectiveness. Further, given the greater context of the report in which this statement is contained (specifically the context of fairly strong criticism of the effectiveness of IRBs, see next paragraph) it seems inconsistent to (then) use an IRB review as evidence that "more efficient" protections are delivered.

For example, *on the same very same page* of the ACHRE report (Chapter 15, Discussion section, p. 1), the report states:

> ...our review suggests that there are significant deficiencies in some aspects of the current system for the protection of human subjects. We have evidence that the documents provided to IRBs often do not contain enough information about topics that are central to the ethics of research involving human subjects such as voluntariness of participation, fairness in the selection of subjects, and scientific merit. (ACHRE, 1995, Chapter 15, Discussion section, p. 1)

In this passage, it appears the Commission is labeling and defining problems and expressing concerns, implying the importance of their concerns, declaring deficiencies and defining the degree of them, and defining what constitutes "scientific merit." First, with respect to implications about setting criteria, the degree of deficiencies is "significant" (line 1) in "some aspects" (line 2) of the system, according to the report. The term "enough" (line 4) used to describe the information provided to IRBs implies the Commission knows not only what *quantity* of information is needed by IRBs, but also the *types* of information that is required, *i.e.*, assuming knowledge of the "topics that are central to the ethics of" (line 4) human subjects research. Further, the ACHRE indicates exactly what these "central" topics are in lines 5 and 6: "voluntariness of participation, fairness in the selection of subjects, and scientific merit." The importance of these assumptions is that they imply that the Commission (or other policy makers using the Commission's report) can set the criteria, as mentioned, but also it implies/assumes that IRBs are *capable of making* these determinations, not only as provided by law but also in reality. Finally, this argument relies on evidence in seeming contradiction to statements about the reliability of that evidence used two paragraphs earlier, *i.e.*, the assumption that reviews of IRB information can lead to conclusions that some research is "[no] more ethically problematic than other kinds of research" yet in the second sample paragraph, IRB documents "often do not contain enough information about topics that are central to the ethics of research."

SINS, specifically simulations (Baudrillard, 1983), are demonstrated in the ACHRE's use of the term "documents," (line 3) rather than any reference to "real"

research activity—the ACHRE used the term "documents" as if they were speaking of the actual research environment. The most that a researcher can tell the IRB in a proposal or a final report will be "simulated" in that the account of what happened would be an "average" or aggregate (and therefore nonexistent) "event" that would be explained by the researcher. Were the documents executed? How many of the participants "really" understood them? According to whom? Was the process adequate? Who says? The documents required tell us very little about what "really" happened in any specific, local case. This textual process may or may not serve a purpose or meet the goal (the process *will* create activity, but that's not the same thing as goal attainment, as the deconstructionist/critical theorist/activist must point out) and the measure of the usefulness of the process will be based on whether the information provided in the document is "true" or not, another empty pursuit, of course.

Could regulators do anything else? YES. They could do nothing (if one considers that nothing IS something).

Documents serving as stand-ins for regulatory/research activity are somewhat similar to comments reportedly made by OU President David Boren, particularly his use of the phrase "model of compliance" rather than "model of protection" (see p. 206; also Schneider, 2000, Nov 6, for similar quote from University of Pennsylvania officials in a similar predicament). It is notable that scientists are not allowed to/do not allow themselves to speak in such situations generally, adding to the detachment of this discourse from the realities of research, *i.e.*, the people most directly involved in what happened (or those involved in similar pursuits) are not participating in the explaining

of what happened (see also Weinberg, 2002, Jun, re: the lack of scientist's voices in the cloning debate).

On the next page of the report, the ACHRE (1995, Chapter 15, Discussion section, p. 2) states that in their own study as well as an independent review of that study it was found:

> ... some consent forms currently in use are flawed in morally significant respects, not merely because they are difficult to read but because they are uninformative or even misleading. These are consent forms that have been approved by an IRB, and still they are problematic ... (p. 2)

As with the use of the term "documents" previously discussed, the use of the term "forms" in line 1 in the preceding paragraph is indicative of the notion that process meets purpose. And, the ACHRE reverts to the negative assessment of IRB review, in fact surpasses the earlier criticisms, stating that IRB review may be "flawed" (line 1)[162] in "morally significant" (line 1-2) ways. The ACHRE's suggestion that the forms are "uninformative" and may be "misleading" (line 3) and "problematic" (line 4), in combination with the Commission's earlier assumptions discussed above, implies the ACHRE has the ability and the right, the authority to determine what is "uninformative," "misleading," and "problematic" in the informed consent process, in *all kinds* of research and, therefore, *all kinds* of participants, and that (evidently) IRBs, at least some of them, cannot. Even though the local IRB is right there, closer to the liquid and local, *i.e.*, "real" research activity, the ACHRE views itself as more knowledgeable, more able to know how to inform, how to avoid misleading

[162] Perhaps this is due to the production of flawed forms in the first place, or failing to acknowledge that all forms are flawed, and therefore all reviews based on forms are also flawed.

participants, and how to define and avoid morally significant problems. These assumptions are not reasonable, sensible, or possible.

In 1996, about a year after the release of the ACHRE report, the General Accounting Office (GAO) issued a report to the "Ranking Minority Member, Committee on Governmental Affairs, U.S. Senate" who was, at the time, Senator John Glenn. Glenn later sponsored a bill, S.193, 1997; the bill and its relationship with the GAO document analyzed next are described later in this chapter.

GAO: Analysis

The first feature of the GAO report (1996) for consideration is contained in the cover letter. In the first paragraph of that letter, the GAO acknowledges, employs, perpetuates, and legitimizes the results of the ACHRE (1995) report by stating: "These and other issues [the 40-year Tuskegee syphilis study, the injection of elderly patients with live cancer cells, and the U.S. government's radiation experiments] related to protecting human research subjects were recently addressed by the President's Advisory Committee on Human Radiation Experiments" (p. 1). The GAO (1996) concludes (and implies that others including the ACHRE have also concluded) that these atrocities have "demonstrated breakdowns in the protection of human subjects in scientific experiments sponsored by the federal government and others" (p. 1).

The power of certain discursive forms: "In Brief" and "Results" synopses. The GAO (1996) in the report to Sen. Glenn, states:

> Today's oversight of tens of thousands of HHS-funded research and FDA-regulated drug studies appears to have reduced the likelihood that serious abuses of human subjects, comparable to past tragic events, will occur. The conspicuous activity of local institutional review boards and human subject protection efforts by federal agencies have heightened the research community's awareness of ethical conduct standards, increased compliance with federal regulations, and served as deterrents to abuse of subjects' rights and welfare. However, little data exist that directly measure the effectiveness of human subject protection regulations. (p. 2)

This passage is the first paragraph under the heading "Results in Brief" (GAO, 1996, p. 2). The abundance of qualifiers in the passage dilutes the impact of "results." For example, the GAO states that oversight today "appears" to have "reduced" the "likelihood" (line 2) that "serious" abuses (line 2) will occur. "Serious abuses" are at least partly defined as being "comparable to past tragic events" (line 3). In spite of the qualifiers and the tentative nature of the first sentence of the passage, the next sentence seems to ignore the limitations posed by the first, making a sweeping three-part conclusion. First, the GAO states that "conspicuous activity" (line 4) of IRBs and federal agencies "have heightened the research community's awareness" (not "appear to have" but *have*, and further, not simply changed awareness, but heightened it, and not just certain individuals but, it is implied, the entire "community") of "ethical conduct standards" (line 6). On the surface, this second sentence appears to be a more assertive statement, however, if one considers the statement speaks to "heightened" "awareness" (fairly elusive concepts, both awareness and height of it across individuals) rather than

improved protections. The second broad conclusion (positioned as "results") is that this "conspicuous activity" on the part of IRBs and federal regulators has "increased compliance with federal regulations" (lines 6-7) and the third sweeping conclusion is that these activities have "served as deterrents to abuse of subjects rights and welfare" (line 7-8). It is difficult to understand the next sentence in this context, especially the acknowledgement that "little data exist" that "directly measure" the "effectiveness" of regulations. If we consider what "effective" regulations might be, primarily they would be *followed, i.e.*, complied with. For regulations to be ignored doesn't imply they are "effective." So if there is no data (evidence) that the rules are effective, how does the GAO conclude (within the same paragraph, especially) that the "heightened awareness" of the "research community" leads somehow to " increased compliance" and as "deterrents to abuse?" I conclude that such "Reviews of Findings" and similar discursive forms are powerful (and substantially oversimplified) texts, whether accurate or epistemologically sound or not. They help create and perpetuate illusions. Synopses (and sound bytes) simulate reality, mostly via over-simplification.

In viewing these passages collectively, not only are these commissions and federal agencies allowed to say that something *is* (consent forms flawed, awareness heightened, and compliance increased, for example), but what the (alleged) flaws *are*, what the effects of (allegedly) heightened awareness and (allegedly) increased compliance are. This requires any *contra* argument include at least two levels: first, countering the existence of the phenomenon at all, and only then addressing the folly of any proposed conclusions, results, or solutions. I argue, based on these examples, that it

is at this first level, *i.e.*, the assumption without question of the existence of the phenomena as described by the "experts" presented by the government, where many (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS operate, *i.e.*, the SINS dwell in the assumptions by researchers (and regulators and others) that regulators know what needs to be included in consent forms across the range of study types and risks, and/or that measures required of researchers produce the intended effects on research participants or are even accomplished in the way the regulators intended, and/or assumptions that statements such as "we're all working together to produce (in some logical way) a system that benefits the participants of research" are true (for everyone involved). Further, the commissioners and regulators seem to be myopically focused on the *process*, making little if any distinction between the process and the *purpose* of regulation, and operate with the apparent bias that more rules, regardless of the ineffectiveness of past rules, offer solutions to problems. Finally, as pointed out, the rules offered as solutions have little to do with the original "problem" which itself is often not established. As the preceding three passages indicate, (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS are shown to be operating in many of the assumptions made by both the ACHRE (1995) and the GAO (1996), as well as the regulatory bodies about which they are reporting.

Human Research Subject Protection Act of 1997: Analysis

The year after the GAO (1996) report, Sen. John Glenn introduced the Human Research Subject Protection Act (S. 193, 1997).[163] As proposed, Glenn's bill would have escalated regulatory power. In his comments introducing the bill (S. 193, 1997; see Congressional Record, p. S645, 1997, Jan 22) Glenn states, "What it comes down to is there are no criminal fines or penalties for violating the spirit or the letter of that Nuremberg Code that should be the basis of all of our informed consent in this country... In fact, our own Constitution says 'The right of the people to be secure in their persons ... shall not be violated'" (Congressional Record, S645, 1997, Jan 22). He adds, "there is no explicit statutory prohibition against improper research ... there is no law on the books requiring that informed consent be obtained" (Congressional Record, p. S645, 1997, Jan 22). These statements suggest that criminal penalties would make laws better (both the spirit and the letters; of course making laws against violating the "spirits" of laws has proved to be problematic historically; see also GAO, 2001, p. 7). Glenn also cites in his comments the ACHRE (1995, final report), the NBAC (1995, interim progress and status reports), and the GAO (1996).

Glenn (Congressional Record, 1997, Jan 22, p. S645) states that four "major gaps" exist in the current regulatory system. Several (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS can be illuminated within this political, as distinguished from scientific, discourse.

[163] Glenn had became one of the most famous research subjects in the U.S. when he returned to space more than 35 years after his first voyage.

First, Glenn says, not all agencies have adopted the Common Rule; he names specifically the U.S. Department of Labor and the Nuclear Regulatory Commission (NRC). This suggests a SINS-ful bias toward regulation, specifically toward belief in the effectiveness of at least the Common Rule (an institutionalization; "I" in SINS), if not rules in general and/or the belief that rules operate for the "common good" (belief in rules in general/for the common good are examples of the first "S" in SINS, structures, and a Habermasian cultural reproduction). Further, Glenn's' remark suggests that a "common" rule for all agencies is not only possible, but desirable (a structure, *i.e.*, the belief that standardization is good, possible, needed, required, etc., and also the Common Rule itself is an institutionalization-al outcome of the structure; and, finally, these activities and the talk seem normal to most of us, *i.e.*, whether we agree with Glenn, or even believe him, we find it normal that people would talk about rules in this way of "rules solve problems" or "rules protect people."

In the several incidents Glenn uses to support his contention (see below, in this paragraph) that there "really [is] a problem out there" and not just a "paper loophole,"[164] Glenn's evidence addresses only in tangential ways the "lack of Common Rule adoption" (the "problem" as Glenn expresses it, *i.e.*, failure to adopt the Common Rule will result in a catastrophe). In making his case that there are problems that his law would fix,[165] Glenn relies on the ACHRE report (1995), and several incidents: the use of homeless alcoholics by a pharmaceutical company, psychiatric experiments on

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[164] Here Glenn is defining, contrasting "real" problems with "paper" problems, interestingly.
[165] SINS at structure level, *i.e.*, people operating with the idea that laws fix problems; it's what we *do*, we pass laws or advocate the passing of laws, even if we may often say/hear "laws don't work" or "the punishment doesn't fit the crime," etc.

children and mentally ill in New York, FDA approval of the use of human growth hormone, implantation of fertilized embryos in patients without the consent of the donor, and unapproved use of drugs. Only in the case of the implantation of embryos is one of the main provisions of the Common Rule (informed consent) addressed. And, none of the situations Glenn describes involve the two agencies (Department of Labor and the Nuclear Regulatory Commission) he mentioned as not having adopted the Common Rule, central to supporting his "problem" thesis. (See also Foucault's questions and examples of analysis, Appendix A, Examples 1 & 2, p. 346-347.)

The second gap in the system as Glenn views it is that not all research institutions voluntarily adopt the system, and "if any improper research is discovered at these institutions, there are very few steps available to the federal government to do much about it" (p. S645; see also Ellis testimony before U.S. House, 1998, Jun 11).[166] Glenn points out most institutions receiving federal funds for any purpose do apply the Common Rule. This (SINSful) statement implies the federal government is effective at doing something about improper research, and begging the questions once again of the need for the Common (or any) Rule, and how a system that lacks direct oversight differs in any meaningful way from a system based on voluntary compliance. Finally, his provisions for penalties, etc. (see p. 153, below) do not address this statement, *i.e.*, the solution doesn't match the problem as presented (if not established).

[166] This statement demonstrates structural-level SINS, *i.e.*, a bias toward the belief that government can and will do something and knows what to do, etc. and also demonstrates a naturalization of the reliance on government *to* do something.

Third, "a huge area of all the private medical research out there ... is not under the Common Rule unless they just choose themselves to just voluntarily do it" (p. S645), Glenn says. With this statement, Glenn reinforces the (SINSful) notion that human agency (active voluntary compliance in this case) is somehow less legitimate or effective or valuable than laws on the books with no or little oversight of them. Again, if no oversight is conducted, compliance *is* (in any "real" way) voluntary. Glenn further implies with his statement that voluntary compliance is not adequate,[167] and further it implies that there can be something like "compulsory compliance." (I would add that the local liquid nature of the world would imply that the term "voluntary compliance" is redundant, and "compulsory compliance" is impossible.) Glenn's statement also indicates a (SINSful) belief that the Common Rule *constitutes* protection, that application of the Common Rule—by law—is needed. (Notice the use of "by law," rather than by *action*, see quote from the Dalai Lama, p. 1, herein.)

Glenn's bill (S. 193) proposed new rules that would require all research facilities to register with DHHS, and the registration would include stating "the principles governing the research facility" with respect to human subject research, naming the official responsible for the human subjects of research at the facility, providing a membership roster of IRBs at the facility, and "attestation that the research facility is complying with the protection requirements of the Common Rule" (Congressional

[167] Glenn states regarding a case he read about involving the use of drugs for "off label" purposes, "because the drugs were FDA approved and the doctor was not funded or connected to federally sponsored research, no IRB or informed consent procedures were required. Apparently, each patient signed a three-page consent form, but this was not approved by an IRB" (Congressional Report, 1997, Jan 22, p. S645). This carries the implication that a three-page consent document that hasn't been approved by an IRB is somehow less effective than a consent document of any length that has been reviewed. Further, he makes no claim about anyone being harmed.

Record, 1997, Jan 22, p. S645). The legislation included a three-year re-registration requirement and a grandfather provision for those entities already operating under project assurances with DHHS; Glenn pointed out that "the vast majority" of U.S. research facilities "have such assurances." Use of the term "assurances" rather than "assurance documents" indicates the *institutionalization* of paperwork as protection and the *naturalization* that a signature on a document assures compliance. This usage is also an example of a simulation (Baudrillard, 1983) in that the difference between the assurance and assurance document has become indiscernible.

In addition, the proposed law included "criminal penalties for failure to comply with the act ... [making it] a felony offense to experiment on someone without their informed consent" Glenn states (Congressional Record, 1997, Jan 22, p. S645; for related activity with respect to DHHS proposals to implement fines[168], see Brainard, 2000, Jun 2; for more recent federal views, see GAO, 2001, Research Protection and Promotion Act of 2000, and, at this writing, the current legislative incarnation, Human Research Subject Protections Act of 2002, dubbed the "biggest overhaul" of human research protections since the enactment of the Common Rule legislation in 1974, and in which greater statutory authority and more severe penalties—than in Glenn's 1997 bill—are proposed; see Washington Fax, 2002, Mar 28).

The proposed legislation does not address the problems or needs as described, and only one of Glenn's four "gaps" was consistent with the evidence he brought to

[168] Proposing penalties demonstrates a belief in the effectiveness of the *institution* of punishment, and the rather prevalent bias toward the belief that without some threat (and demonstrated in the sequence of proposed bills and resolutions, ever increasingly intense threats) of punishment, society couldn't function. Chaos is surely not the only result of a lack of punishment, threats, coercion, etc.

support for the need for a law: the fourth "gap," specifically that some agencies have not adopted the DHHS rules regarding protected classes (such as the mentally infirmed, prisoners, children, etc.). It would appear, given the problems Glenn cited, that a broadening of the procedural provisions might enhance awareness of these additional protection mechanisms. That of course does not automatically translate to more actual protection. Further a huge majority of the research in the U.S. is channeled through DHHS, which has adopted the Common Rule.[169] Though the fourth "problem" as presented by Glenn does seem more supported than the other three, the affect of the law he recommends would be minimal because not much research proportionately is done by other agencies and many of those have already "voluntarily" adopted them. Even though this may be a "real" problem, its existence in this system is in no way clear. In deconstructing-language, then, it is a whole bunch of talk about a teeny-tiny slice of the "real" world, and a big political production having little to do with protection of research participants (see also Appendix A, Example 2, p. 346-347).

An additional point may be made about Glenn's evidence. The "results" of Glenn's research, and "legitimizing discourse" are based on the use of (somewhat incestuous *textual*) data, (GAO, 1996, reliant in substantial part on ACHRE, 1995, and both then used to build the case for the Act of 1997).[170] This series of political discourse includes President Clinton's apology for the Tuskegee incident later in 1997, the series of DHHS OIG reports issued between 1998 and 2000 from the executive branch, along

[169] The overwhelming bulk of research in the U.S. is done by two agencies: DHHS and FDA.
[170] This is reminiscent of Becker's (1963) analysis of the proliferation of marijuana stories that significantly influenced public opinion based on a few government (*i.e.*, political, and also unquestioned) reports, rather than a reliance on numerous scientific ones (p. 141).

with the various congressional hearings conducted in close temporal proximity (and, it could be argued, in response) to each other (see Appendix A, Example 3, p. 347). These activities constitute essentially a debate between the executive and legislative branches of the federal government, designed around a topic that allows politicians to show concern about "innocent victims" of research, to assume moral high ground, appear busy doing something good, important, and effective, etc. Few voices of scientist, researchers, or the researched or even local IRB members are heard. These political activities might also be used to illustrate the spinning (literally in contemporary usage) of the seduction (*i.e.*, "political positioning") into the *simulation* of "public service."[171]

While it is not reasonable to offer "causal links" (in an absolutist sense) between these events[172], it is also unnecessary to do so. That these events flow from each other, *i.e.*, are temporally located near each other, is an important consideration (see also Appendix A, Example 4, p. 347-348). The release of the ACHRE final report in 1995, the establishment of the NBAC and production of interim reports by the Commission, the introduction of S. 193 in 1997 and H.R. 3569 in 2000, release of the DHHS OIG reports between 1998 and 2000, fueled by the Tuskegee apology in 1997, Gelsinger's

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[171] David Kaczynski (brother of uni-bomber Ted), in talking about turning his brother in and the government's (at least implied) agreement not to pursue the death penalty: "I really assumed, based on our good intentions, based on our cooperation, that the system would pursue justice. Instead, what I was to see over the next couple of years was not the pursuit of justice. It was a very involved legal chess game with political ramification and somewhere justice got laid aside." He continues to point out that we've had (in the U.S.) the death penalty for about 24 years, since the Supreme Court reinstated it, but that people who formerly agreed with it are abandoning their position because "they have seen how badly the system works. It's not doing what it's intended to do. It's putting innocent people at risk..." (CNN.com, 2001, Aug 1, accessed April 11, 2002).

[172] Many do, and I would suggest it is "mostly" logical to do so. Patterns emerge, as I've illustrated, *i.e.*, an atrocity focuses our attention, parties to the situation build cases about what should be done, and the people allowed to do something do or don't act. An example (of a logical) assumption of causality, among many, is the title of Brainard's (1999, Dec 17) article, "Death of research subject prompts debate about oversight of gene-therapy trials."

death in 1999, and Roche's in 2001 have culminated at least so far in a few very minor changes in the process.[173]

Other political observations. Another argument that this activity on the part of Congress and the administration was (mostly) politically motivated is that Congress and President Clinton (who weren't exactly playing well together at the time; Clinton was impeached in December 1998) had to show deep (at least equal) concern and outrage for the victims of research (specifically, the long-overdue public acknowledgment of the Tuskegee tragedy). President Clinton's highly publicized (and politically effective, maybe even sincere) apology in 1997 to the victims and survivors of Tuskegee was not lost on the U.S. Congress, each house of which introduced a bill in the 1997 session (see also Appendix A, Example 5, p. 348). Science is politics, and "has always been in conflict with narratives" (Lyotard, 1984, p. *xxiii*; see also Greenberg, 2001, Jan 19). The spin and positioning of the campaigners (some regulators, some researchers, university presidents, professional organizations, senators, and presidents) are apparent. The competition to claim ownership of the solution, not to mention the political value of demonstrating interest in protecting people, concern, compassion, outrage, etc. (and in the process vilifying all researchers) is evident, and not unique to this system. Larger cultural reproductions (SINS) of compassion (that everyone should be compassionate and in defining what constitutes compassion in any given situation), intelligence (that we can measure it or that we can meaningfully use the term given there are so many

[173] Minor in comparison to the National Research Act (1974) or codification of the Common Rule (1991).

different intelligences), doing a good job (who sets the standards for "good" etc., and the bias for work over play), operating in the public interest (a simulation, as described above), etc., provide substantial political mileage for legislators, federal regulators, and presidents. This political activity affects the "real" world of research in only minor ways in terms of the purpose but creates sometimes mind-boggling procedural effects. While the political activity may result in changes in approval ratings, it much less frequently results in substantive rule changes: neither S. 193 nor H.R. 3569 passed, for instance, and no changes were made to Title 45 during this time.[174] H.R. 4697 was introduced May 9, 2002 (Human Research Subject Protections Act of 2002), and called by Sen. Edward Kennedy, the "biggest overhaul" of the system since 1974 (see Southwick, 2002, May 3; and Washington Fax, 2002, Mar 28).

One "real" effect of these political activities was the proliferation of sanctions (not to be confused with a proliferation of *protection* nor even a proliferation of *compliance*, though either or both might occur) issued from May 1998 to June 2000 when Ellis was OPRR director. His subsequent removal and the dismantling of the office, in the name of "concern" and "reform" seemed contrary to those ends. The activities were more about politics than protection (see Deetz, 1995, p. 130, re: politics of perception, politics of experience, politics of personal identities, etc.).

If Glenn's bill had passed, all research on human subjects would have been governed by federal protections. Data would have been collected that, for the first time,

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[174] I mention this lack of rule changes without assuming the argument that rules *should* change, or rules themselves provide protection. As expressed, I reject those assumptions in favor of one that holds personal values are much more closely related to protections and are much less regulate-able (see Sealey, 2001, Aug 17, particularly Winckler quote, and Cassell, 1982, p. 155).

would document the extent and conditions of research on human beings in the U.S. Anyone using human subjects without their consent would have been subject to criminal penalties although as I have argued, protections are provided in already existent civil and criminal laws (which may be among the reasons the bill died without a hearing). These bills, as with many similar ones, worked well politically but were legally, and mostly practically, impotent. This discourse does speak to the desire on the part of some (Glenn and U.S. Representatives Towns and Shays, GAO, 2001, and others) to broaden and deepen regulatory power, and to make criminal penalties more explicit, (illustrating several SINS including notions that laws work, that people accept the notion that laws work, that more control is possible (through law), or is required, needed, desirable, etc.)

USAID: Analysis

The U.S. Agency for International Development (USAID) points out in its 1999 publication entitled "How to Interpret the Federal Policy for the Protection of Human Subjects or 'Common Rule,'" (February 2, 1999; see http://www.usaid.gov/pop_health/resource/phncomrule2.htm, accessed May 25, 2002) that the publication is intended to be used as a "companion" to the Common Rule. USAID authors state, "institutions must also adhere to other laws and regulations applicable to their human subjects research including state law, foreign laws, and human subjects procedures of the FDA" (p. 1). "Trust in the honest, conscientious judgment of the human beings who serve on IRBs is pivotal to the entire system of

protection of research subjects" (p. 1). Further, the USAID (1999) document states though certain types of research are exempt under the Common Rule, "they should not be considered exempt from common ethical standards" (p. 4). For example, a particular survey may be exempt, but USAID (1999) points out that it is "common courtesy and otherwise generally reasonable to ask permission and provide some simple information to respondents" (p. 4). The interest in promoting ethical behavior outside the Common Rule is "not intended as a mandate for more structured procedures," they continue, but rather "to advance cultural ethical norms for research and non-research activities alike, to be exercised with discretion by institutions and individuals" (p. 4). They point out that consent *forms* should not be confused with the informed consent *process*: "It is important to recognize the informed consent process is a process of communication and not just a legal requirement" (p. 3). The guide's authors suggest the process should use "simple, understandable language" and should emphasize "required and most important" information, avoiding large amounts of "additional information of marginal use" to giving consent (p. 3)[175]. The authors add that the process should also involve actively listening to participants' individual concerns, and that researchers should request participants restate the major points related to the study.

The suggestion (or what might be termed, risking the oxymoron, suggested requirement?) that participants be *asked* to restate the major points related to the study rather than a suggestion that participants be *able* to restate the major points seems inconsistent with the USAID statement that informed consent *forms* should not be

[175] This is in contrast to some local IRB's interpretations (see p. 221, herein, re: length of instructions vs. recommended length of document).

confused with the *process*. Further, it seems the authors are beyond the scope of their charge with the comment about the advancement of cultural ethical norms for both research *and non-research* activities. And the "trust" in "human beings who serve on IRBs" may be pivotal, but more crucial (because so little oversight of the process is conducted, possible, needed, or desirable) is trust in researchers and participants themselves (see O'Connor, 1979).

Other General Observations

Critics (deconstruction of term). GAO (2001) states, "Some critics have argued that there are too few sanctions to match the range of violations that occur. Acknowledging this problem, DHHS is considering a proposal for legislation that would enable FDA to levy civil monetary penalties for violations of ... important research practices" (p. 7). The GAO did not elaborate on who the "critics" are (we can fairly presume these critics are not associated very closely with social science pursuits), nor do they provide any evidence on which they "acknowledge" (or establish, if and when they feel compelled to do so) the "problem." And, as mentioned, this report and others illustrate the bias toward the belief that any of this makes a difference to the participants of research. "Critics of the bill argued [there is] no evidence that the absence of regulation had caused significant harm to substantial numbers of people, and asserted that the measure was a solution in search of a problem" (Charo, 1999, Jun 25, p. A64).

The use of the term "critics" quoted in the previous paragraph is notable. This often-used term is almost a disparaging one, implying "troublemaker," "rebel," "boat rocker," or the nearly-if-not-ultimately objectifying "obstacle." The term certainly carries substantially less weight than "U.S. Senate," or House, or Senator or Representative, Cabinet Secretary, or even Presidential spokesperson, or OPRR Director, especially when "critics" aren't named specifically, or balanced in stature with proponents. In the written language, the proponent group is comprised of People described with Proper Nouns garnering Capitalization Status. A less biased presentation would be comparison of comments from two senators—one pro, the other con—or two researchers, etc. Use of the voiceless objectification "critics" is an example of the ways cultural-level (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS become entrenched, and work to vilify criticism, conflict, and dissention, in spite of often explicit but seemingly empty comments about their usefulness.

Institution and researcher impact. The changes that actually made a difference in the "real" world of research involved moving the OPRR essentially up two hierarchical steps in the organizational chart. The organizational structure, prior to the change, was: at the top, the Secretary of DHHS, then DHHS director, then director of the Office of Extramural Research, then OPRR. The change placed the OHRP directly under the Secretary of DHHS (Federal Register, 2000, Jun 13; Brainard, 2000, May 26b). A new director was named, which is significant as mentioned previously, because

more sanctions had been issued by Ellis than all other previous directors combined and only one sanction has been issued since, that against Johns Hopkins in July 2001 (see Appendix A, Example 6, p. 348).

Summary

These political debates, bills, hearings, and proposals from the federal government are an indication of who has (been given) the right to change things and the criteria they may establish. And it demonstrates the way *contra* activity is controlled. The mostly disgusting proliferation of suggestions about ways to standardize, centralize, and regulate research practices has occurred, but "real" changes in "real" research (and the elimination of "real" atrocities) have not occurred nearly as often.

The system, at the federal level, has grown bigger and slower, more specific yet more ambiguous, less responsive yet more aggressive. This growth is just as apparent at the institutional level, with more IRBs of more types reviewing more research, in terms of volume and diversity, than ever before (DHHS OIG 2000b).

The federal portion of this system reacts in emergencies, called "major" problems, "precipitating events," or "catalysts."[176] Too often, these are euphemisms for "atrocities" and (generally overcoming remorse) "fear of litigation." According to Daniel K. Nelson, University of North Carolina, "Our system for protecting human research subjects has evolved in response to relatively isolated events" (as quoted in Brainard, 2000, Apr 14, p. A45). Former Secretary of Health and Human Services Shalala stated, in response to the Gelsinger death "in this town, anecdote becomes data" (as quoted by Marwick, 2000, May 4, p. 1). These events affect all researchers particularly because essentially the same processes, *i.e.*, reactionary regulatory responses, have occurred at the institutional level, to be considered in the following chapter.

Perhaps nowhere is there a better demonstration of the explosion of information than in the world of academic inquiry (consider medical innovations alone!). Regulating that inquiry is important, and this is because people, the human subjects of research, in this case, are important. Of equal concern I contend is the avoidance of over-

[176] Kuhn (1970) is also useful in enhancing understanding about the events and processes related to IRBs. In examining documents written during and about a period spanning 50 or more years, something akin to Kuhnian paradigm shifts (what I'll call "position shifts" dealing with a more localized situation than Kuhn was) can be demonstrated in the creation of the regulatory system and its functioning since. Kuhn suggests that when a particular paradigm in use is unable to account for anomalies (appearing with regularity everywhere in the lifeworld, including in human subject protection and regulatory matters), a switch to a new paradigm occurs. The switch to a different paradigm, Kuhn said, is discontinuous, not evolutionary nor developmental (by design, at least). This is most apparent in the two primary positions assumed by the federal portion of this system. Federal regulators position themselves as enforcers (of rules which "ensure" safety and humanity) when that position seems to be politically beneficial, and as educators (possessors of knowledge and expertise) when that position seems more advantageous. These "position shifts" occur not in the interest of protection of people but in the interest of positioning before them.

regulation,[177] not only at the federal level but at the institutional level of interpretation as well.[178] These interpretations are the focus for the analysis included in the next chapter.

[177] The AAUP (2001) concludes "members of an IRB who have doubts about whether a research project should be exempt favor classifying the research as not exempt in order to avoid appearing cavalier about risks to human subjects. No one is likely to get into trouble for insisting that a research proposal is not exempt" (p. 7). I would suggest this speaks to the depth of the concessions made by qualitative researchers, *i.e.*, IRBs don't fear litigation from abused researchers who have their rights to free inquiry smashed by this tendency. Also note that the AAUP describes this behavior of IRB members as avoidance of "appearing cavalier" as opposed to what might be described as "real" fear of "real" risk to "real" humans (see also O'Connor, 1979).

[178] Brainard (2001, Mar 9) quotes E. Greg Koski, director of OHRP, [Some IRBs are too cautious and need to find] "the appropriate middle ground" ... "We want to be sure we're not using a 50-pound hammer to drive a thumbtack," Koski said (p. A21).

Chapter Six: Displays of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS) in Institutional Interpretation of Federal Texts

"Above all, I am talking about [the] systematic tendency to a kind of behavioral reductionism, consistently translating matters that have to do with signification, meaning, language, and symbolization into crude behavioral indicators, often justified in the name of a spurious 'scientism'" Stuart Hall, *Ideology and Communication Theory*, 1989, p. 43.

Cultural reproductions (Habermas, 1984) of worldviews, ideas, knowledge, and beliefs contributing to the creation, evolution, and operation of the IRB system were shown in the last chapter. Turning now to the second part of Habermas's (1984) model of reproduction, *i.e.*, social integration, this idea will be utilized to explore the ways federal regulations are reproduced in institutional handbooks, on websites and other postings, and in the press. Social integration involves the reproduction of norms and other patterns of social membership (Habermas, 1984).

For more than a quarter century (since the enactment of the National Research Act in 1974), institutional IRBs have been playing a central part in the (presumed, and overwhelmingly intended) protection of human subjects participating in research projects. And for all the regulatory efforts, (infamous, sometimes horrendous, yet) prominent studies continue to draw attention to inadequacies of IRBs and the regulatory system generally, *i.e.*, abuses still occur, and lapses in compliance appear to be rather frequent (ACHRE, 1995; DHHS OIG 1998b, 2000b; GAO, 1996, and others). This might lead one to ask what is it that makes this kind of regulation worth doing?

Until the creation of a regulatory apparatus, which was not in place until decades after various concepts were accommodated as matters of policy (ACHRE, 1995, particularly the Wilson letters dealing with informed consent, and written in 1947). The rules of research ethics are "more articulated" today (ACHRE, 1995, Discussion of Part III, p. 1; see also DHHS [2000, Jun 6] Fact Sheet, especially section regarding Civil Monetary Penalties; Brainard, 2000, Jun 2.) Various templates for informed consent forms are examples of this. The University of Utah's informed consent template is five pages long; University of Texas at Austin's form has expanded during the past two years, from about one and a half pages to 10 pages as of May 2002; and the University of California at Berkeley's model is barely one page in length. UC Berkeley's form is titled "Low-risk Adult Survey/Interview Form" and is more targeted to social science concerns. (See University of Utah, University of Texas at Austin, and University of California at Berkeley entries in bibliography for website addresses for each of these documents.)

Not only must there be an IRB in place where federally funded studies are conducted, but board membership criteria are also required by federal rules. IRBs have traditionally been required to have at least one person on the board who is non-affiliated with the university or other organization where the IRB operates, and one member with non-scientific interests.[179] As mentioned, the norm in complying with this regulation

[179] According to the OHRP guidebook, posted at http://ohrp.osophs.dhhs.gov/irb/irb_chapter1.htm and accessed May 25, 2002, "The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." Additionally, "The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender. The nonaffiliated member of the IRB

has been since inception that the same individual serves in both capacities (DHHS OIG 1998b; ACHRE, 1995), sort of a dual token minority, a "non^2." As pointed out by Rep. Towns (U.S. House, 1998, June 11; also see next page) and others, this situation has served to marginalize the non-affiliated, non-scientific person, making the member a distinct minority-on-purpose. It seems reasonable to believe this "non^2" person might be hesitant on most occasions to articulate concerns, and on the rare occasion when s/he might, might actually say something irrelevant (or that seems irrelevant to other, *i.e.*, affiliated, scientific IRB members), or be focused on an issue outside the purview of the IRB (and over time, stop contributing or questioning altogether). This is not to imply these members are in a general way incompetent, but they, by categorical admission, are less apt to know what *is* relevant, *i.e.*, within the purview of the board. Therefore, having the regulation in place has produced little if any effect. It is another cumbersome yet meaningless activity (with the exception of obligating non^{2}s to attend meetings). The ambiguity in the rule provides opportunity to negate the effects of the rule requiring non-affiliated, non-scientific representation on IRBs.

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should be drawn from the local community-at-large. Ministers, teachers, attorneys, business persons, or homemakers are possible candidates. The person selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to the type of community from which the institution will draw its research subjects. If the community is rural and agricultural, perhaps a farmer would be appropriate, in addition to a minister and or attorney. If the community is predominately African-American, Hispanic, or other minority, then it would be advisable to have a member of that particular minority (or those minorities, if there is more than one significant minority population) on the IRB. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB" (see guidebook at http://ohrp.osophs.dhhs.gov/irb/irb_chapter1.htm, Chapter 1, Administration of IRB, Membership; see also http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbt.htm, regarding new registration rules posted Jan 11, 2001 and accessed May 25, 2002). These rules are presently being reconsidered, reflecting concerns voiced in U.S. House hearings (1998, Jun 11, and discussed on p. 152 and 197 herein).

The OHRP guidebook indicates the non-affiliate should represent the local community, should not be vulnerable to intimidation by the professionals on the IRB, and that the non-affiliate should be "fully utilized by" the IRB (see footnote # 179, p. 166; see also OPRR, 1993, p. I-7). But, rather than the rule itself, it is the interpretation and execution of the rule that is important to consider in this situation. The interpretation and execution have not historically (since implementation of the IRB system in 1974) operated in a way that supports the spirit of the rule. And this widespread (institutionalized) demonstration of resistance to the inclusion of different points of view seems counter to the most basic goals in academic pursuits.

Rep. Towns, in a statement during U.S. House (1998, Jun 11) subcommittee hearings, expressed his concern about the proportions of IRB membership. "If federal law only requires one non-medical member, couldn't a board dilute that member's vote simply by expanding the numbers of other members? Shouldn't the number of non-medical members [be] proportional to the number of medical members?" (p. 52; see also DHHS OIG, 1998e, p. 11).

The NBAC in May 2001 recommended nonscientists make up at least 25 percent of an IRB's membership, and that a quarter of the members should come from outside the institution. (A draft report issued in December 2000 had required half in both instances; see Southwick & Monastersky, 2001, Jun 1.) George J. Annas, professor of health law at Boston University School of Public Health, questioned the potential effectiveness of the NBAC recommendation, saying "Community representatives have no authority and weight when they are outnumbered three-to-one by the researchers" (as

quoted in Southwick & Monastersky, 2001, Jun 1, p. A22). Community representatives (nons, "outsiders") have traditionally been outnumbered by "scientific" members by four-to-one, or more. (The same could probably be said of the ratio between qualitative and quantitative researchers; see NBAC, 2001, which found 75 percent of current research reviewed by IRBs is clinical/biomedical).

Informed consent templates and the way non[2]s have been developed are two of the ways federal provisions and historical development of the system are played out at the institutional level. Next to be considered is the domain of the local IRB in the regulatory context that includes the federal apparatus.

Local IRB Domain

IRB responsibility falls into two main categories: initial review and continuing review of research projects (DHHS OIG 1998e). According to Ellis, former director of the former OPRR, in his testimony before the U.S. House (1998, Jun 11), "The local IRB at the research site is the cornerstone of our system of protection of human subjects. No research on human subjects may be initiated and no ongoing research may continue in the absence of an IRB approval (45 C.F.R. § 46, see also U.S. House, 1998, Jun 11, p. 38). This is only true of federally funded research, in legal terms, though in "reality," nearly all research is subjected to IRB scrutiny, and even those studies defined as "exempt" are scrutinized, as mentioned (see GAO 2001, for example).

As research activities have spread from secret military studies and "atomic" medicine to university teaching hospitals, now spilling into the private sector, IRBs

have been established in these new settings (DHHS OIG 1998c). Sites include state governments, managed care organizations, private universities, state psychiatric hospitals and other agencies, vitro-fertilization and weight-loss clinics, genetic tests developers, physicians, dentists, psychotherapists in private practice, industrial and corporate programs, and hybrids.[180] Independent, commercially driven review boards have developed (or have become more explicitly commercial; see DHHS OIG 2000a) to review research protocols and even conduct research, particularly for drug companies.

Institutional Institutionalizations and Ideologies

Four themes recur in the numerous and varied writings about organizations working from the perspective of ideology critique first offered by Marx (Alvesson & Deetz, 1996)[181]. These are applicable not only in the present discussion of institutional contributions to the system, but to the evolution of IRBs, as presented earlier, and the co-opting of social scientists, presented here and in Chapter Seven.

Alvesson and Deetz (1996, p. 199-201) explain these four themes:

> In naturalization a social formation is abstracted from the historical conflictual site of its origin and treated as a concrete, relatively fixed entity. As such the reification becomes the reality rather than life processes. Through obscuring the construction process, institutional arrangements are no longer seen as choices but as natural and self-evident. The illusion that organizations and their processes are 'natural' objects and functional responses to 'needs' protects them

[180] According to Gillham (2000, Jul 23), reporting for the *Tulsa World*, the H.A. Chapman Institute of Medical Genetics, a private research group, was moving its operations to the OU Tulsa Schusterman campus in the fall (2000). I called to verify (6/5/2001) and was told the Chapman Institute is located on the Schusterman campus.

[181] Deetz (1995) states, "ideological critique was developed by German scholars in the 1920s and 1930s in response both to the failure of Marxist economic analysis to account for new systems of domination and the lack of organized worker resistance, and to the capacity of Hitler to utilize the culture industries to produce consent to national policies through appeals to existing social value premises" (p. 164).

from examination as produced under specific historical conditions (which are potentially passing) and out of specific power relations" (p. 199) ... [With respect to the universalization of managerial interests] "particular sectional interests are often universalized and treated as if they were everyone's interests. In contemporary corporate practices, managerial groups are privileged in decision-making and research. Management is ascribed a superior position in terms of defining the interests and interest realizations of the corporation and thereby of wide segments of the population. The interests of the corporation are frequently equated with specific managerial self-interests" (p. 200) ..."Central to the universalization of managerial interest is the reduction of the multiple claims of ownership to financial ownership. [In the cases of interest here, the reduction is to formal authority.]...The investments made by other stakeholders are minimized while capital investment is made central" (p. 200). [Regarding the primacy of instrumental reasoning] "Habermas (1971, 1975, 1984, 1987) has traced the social/historical emergence of *technical rationality* over competing forms of reason. Habermas described technical reasoning as instrumental, tending to be governed by the theoretical and hypothetical and focusing on control through the development of means—ends chains. The natural opposite to this Habermas conceptualizes as a *practical interest*. Practical reasoning focuses on the process of understanding and mutual determination of the ends to be sought rather than control and development of means of goal accomplishment (Apel, 1979) ... "In a balanced system these two forms of reasoning become natural complements. But, in the contemporary social situation, the form and content of modern social science and the social constitution of expertise align with organizational structures to produce the domination of technical reasoning ... to the extent that technical reasoning dominates, it lays claim to the entire concept of rationality and alternative forms of reason appear irrational" (p. 200). [And with respect to hegemony] "The conception of hegemony suggests the presence of multiple dominant groups with different interests and the presence of power and activity even in dominated groups. The integration of these arrangements, however, favors dominant groups and the activity of both dominant and dominated groups is best characterized as a type of produced 'consent.' The hegemonic system works through pervading common sense and becoming part of the ordinary way of seeing the world, understanding one's self and experiencing needs (see Angus, 1992)" (p. 201). [Alvesson and Deetz continue,] "Several studies have shown how employees 'strategize their own subordination,' achieving marginal gains for themselves through subordination but also perpetuating dominant systems which preclude their autonomy and

> ability to act on their own wider interests (see Burawoy, 1985; Deetz, 1995; Willmott, 1993) ... Willmott, for example, has explored how 'corporate culture programmes are designed to deny or frustrate the development of conditions in which critical reflection is fostered'" ... (1993, p. 534 of Willmott; as quoted by Alvesson & Deetz, 1996, p. 201).

It is apparent that regulators and researchers maintain the process even when they find it absurd, pointless, counterproductive, and even when parts of the process do not seem right in a moral sense, *i.e.*, they seem unfair, unjustified, unreasonable, doable, etc. (What power the structure has! More accurately, what power we give to the structure!!)[182] To gain this kind of compliance, the system must be constructed, to "seem real" at the very least. And, it seems to be a requirement, in order for the system to operate, that the simulation "seem right" (*i.e.*, reasonable, important, etc.) though sometimes compliance is gained simply because the system appears unavoidable, pointless to resist, or that it is self-evident, the "way we do things" (and eventually becoming "the way we have always done things"). No questions asked (anymore). Whying isn't understood (or tolerated, even within oneself) anymore. (Also see Adorno's comment, footnote # 67, p. 60, herein.) The idea that (some of) these systems are unavoidable appears to be the general consensus concerning, for example, the Internal Revenue Service (IRS), frequently described as being as inevitable as death. Similarly, the IRB system is presented as "inevitable" in methods classes *i.e.*, the

[182] See Wilson, 2002, Mar 18, for an example of this "giving of power" involving the National Highway Traffic Safety Administration, and the recognition that the "real world" is not what the regulations are based on.

system has been normalized by faculty who are in turn illuminating the naturalization path (*i.e.*, culting, indoctrinating) for students. The IRB process is presented as "required" and often simultaneously described as "unclear," "unreasonable," and "nonsensical."[183]

The development and implementation of the rules at the federal level take on Theory Y characteristics (McGregor, 1960, also see discussion about effects of scientific management and classical management schools on development of IRB system, p. 216).[184] However, institutional IRB members appear to differ from the federal regulators. In institutional policy handbooks, web postings, answers to applications, etc., a somewhat different approach is apparent, one which implies (on the part of the institutional-level regulators) a serious (and unwarranted) decline in the trust of others to be humane and reasonable (Theory X, in McGregor-ese), to "discharge their authority and responsibility in an honorable way," (see footnote # 184, below). This situation exemplifies a universalization of managerial interests, *i.e.*, the existence of regulations that involve obtaining permission to proceed carry the implications that researchers need to be told by managers/regulators what to do and how to do it, that

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[183] I have frequently heard students and faculty members in several methods classes say these things, and many of the articles cited herein include similar comments.

[184] According to George Grob, Deputy Inspector General for Evaluation and Inspections (a federal position, somewhat obviously), in testimony before the U.S. House stated, "We don't claim that the research abuses are particularly widespread. We just haven't done enough random studies to know that that is the case." [Notice the bias toward the need to do "studies" rather than believing their own experience. Further, DHHS produced four major reports analyzing the system and calling for reform, along with the ACHRE and the NBAC reports, and several GAO reports all issued in a 5-year span.] Grob continued, "And we recognize very much the dedicated and conscientious board members often working long hours as volunteers to deal with these problems" (U.S. House, 1998, Jun 11, p. 11). And Ellis, as head of the OPRR, echoed Grob's comments: "By goodwill, I mean people [researchers, in this reference] discharging their authority and responsibility in an honorable way and recognizing that in those instances where the protection of human subjects may conflict with the mission of an agency or an

they need to be controlled, etc., giving managers/regulators "a superior position in terms of defining the interests and interest realizations" as described by Alvesson and Deetz (1996, p. 200). Deetz (1995) states, "What might be accepted as legitimate power differences is best represented as a system of domination, because the empirical manifestation is that of free consent, but yet structures are reproduced that work against competitive practices and fulfillment of the variety of interests" (p. 164).

OUIRB Application Form: Analysis

The OUIRB application form (http://research.ou.edu/Forms/index.htm, accessed May 25, 2002), a typical example, does not accommodate qualitative research. For example, the form requires substantial explanation beyond information about who the participants are, in the categorical sense. This, in theory, would be the first and in many cases, based on federal law, the only question a researcher should (or should be asked to) address. The specific treatment the researcher intends to utilize is the only other relevant issue for exemption consideration. The lengthy application form is not only counter to anything resembling "exemption," but also to the nature of much qualitative research, as discussed in this section.

The authors of the form write: "Your application for the approval of the use of human subjects should consist of eleven (11) copies of three parts: Part I, a completed application form; Part II, a description of your research study; and Part III, subject's informed consent form for participation in your study" (OU Application, p. 1).

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office, society dictates that the protection of human subjects must come first, that the pursuit of new knowledge is optional and can be deferred" (*Ibid.*, p. 50).

Additionally, the author(s) state(s), "You should attach supplementary information pertinent to this study that will help the board members in their review of your application, *i.e.*, questionnaires, test instruments, and letters of approval from cooperating institutions or/and organizations.[185] (Of course, one might question the need to "really" develop these items until one knows they will be needed). Failure to submit these items will only delay your review" (p. 1, OU Application). Another managerial suggestion that resistance is futile.

This is the only application form available for human subjects research at OU. There is no "exemption" or abbreviated version (the only difference for the applicant is whether s/he is required to submit two copies or 11 copies of the application, as indicated below; the same form must be completed entirely in either case).[186] On page two of the application form, the author(s) write(s) "If you believe your use of human subjects would be considered exempt from review or qualifies for expedited review as defined in Sections 4 and 12 of the University of Oklahoma, IRB policy and procedures (website in bibliography), [an applicant] may submit two (2) copies of this application for initial review. If full Board review is required, [the applicant] will be required to submit nine (9) additional copies." This means that if the study is "really" exempt-able,

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[185] In requiring the permission letters, is the IRB not operating to protect operators of "cooperating institutions and organizations" (*i.e.*, business owners, or operators of parks, government administrators, etc., who aren't (themselves) being studied? How, in the view of the IRB members themselves, is this within the board's purview? I would like to have asked.

[186] It would seem reasonable that the application form could be designed in a (rather common) way to include such statements as "If you answer 'No' to the next question, skip to question X." (Student loan forms are like this; if a student is taken as a deduction on the parent's income taxes, they complete certain questions, if not, they answer other questions. And, incidentally, the student loan program now has a provision for a "master promissory note" requiring a much shorter renewal form for continuing students rather than the complete form every year. This is somewhat like the blanket assurance alternative I mention in Chapter Eight.) For example, if the researcher selects "No protected classes" and/or "No

a researcher must complete the fairly lengthy application, and wait until it is the pleasure of the OUIRB to find out whether or not they rule the study "exempt." [187] The OUIRB (and others) seem to be confusing *exempt from the process* with *exempt from full-board review*. Exempt from the process should (come to) mean exempt from the process. No application, no waiting, no interference from the local IRB.

In Part I of the application, (potential, hopeful) researcher/applicants are asked to provide the "project" time period. It is unclear if this question is designed to solicit an answer about the duration of the data collection portion of the proposed study, or if it is to include other aspects of the "project." The authors may be asking this question as a way of determining if the study will be subject to continuing review, *i.e.*, if the "project" lasts more than one year, under federal law it must be reviewed annually (see 45 CFR §46.109[e]). This question could be posed differently, meeting the (presumed) need of the IRB, yet not creating a problem for researchers (in understanding the question in the first place, and in the impossibility of anticipating the "exact" time frame for the "project"). If applicants were asked whether or not they anticipate the project lasting more than a year, (a simple yes/no proposition), and provided a reminder that if the answer is "yes" their project will be subject to, according to 45 CFR §46.109(e), continuing review and indicate where the applicant can obtain more information. As posed, the question is unclear, the reason for it is unclear, and, it appears, is unnecessarily specific.

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identifiable participants," the application form instructions might then say "Stop! You are not required to apply. You are exempt."

[188] I do not suggest an "exemption" form be created, though I might urge that the actual process of "real" *exemption* be "really" implemented.

Also in Part I of the form, the authors require the applicant provide the number of subjects. There is no reference to the number of subjects in a study being used as criteria for any regulatory activity at the federal level.[188] The reason for the question is not clear, but it does appear to be an institutional development, *i.e.*, not linked to any federal rule or provision. The number of subjects is not significant, or pertinent to the regulatory function, and particularly as it applies to exemption considerations.

In addition to being cumbersome, Part II of the application form is nearly impossible (and unnecessary) for qualitative researchers to complete. A description of the study is required of the applicant, which is to include four parts: a statement of the purpose/objectives, research protocol, confidentiality provisions, and an assessment of the benefits/risks to subjects. In the purpose/objectives section, the authors instruct, "Explain the overall purpose of your study and its primary objectives, including the importance of the knowledge expected to result" (OU Application, p. 2). To explain the overall purpose is not a particularly problematic task for researchers, as it is often what a researcher starts with, *i.e.*, an idea, a purpose for looking at a phenomenon, a curiosity about something. However the last part, *i.e.*, being asked to "include the importance of the knowledge expected to result" is problematic (see Feller quote in Brainard, 2002, Mar 29b, p. A25, re: sometimes not knowing the relevance of research in 5, 10, 15, or 20 years). While knowing the importance of the prospective knowledge is problematic for any social science researcher, it is perhaps even more true for a qualitative researcher who may have less knowledge *a priori* about what the (range of) results

[188] Somewhat like the U.S. Representatives wanting to know how many IRBs operate. What difference does it make?

might be. A key difference between these two types of research is this: quantitative researchers almost always employ hypotheses (sometimes even directional ones), and while the researcher doesn't know, in advance, whether or not any given hypothesis will be supported (or even what that support or lack of it might "really" mean), the hypothesis creates a more "knowable" set of activities for the researcher, a more precise "direction" for the research to take, and a more precise (and predictable) "form" for the results (see Goffman, 1971, re: formulaic, hypothesis-driven pursuits, quoted on p. 90, herein).

Alternatively, qualitative research (*i.e.*, nearly always designed without formal hypotheses) involves less advance knowledge about the direction the research activities will take or the final form for a research report about the activities. Asking for details about what knowledge may result from a qualitative study are not reasonable questions given the nature of much qualitative research (observations, for example). In the case of observations, it is not possible for the researcher to know what s/he will actually see; it is only possible to state in a general sense what it is the researcher would be observing.

A similarity between qualitative and quantitative research is the lack of knowledge on the part of either about how important any findings might be, though both groups are asked to provide such "information" on application forms, grant proposals, etc. (In fact, it has become "natural" to be asked to supply such information, even if it is impossible many times to do so.) Being required to answer such questions suggests the applicant can somehow project benefits or knowledge that future readers

might derive, hardly possible, I argue, and (totally) unnecessary for the protection of subjects (especially when no treatment is administered).

The research protocol section of Part II requires the applicant to "Describe the study and procedures you will use, including a step-by-step description of the procedures you plan to use with your subjects" (OU Application, p. 2). This entire Part II is labeled "description of the study," making it unclear what the authors of this sub-section, also labeled "describe the study," are seeking in terms of an answer. To describe the procedures is not particularly problematic for the qualitative researcher; in fact, describing is simple for many procedures, *i.e.*, "watching people in their natural environment," or "asking people questions about what they are doing." Not much more can be said about the data gathering procedure (Wax, 1971, especially p. 6-10; Weppner, 1977; Whyte, 1987; Gray, 1979, and 1982; Garfinkel, 1967; Geertz, 1988; Agar, 1980; Alvesson & Sköldberg, 2000; Bantz, 1983; Brainard, 2001, Mar 9; Deetz & Kersten, 1983; Denzin & Lincoln, 2000; Fontana & Frey, 1994; Gubrium & Silverman, 1989; Hall, 1989; Hamilton, 1998; Klockars, 1977; Lofland & Lofland, 1995; O'Connor, 1979; Klockars, 1979; Wilkins, 1979; Punch, 1998; Reiss, 1979; Van Maanen, 1988). Or, if interview data is to be used, the required (yet mostly pointless) description of the procedure might be "I'll ask questions." For the step-by-step description, a researcher might include, "I'll ask if the participant would like something to drink. If the participant indicates s/he does wish to have something to drink, I'll probe about the participant's drinking preferences, and offer the available options (water, soda, tea, tequila, Aqua-Velva®, hemlock). If s/he indicates s/he is not

interested, I'll suggest we get started with the interview. I'll then ask the first question, " etc.

In explaining the confidentiality section, the authors of the application form write:

> Briefly describe the procedures you will use to assure confidentiality of the data you collect from your subjects, specifically address whether subjects will be identifiable from raw and/or refined data, how data will be protected from non-project personnel (e.g., stored in locked cabinets), whether the identifiable data will be destroyed[189] when no longer needed, and whether project publications (theses, papers, videotapes, etc.) will allow identification of individual subjects." (p. 2 of OU application form)

First, shouldn't the (adult, un-incarcerated, mentally capable) research participants be able to decide if they care about their identities remaining secret? What if the participants themselves have no concern about it? And with much qualitative data, the researcher wouldn't know the identities of the subjects at all, unless, of course, an IRB forced the researcher to gather informed consent forms from subjects (who can

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[189] One problem with destroying information is raised by the American Anthropological Association (AAA, 2001, Feb 15) in a response to the NBAC (2001) report: "Of great concern to anthropology is the attempt to restrict the preservation of research records and materials necessary for future analysis and inquiry or comparative studies. In some cases, researchers are required to destroy research data after a specified period of time. We understand how research records and materials from higher risk biomedical research may need to be destroyed. However, for many disciplines like anthropology and history the utility of research records and materials may not be realized until later." The AAA goes on to ask for an exemption for "field notes, audio or videotape or film recordings of interviews or social interactions, photographs, historical documents, among others." The AAA points out that these research records and materials are "vitally important for future consultation in longitudinal and comparative studies." They recommend that "research records and materials from minimal risk research be exempted from the requirement ..." (AAA Response to National Bioethics Advisory report on Human Research Ethics, available online at http://www.aaanet.org/gvt/resnbac.htm, accessed June 3, 2002, cited as AAA, 2001, Feb 15). (NOTE: the AAA "supports strengthening the protection of human participants in research" consistent with the federal government's "mission," and also suggests that if not "carefully honed" the "proposed changes (those recommended by NBAC) "could jeopardize the future of anthropological research." See also Morley & Shockley-Zalabak, 1991, re: commitment level of individuals not "vested" in decision making. And, see Geertz, 1988, p. 133-135. I also recall a faculty member's comment

hardly be called "participants" in strictly observational data gathering activities). Federal rules exempt these activities from the process, if data is recorded in such a way that participants/subjects are not identifiable. Once again, the local institution is intruding "more rigorously" in areas where the federal government doesn't tread at all; see 45 CFR §46.101(b)(2)[190]. Qualitative researchers aren't likely to know when data "are no longer needed" and their field notes are not likely to need "protection from non-project personnel,[191]" at least not in the ways that would typically be of interest to an IRB.[192]

The fourth section of Part II, titled "Subject Benefit/Risk" includes these instructions: "Describe both the potential benefits and risks to subjects and society that may result from their participation in this project" (p. 2 of application form). Several (unnecessary) problems are created for (qualitative) researchers in this regard. It is not that benefits and risks can't be spoken about by these researchers, but this requirement is unnecessary for qualitative researchers in the overwhelming number of cases simply because no risk (beyond that encountered in one's life generally, *i.e.*, "minimal" risk in federal terms) exists. This makes a contrived description the best (if not the only) possibility for the application form. Further, explaining risk/benefits (or validity and reliability; see O'Connor, 1979; Bantz, 1983; Bloor, 1997; Denzin & Lincoln, 2000,

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regarding the response to my applications; referring to IRB members she said, "They are making this kind of research impossible to do."

[190] H.R. 4697, introduced in May 2002, the term "human subject research" is defined as "clinical research that is conducted with the direct involvement of one or more human subjects." Section 491A, Part 3(a).

[191] There are exceptions, of course, but they are rare. Mostly we are ordinary people watching other ordinary people doing ordinary things. And, it is also a very rare person who bothers to break into our offices to read field notes.

[192] Roommates and/or office mates may spill coffee all over the data, for example, but this protection is of no concern to an IRB, one must presume.

and others) is done in a somewhat different language by qualitative researchers than the same description offered by quantitative types (Denzin & Lincoln, 2000; Rorty, 1979[193]). And with respect to fieldwork in particular, Cassell (1982) states "Calculating potential harms versus benefits offers little guidance to actors under the intense pressures of the field. Few fieldworkers wish to harm those studied; most are eager to help them. Predicting the consequences of one's actions, however, is even chancier in the field than at home" (p. 155).

The IRB requirement for applicants to provide information about the "potential benefits ... to subjects and society that may result from their participation in this project," is problematic for all researchers, producing forced self-aggrandizement perhaps, but little in the way of actual, relevant information. Far ranging social benefits, or risks for that matter, can't be known in advance. What a researcher hopes to find frequently has no distinct form. This is the case in qualitative and other forms of exploration that involve looking-at exercises, rather than looking-for pursuits, *i.e.*, generalized explorations without any hypotheses (much less *directional* ones). Further, if the IRB supposes researchers are capable of making sophisticated predictions about potential benefits and risks, and honestly report about them, it seems reasonable to assume these same researchers could accurately and honestly report the simpler issue of whether or not the study is "low risk," "no risk," or "minimal risk," (based on definitions provided by what might come to be known as *system* overseers rather than *direct* overseers). Researchers are at least as capable of accurately and honestly

[193] Rorty says of the scientific and humanistic camps, "both groups are self-sealing language communities that don't—and really can't—talk to each other" (see present study, p. 89).

exempting themselves as anyone else is[194], including regulators. Adding to regulatory problems is the ambiguity in the (federal) rules themselves, and considerable more ambiguity in the layers of (institutional and individual) interpretation of each of the rules.

Part III (OU Application, p. 3-4) is nearly an exact duplicate of Part II, *i.e.*, both include sections in which applicants are required to describe the study, potential risks and benefits, and confidentiality provisions. The difference is that in Part III (the informed consent form) the wording of the descriptions must be in "lay language," defined as "easily comprehensible to the person who is being asked to sign it as a legal indication of voluntary participation in the proposed study and every effort should be made to limit the consent form to one page including space for the participant's signature" (OU Application, p. 3). Yet the *description* of what is to be included on the informed consent form is twice that long.[195] Additionally, as Cassell (1982) points out, the definition of "subject" should be debated in many cases, in an effort to find better rules (for unobtrusive methods for example). As mentioned, researchers should be asking questions related to whether they should apply at all, rather than how to go about it, or how long the application process will take in any given instance, etc.

Following the arguments of the qualitative methodologists cited above, the informed consent process, as required by many institutions, doesn't work if a researcher intends to study the natural environment. The process doesn't allow for the preservation

[194] And in a *de facto* sense they do, in that they create the story of their study for the application form.
[195] By way of comparison, the University of Utah's informed consent template is five pages long; no desired length for the actual form is mentioned (see University of Utah entries in bibliography).

of the natural environment; it corrupts it. Only the degree to which this occurs might be argued (see Geertz, 1988, p. 133; Capron, 1982).

The federal government's definition of "minimal risk" states "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" [45 CFR §406.102 (i)]. This would seem to allow preservation of the natural world for the numerous studies that require it, such as observational research, most surveys, and ethnography. Therefore, it appears it is the institutional level of interpretation where a "zone of unreasonable interference"[196] exists. People who are being observed are not participants, and they certainly aren't patients. They aren't subjects. They are objects in the natural world (see Foucault, 1972, pp. 40-49, re: the formation of objects). That is, they are objectified (see also Reiss, 1979, p. 67), called participants, patients, subjects, etc. However, those being observed, interviewed, and surveyed are receiving no treatment. And, most importantly, they are at no greater risk than that encountered in "daily life or during the performance of routine physical or psychological examinations or tests" as specified in federal law [45 CFR §406.102 (i)].

A related observation about the OU Application: the protected classes (pregnant women, mentally disabled, mentally retarded, fetuses, elderly, prisoners, and children) are listed with boxes beside each to indicate yes or no to the question of whether or not the study involves any of those groups (p. 2). In a similar way, a question could be

[196] or ZUI (zoo-ey), used because of the euphonic, and tactile relationship to gooey.

added about whether or not the study involves public officials or other (*prima facie*) exemptible classes. This would make the process often much shorter for everyone, *i.e.*, if a study involves only public officials, instructions could indicate it is not necessary to complete the remainder of the application. Similar checklists might be utilized to reduce the likelihood that the entire application would be necessary, for example the degrees of risk as defined by the federal government, a list of exempted categories, or a checklist of general treatment types or methods, all of which would, logically, be best assessed by the researcher. And, this mechanization of the process appears consistent with the "standardization" obsession of regulators in general and other universities that provide for review of exempt studies.

As is apparent, the OU application process, even for studies that are exempt, is cumbersome. Required but unnecessary. When we "really" think about it, doesn't "seem right," or reasonable, and hardly resembles an *exemption* as we would, outside this context, define one. This situation is consistent with the view expressed by Alvesson and Deetz (1996) quoted earlier, about naturalizations, compliance with managerial (regulator) demands, hegemonic acceptance, etc. What is the difference, for the applicant, between an exempted study and one that involves higher risk or protected classes? There are differences in the procedures for the *actual study*, but very few differences in the *application process* as it is interpreted and imposed by local IRBs.[197]

[197] Changes made to the OU Application form between November 1999 (download date; no origination/revision date given) and October 2001: Part I: a) Applications are now due on the 1st rather than the 5th day of the month; b) Space added for a request for applicant's email address. Part II had no changes. Part III: a) addition of the sentence "Two copies of the Informed Consent Form should be provided, one for the subject to retain for his/her records and the signed form which is returned to the researcher" to the end of the first paragraph of instructions for this part; b) addition of the phrase "and every effort should be made to limit the consent form to one page including space for the participant's

To summarize, it has become a self-evident "naturalization" (Alvesson & Deetz, 1996, p. 199) that researchers must participate in the IRB system without regard to the kind of research it is they wish to conduct. *Naturalization* concerns ways a socially/historically constructed world comes to be treated as necessary, natural, rational, and self-evident (the "N" in SINS). The IRB application process (even for

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signature" to the end of the first sentence of paragraph two of the instructions for this part; c) the outline for the informed consent form is re-structured to replace the category "Title" with "Heading," with the explanation, "The form should be clearly titled Informed Consent Form for research being conducted under the auspices of the University of Oklahoma-Norman Campus" which had previously included the phrase "and indicated that the document is an individual's consent for participation in a research project" (which is included in the "Introduction" section in the newer version); d) In Roman numeral III, "Description of the study," the new version has a phrase added to sentence one, "in language which is appropriate considering the age, educational level, etc. of the subject pool;" e) the last sentence of Roman numeral III changes from "Specify the expected duration of the subject's participation" to "Specify the amount of time required for the subject's participation;" f) In Roman numeral IV, part a, "Risks," a sentence is added to the end of the instructions: "If no foreseeable risks beyond those present in normal everyday life are anticipated, a statement to that effect should be included;" g) In Roman numeral V, part a, "Conditions of participation," two sentences are added to the end of what had been in the 1999 document, "For studies involving only adults, include a statement such as: *To participate, you must be 18 years of age or older.* (Italic in original); and following that, "For studies involving minor children, a parental consent form must be included in addition to the participant's assent form (Underscore in original.); h) part V-b, "Confidentiality," was previously a one-sentence explanation and now has three lengthy sentences added: "Avoid use of the term anonymous if there is any reasonable possibility that subject's identities can be established. If the research is anonymous (*i.e.*, a survey returned in pre-addressed postage paid envelope with no way of identifying the participant), a cover letter which clearly addresses all the components of informed consent may be substituted for signed consent form. In the case of a telephone survey, a script clearly addressing all the components of informed consent should be submitted for review;" i) three sections are added to Roman numeral V: part d, "Course credit/compensation for participation; part e, "Video/audio taping of any research activities; and part f, "Use of electronic media for informed consent;" and what had been part d, "Contacts for questions about research subject's rights" in 1999 became part g in 2001, and retained its name. Minor wording changes in the first sentence were done, along with the addition of "A statement directing inquires *(sic)* about rights, as a research participant to be made to the Office of Research Administration at (405) 325-4757 is a required component of informed consent;" and finally, Part VI, "Signatures" section, is much more articulated in the 2001 version. In 1999 a general statement about who must sign the form was included, but the new version is "Include the statement: *I hereby agree to participate in the above-described research. I understand my participation is voluntary and that I may withdraw at any time without penalty or loss of benefits* (Italic in original), and a really confusing sentence replaces the one that had constituted the section before. The old section, in its entirety, read: "Informed consent must be documented by the signatures of the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form." But now, in addition to the "Include the statement:" (also notice the use of "the" sentence, much more prescription now), it reads, "Informed consent must be documented by the signature of the subject on subject's informed consent form. When necessary, a separate form also should be provided for the subject's legally authorized representative or guardian. A space to indicate the date signed should be included on all informed consent forms."

minimal risk, non-treatment studies) has become "normal," even when many parts of it are considered unreasonable (and even impossible) for some kinds of studies as shown in the application analysis offered above.

The *universalization* of managerial interest and suppression of conflicting interests, as described by Alvesson and Deetz (1996), is apparent in the way the IRB processes are "handed down" from the federal and institutional regulators (as well as from faculty teaching methods classes) and "passed around" by researcher among themselves. Dissent among researchers, collectively or individually, is nearly unheard of; though many researchers and some regulators do complain, they don't often act. This is evidence of the entrenchment of the system and its processes.

The "the primacy of instrumental reasoning" as described by Alvesson and Deetz (1996), is evident in the roots of the system, *i.e.*, it is a system designed for clinical/medical studies, and, therefore, it is a system that is irrelevant and ill-fitting for many methods in use today (particularly surveys, interviews, and observational research).[198] One of the primary intents of regulation is standardization (and through that a large amount of control) of decision making procedures, and as shown in the analysis of the application form, for example, it is unreasonable to believe, given the range of research methods, that any single form or procedure will fit all circumstances. This "one single system for medical and social research" mentality is in rather stark opposition, as Alvesson and Deetz (1996) point out, to Habermas' "practical interest"

[198] The NIH, in a report about behavioral and social sciences, demonstrates this well. In the report, treatment is mentioned frequently, and prediction, prevention, and control of illness is stated as the goal of the research (unlike descriptions from qualitative researchers quoted herein, including Denzin and

thinking (consistent with what I have described as "liquid and local" conditions). The more local (*i.e.*, "real") the decision making process, the more valuable, useful, practical, and possible it can be for the participants and researchers.

Finally with respect to hegemonic behavior, the IRB system and its processes are "hegemonically" maintained by the regulators and researchers. The rules and procedures are not questioned by many participants, who (hegemonically) accept the idea that rules and regulations in general work to intended effect and/or are unavoidable. Questions (of the whying sort) are rarely asked. When questions are posed, as discussed earlier, they often focus on minutiae, *i.e.*, how to revise or accomplish a procedure rather than about the need for it (see also footnote # 17, p. 15). In addition to the bias that rules work or are needed, the application form demonstrates instances where common sense has been pervaded, allowing the form and the completion and submission of it, to become part of the "ordinary" world of research, *i.e.*, natural. Researchers are accomplices in their own subordination by participating in an unreasonable, ill-fitting system operated/dominated by people who often know substantially less (and often care even less than that) about (the details of) what is "really" going on in a given situation, method, or field of research. Similarly, researchers aren't demonstrating they care enough to "risk" changing the system.

The Entrenchment of Bureaucratic Ideology

Lincoln, Agar, Geertz, and others, who talk about enhancing our understandings and offering thick description, etc. (See NIH, 2001, Jun 26, especially p. 4 and 5.)

These micro-managerial interpretations of the federal rules, particularly as they pertain to social research, constitute regulatory/administrative imperialism on the part of (institutional) IRBs, and, often, (at the federal and institutional levels) solutions in search of problems. The IRB system, particularly at the institutional level, carries the implicit suggestion via explicit discourse that researchers must be carefully monitored—a Theory X approach (McGregor, 1960; also see Taylor, 1919/1947), *i.e.*, the idea that researchers can't be trusted and must be closely and constantly supervised, spoon-fed via "templates," and monitored via the institution of paperwork processes (see Brainard, 2001, Sep 28, for an alarming example). The application process is just one form of micro-management.[199] The institutional-level system, *i.e.*, the actual IRBs, as with many other regulatory organizations,[200] often posture (rather than act) in the name of fairness, equity, safety, etc., and they do so utilizing a "lowest common denominator" mentality, *i.e.*, the IRBs often address problems that are first, rare; second, problems that existing rules didn't prevent; third, problems that rules won't or can't fix (rules written that are beyond any practical scope of enforceability or even

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[199] This is particularly true of the mostly "social science" OUIRB (*i.e.*, they oversee no medical trials), re: intrusive application procedures. The clinical/medical IRB at the OU Health Sciences Center has only a two-page application (see http://w3.ouhsc.edu/ORA/irb/IRBforms.htm, accessed May 25, 2002), and no lengthy explanations, risk/benefit analysis, etc. is required, even though for most studies, the risks to participants at the medical center would be greater than those in the social sciences. It would be reasonable to conclude that greater risks associated with medical trials would imply a greater need for scrutiny, perhaps involving a form longer than that used for less-risky social science projects. In short, in medial trials there are more questions that should be asked and more explanations that must be offered. The average participant knows more about being interviewed than about appropriate medical treatment.

[200] The National Highway Traffic Safety Administration (NHTSA) issued new standards for car and truck rollover resistance ratings in February 2002. Stephen Kratzke, associate administrator of NHTSA, when asked why NHTSA would even bother creating a new regulation if it didn't do a better job of predicting accidents than the system already in place, said, "Because Congress told us we have to, and that's the system we live under" (quoted in Wilson, 2002, Mar 18, p. 8). For a similar situation at U.S. Department of Agriculture regarding the failure of meat inspections, see Ackerman (2002, May, p. 22) and related information in Tacio (2002).

understandability); and fourth, rules that don't apply to the "problem" at hand (and the enactment and enforcement of which beg the question of a problem, or a "fixable" one, at all). Given the circumstances of reality, specifically that the future can't be known, that people can't be controlled every instant, that interpretations across people are not standard, life can't be standardized, etc., it would seem that a Theory Y approach is the only realistic orientation for the regulators to assume, and, most importantly, it is apparently an adequate approach (based on the overwhelming lack of problems in social research).[201]

Additional analytical frames. According to Alvesson and Deetz (1996), in the process of naturalization a social formation is taken from its place and time, the "site of its origin," and treated as a concrete, relatively static entity. So, once the IRB is established, and rules posted, forms designed, and uploaded,[202] that often signals the end of questioning (no more whying, if it was ever allowed, or if anyone allowed themselves to indulge). The simulation is comprised of the mundane story of compliance, mostly told *textual*ogically time after time. "As such the reification [of various IRB processes and the purported "needs" for them] becomes the reality rather than life processes" (Alvesson & Deetz, 1996, p. 199; see also Baudrillard, 1983). Within the IRB system, for example, forms required by the IRBs at various institutions

[201] See footnote # 253, p. 251

[202] A faculty member told me early in 2002 that his local IRB chair bragged that the "whole procedure" was "updated" and "redone." Apparently the IRB chair had no thought that the faculty member perhaps was wondering who came up with the new rules, and why he wasn't given an opportunity to provide some input into the system rather than receiving it as a sort of "gift from above." I personally believe the system would be better for everyone if these administrators sought and utilized the input of faculty/researchers on a regular basis.

have taken priority over the substance of direct oversight (which, even if possible, would produce an image similar to Baudrillard's description of second phase images, *i.e.*, the masking or perversion of a basic reality, 1983, p. 11). That is, an image that is distorted because the people being observed know they are being observed, *á la* the Hawthorne Effect (Mayo, 1933).

By obscuring the construction process, institutional arrangements such as application forms and processes, who must apply to whom, definitions and who can create and interpret them, etc., are no longer seen as matters of choice, but as natural and self-evident (activities we "must" or at least "should" do, and definitions, particularly inclusionary ones in this case, that we "must" accept, etc.). This lack of scrutiny/high level of acceptance protects (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS from examination and eventually even from visibility. SINS in this case include notions that rules are generally good as a *structure* that "sets up" the possibility of *institutionalizing* an application process, and the subsequent acceptance of this form and process as *natural* if unreasonable, and the resulting *simulation* that the process is "really" doing what it was intended to do. The SINS contribute to the notion of the process as "inevitable." And, very significantly, the process becomes a part of methods class curricula, *i.e.*, indoctrination into the system is accomplished, and the system perpetuated. Foucault (1980) has suggested this (zone of) invisibility is where "real" power lives.

Regulations are debated in public and private arenas by various parties, but these regulations are largely developed, adopted and interpreted in private (for example, the changes in the OU Application form and other changes, see footnote # 197, p. 185; and footnote # 202, p. 190). Because meetings are closed at OU, input from researchers about policy issues, including the application form, is rarely if ever solicited or given at the local, institutional level.[203]

For these administrative activities to be conducted in an open environment, *i.e.*, open to all participants who are interested (and for researchers to require this where it is not "done this way") would appear to be desirable to all involved in the system. A provision, similar to that in the federal system, to solicit and allow for written responses to rule changes might be usefully adopted by local IRBs (or, again, demanded by researchers; that this is *not* the case seems odd). Local IRBs might elect, for example, to convene an executive session to consider individual proposals, in the interest of protecting the privacy of individual researchers or participants. But when considering administrative issues, such as rule changes and appointments to the IRB, it should be apparent to the local IRB and other regulators that the more input from the participants in the system, the better the system will be, or at least the better the level of acceptance will be.

Regulations are highly subject to change and are not subject to much scrutiny about the purpose or justification for them, particularly on the part of those trying to

[203] Brainard (2000, Mar 17) indicates the meetings at Duke University are usually closed. Further, an apparent lack of understanding among OUIRB staff was also demonstrated from events in my own experience, *i.e.*, I was invited to an OUIRB meeting by one staff member, and then not allowed to attend

follow them. Scrutiny and talk about purpose might, of course, lead to de-regulation, or de-escalation in regulation. The purpose of ideology critique is to reclaim organizations as "social-historical constructions," investigating the formation of the organizations and ways they are sustained and transformed "by processes both internal and external to them" (Alvesson & Deetz, 1996, p. 200; see also Giddens, 1979; Deetz, 1985). Institutions comply with the federal system voluntarily, except in the relatively limited number of cases involving federal funding.[204] Clinical researchers were the first to be regulated (and now many times fall under the purview of the FDA[205]). But when social scientists were (or allowed themselves to be) co-opted by the system, the regulatory process, in many ways, became absurd.

The IRB system has been allowed to go too far, with respect to minimal risk[206] studies in particular (Flyvbjerg, 2001). This is evidence of the second theme presented by Alvesson and Deetz (1996), universalization of managerial interest. This case involves the missions and cultural reproductions of operators within government bureaus, departments, agencies, legislative bodies, and the professional press, with their

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by higher-level administrator who told me the meetings are closed. It seems this would be common knowledge among the staff, rather than a source of confusion

[204] This decision seems "really" reasonable, if one thinks that the focus of review of protocols, and subsequent approval or rejection (or exemption or expedition), should be based on the treatment, rather than on the funding source or other criteria less relevant to the human subjects themselves.

[205] The FDA oversees (by virtue of interstate commerce provisions) research conducted to test drugs, food additives, and medical devices, as they are (nearly always) developed for use across the U.S., at least. The oversight is done whether studies are federally-funded or not, because in order to market these products, they must have FDA approval.

[206] As mentioned (much) earlier (footnote # 61, p. 52) and other places herein, according to the Common Rule (45 CFR § 46.102 (i), minimal risk means "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

near myopic focus on clinical trials[207] (see Figure 1, p. 50). This exclusion of the needs and interests of social science researchers (because of the seemingly singular focus on clinical trials, or the unfortunately prevalent idea that somehow one set of rules can work for both clinical and social research) creates many problems. Regulators, if they have conducted research and are typical researchers, have mostly been involved in clinical research (this is also perhaps a bias/blindness on the part of those hiring/appointing regulators; see also NIH, 2001, Jun 26, p. 1-6; and NBAC, 2001, re: percentage of clinical studies reviewed by IRBs). The rules are made with clinical trials in mind.[208] Alvesson and Deetz (1996) suggest "management is ascribed the superior position in terms of defining the interests and interest realizations of the corporation and thereby of wide segments of the population" (p. 200). Guided, at least loosely, by the general federal rules, local institutional regulators through their interpretations, tell researchers in highly specific ways what is important in the conducting of research, *i.e.*, when they are in compliance with the details of IRB interpretations. The local IRB, via

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[207] In the numerous reports in the *Tulsa World*, *USA Today*, and *Chronicle of Higher Education* (see Gillham, 2000, Jul 23; Winslow, 2000, Jul 22; Basinger, 2000 Jul 24; and Pound, 2000, Jul 10a and b and 2000, Jul 11,as examples) regarding the sanctions at the University of Oklahoma, no indication that any kind of research (that was supervised by IRBs) other than medical trials existed. In Ellis' comments before the U.S. House (1998, Jun 11), he did actually refer to "behavioral research" as part of a denominator (see transcript, p. 94). With respect to the media coverage specifically, the information is given to reporters by regulators and university officials (much less often by scientists or participants), and is indicative of how they think and, therefore, how they approach rule making, *i.e.*, with little understanding, and even less regard (acknowledgement, even) of behavioral science. In an evaluative report of NIH commissioned by the National Bioethics Advisory Commission (see NBAC 2001), it was found that 75 percent of current research reviewed by IRBs is clinical and biomedical in nature. Also see NIH, 2001, Jun 26, particularly p. 1-6 for an example of this myopia.

[208] And, rather than engage in the "real" struggle to decide about a system to fit social science needs, it is much easier to simply adopt the (uninformed if not imbecilic) attitude, as expressed by federal regulators at an open meeting at OU, that "there's no conflict" between the rules as applied to clinical trials and social science. Amazingly, the response to that comment from those attending the forum was not to object to the comment, but the subsequent statement, in hegemonic support of a bad system and without doubt demonstrating an imbecilic attitude, was an argument about how asking questions in an interview can be more dangerous than drawing blood or administering drugs.

the discursive formation that constitutes the system (Foucault, 1972) tells researchers what constitutes "appropriate" human subjects research, and when they are doing it. (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS contribute to the attitude that IRB processes are necessary, self-evident, inevitable or unchangeable; the idea that local IRBs make rules consistent with federal rules; the belief that conflict, dissention, and anarchy are negative (often inherently evil) forces; and the notion that in spite of what seem to be highly unreasonable and nonsensical processes within the system, that somehow the overall system is reasonable and sensible. We tell ourselves that there must be something we don't know, or aren't able to understand (*i.e.*, we rely on mysticism). This is another byproduct of a simulated existence, *i.e.*, we confront what is clearly, locally "really" stupid, and suggest it is stupid because of our own ignorance. That is likely true only some of the time.

The emergence, dominance, and persistence of instrumental reasoning, specifically technical rationality, "governed by the theoretical and hypothetical and focusing on control" (Alvesson & Deetz, 1996, p. 200) an "unswerving application of [science] methods without reflecting on knowledge-constitutive interest", *i.e.*, "[taking] the historical traces of suppressed dialogue and reconstruct[ing] what has been suppressed" (Habermas, 1971, p. 315),[209] is readily apparent at the institutional level in the IRB system. This instrumental reasoning is apparent in the way the rules are written, by and for whom. It is also apparent that the interests of the participants are at least

[209] Habermas says that "false consciousness has a protective function" (1971, p. 315).

occasionally supplanted by alternative purposes, *i.e.*, protection of funding sources, avoiding litigation, political posturing, etc. As mentioned, most of the activity is paperwork that clearly dominates the system and the people (researchers and regulators) participating in it. These participants go along, most generally without much resistance, as if this paperwork, original or revised, produces the desired (and/or an undesired, and/or any or no) result. Adopting and following this process in great detail "protects" us from actual engagement in issues surrounding the *purpose* of what is being done. Treating the procedures as handed-down, customary, "self-evident" routines "unburdens" researchers from the necessity of directly examining issues in the use of human subjects and issues in steps to protect them. (For customs as unburdening, see Schutz & Luckmann (1973, p. 298).

Historically, much more two-way communication is generated in the local IRB/individual researcher interface than in either the federal regulator/local IRB interface or the federal regulator/individual researcher level. The two latter interfaces are almost exclusively one-way, and the large majority of interfaces involve mostly impersonal communication, unless some anomaly/tragedy occurs (a death and/or sanctions, as examples). Researchers don't interact and correspond with federal regulators until/unless a "problem" arises. There is no natural interface in the system design.

Testimony given during the U.S. House (1998, Jun 11) hearing revealed the OPRR didn't know the exact number (could not offer a guess to within several hundred) of IRBs operating at that time, maintained no central registry, nor a clearinghouse of

complaints or any other paperwork institutions are required to file with the federal government. Only the assurance documents (and then only if federal funding is involved) were maintained by the OPRR. Ellis indicated, "We do currently have a list of the name and address of every IRB that's under our authority" (U.S. House, 1998, Jun 11, p. 65). The OPRR had no legal reason to keep such a list; they have no jurisdiction unless federal funds are involved. It may have been the posture of the OPRR that (given the overwhelming majority of institutions follow the rules voluntarily) there was no organizational compulsion to insist upon a registration process for IRBs. However, this is one of the first things that the new incarnation of regulators, *i.e.*, the OHRP, changed after the (somewhat superficial) structural changes to the system in June 2000 (see IRB Registration and Federalwide Assurance [FWA] Questions and Answers at http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/faq.htm, accessed May 25, 2002). The OHRP now has a highly articulated, complex, and mandatory registration procedure for IRBs and discussion of certification or accreditation activities are gaining prominence in the discourse (see Southwick, 2002, May 3; Human Research Subject Protections Act of 2002; and Southwick & Monastersky, 2001, Jun 1).

Reliance on instrumental reasoning, aiding dominant groups' ability to invisibly accomplish their ends, is described by Habermas (1971) as instrumental technical reasoning. "The understanding of meaning is directed in its very structure toward the attainment of possible consensus among actors in the framework of a self-understanding derived from tradition" (p. 310). Instrumental technical reasoning is apparent in the way regulators (appear to view) themselves and their power, responsibilities, authority, etc.

For example, by offering training, as suggested by Ellis when he was head of OPRR (and now Greg Koski, director of the new OHRP) these regulators create and maintain the "proper" view that is to be held (somewhat like textbooks, stylebooks, handbooks, guidelines, curricula, summaries, reviews, etc.). Koski, as quoted in Brainard (2000, Jul 21, p. A21), says, "Most clinical researchers lack formal training about how to conduct clinical research in an ethically appropriate manner, and should be provided with such training." Koski's comment demonstrates this creation and maintenance of the "proper view," *i.e.*, through his use of "formal training" in order to act in an "ethically appropriate manner." He did not say that clinical researchers *don't know how* to act ethically, or that they *are not acting* ethically, but that they lack formal training about how to act ethically, and that the OHRP can provide such "knowledge" (begging at least two questions: whether researchers know or not, and whether the OHRP knows or not). The federal views become institutionalized in this way (Koski's "right" to define what the problem is and who has it, and the solution and who has that) and his (organizational) right to establish and maintain the (only) "proper" views and behaviors (demonstrating the managerial/regulator imposition set forth in Alvesson and Deetz, 1996).

Based on their interpretations of the federal provisions (not only each individual provision, but also the view of the role of the federal government/regulation overall), institutional regulators create lists of approved standardized forms, templates for forms, and provide even more highly specific (and more-rigorous-as-virtuous) details about

what must be stated on the forms.[210] In other behavior at least in part designed to standardize, *i.e.*, define and set and police standards in this case, the National Association of IRB Managers has offered the IRB Management Certification Examination since 1995, indicating the development of tools to standardize the thinking, and subsequent certification of IRB members themselves (see National Association of IRB Managers [NAIM, 2001], or http://www.naim.org/cert.htm, accessed May 25, 2002; see also Southwick & Monastersky, 2001, Jun 1; and Southwick, 2002, May 3). These are highly presumptuous attempts to control the process. Hegemony is a process of infiltrating common sense (after having devalued it in the hegemonic discourse of science, as mentioned) and becoming part of the way we construct reality, the way we view the world, understand ourselves, experience needs, or get certified (Alvesson & Deetz, 1996; Gramsci, 1971). We now "need" (and actively seek) IRB approval as researchers (and regulators, based on the previous paragraph, may be actively seeking approval too, *i.e.*, certification), however, the "real" the need is for people to be treated ethically (*i.e.*, fairly, safely honestly, etc.). This creates a discrepancy between what *is* and what could have been or what could be, regardless of how wide or narrow the gap between (the size of which can't be known). As postmodernists might argue, if we leave the future to the future, it might be better than anything we can engineer, or delude ourselves into believing we have designed, strategically planned, or even affected. The need for IRB approval is not inevitable; death is inevitable; filling out forms is minutiae, and not inevitable.

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[210] See the consent form templates from University of Utah, University of Texas at Austin, University of California at Berkeley, and the University of Oklahoma; websites are in the bibliography, p. 339-340.

There is *usually* a difference between the interests of the dominators and the dominated, even if the dominated don't feel dominated (this speaks to the depth of the SINS) or are not able (or willing) to admit/articulate the problem. It is unreasonable to presume to know what the dominated want or need, or even who they are, but to argue a discrepancy can be seen, as in this case, is reasonable. Regulators, in order to complete their job mission, attempt to standardize the process of gaining approval for human subjects research. Researchers, though not continually re-inventing wheels, are inherently looking for something that hasn't been done before (perhaps describable as "neo-standard"). In fact, the size of the discrepancy, (an unknown value), might be viewed as an indicator of the (necessarily estimated) depth of oppression (at least in part attributable to SINSful acceptance). Lack of visibility, as Foucault (1980) would suggest, enhances the effectiveness of power (see also O'Connor, 1979, especially p. 226).

When visible, motives, reasons, damages, and other objects can be described and critiqued, and debated and changed much more readily. Open conflict about the differences in those motives, reasons, and points of view are more likely to occur; new decisions can be made (as well as new *ways of going about* making them), old ones abandoned, usually with plenty of creativity, blame, satisfaction and other by-products of the activity readily apparent.

A sterile world of sameness is, of course, the great risk in hegemonic success. "Cultural diversity is dissolved in the acid bath of the core corporate values" (Willmott, 1993, p. 534), but "management control strategies are seldom fully successful ...

Resistance and some level of cultural diversity normally prevail" (Alvesson & Deetz, 1996, p. 201). Telecommuters and others who take unorthodox approaches to work and organizing[211] have survived, for example; some have even become more prevalent over time. According to *In-Stat* (2001, Feb 24), roughly 24% of the U.S. workforce is estimated to telecommute some time during the week in 2001. This works out to be more than 30 million at-home workers. *In-Stat* expects this percentage to increase to 28% in 2004, growing to nearly 40 million workers. Research diversity, including the ways of approaching the work of research, is important (in my own hegemonic discourse). The system we have installed, however, works against diversity (as many similar systems do). Trends toward homogeneous processes are particularly important to avoid in educational pursuits where developing "new" ways of going about or looking at things is often a major purpose of the activity.

At the workplace, people now "find" their physical (company softball and/or training facility), social (company parties, support groups), political (union dues funneled to PACs, the boss' bumper sticker, and more overt means),[212] financial (paychecks, insurance, retirement plans, and assorted carrots), and even spiritual lives (company mentors, motivators, inspirational corporate counseling). This creates a "total" environment, much like cultists of other sorts, that serves to strengthen the bonds of control within the system, and weaken "outside" links with family, community, etc.

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[211] Troublemakers, critics, and anarchists, including investigators of investigators and those who abdicate regulatory systems, also come to mind. Also see Van Maanen (1978) on watching the watchers.
[212] See Blackwell (2001, Jan 9), *On career and citizenship and companies: When employers play politics*.

In this way, management control is not limited to our professional lives. Deetz (1992) suggests "the decline of vision, hope, and community in politics has paved the way for management ideologies and practices" to fill what he calls "the vacuum" (as discussed p. 209 of Alvesson & Deetz, 1996). If a person's life is/contains a vacuum, I suspect these forms of control work even better than if a person has a strong identity in place. This is relevant to the student researchers, as mentioned previously (see p. 202 and p. 247-248, herein). I don't mean to suggest students' lives are any more or less vacuous than other lives, however, students are not as likely to have a strong identity *as researchers* the first few times they make an application to an IRB. This "control" idea also bears strong resemblance to Theory X (McGregor, 1960) thinking, implying challenges to the integrity, recall, and humanity of all researchers, students and others. Student researchers, therefore, while being exempted in some disturbing ways, are, perhaps, more abused by (an unclear, contradictory, unreasonably convoluted) the system than application savvy, politically astute researchers, ones with IRB experience, and who have perhaps more confidence, ability, and willingness to circumvent what they have concluded are tedious and pointless, required but unnecessary processes (see Manning, 1978; see also Overland, 2002, Feb 19, re: corporate circumvention of IRB processes via conducting trials in other countries).

Corporate cultures and government/institutional structures, when viewed as text, suggest culture members become "readers" who bring their experiences and awareness of other texts and other cultural forms, their histories and their own moods and personalities to their reading of texts. They "enter into the text, changing its nature and

reproducing it as they consume it" (Linstead & Grafton-Small, 1992, p. 344). Reality and truth are *liquid* rather than solid, it appears, logically alarming some (positivists, propagandists, and itinerarians, as examples) who believe it is possible, necessary, and/or desirable to control the routines of others.

Whether regulators label a situation as "problematic" or an "infraction," or describe a situation as "systemic" or "local," whether they impose sanctions or conduct investigations, whether the U.S. Congress passes a bill to supplement current laws with the force of more law or not, and whether a researcher considers a study *doable* or not in the face of IRB rules are examples of the outcomes of "text reading." Variance in readings reveals underlying values in conflict (notions about the rights of individuals versus the common good, for example), the range of interpretations brought to any given text, and even which texts one will "read" at all. And, in matters of academic free inquiry, federal regulators appear to adopt a "least restrictive environment" position. But this policy does not hold at the institutional level of interpretation (see AAUP, 2001). It appears odd that institutions do not embrace this basic tenet of administrative law (*i.e.*, "least restrictive" as preferred over "more rigorous") as a win-win possibility among IRB members, researchers, and participants in research.

Dialectical tensions in the system. Work in hermeneutics (see Alvesson & Sköldberg, 2000, particularly p. 52-109) is useful in considering the IRB system in its very complex social context, particularly in helping to formulate questions for the purpose of continued and enhanced whying. For example, framing the tensions between

institutional *compliance* with regulation (the event) and *competition* with other research institutions for funding (the context), and attempts of institutions and researchers to negotiate the political environment, avoid litigation and sanctions (or explain either or both and to balance all these things and more) lead to many important questions about the IRB system of protections, focusing on those questions about actual *protection of human subjects*, such as conflicts of interest, personal and institutional funding pressure and its effects on researchers' strategies, considerations about the qualifications (and/or accreditation) of IRBs and/or the members of them, etc. (See Andrews, 2000, Mar 10; AAUP, 2001; ACHRE, 1995; NBAC, 2001; Blumenstyk, 2000, Nov 6; 2001, Apr 26; Blumenstyk & Wheeler, 1998, Mar 20, Southwick & Monastersky, 2001, Jun 1; Southwick, 2002, May 3; and Human Research Subject Protections Act of 2002.)

Sanctions against the University of Oklahoma-Tulsa Campus issued in June 2000 were related to concerns about patient safety, and brought about as a result of an outside consulting firm's report and a whistleblower's efforts. This situation involved a clinical study in which the principle researcher was also the inventor (and the manufacturer, see below) of the vaccine used in the study, as well as being a doctor to the patients participating in the study. (None of the patients referred to this individual as a researcher, as anything other than "doctor," which is indicative that the consent was "really" as confused as it was informed.) In addition to this conflict of interest, the situation on that campus was incestuous in that the doctor/researcher in charge of the study, Michael McGee, had also, and without FDA or any other authorization, manufactured (without the required outside monitoring) the vaccine that he then

administered to patients. The events were conspiratorial in that McGee and IRB chairman Daniel Plunket misrepresented to patients and members of the IRB the reasons for an earlier suspension of the study, *i.e.*, Plunket, who later retired rather than resign or be fired, didn't inform the rest of the IRB or the president of the Tulsa campus, the vice president for research, the federal government, or anyone else about the earlier suspension of the trial. Plunket and McGee kept the issue between themselves.[213] It took one (rather courageous and persistent) whistle-blowing nurse to take the information about the mis-management of this clinical trial to the federal regulators, who issued sanctions in June 2000. In all, four heads rolled including those of the principal researcher in charge of the trial, Michael McGee, who was also vice chairman of the Department of Surgery; Harold Brooks, dean of the college of medicine at the University of Oklahoma-Tulsa; Edward Wortham Jr., the director of the Office of Research at the OU Health Sciences Center; and Daniel Plunket, the chairman of the college of Medicine's IRB and senior associate dean for clinical affairs (see Winslow, 2000, Jul 22). Winslow (2000, Aug 1) reported about the aftermath of the sanctions and firing, specifically the level of confidence patients had in the vaccine and the doctor/researcher. There were also letters to the [*Tulsa World*] editor from patients during this time, and *Time* (Lemonick & Goldstein, 2002, April 22) featured the events in a cover story). None of those rules worked in this case. In spite of this rather massive

[213] The "story" that McGee and Plunket presented indicated the vaccine was in short supply due to the overwhelming response to the study. In fact, a private auditing firm had recommended the study be stopped because of numerous safety concerns.

rule failure,[214] OU officials then *created new rules* and processes such as new layers of checks, including unannounced spot checks; the appointment of a new central research compliance office; a 24-hour hotline allowing anonymous callers to report violations; mandatory employee training about compliance; and, similar to the institution-to-federal government assurance document, an oath, processed from individual to institution. And, officials stated the obligatory cliché, *i.e.*, the new rules are designed to, according to the *Tulsa World* (Kerr, 2000, Jul 21) "ensure an incident like this wouldn't happen again," as was heard in similar form from officials in response to Nuremberg, Tuskegee, University of Pennsylvania, Duke, Johns Hopkins, and so on and on. OU President David Boren said it was "good" that the incident happened when it did (before more than one percent of OU's research was conducted in Tulsa), and talked about becoming, not (necessarily) the model of human *protection*, but the model of *compliance*, "I do think we will see the day when these procedures will be used by other universities as a handbook" (Boren, quoted in Gillham, 2000, Jul 23; for details of other cases, see Andrews, 2000, Mar 10 regarding the Gelsinger case at the University of Pennsylvania; Cho, 1997, Aug 1, a discussion about the increasingly dubious ties between money and academics/clinical trials and the effects on rules; Brainard, 1999, Oct 1, about sanctions at the University of Chicago and the resignation of a chancellor there). Rather than a handbook, the events at OU are being used as a case study in how *not* to conduct studies

[214] Obviously rules requiring researchers to get approval to manufacture vaccines, and to report problems they experience in a trial, and to bring problems to the entire IRB (not just the chair), along with rules designed to prevent conflicts of interest did not work to prevent these acts of (professional) incest, and conspiracy.

(see Lemonick & Goldstein, 2002, Apr 22; and Southwick, 2002, May 3, re: testimony about the case in Senate committee hearings).

Tensions about priorities. IRBs focus on minutiae,[215] even sub-minutiae and concerns well outside their purview (Brainard, 2000, Mar 17). Beyond those used by Brainard, examples of minutiae, myopia, and expansionism I have learned about directly (*i.e.*, in "real" life) include board member "suggestions" about the title of studies, whether or not the IRB has "jurisdiction," and whether or not a study is "valid," (a study which may employ methods with which the IRB member has little or no familiarity, but who may assume s/he does, and in a manner of confusing authority with superior knowledge, apply "clinical trial" standards. And it appears IRBs focus too intently on (representations of) studies (*i.e.*, protocols from researchers) requesting permission to conduct studies involving no treatment[216] (see Brainard's study, "An inside look at how a university tries to protect human subjects," 2000, Mar 17, in which he observed and interviewed Duke officials after the sanctions there and came to conclusions similar to those mentioned here). Many university scholars and government officials at an August 2001 conference sponsored by the DHHS expressed concern that scrutiny of researcher's financial interests would fall to IRBs. "These panels, which are required by federal regulations to monitor the risks of proposed research involving

[215] This is not to suggest federal regulators are substantially different from institutional ones in this regard. See Brainard (1999, Sep 10) regarding sanctions at the University of Illinois at Chicago, and Burd (1995, Apr 14), for similar information about the University of Virginia. Many government reports cited herein have indicated the same problem, particularly DHHS OIG and GAO reports in 2000 and 2001.
[216] For example, a history professor, Alan Lessof, of Illinois State University states that oral history "is so outside the realm of what human-subjects protections were originally designed to deal with that a rational person would wonder what is happening," as quoted in Brainard (2001, Mar 9, p. A21).

human subjects, are widely viewed as overworked and understaffed. Only about a fourth of the IRBs surveyed by the inspector general at [DHHS] routinely review conflict-of-interest issues" (Brainard, 2001, Feb 16, p. A33; see also DHHS OIG 1998b, 2000b; Mangan, 2000, May 19, and 2000, Oct 30; Blumenstyk, 2000, Nov 6; Okie, 2001, Aug 6). I would add that the local IRB members would be under undue pressure, i.e., they would be under pressure not to stand in the way of funds, i.e., disapprove certain studies. This is a situation in which "local" may be too close to home. It is not the best system that could be developed if the goal is human subjects protection. But, as mentioned, that goal is mostly superficial in the way processes are developed.

Conflicts of interest tensions. Large financial rewards have become more and more a part of the research environment. Conflict of interest policies have evolved, including disclosure requirements, at research facilities in universities and in professional journals. In May 2000, Harvard University drew fire for "considering whether to ease some financial restrictions in its conflict-of-interest policies" (Mangan, 2000, May 19, p. A47; see also Mangan, 2000, May 26). According to Mangan, the new guidelines were perhaps necessary to retain researchers. Harvard's policy, according to many of those quoted in Mangan's articles, is the strictest policy in the country. Sheldon Krimsky, a professor of urban and environmental policy at Tufts University, said "Harvard seems to be moving in a direction that's going to lead to more conflicts of interest and greater secrecy in research" (as quoted in Mangan, 2000, May 19, p. A47). Krimsky continues, saying if Harvard relaxes its policy, it would be "lowering the bar at

a time when we're getting more information that indicates that close ties between universities and industry have adverse consequences to the health of science and to the public interest" (as quoted in Mangan, 2000, May 19, p. A47).[217] Mangan also states that Harvard's consideration to ease its policy is "responding to competitive pressure" and surmised that the death of gene therapy patient Gelsinger in 1999 "may cause some schools to tighten their controls over sponsored research" (2000, May 19, p. A47).[218]

By October, in another article by Mangan (2000, Oct 30), the debate about conflict of interest had escalated, leading to the formation of a panel (the effort led by the president of the Association of American Medical Colleges) to "help forge a consensus on how schools should deal with the problem" (*Daily News* section). The president of the Association of American Medical Colleges, Jordan Cohen, said, medical schools need to agree on a consistent strategy for confronting financial conflicts of interest that are steadily eroding public confidence in clinical research (and taking social scientists with them, incidentally and unfortunately). "We risk great peril if we fail to respond to the growing perception that financial conflicts of interest have gotten out of control" (*Daily News* section). (Notice the use of the term "growing perception" rather than an acknowledgement that financial conflict of interest is a "real" problem.[219]) Cohen states "A conflict of interest is like potential energy: it has the

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[217] Krimsky was also quoted in Blumenstyk (2001, Apr 26), about disclosure policy in scientific journals. "Something's off" Krimsky said, when the results indicated conflict of interest/financial disclosures were only found in 0.5 percent of the articles examined in the study (*Daily News* section).

[218] Harvard eventually decided not to ease their restrictions (see Mangan, 2000, May 26).

[219] The results of a survey of doctors in 2002 found 58 percent of those doctors responding had received research funding from drug companies, and 38 percent served as company employees or consultants. Further, only 7 percent thought their ties to the companies affected their own recommendations, and 19 percent thought such ties did influence other doctors (Choudhry, et al., 2002, Feb 6; see also CNN.com, 2002, Feb 6).

capacity to cause something to happen, but until unleashed, [it] is simply a lurking presence" (as quoted in Mangan, 2000, Oct 30, *Daily News* section).[220] The debate has further escalated to the level of the OHRP proposing rules for "institutions, clinical investigators, and IRBs to consider when dealing with issues of financial interest and human subject protection" (see OHRP, 2001, Jan 10; available: http://ohrp.osophs.dhhs.gov/nhrpac/mtg12-00/finguid.htm, accessed May 25, 2002; also see Brainard, 2001, Feb 16.) However, more than half the states are considering or have already passed laws designed to eliminate barriers to collaboration between universities and private companies, with "conflict-of-interest fears [taking] a back seat to economic development" (Schmidt, 2002, Mar 29, p. A26).[221] Many of these states made sizable expenditures on research universities, tightening up the relationship between "learning" and "learning to profit."

Ricoeur (1971) states "In the same way that a text is detached from its author, an action is detached from its agent and develops consequences of its own. This autonomization of human action constitutes the social dimension of action" (p. 541) not

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[220] It would appear that even proposed accreditation groups in this system are not immune to conflict-of-interest difficulties. Southwick and Monastersky (2001, Jun 1) report that an IRB accrediting group, in a wolves-guarding-the-hen-house arrangement, "will be financed by fees from universities and institutions that seek the group's seal of approval. In addition, the Pharmaceutical Research and Manufacturers of America, a trade group representing drug and biotechnology firms, and the Burroughs Wellcome Fund will help finance the organization" (p. A22; see also Southwick, 2002, May 3). This hardly helps stop the "steadily eroding public confidence" and "growing perceptions" that financial conflicts have gotten out of control. (See also Boseley, 2002, Feb 7, re: scientists taking money for papers ghostwritten by drug companies.)

[221] Oklahomans adopted a constitutional amendment in 1998 and also approved a change in a law that had prohibited public property from being used for private gain, to allow private companies to have access to university laboratories (State Question 680 and 681). The state chapter of Common Cause complained that the initiatives put taxpayers in the position of subsidizing corporate research (see Schmidt, 2002, Mar 29 and also the Oklahoma Election Board website, http://www.oklaosf.state.ok.us/~elections/98gen_sq.html, accessed May 25, 2002, for information about the amendments).

only because organizations are produced by numerous actors whose individual roles are not distinguishable, but also because "our deeds escape us and have effects which we did not intend" (p. 541). This includes what we write. These effects are apparent in the IRB system, as in Cohen's comments above, *i.e.*, conflict of interest issues are a "lurking presence" constituted by "growing perception[s]." These ideas resonate with those from the NIH: "Why are there concerns? Concerns are raised when financial considerations may compromise or *have the appearance of* compromising an investigator's professional judgment and independence in the design, conduct, or publication of research" (NIH, 2000, Jun 5, Notice OD-00-040, emphasis added). These concerns don't mention human subjects specifically, and point out the "appearance of compromising" as (equally) important. [222]

The power of atrocities. At the institutional level, changes and interpretations are rarely driven, at least directly, by atrocities or sanctions. Both, thankfully, are rare; unless the system changes dramatically, most institutions will never experience them directly. However, many institutions are affected when atrocities or sanctions occur anywhere (see comments after Duke sanctions in Brainard, 2000, Mar 17, especially Duke associate professor of medicine and philosophy and bioethicist Jeremy Sugarman, who is quoted, "I got e-mail every day [after the suspensions were announced] from

[222] That financial considerations *do* compromise researcher integrity (the degree might be argued, and would vary from individual to individual, life being liquid and local) might be considered a phase one image, *à la* Baudrillard, 1983). The idea of "appearance of compromising" can be described as "masking or perverting" a basic reality (phase two), and the failure to acknowledge that compromise exists in these situations contributes to sorcery (phase three) in "masking" *the absence* of reality (see also p. 63, herein). These ideas may also be applied to the ideas that the same rules are adequate for both clinical and social research (see footnote # 208, p. 194).

people at other universities who said, 'There go we, but for the grace of God'"). Self-regulation, normalizing cultural creations, conceding, and behavior too similar to mooing follow atrocities and sanctions, with institutional regulators (with managerial superiority) often being the first over the cliff, followed very shortly by the compliant non-whying herd of researchers.[223]

In the absence of (almost exclusively medical) atrocities, tragedies, or sanctions, local institutional regulatory drive must (necessarily) come from local experiences. Changes in personnel of an IRB itself or higher-level managers/administrators may create change. New people have new (if not necessarily good ideas, in the view of some; ideas are perceived as bad if they don't support the status quo, of course), and incumbents possess a generalized anxiety toward change and difference, a "natural" desire to maintain their way of life, to avoid change and the unknown (a form of psychological inertia perhaps) regardless of the organization examined. This contributes to the static nature of IRB systems (and plenty of other bureaucracies). This is not to say that resistance to changing rules means there is no activity in the IRB system, rather that the activity *leads* (nearly) nowhere (see next section). As Brainard (2000, Mar 17) suggested, it is easier, and safer, to focus on wordsmithing consent forms than to attempt to answer larger—and self-reflective—philosophical questions about what they as regulators are doing overall, or what they are entitled to do in any given instance. As Adorno (1989a) writes, "the completely reified and mediated is a sanctuary from

[223] Adorno (1989b) says, "Lower classes have fewer illusions, are less 'idealistic'" (p. 272).

immediacy and life" (p. 130; see also Schutz, 1973, p. 298, and footnote # 209, p. 195 herein for a relevant statement from Habermas).

SINS-ful sameness. It might be expected that the IRB system would produce high levels of standardized, often strategized, formulaic discourse that doesn't change in meaningful ways the "real" world of human protection. As shown in various examples herein (including Glenn's discourse, both in the writing of the bill and the act of defending the virtues/establishing the need for it, and, further, in the result of the efforts—the bill never got out of committee, *i.e.*, any result related to the purpose of regulations was nothing much, though other benefits may be said to have been gained. The discourse may have enhanced Glenn's political capital, or reduced litigation potential for institutions, including many government agencies conducting research. But to a much lesser extent were protection provisions affected.[224]

(SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS (such things as the institutionalization of the application process/forms, the naturalizations associated with "the way we do things" at the IRB, etc.) operating in the local regulatory system have worked to create sameness[225]. This standardization may be beneficial to the IRBs by alleviating, if not

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[224] Postmodernists might argue there can be no "single" change as a result of any discourse, such as a rule, and that we cannot know the effects of the discourse anyway; there may be many several effects, or none, and they would vary greatly regardless, making many effects hardly recognizable at all, and not conclusively related to any particular piece of discourse, for any particular individual, at any particular time or place.

[225] Adorno (1989b) says, "Society needs this tireless intellectual reduplication of everything that is, because without this praise of the monotonously alike and with waning efforts to justify that which exists on the grounds of its mere existence, men would ultimately do away with this state of things in impatience" (p. 274).

eliminating, the need to fully engage in protocol reviews because eventually (maybe even rapidly) the proposals become intensely formulaic as researchers adopt the IRB rules, specifically, conforming to the application process (a comfortable "default" as described by Habermas, Schutz, and Adorno and mentioned on the preceding page). Conformity, by definition, breeds sameness. I would suggest it is possible, even likely, that applicants whose proposals conform, *i.e.*, reflect the formula, are more often and more quickly approved, and those applicants whose proposals do not conform are subjected to more scrutiny and more often rejected than "standard" applications (this is the case at the OUIRB, though if my own somewhat unorthodox applications had been approved it would have been possible for me to provide more precise observations). This is, it might be argued, a form of "pre-approval" bias, albeit with no guarantees. Often IRBs, in the revise-and-resubmit routine, "guide" the researcher to conformity and cookie-cutter sameness, if the researcher doesn't find it on her/his own[226] (see Brainard, 2000, Mar 17 and White, et al., 1995, for discussion of typical reasons for IRB rejection; see footnote # 233, p. 226). The process, particularly of the researcher's application, becomes an IRB review of the structure of the proposal rather than a review of the treatments described in the proposal.

[226] This way of conforming is similar to the tendency of many people to "listen for what to say" rather than listen and consider what one "really" thinks or might wish to say. In an example of Baudrillard's image phases, we often are listening to others in order to determine what it is the "other" wants to hear (rather than "really" listening to what it is they are saying), then we deliver the appropriate script (rather than what it is we might "really" wish to say). Another example involves researchers who know that in their study there is no risk to participants. For these researchers, then, the entire application exercise (necessarily) becomes about "pleasing the IRB" and not about "protecting human subjects" who have nothing from which to be protected.

Other effects. Other local effects include the following as potentialities of the system, given the federally mandated structure and a university based IRB's expectable membership (at least historically): activities related to the avoidance of lawsuits; previous experience with the applicant, topic, and/or methods; and the IRB member's own view of power. A generally absent yet potentially important "local effect" is researcher insistence on a better system; resistance of a simultaneously intrusive and impotent one. Demanding a voice in the process (*i.e.*, legitimation rather than marginalization) and/or participating in passive rebellion rather than in an inappropriate system are rather obvious choices not often selected (perhaps in a socio-professional version of survival of the fittest, *i.e.*, to win, one must play the game; dissenters, by definition almost, don't "fit in" as they are playing a different game, too often whying about rules, making trouble, etc.)[227]. Adorno (1989b) says it this way:

> If we were looking for an ideological justification of a situation in which men are little better than cogs to their own machines, we might claim without much exaggeration that present-day human beings serve as such an ideology in their own existence, for they seek of their own free will to perpetuate what is obviously a perversion of real life. So we come full circle. Men must act in order to change the present petrified conditions of existence, but the latter have left their mark so deeply on people, have deprived them of so much of their life and individuation, that they scarcely seem capable of the spontaneity necessary to do so. (p. 275)

Power sources. Legitimate power, it is argued in the definition provided by French and Raven (1959), is exercised only to the extent that control is acceptable to the

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[227] Deetz (1995) says, "Tautologically, workers are considered motivated as long as they are productive" (p. 103). He continues, saying that human resources are [positioned as] objects for managerial control, "and the discursive fiction of motivation is treated as if it were the thing being manipulated, not the people, thus hiding the control move, suppressing conflict over the legitimacy of control, and prohibiting discussion of meaning" (p. 103).

controlled. This idea is not inconsistent with Foucault (1980), Giroux (1988), Hall (1986, 1989), and Weber (1947, pp. 324-341), who was an original source on this sort of definition – he called it "legitimate authority" rather than "power." These notions about power are particularly relevant in the IRB system, as this system is heavily reliant, on both the federal and institutional levels, upon voluntary compliance[228], and most research is unsupervised (see "lack of direct oversight" concerns in DHHS OIG 1998b, 1998d; GAO, 2001; NBAC 2001, and others). This is another example of the way power operates as a relationship (Foucault, 1980), *i.e.*, power must be given before power may be possessed. Researchers have given power to the system. And, if one is to follow the liquid and local line of argument, specific researchers give specific power(s) to specific regulators at specific times. They don't have to. They do. They may (falsely) believe they have no choice. But, "really," they, we, do.

Impacts of Various Dogma on Current System

Scientific management theory. Scientific and classical management theories as mentioned previously, comprise some of the earliest attempts to understand the complexity of organizations. The works of Taylor, Fayol, and Weber are examples. Taylor (1919/1947) first set forth his views of scientific management as early as 1911. Fayol and Weber published work about the same time, although not available in English until the 1940s; Taylor's work wasn't compiled and published until 1947. The IRB system was being formed about the same time as these works were becoming available

[228] The AAUP (2001) reports, "approximately 75 percent of the largest American research institutions, which for the most part are research universities or hospital affiliates of universities, have voluntarily

(the AEC was formed in 1947). These theories share a common tenet, namely that organizational efficiency is determined by the efficient design of work and the organizational structure, not inconsistent with Lyotard's (1984) performativity ideas. In looking at the historical developments, these classical theories may be useful in gaining better understanding of the social context that existed at the time of IRB development, and the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS we enjoy/endure today.

Taylor's (1919/1947) scientific management system suggests, among other things, that there is "one best way" to perform any job (part of the root ball of the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS of standardization), and that employees should be selected in a measured way (based on test performance or longevity, for example). In the IRB situation, not only federal rules about how many people and what categories must be maintained on the board, but local traditions may exist, such as having all the colleges represented on the board, or other "local" criteria that may become viewed as the "one best way" of "doing regulation" (see Sacks, 1970).

Another element of the scientific management system is that labor should be divided so that managers plan and workers follow those plans, *i.e.*, an authoritarian hierarchical system. IRB members operate, as do many regulators, with don't-ask-why, do-it-because-I-said-so, I-didn't-make-the-rules, it's-the-way-we-do-it-around-here attitudes. Rules may be interpreted in sometimes vastly differing ways and applied in still other ways, suggesting the rules themselves are liquid, but the *pattern* of the

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extended the IRB review system to all human-subject research" (p. 3).

process is more solid. For example, one application may take much longer to consider than a similar one for no apparent reason, (knowledge gained from numerous personal conversations during the past few years with fellow graduate students and professors) yet the *process* of making the two applications is virtually identical. And, sometimes even similar content may be in present in two or more applications treated differently by an IRB, *i.e.*, depending upon a particular reviewer's view on a particular day, decisions may be inconsistent over (rather short periods of) time. These inconsistencies may also be due, in part, to the attitudes of both the regulators and researchers that (at least occasionally) they are doing something that seems "nonsensical" or contrived (a we-have-to-do-this-even-though-it-seems-silly feeling even regulators must get from time-to-time). It is difficult to be "logical" or under a blanket of nonsensical circumstances/circumventions (creating/contributing to circum*visions* perhaps?).

Fayol's (1916/1949) general management theory outlines 14 fundamental principles. Those relevant to this study are his notions of authority and responsibility, discipline, order, and perhaps most relevant, the subordination of individual interests and the development of *esprit de corps* (or more contemporary monikers: "production teams," or "corporate cults"). Faculty members encourage students to write applications with the goal of gaining approval—that is the focus of discussion in methods classes, both qualitative and quantitative. The discussions are not focused on the "real" *purpose* but on the *process* and strategies for enduring/accomplishing it.[229] This is unfortunate

[229] This is an example of getting a *know-how* education, without getting much know *why*, and this is primarily because whying is not encouraged in classrooms or in the broader educational environment – we haven't the *time*, which is another entire study of a strange counterproductive process-over-purpose situation. Could faculty say why, discuss why, in any sensible way and with a straight face?

for everyone concerned, with the possible exception of the IRB members themselves. They enjoy standardized applications and even (an insidiously) comfortable standardization of *studies*, contributing to job conditions that are simpler (and safer, politically and legally.) "Standardization" may be a preference of many people (not just regulators, but faculty, too, for example). But I would suggest this is an example of hegemonic thinking. Many of these same people might also acknowledge, if they "really" thought about it, that almost always standardization of a (nonsensical) process is not a superior option to exemption from that process. In qualitative methods classes, for example, it would be preferable (and consistent with the *purpose* of IRB regulation) for many of the IRB proposals required of students (and subsequently evaluated by faculty) to be eliminated. Exemption is far preferable to standardization, I argue, for some Very Big reasons (avoiding intellectual suffocation not the least among them) and some smaller reasons (attempts to standardize the non-standard world can be a Very Big pain in the ass, though dismantling a standardizing structure is an Even Bigger One). Of course, thinking un-hegemonically is difficult, troubling, risky, and exhausting.[230]

Process "templates" are a manifestation of managers' (regulators' in this case) co-opting of *volunteer* "subordinates" (researchers, particularly) to take part in the system, *i.e.*, to participate in the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS of the regulatory (and as a gift, dominant) "scientifically managed" cultural reproduction.

[230] And it can lead to rather substantial trouble for the thinker (especially thinker-as-activist), internally and externally. Troubles like the loss of popularity and status that comes with staging passive (or active) rebellion, pesky incarceration/assault threats, or the development of an actual and/or ongoing need for bail bonds and/or bodyguards are (perhaps overly colorful) examples.

Illustrating this is the behavior of the many graduate students and faculty members who circulate advice about what sorts of studies should be avoided (or adopted) if reasonably quick IRB approval is to happen. Their advice is based on their own individual histories with the IRB, what they feel they understand of the IRB policies, and rumor, too.

One of the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS in the IRB system is the belief that a "best for all" condition exists, *á la* Taylor, and Plato. (I would suggest that the idea of a "common good" as possible is required to drive a system toward standardization, *i.e.*, "template fever.") Even regulators themselves indicate that if "template fever" runs too high, the template may add symptoms (demonstrating, incidentally, that regulators can admit that even templates have points of diminishing returns) rather than operating as a cure for a sick system. (In this "fever" scenario, it would follow that the system could occasionally become delirious). The OHRP, in its letter to Johns Hopkins University (OHRP, 2001, Jul 19) outlining the reasons for sanctions in the wake of the death of a healthy volunteer in an asthma trial, stated, "OHRP is concerned that the boilerplate informed consent document is difficult to understand and contains information that may be irrelevant for certain research projects" (p. 8) yet on the previous page, language used by the OHRP seems to contradict, or at least point out the difficult dialectical tensions between providing enough but not too much information on the consent form.[231] In particular, OHRP (2001, Jul 19) suggests that the IRBs "encourage

[231] Among other things. Forester (1989) argues "planners who seek to meet public needs face even greater challenges than their more romanticized private-sector counterparts, the corporate 'strategic' planners" (p. 4). Forester (1989) concludes, "Compared to the job the public sector planners have, the planner with private-sector clients has it easy" (p. 4).

investigators to limit the length of informed consent documents, and as a result, important information is being excluded;" "OHRP again strongly recommends that the informed consent document boilerplate used by the IRBs and checklist be modified to include the additional elements at 45 CFR 46.116(b);" and "OHRP is concerned that the informed consent documents approved by the IRBs often appeared to include complex language that would not be understandable to all subjects" (p. 7). A similar situation, with respect to limiting the length of informed consent forms to something substantially shorter than the instructions provided, exists at the University of Oklahoma, as mentioned (see University of Oklahoma, IRB application form, http://research.ou.edu/Forms/index.htm, accessed May 25, 2002.). These statements do little to clarify what Johns Hopkins should do, but they speak volumes about the difficulties in delivering informed consent in the "real world"[232] and the inconsistency in the simulation, born from dialectical tensions in the "real" world. In the OHRP letter to Johns Hopkins (OHRP, 2001, Jul 19), regulators indicate that the use of a boilerplate and complexity of the form may have contributed to the problems related to the death of a volunteer, that the informed consent form "appeared to include complex language that would not be understandable to all subjects."

Not only are the subjects of research perhaps unable to understand the complex language of consent forms, similarly, researchers may not, as mentioned, understand the complex language used in or the structure of the process. For example, the instructions

[232] A web search (Google, October 5, 2001) for the term "informed consent" yielded 724,000 hits. These included both federal and institutional references. Just at the federal level, the DHHS website rendered a total of 3,460 documents; within the NIH site, a total of 2,185 hits; and the OHRP website alone yielded 103 documents. Add to this din the interpretations at the institutional level, and the notion of "confused

OU provides to explain the informed consent document and how to successfully negotiate it are substantially longer than the "recommended length" of the informed consent document itself. While it is understandable that this would occasionally be the case in the world, it is particularly troublesome here. Given that many of the instructions include lengthy passages about actual verbiage that must be included on the informed consent document (an example of wordsmithing, as has been mentioned previously, see footnote # 18, p. 16, p. 212, and p. 221), it appears the "instructions" are impossible (or nearly so) to follow, *i.e.*, to include all the required information produces a document longer than the recommended length, found in the same set of instructions.

Finally, Weber (1947), in reporting his observations of bureaucratic functioning, suggests the "ideal" organization (*i.e.*, a "real" bureaucracy) in the eyes of practiced bureaucrats has six basic features: a clear hierarchical system of authority; a division of labor according to specialization; a complete system of rules regarding the rights, responsibilities, and duties of personnel; exhaustive procedures for work performance; impersonality in human organizational relationships; and selection and promotion of personnel solely on the basis of technical competence. These ideas are institutions, visible in merit systems of public employment, for example, and certainly in the IRB regulatory system. Finally, Alvesson and Deetz (1996) suggest "Taylor's and Weber's treatment of rationalization and bureaucratization showed from the start the corporation as a site of the development of modernist logic and instrumental reasoning" (p. 194).

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consent" (see p. 17) becomes a reasonable, even likely scenario, among everyone, *i.e.*, the regulators, the researchers, and the participants.

The IRB system creates a thorough illusion that Weber, Fayol, and Taylor were published yesterday.

Structural/Functional explanations. In the 1950s, structural-functional theory dominated sociology, the emphasis placed on the power of institutionalized norms to determine behavior. Beginning in the 1960s, sociologists began to abandon this thinking. In 1967, Garfinkel rebelled, arguing the deterministic models presented people as "judgmental dopes" who couldn't do their own thinking. It's fairly clear that sometimes we won't do our own thinking. And other times, it appears, we cannot. Not under the rules, anyway. The informed consent process in social sciences, and the Theory X management techniques of institutional (and institutionalized) IRBs have provided a system that treats both social science researchers and participants as unthinking and imbecilic, respectively (if not respectfully). In the IRB system, the process now dictates much researcher behavior. But, as described in earlier chapters, the IRB system is especially sensitive to the larger political context, and therefore driven by various outside forces. Few of the changes produced are directly related to human subjects protections, and even more rarely related to the actual event that "started" a given debate (see p. 22, and footnote # 172, p. 155). It is understandable why researchers might become confused in making applications. Strategies that worked at one time (when Ellis was director of OPRR vs. Koski as head of OHRP, for example, or rules regarding stem cell research with Clinton as president vs. rules under the Bush administration, or when the local IRB changes membership composition, experiences

outside criticism, or is sanctioned) are deemed (or "really" become) ineffective (or less than optimally so) for no apparently good reason, *i.e.*, no evidence is provided to support a/the change(s) proposed. Institutional regulatory responses to these outside (and some at least arguably irrelevant) forces take a variety of forms, (most often, rule or enforcement proliferation in response to a generalized need to "do something," see particularly the headlines in Brainard, 1999, Dec 17; 2000, Feb 4; 2000, Apr 14; 2000, May 26a & b; 2000, Jun 2; 2001, Jan 5; 2001, Jan 12; and 2001, Feb 16, as examples) and numerous activities occur simultaneously (parties to the situation feel compelled to "do something," demonstrated in the same Brainard headlines cited above, as well as the articles themselves), the synergy of which transcends individual events in affecting the system.

de Saussure (1915/1966), a father of structuralism, stated that words are not meaningful in isolation (consistent with G.H. Mead and others), but receive their meanings because of their differences (*i.e.*, in the *minds of the meaning makers*, an anti people-are-dopes position) from other words of the same systems. de Saussure used the term *la langue* to describe the system of a language, which needs to be treated differently than the actual speech of the people who use the language, which he described as *parole*. *La langue* is a social product, transmitted to the members of the linguistic community, and it comes to exist "in the mind" of each speaker, affecting the way the world is understood. I believe that even though the phrase "in the mind" is used, what is being described is an example of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS operating

mostly *out of mind* once they are learned. This lack of visibility contributes to the power of these terms and processes. Many fewer questions arise once the system is installed, once it is learned, whether it is "understood" or "questioned" or not.

Entrenchment. The IRB regulatory system is so entrenched (full of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS) it no longer needs overt coercion to operate smoothly. Fear of litigation, fear of sanctions, fear of personal humiliation, fear of financial loss *are* coercion, and are often perpetrated (covertly) on *oneself.* These bars (see p. 44) are seen as an inevitable part of research life.

IRBs have lots of carrots, especially as far as student researchers are concerned, and unless IRB members are highly vigilant, they are inherently coercive – students "know" they can't publish (and will, therefore, certainly perish attributable to other SINS beyond the scope of the present study) without the approval of the IRB to live their research lives, or at least finish their programs. IRBs control the definition of "timely" (for example, what constitutes a timely response from the IRB or from researchers, what constitutes a timely report to regulators about problems with a study, and determining what is considered a "timely" submission or a "timely" response from a local IRB. See also OU Policy, Section 6, parts 1 and 3; Section 11.2, part 1; Section 12.2, part 1) and are above student scrutiny, *i.e.*, the board doesn't have to answer to student whying, evident by the lack of due process or appeals structures. The OUIRB policy regarding the use of human subjects states in Section 10, part 5, when the

OUIRB disapproves an investigator's request[233], "notification shall include a statement of the reasons for its decision and the investigator shall be given an opportunity to respond in writing or in person." [The OUIRB] may, at its own discretion, "re-review and reconsider its decision to disapprove a research activity at any time" (OU Policy, Section 10, part 5). This could hardly be considered the intersection of Adequate Appeal Avenue and Reasonable Regulation Road.

To provide guidelines, as the federal regulators do, suggesting what is *right* is substantially less intrusive than requiring paperwork that is designed (in futility and perpetuity at once) to *ensure* people do the right thing. Rules do not replace a researcher's personal values or lack of them, as argued previously (see p. 27-29 and 244-246; see also Cassell, 1982). Trust of researchers on the part of institutions allows "blanket assurance" from researchers (and that is a leadership option they have available, *i.e.*, no federal rules prevent it). But, a blanket assurance for researchers is not "normal," therefore, system staticity (*i.e.*, inertia) being a strong prevailing tendency, blanket assurance is less likely to be done at the institutional level. If it were adopted, the focus of classroom discussion might shift toward discussion about protection, because the process would be minimal, simple, painless, mostly unremarkable and forgettable, as, I would argue, a "good" process should be. There are, of course, political and psychological, even financial benefits to making things appear worse than

[233] According to a study conducted by the Emergency Medicine Residency Programs at Akron General Medical Center and Butterworth Hospital in Grand Rapids, Michigan, (White, et al., 1995) common reasons for (medical) protocol rejections were informed consent problems (54 percent), poor study design (44 percent), unacceptable risk to subjects (34 percent), ethical or legal reasons (24 percent), and lack of scientific merit (14 percent). (Note: Some applications had more than one "problem.")

they are,[234] namely the establishment of the illusion of the "need" to "do something" in a given situation and that "doing something" would actually positively impact anything (also see footnotes # 26 and 27, p. 22).

Under the proper conditions, such as clear, non-coercive written agreements and the tendency to keep one's word, employees (researchers) seek out and accept responsibility and exercise self-control and self-direction (McGregor, 1960). Policies like these are more likely to develop a climate of trust. Distrust and coercion was demonstrated in the past few years of federal regulatory activity, when more sanctions were imposed in 20 months than in the 20 years prior (Brainard, 2000, Feb 4). And, Congressional activities in 1997 (and those since) were attempts to put a system promoting distrust and coercion in place, *i.e.*, more rules, more direct supervision, and (redundant) criminal punishment provisions. These actions appear to have been attempts to enhance political capital (see Joe Kennedy's prepared statement to the U.S. Senate Committee on Labor and Human Resources, U.S. Senate, 1994, Jan 13, p. 3-4). And, Campbell (1999, May 28) quotes a university IRB official as saying "I think it is more than just a coincidence that the Inspector General releases this damning report about IRBs last summer (referring to DHHS OIG 1998b; see also Campbell, 1998, Jun 12), Congress holds a hearing about it, then all of a sudden OPRR comes out with this flurry of suspensions," p. A30).

[234] For example, very few baby sitters slap kids around, but if a few are caught (or staged) on videotape and these tapes are viewed on news programs, talk shows, and in court rooms, a whole new industry is born: miniature portable, wireless cameras, and a whole new level of surveillance, fear, distrust, and, the not-so-new (over) drive to profit.

Diverse Voices Offer Similar Reasons for Change

The authors of the DHHS OIG reports and similar documents have concluded that the IRB regulatory system is in need of reform, and diverse voices have identified similar problems and offered similar reasons for and suggestions about them. These voices include the following: OPRR, 1999; NBAC, 2001; NIH, 1999; Monastersky, 2001, May 21; Greenberg, 2001, Jan 19; Brainard, 2001, Jan 12; Brainard, 2001, Mar 9; Brainard, 2000, September 13; Wheeler, 1991, Dec 4 (who quoted long–time regulatory observer and Yale professor of law, medicine, and psychiatry Jay Katz as having called informed consent "a charade"); Burd, 1994, Feb 9; AAUP, 2001; ACHRE, 1995; Brainard, 2000, Feb 4, Brainard, 2000, Mar 17, Brainard, 2000, May 30; Brainard, 2000, Sep 13; Campbell, 1997, Sep 12; Campbell, 1998, Apr 3; Charo, 1999, Jun 25; Charo, 1999, Mar 26; GAO, 1996; GAO, 2001; Geertz, 1988; Gray, 1982; *Institutional review boards: A system in jeopardy*, 1998, Jun 11; Hayes, Hayes & Dykstra, 1995; Healy, 1999, Jul 30; NBAC, 1997; OHRP, 2001, Jan 10; Okie, 2001, Aug 6; Pence, 2001, Jan 12; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1981; U.S. House, 2000, May 3; Punch, 1998; Tropp, 1982; and Wheeler, 1991, Dec 4.

"IRBs review too much, too quickly, and with too little expertise" (DHHS OIG, 1998b, p. *ii*)[235]. "This system was created to deal with a simpler research environment," says Arthur L. Caplan, director of the Center for Bioethics at the University of Pennsylvania (as quoted in Walker, 1996, Nov 8, p. A29). Caplan continues, "The

[235] Members of a review board at Columbia University, for example, were overwhelmed when asked to review a study on xenotransplantation (Walker, 1996, Nov 8).

volume of research proposals has gone up, the pace of scientific activity has increased considerably" (p. A29). In addition, some researchers and universities have acquired a financial stake in the growing number of studies sponsored by private industry, Caplan says, raising concerns about conflicts of interests. Some argue it no longer makes sense to give university officials, whose institutions depend on money brought in by government-sponsored clinical research, so much of the responsibility for maintaining the ethical standards of research. "The local character of these panels is more and more dubious," given the "amount of money at stake," says David J. Rothman, professor of social medicine at Columbia University's College of Physicians and Surgeons, and a member of that university's IRB (as quoted in Walker, 1996, Nov 8, p. A29).

This perceived need for reform (DHHS OIG 1998b; Brainard, 2000, Sep 13; GAO, 2001, and others) is based on problems such as those found to be inherent in bureaucracies, *i.e.*, the system is slow moving and reactionary, with a bias toward over-regulation, overly complex and ambiguous federal regulations, and even more ambiguous institutional renditions of them.[236]

At the institutional level, (and based on the proliferation of rules there), distrust of researchers and coercion appear prevalent. And as mentioned, inconsistencies across IRBs exist, at least in part due to the localized nature of the IRB system, and perhaps enhanced by the transience of faculty/scholars. Finally, problems are apparent with new

[236] Brainard (2000, Mar 17) states "Although the board [Duke's IRB] tinkers more with the wording than the substance of proposed experiments, some researchers at Duke and elsewhere say clinical research has become so specialized that IRB members—especially the community and medical-student representatives—lack sufficient expertise to adequately evaluate risks posed by research proposals" (p. A31). Robert Califf, chief executive officer of the Duke Clinical Research Institute, which coordinates multi-site clinical trials in 50 nations, said "All over the U.S., you have amateurs reviewing professionally

areas of research that are not covered under the rules (as shown in the gene therapy cases, particularly Gelsinger) and new/emerging/re-emerging unobtrusive methods (many have argued unduly) restricted by the rules (see AAUP, 2001). Several views, critical and others, are desirable in attempting to gain an understanding of the system (an understanding that would be likely enhanced by direct observation). That understanding must surely precede any intelligent attempt to effectively (by any dogmatic standard) reform the system. Compared to what it took to develop, maintain, expand, and entrench the system, it appears it takes much more effort to reform (or eliminate or ignore) it. And, to eliminate any parts of it will require, it appears, substantially greater effort than the more frequent but still somewhat rare[237] "lateral revisions" (what we might call minor rule changes that don't "really" increase or decrease the burden of the regulation nor change the effects of it in any significant way; *i.e.*, change for the sake of change, activity for the sake of image). But to convince people (researchers and regulators) that it *can be eliminated* will, it is likely, take the most effort of all. (I recall a story about, I believe, W.K. Kellogg. When asked how much money it takes to get into the cornflakes business, he replied, "To build the facility? SX million. To get people to buy them? Three times as much.")

Even with the widespread voluntary adoption of regulations by institutions (at least, supplying the text that "constitutes" adoption), many research settings do not adhere to the Common Rule (45 C.F.R. § 46, 1991), intentionally or not. Some may

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done clinical research." as quoted in Brainard (2000, Mar 17, p. A31). For historical perspectives, see O'Connor (1979).

[237] Mostly there is talk rather than action, which probably produces a positive effect on the process.

interpret the Rule in any given situation differently than regulators or lawmakers intended, or fail to apply the Rule in instances when regulators would, and so on. Additionally, there certainly must be some degree of intersubjective disagreement among various IRB members, discontinuity with change in the board chair, outside pressures, etc.

Still the larger questions are not related to *how* we have come to accept, expect, dread being treated like incompetent, immoral idiots by power-crazed jackasses[238], but *why*? Adorno (1989a, p. 133), states "conformity has replaced consciousness" and observes advice that is valid every day is idiotic (see Adorno quote below, p. 233).

Risks of Over-regulation

Charo (1999, Jun 25), professor of law and medical ethics at the University of Wisconsin at Madison, and a member of the National Bioethics Advisory Commission (NBAC) asks:

> How many people have been used in studies that lacked the basic protections of the Common Rule? Nobody knows, because no law mandates the collection of data on human subjects used in research. How many of those people thought they were patients rather than research subjects? Nobody knows. How many were injured or received substandard care? Nobody knows. How many of them paid, privately or through their insurance, for the privilege of being unwitting subjects? Nobody knows. (p. A64)

[238] The term "jackass" has a fairly specific meaning in this usage. "Jackass" is used to describe, generally, a male (a brother, cousin, friend, or more rarely an uncle or father, or close colleague) or a collective of both genders (often applied to politicians, police, regulatory boards, etc.). It implies the person or entity is being excessively stubborn and obstinate, and is *acting* stupid. If the person is *actually* stupid, s/he is generally referred to as a "dumbass" rather than a "jackass." These definitions and their nuances hold in Oklahoma and somewhat beyond, though I'm not sure of the outside boundary of the vernacular region (see Zdorkowski & Carney, 1985, re; vernacular regions).

Given that criminal charges are rarely brought, even in medical trials, and there is no explosion in civil damage suits, it appears that these questions are slightly paranoid, especially as they might be applied to the "minimal risk" conditions of much social scientific research "treatments," *i.e.*, involving *participants* who are not *patients*. While vigilance is perhaps good, paranoia is debilitating. I would counter Charo's questions with (perhaps) paranoid ones of my own: How many studies aren't attempted because of stifling regulation? How many researchers have given up attempts to study sensitive issues, unlawful activities, protected classes, the important fringe? How many times? How many people might have been helped if regulation hadn't prevented certain studies?

Within the IRB system, it is not apparent that decisions are based on widespread observation of the system. No data exist because (virtually) no oversight exists.[239] How can we expect to understand a system such as the IRB if we can't even look at it closely to see how it operates?[240]

IRB decisions about sanctions, "needed" rule changes, new (marketed as better by regulators' definitions) procedures, etc., are often based on emergency responses to various pressures. These pressures are often political ones, those induced and perpetuated by media and spin doctors. This may contribute to over-regulation, *i.e.*, over correcting after an atrocity or compliance violation is discovered and becomes

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[239] Ellis in testimony before U.S. House Subcommittee on Human Resources, (see U.S. House, 1998, Jun 11), stated [OPRR] files "are replete with examples of human subjects involved in research that are not formally protected by the twin protections of IRB review and informed consent. These are very frustrating cases for our office because our authority stops the moment we determine that there are no federal funds involved" (p. 52). We might presume that once the "authority" stops, so does observation, *i.e.*, investigation, at least on the federal level.

[240] See footnote # 54, p. 48, re: my own application status at the OUIRB.

public (see Koski's comment in footnote # 178, p. 164, regarding hammers and thumbtacks). And (process based) "compliance" has replaced (purpose based) "protection" as the most salient set of issues—a simulation in which the process obscures the purpose.

The prevalent belief that regulatory systems, including IRBs, cause little if any "real" harm by over regulating is dangerous (see O'Connor, 1979, who compares research regulation with that of business, stating "The record of federal attempts to regulate business is hardly encouraging as a model to be followed," p. 226). Too much regulation *is* the preferred error when the health and safety of human subjects of research (overwhelmingly patients) are involved, to be sure. But as indicated, that situation is uncommon; punishment here has been generally for violations of rules, not harm to people. But just because too much regulation may be preferable if a true dilemma should exist, that does not render over-regulation harmless (see O'Connor, 1979), and the harms are exponentially higher when the problem is system-wide, and invisible. Further, news of atrocities and abuses has increased the tendency toward more (over) regulation. As mentioned, rules don't work to give values to those who don't already have them, and lack of rules doesn't take a person's values away. Yet, when a researcher defaults to what is perceived as a more doable study (*i.e.*, more doable under the burden of too many and too many ill-fitting and/or irrelevant rules), this defaulting may be harmful. (See my questions in answer to Charo, p. 231 above.)

Adorno (1989a) states "The attitudes which the culture industry calls forth are anything but harmless. If an astrologer urges his readers to drive carefully on a

particular day, that certainly hurts no one; they will, however, be harmed indeed by the stupefaction which lies in the claim that advice which is valid every day, and which is therefore idiotic, needs the approval of the stars" (p. 134).

The system as it presents itself at the OUIRB appears oftentimes to stifle rather than facilitate the pursuit of knowledge (academic inquiry, at least), but the hegemonic (positivistic) discourse also promotes "thinking-in-a-box-ism" in a place where that kind of non-thinking should be discouraged, rather than prescribed. Who can blame researchers, especially students, for following a path of least resistance, especially in the face of all the encouragement they receive in that regard? The "real" pressure to finish one's program of study, and tendencies to follow the path of least resistance are anti-educational. Why should we expect students indoctrinated in this way to become "educated" later? [241]

It appears we "really" need to do something, and it seems apparent no one else cares as much, has as big an incentive, (is in as much "danger") or is as qualified as the researchers themselves. Reform of the system perhaps, then, begins with reforming our own attitudes about the system, and about reform. And an acknowledgement of, no matter how confusing, painful, or exhausting, the "real" nature of things.

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[241] Punch (1998) reports some professors argue students should abandon the classroom in order to "knock on doors, troop the streets, and join groups;" they should just "get in there and see what is going on" (as Punch cites Howard Becker advising a bemused British student asking what "paradigm" he should employ in the field). Qualitative research may be seen as potentially volatile, even hazardous, necessitating adequate preparation before someone is allowed to do field work. Punch recalls this position was strongly advocated by John Lofland at an ASA seminar on participant observation, where he "virtually demanded a certification of competence before the researcher be let loose in the field" (p. 157). Punch argues for the "get out and do it" perspective and warns against "leaning too far toward a highly restrictive model for research that serves to prevent academics from exploring complex social realities that are not always amenable to more formal methods" (p. 157). And Denzin and Lincoln (1998a) suggest "too much critique will stifle this [qualitative] project" (p. 410).

Chapter Seven: SINS in Qualitative Research Endeavors, Individual Effects

"For the present, it will be sufficient that I repeat to you what I have said before about our two minds. One is our true mind, the product of all our life experiences, the one that rarely speaks because it has been defeated and relegated to obscurity. The other, the mind we use daily for everything we do, is a foreign installation." don Juan, to Carlos Castaneda, quoted in *The Active Side of Infinity*, p. 9 (emphasis in original).

Habermas (1984) termed the third part of his model of reproduction "socialization" in which social identities, motives, and expressions of the self are altered and developed. Ideas about the individual-in-society will be explored in this chapter. Adorno (1989b) says,

> Human beings find their 'roles' in that structural mechanism of society which trains them to pure self-conservation at the same time that it denies them conservation of their Selves ... The all-powerful principle of identity itself, the abstract interchangeability of social tasks, works toward the extinction of their personal identities. (p. 270)

In terms of method, Forester (1993) argues for the exploration of concrete social interactions, i.e. promises, threats, agreements, deals, conflicts and so on. Forester, along with Foucault (1972), utilizes textual interactions for study, as will be done here.

Relevant Aspects of Qualitative Research

As established, qualitative research implies an emphasis on process and a search for depth of understanding of perceptions, meanings, interpretations, and behaviors, in contrast with the measurement of the quantity, frequency, or even intensity of some externally defined variables (operationalizations, most prominently). I focus on those

aspects of qualitative research that make the phenomena very difficult to control, predict, or standardize.[242] Much qualitative work is designed to detect SINS. It is an area of the "real" world where (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS (here obvious methodological examples include ideology critique, resistance readings, observing, surveying, and interviewing—especially about how one goes about ordinary ways of living and reasons offered about why, etc.) are perhaps more apparent to qualitative researchers—it is the qualitative researcher's *area*, *i.e.*, a relatively common part of their work, to discover, describe, discuss, and/or deconstruct (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS. The kinds of SINS on which a researcher may focus, and what the researcher does with the SINS (describe, deconstruct, defend, debunk, etc.) varies, contributing to diversity (and many different labels such as critical theory, ethnomethodology, textual analysis, participant observation, etc.) in qualitative research approaches and results.[243]

Individual qualitative researchers use a wide array of interconnected methods, and the enterprise is a creative adaptive process (Denzin & Lincoln, 2000, and numerous others cited herein, including the work of Van Maanen, Agar, and Punch). It

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[242] Scholars in the social sciences and humanities are "reporting similar run-ins with IRBs," Brainard (2001, Mar 9) states. "The projects in question include oral-history interviews, survey research, anthropological fieldwork, and journalistic interviews" (p. A21). "Some researchers complain that IRBs are reviewing research projects that are exempt from review, or that they are delaying the approval process for projects that should be exempt" (Brainard, 2001, Mar 9, p. A21). It is perhaps because qualitative methods (interviews, surveys, anthropological fieldwork, etc.) are difficult to control, predict, or standardize that they should be exempt, and that any attempt to regulate them will produce (as I have argued) "real" data contamination and legitimate researcher complaints.

[243] See Smith (1988) who proposes skeptical pluralism as a way of making sense of human communication and knowledge about it, as an alternative to the laws/systems/rules trichotomy (Cushman, 1977; Cushman & Pearce, 1977a). Smith categorizes modern philosophies into four styles: phenomenal

is inherently impossible to know in advance exactly what will be done or found in qualitative research (see also discussion, Chapter Six, re: application form difficulties, p. 174-185, herein). If new methods are needed, they are created, often parts of existing methods pieced together or used in new ways. All (or some) of this often occurs retrospectively. The qualitative researcher engages in what might be called "emergent construction" of the study, in terms of both content and method. Qualitative research is *inductive*, the research process cannot be formulated in detail in advance. It is this creative discovery process that, while increasing the difficulty of regulating it, greatly contributes to the scientific value of qualitative research. Much qualitative research is conducted in the course of doing quantitative studies, although this activity is often not considered (therefore not labeled) "research." Via this (lack of) labeling, a very "real" exemption is created.

What is an organization? Schutz (1973, especially p. 16-17) focused on the meaning interaction has for the participants, and Berger and Luckmann (1966) contend that reality is constituted by the participants, i.e., participant meaning is reality. Foucault (1972) takes a step to the position that discourse actually constitutes organizations. Foucault (1972) also puts forth a useful framework for illuminating various aspects of organizations, including what he terms "discursive formations." This would suggest that researchers have more power to deconstruct the IRB process, in the literal sense, than they may presume they have. The process is constituted, as Foucault

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(focused on things, empiricism), operational (focused on thoughts; operationalism), naturalistic (focused on actions; emotion), and phenomenological (focused on words; reason).

(1972) contends, through discourse (and certainly the IRB system relies on written texts). Therefore, regulators cannot "really" accomplish the process without the researchers' cooperation, i.e., researchers have to play along (and research participants, too) in order to make the regulation process work. In this way, power to regulate is given rather than a given but this distinction does not often rise above the horizon of awareness. (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS such as "operating for the greater good" and perceptions of the IRB processes as being "necessary" or "unavoidable" are apparent.

Schutz' (1973) ideas are related to the work of Habermas (truth as intersubjectivity, 1987, p. 71-72) and Goffman (frame analysis, 1974). Lived experience is "intersected by world time, biological time, and social time, and is sedimented in the unique sequence of an articulated biography" (Schutz and Luckmann, 1973, p. 103). Mead (1934), according to Schutz and Luckmann (1973, p. 42-43), is to be given credit for having analyzed the "reality structure" of the relationship between physical objects and human action and the manipulation of those structures. Mead's (1934) idea of the "manipulative zone" supports the description of the lifeworld offered by Schutz (1973, p. 208). Mead (1934) set forth the idea that meanings are not individually determined but are derived through social interaction. Meaning, like power, doesn't occur in a vacuum, *i.e.*, power is given and meaning is made, as described above. They (power and meaning) are *negotiated* in the discourse, through what Foucault (1972) has described as the "relationships of power."

The shared group meanings make up the world of individual actors, and these shared meanings provide the framework in which action is carried out, although they do not cause or fully determine behavior, Mead (1934) contends. These ideas are related to the IRB system in that they describe the "common world" of the IRB system, the shared meanings among and between regulators and researchers, the (overwhelmingly textual) framework that indicates what actions are "supposed" to be taken by an individual, etc. It is particularly crucial in a regulatory system that shared meaning exist for the participants, especially the (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS (such as the mysticism embedded in beliefs that "rules are good," "following rules is good," "rules are needed," etc.), with gradually more and more layers of interpretation (whether or not a certain rule is a good rule is, who must follow which rules, etc.) heaped on. And, it is essential (for the system to work) that power be given to the regulators. This may be a source of researcher justification and rationalization for "bending" the rules, *i.e.*, circumventing various processes, occasionally talking (officially or not, whether considered reasonable or not, and from any side of a controversy) about the absurdities of a system.[244]

Emerging issues. Situations developing in the research arena, for example gene therapy and stem cell research, require new labels. This is a right generally extended to regulators—even when the researchers themselves during the course of their work and

[244] With respect to the stem cell controversy for example, Douglas Johnson, legislative director for the National Right to Life Committee, told the Los Angeles Times, the NIH "may think it can protect itself by requiring that the embryos actually be killed by someone not receiving federal funds, or by requiring

in their applications or elsewhere first suggest terms, the endorsement, positioning, and vilification of terms is a function of regulators (along with, most often subsequently, the press). In view of Foucault's (1972) position that institutions are actually comprised of discourse, labeling, categorizing, and characterizing phenomena are especially strong sources of power.[245] Examples of labeling activity in the IRB system include special discursive constructions such as "informed consent" and *The* Common Rule, Multiple Project Assurances, etc. Regulators construct these, define them, "acronymize" them, and implement them, and researchers accept them as required without much regard for whether or not they are necessary or how much they restrict research and/or affect the findings of research.

The initial creation of rules and definitions, and the subsequent interpretations of them comprise the vast majority of the communication activity involved in this system, and many of these socio-historical structures are considered as "real" concrete physical objects by individuals, as obvious, and unquestionable, and (the focus of this chapter) mostly, self-evident. Further, as Deetz (1995) points out, "To the extent that a person uses [a] codified form, he or she implicitly consents to the values and processes by which it was formed. The potential interest-laden value debate is thus suppressed in the face of the neutral and natural" (p. 136).

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the federally funded researcher to clock out when he kills the embryos, but these would be subterfuges and do violence to the clear intent of the law" (as quoted in Andrews, 1999, Jan 29, p. B4).

[245] For example, Davis (2000, Aug 12) suggests the label homosexual "perversion" says as much about society as it does about science.

Other Relevant Theories and Observations

Many of these (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS can be seen and have been reported by others, including the findings of the AAUP survey conducted in spring 2000 (AAUP, 2001).[246] The survey responses indicated:

> Some researchers gave good marks to their campus IRBs for drawing their attention to ethical issues and for improving their proposals. Others reported excessive delays in review of researcher proposals, failures of IRBs to follow federal regulations that apply to survey research and oral history, and members of IRBs having little familiarity with social-science research compared to what they know about clinical and biomedical research. Some worried that the regulatory structure could improperly restrain freedom of inquiry and the pursuit of knowledge, and others claimed that it had done so already. (p. 3)

A (complete) lack of ambiguity (impossible of course) in the system is sought by regulators, consistent with Weber's observations about the goals of bureaucracy and McGregor's description of the Theory X view of the capabilities and culpabilities of people. Even researchers, often frustrated by a lack of clarity in the rules, seem to want a lack of ambiguity and more consistent interpretations. This contention is supported by Schutz' notion that people may enjoy the simplicity regulation brings.[247]

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[246] The AAUP report is the result of meetings held in 1999 and 2000 involving representatives of the American Anthropological Association, the American Historical Association, the American Political Science Association, the American Sociological Association, the Oral History Association, and the Organization of American Historians. The primary purpose of the meetings was to explore the experiences of social scientists in the IRB regulatory system.

[247] Schutz and Luckmann (1973) state "The social stock of knowledge transmitted to the individual relieves him of the necessity of 'independently' solving a whole series of important everyday occurrences. As a consequence of this, the individual has in principle the possibility of turning toward 'new' and thus not-yet-solved problems that are also perhaps not even recognized. This is not just the case for 'new' problems in everyday life. More importantly, such an unburdening allows one to turn to non-everyday problems. Making use of this opportunity to acquire new knowledge 'independently' is in turn socially conditioned. Because the prevailing social stock of knowledge frees every individual from finding 'independent' solutions to broad provinces of typical everyday problems, one could in principle assume that new elements always flow out of subjective, more or less 'independent' solutions to 'new'

Goffman's frames. In the social interaction/social construction area, Goffman (1974) points out various ways that primary frames can be transformed or altered, and analyzes the way experience is organized for individuals. (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS may be considered "primary" frames (see Goffman, 1974, p. 21-39), *i.e.*, many aspects of the IRB system "are neatly presentable as a system of entities, postulates, and rules" (Goffman, 1974, p. 21), and "allows its user to locate, perceive, identify, and label a seemingly infinite number of concrete occurrences defined in its terms" (p. 21). Frames may be created through discourse, and are at least mostly invisible to the participants themselves in the day-to-day lifeworld, even if they weren't always so, *i.e.*, frames are learned, so when they were first being learned they were more visible, perhaps.

Goffman (1974) adds, when writing about primary frames, that the person is "likely to be unaware of such organized features as the framework has and unable to describe the framework with any completeness if asked, yet these handicaps are no bar to ... easily and fully applying it" (p. 21). As mentioned earlier, when considering active consent, and the systemic processes that render coercion unnecessary, the worker's own *self*-understanding of his/her experiences becomes central (see p. 59, 99, and 224).

Questions useful in considering these aspects of the IRB system (in addition to those provided by Foucault, see Appendix A, p. 344) are provided by Forester (1993): "What makes possible or impedes a worker's finding out information at the workplace,

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problems, into the stock of knowledge" (p. 298). These ideas speak to the notion of self-regulation and its prominence in that they suggest we (sometimes necessarily) default to rules by choice.

challenging rules or norms, or expressing needs, feelings, his or her identity, way of being?" (p. 131) Answers to these questions aid understanding of the ways SINS operate in the IRB system, for example, why don't researchers challenge norms? Express needs? Reject the ridiculous?

Schutz and Adorno: Relief and sanctuary. One of Schutz' notions is particularly relevant to the IRB system as it relates to individual researchers. Schutz and Luckmann (1973) state, "The social stock of knowledge transmitted to the individual relieves him of the necessity of independently solving a whole series of important everyday occurrences ... more importantly, such an unburdening allows one to turn to non-everyday problems" (p. 298). Adorno (1989a) says "each product [of the culture industry] affects an individual air; individuality itself serves to reinforce ideology, insofar as the illusion is conjured up that the completely reified and mediated is a sanctuary from immediacy and life" (p. 130). We erect and respect (and eventually become blind to) the bars. We "contain" ourselves.

This freedom not to think is an example, even if troubling in other respects, of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS described by many of the theorists mentioned here including Adorno (1989a, p.132) regarding the SINS related to the adoption of the "vacuous, banal, or worse" culture industry); and Schutz, (1973, p. 3-4) regarding the SINS of experiencing things in the world as self-evident and/or unavoidable, and an overall lack of questioning. In addition to the more common use of stereotyping (Lippman, 1922) as it

is applied to people, I believe that we also stereotype systems (*i.e.*, social structures) and for the same reasons we stereotype people: in order to make the world more manageable/comprehendible/simpler/easier. One might say, for example, " IRB (or any) regulation works." If the person convinces him/herself that it is true, s/he doesn't have to think more intensely or directly about human protection (or whatever a particular regulation is about). Following the rules (the means) becomes the (relatively simple) end. Brings relief (Schutz). Is a sanctuary (Adorno).

Values and rules. Gadamer (1960/1989) maintains we cannot escape the historically conditioned character of our own understanding of texts, laws, rites, and other objects of hermeneutical study. We cannot approach objects (life or science) in a value-free, undistorted context[248] (see also Deetz, 1978). In other words (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS, in this case in the form of values, are present in every researcher's worldview (by virtue of his/her person-hood) including the perhaps desirable SINS such as humanity, compassion, trustworthiness, etc., whether discussing structures of the lifeworld, discursive formations, or values; whether conducting quantitative, qualitative, rhetorical, critical analysis or some other analysis; and whether the researcher acknowledges the presence of his/her values or does not.

[248] We could attempt this, but it would be pointless as one person's value is another's vice; one's protection, another's intrusion. Abortion v. individual freedoms and capital punishment are examples. Life is liquid and local, and universals don't work to describe it very effectively. This may be especially true where values/morals are concerned.

Values are more deeply held (in the heads and hearts of individuals, *i.e.*, intrinsic phenomena), perhaps because they are more "readily available" (rules are extrinsic, found in books or on websites, or somewhere apart from the individual). Further, we "write" our own values, we control them (even when we don't think we can or don't exercise control). Ordinarily, most of us have much less control over the writing of rules. And, finally, we always control our own compliance with and interpretations of the rules, again, even when we don't think we can or don't exercise the control.

Therefore, people act most often on their own (local and liquid) values, and (most times) tolerate (for some reason and to various degrees) the rules (*i.e.*, attempts to standardize personal values, set them in concrete with the expectation that concrete will stay put, and, perhaps, that jackhammers don't exist). Meanwhile, IRB members maintain the fairly strange idea that they are somehow affecting the research environment in the intended way (regarding the ability of the system to establish and meet process goals, see GAO, 1996 and 2001; NIH, 2001, Jun 26, and 2000, Jun 5; ACHRE, 1995; AAUP, 2001; and DHHS OIG, 2000b), and in a positive way, even thinking they (the regulators and the processes) are necessary for the safety of research participants and patients. This demonstrates confusion and is delusional, on the part of the IRB members, but even more curiously, on the part of the researchers who "go along" with procedures that are (often and often clearly) bizarre.[249] Institutional IRB

[249] Rose (1986, Oct) addresses both the values-as-more-immediate-than-rules issue and the ease-with-which-we-participate-in-our-own-subordination observation. "Historically torture has been a tool of legal systems, used to get information needed for a trial or ... to determine guilt or innocence" ... "In other words, torture didn't come into existence to give vent to human sadism" (p. 38). Edward Peters, author of

members are not, I argue, significant to the *purpose* of regulation, regardless of the control they demonstrate over the *process*. Values are most related to the regulatory purpose, and, as with values, *purpose* is therefore more familiar to people. The purpose enters our psyches on an emotional level, it makes good sense to us, it "seems right." Rules, on the other hand, are related to regulatory *process* and are endured rather than embraced, not desired, tolerated at a more superficial level. Rules are less salient than values. Therefore, processes are (generally) *followed*; purposes are *felt*. IRB members don't *affect* researchers and participants (*i.e.*, they don't change what is *felt* toward participants), rather they have *effects* on them (they change what is *done*). The *process* is often criticized for creating problems including problems that have harmed research participants (see Campbell, 1997, Sep 12; 1998, Apr 3; Brainard, 2000, Feb 4; 2000, Mar 17; 2000, Jul 21; 2000, Sep 13; 2001, Mar 9; DHHS OIG, 1998b, 1998d, 2000b; GAO, 2001; Gray, 1982; AAUP, 2001; Whyte, 1987; O'Connor, 1979, and others).

Individual Effects

Alvesson and Deetz (1996) reason that if identity is socially produced, it will be relatively stable in homogeneous societies, but as a society becomes more fragmented and/or more simulated, *i.e.*, the discourse becomes less and less connected to any "real world" reference, identity-stabilizing forces are lost. While suggesting the possibility of tremendous freedom and opportunity for dominated groups, this idea also suggests that

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a book about torture (quoted by Rose, 1986, Oct) says "the institution of torture creates sadists; the weight of a culture is necessary to recruit torturers" (p. 38). Rose (1986, Oct) adds, "What's horrifying is how easily you can persuade someone that he is working for the common good" (p. 39). She uses Milgram's (1963) experiment as an example.

the lack of stability may lead to naturalization strategies in which people voluntarily cling themselves (concede to; contain themselves within) consumer identities (we are what we have), corporate identities (we are what we do), academic identities (we are what we think we know), etc.[250] (see also Willmott, 1994).

With respect to an individual researcher's social and moral obligations, Punch (1998) states, "On the one hand, there is the nature of the researcher's personal relationships with people [s/he] encounters in the field. On the other hand, there are the moral and ethical aspects related to the purpose and conduct of research itself. In effect, how far can you go?" (p. 166). Neither academic programs nor the regulatory system itself seems to be able to make this clear or reasonable.

Student researcher exemption. As a member of a qualitative methods class, I witnessed the problems of many students in the class who had not yet gained approval at the end of the semester for their class projects, even though their applications had been made, generally, a few months earlier. According to the authors of the rules, students are generally exempt from the IRB process.[251] What "real" reason exists for

[250] I see this as very similar to children following rules. We "know" children are "growing up" when they stop (their sometimes incessant, nearly always cumbersome) whying, *i.e.*, questioning of authority. (Slowing down on tattoos and piercings are further signs). When, and if, they begin to acquiesce to what we dominators (adults) know is best (dogma) and when they stop succumbing to peer pressure (usually different dogma) they are termed "more mature." This is amusing in the face of IRB regulation: Very well educated, highly-dominated adults, behaving as obedient (mature) children, *i.e.*, not challenging authority or creating trouble or conflict, succumbing to peer pressure parading as professionalism.

[251] Section 5 of the OUIRB policy handbook states, "In most cases, class research projects which involve human subjects and which are conducted by students as exercises to learn how to conduct research do not require review by the IRB-NC. However, both students and their advisors and instructors are asked to inform themselves of the requirements associated with the use of human subjects in research projects such as maintaining confidentiality and obtaining written informed consent to participate in the study before the project begins to protect subjects from physical and/or mental harm, from putting themselves at risk of civil or criminal liability, and from revealing sensitive aspects about their own behavior. Class

this (lack of) reasoning? What reasoning makes the exemption of students reasonable? None.

First, this exemption appears to indoctrinate students in a way contrary to the goals of education in general, and IRB procedures and the perpetuation of them in particular. The exemption policy suggests to the students (and faculty) that IRB rules are frivolous formalities rather than essential protections. Exempting students from the process *marginalizes the purpose*. Second, it renders the student's data unusable for future projects, "teaching" what might be called "academic wastefulness" or "inefficiency," or another exercise in "class project futility."[252] Finally, and most important, the policy doesn't do what it is "intended" to do, i.e. protect human subjects. Unless extraordinary circumstances exist, what prevents an IRB from acting quickly (*i.e.*, within a week or two) on proposals involving minimal risk to human subjects? Using no unprotected classes? Where no treatment is involved? Why are such studies reviewed at all?

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research projects which are conducted with an expectation that the results of the research will be made public through publication, including publication in a thesis or dissertation or presentation at a meeting, must be reviewed and approved by the IRB-NC before the project begins. In addition, all class research projects which involve protected groups as defined in 45 Code of Federal Regulations Part 46 (*i.e.*, special populations, such as, but not limited to, fetuses, pregnant women, *in vitro* fertilization of human ova, children, prisoners, and persons institutionalized as mentally disabled) must be reviewed and approved by the IRB-NC before the research can begin.

[252] These contrary indoctrinations, wastefulness, inefficiencies and goal-missing may happen all the time, but they are not good reasons to (continue to) perpetuate them. Similarly, the adage "it's easier said than done" (which is almost always true) is inadequate reason for inaction, as is "I can't do it by myself." This last statement is also likely true in terms of accomplishing things, but one can *start* alone.

Concluding Remarks

As discussed elsewhere, the central (legitimate) foci for protections of human subjects of social science research involve matters of privacy, confidentiality, and informed consent. Invasion of privacy issues are addressed with the assurance of confidentiality. But, as with most rules, they are impotent. Even assurances with the best intentions are not absolute. Sometimes, it should be acknowledged, "people who participate in research have to accept a considerable measure of exposure, particularly if the popular media pick up on the research" (Punch, 1998, p. 176).

Assurances of absolute anonymity such as these are at best precarious. To assert that no harm or embarrassment will come to a participant is somewhat like making a promise "to always be there," walking out the door, and being killed by an oncoming truck. There are some promises we can't make, life and death being what they "really" are. This speaks too about the liquidity and locality of promises themselves. Promises, like regulations, have more to do with intent than prediction. More to do with immediate context than remote control.

Chapter Eight: Conclusion

"We are much less Greeks than we believe. We are neither in the amphitheatre, nor on the stage, but in the panoptic machine ... is it surprising [then] that prisons resemble factories, schools, barracks, hospitals, which all resemble prisons?" Michel Foucault, *Discipline and Punish: The Birth of the Prison*, p. 217, 228

Regulation is, inherently yet relatively, restrictive, cumbersome, and myopic. Pursuant of "ideal" forms; focused on standardization. One-best-way absolutism. Bars.

"Every historical period has probably had its particular equivalences of traditionalists, modernists, critical theorists, and postmodernists, those who lament the passing of a purer time, those instrumentally building a future, those concerned with disadvantaged segments and the direction of the future, and those seeing fragmentation and decay mixed with radical potential" (Alvesson & Deetz, 1996, p. 193).

The IRB regulatory system has reached and passed any possible point of diminishing returns, and moved to the creation of detrimental effects. How important is it that we stop participating in our own subjugation, marginalization, and domination, in, at least, the IRB system? It appears that (in this little IRB slice of the world) if we wish to continue to observe the natural world and report what we see in it (*i.e.*, to continue with qualitative methods, it is of critical importance to dismantle major portions of this system, including local "more rigorous" interpretations of federal rules (see p. 181 and 198). We must re-focus on "real" concerns that involve "real" and rapidly expanding risks such as conflicts of interest.

IRB Purpose, and Mine

What are IRBs "really" doing for the benefit of human subjects of qualitative and survey (non)treatments? My experience (not that much of it can be mentioned here in any specific way; in lieu, see quote from AAUP, 2001, p. 241 herein.) suggests that local IRBs convolute the process for researchers, infringe on their rights to conduct free inquiry, and contaminate the natural world. Further, IRBs are not offering "protections" to human subjects of these treatments, mostly because none are needed.[253] Informed consent, for example, has no bearing when the (qualitative) researcher and participant are necessarily "being ordinary people" as Sacks (1970, as compiled by Jefferson, and included in Atkinson & Heritage, 1984) might put it.

The pursuit of process (regulation) has surpassed the pursuit of purpose (protection). My purpose here is to deconstruct the (many) regulatory apparatuses via the illumination of the self-regulatory behaviors present. I believe this is the most expeditious route to deconstruction and eventual deregulation. Regulators won't deconstruct themselves; they need our encouragement and assistance. And, we must first *see* what it is they do to us (the SINS) before we will muster much effort to stop it.

[253] In the past two years of searching, I have not found cases in which social scientists have been sued for damaging a survey or interview participant or a person who was being observed by a social scientist. I have searched Google, OHRP, NIH, Chronicle of Higher Education, and other sites using the following search term combinations: "lawsuit social science," "lawsuit social scientist," "lawsuit social science privacy," and "lawsuit privacy." I found no information relevant to the kinds of "problems" that might need to be solved regarding the protection of interview and survey participants and observed persons. Further, nothing I have read in the materials I have used in this dissertation and in the related research indicates a lawsuit, a pattern of complaints, or any other indications of problems in this area. See also footnote # 37, p. 27, and Gray (1982) specifically p. 331 re: studies without risk. Because "no risk" and "very low risk" (and defined in terms of both number of risks and degree of risk) are labels used by the federal government (and have been used for decades), it is logical to presume categories of "no problem" and "very low [number of/degree of] problems" might result.

Qualitative Research Issues

Long-term as well as immediate effects of both federal and local regulatory decisions are important to consider. To think about, write about, and *act* about. Science is, as is religion, politics (see Forester, 1989, p. 3-4). Like religion before it, positivistic science became and both have mostly remained, to use Marx's words, the opiates of the intellectual and marketing masses for the past few hundred years.[254] "Common" sense may be coming back into vogue (Alvesson & Sköldberg, 2000), and if it is, situations (including regulations) that "seems odd" to people may begin (or continue) to matter more. Positive connotations of terms such as "grassroots" and "town hall meetings" are evidence of this possible regaining of respect for the local, the "common knowledge" or "common sense."[255] It would appear the programs designed to enhance self-respect (especially trusting and acting on one's own knowledge and judgment) might be working to enhance the social capital of skepticism and dissention. To demarginalize, de-objectify critics. To embrace and enjoy (rather than only sometimes tolerate) diversity.

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[254] Marx' actual words were, "Religion is the sigh of the oppressed creature, the heart of a heartless world, and the soul of soulless conditions. It is the opium of the people" from the preface of *Contribution to the Critique of Hegel's Philosophy of Right* (1844). And this quote has been invoked in diverse ways. According to *Bartlett's Familiar Quotations* online, "The formulation has invited many variations, including the observation by Edmund Wilson in *Letters on Literature and Politics* (1977): 'Marxism is the opium of the intellectuals,' and, according to psychiatrist Thomas Szasz writing about drugs in *The Second Sin* (1973): 'In the United States today, opiates are the religion of the people'" (See http://www.bartleby.com/66/23/38123.html, accessed May 25, 2002.)

[255] An event recounted in a book by BBC reporters David Edmonds and John Eidinow (2002) involved Ludwig Wittgenstein, Karl Popper, and Bertrand Russell. During a disagreement with Popper, Wittgenstein allegedly waved a poker at Popper, was told by Russell to put it down, and Wittgenstein complied. In reviewing the book, Trachtman (2002, Apr) said the poker waving was "a warning, to all of us, that whenever philosophers, or scientists, or any other intellectual elite claim to possess some truth that runs counter to common sense, they are talking nonsense" (p.124). Trachtman (2002, Apr) says that Wittgenstein talked about formal languages, like those of philosophy and science, saying that because

Many investigators, particularly students and faculty with whom I've spoken from 1999 to 2002, have said there is something more interesting they would explore if they "could get it past the IRB" or they are breaking the rules occasionally, or circumventing the process in order to do something of greater interest and importance to them, and, at least perhaps, to all of us (suggesting for a moment that some findings are useful!). The "need" for these regulatory processes that control many types of minimal risk studies is rarely if ever supported. But, it isn't questioned in meaningful ways, either. If the need exists, we don't know it. Participants need no protection from unobtrusive researchers. Researchers need protections to their entitlements: they are entitled to their values, their perspectives, and (most all) their pursuits. But, according to the rules, researchers are required to alter the normal experience (the lifeworld, as described by Husserl, Dilthey, Schutz, and others) of the people being studied (by telling them they are being studied, and in other ways) even though those people are not at risk in any significant way or number. Extremely few participants in social scientific studies are in need of *protection* at all, as protection already exists when considering the remedies available in criminal and civil courts. And for those who are at risk, it is, I argue, the decisions of researchers that are critical, and not the rules or lack of them.

In explaining to participants that a study is being conducted, the explanation alters the researcher and the researched, *i.e.*, the "real world." Once they are affected, researchers are, simply, no longer studying the "real" world, but an altered research environment—an artificial world comparable to those of the social psychological

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these languages "follow strict rules and rule out contradictions, they lack common sense and give a misleading view of the world" (p. 135).

experiment and the social survey. And it is altered for no good *purpose*: not the fear of harming humans, but the fear of harming the rules, the *process*.

I'm skeptical about changing, affecting, manipulating the natural environment and referring to the data gathered in that environment as "empirical" data. This situation is the result of what I have called "required but unnecessary" regulatory requirements (see p. 36, 48, 185, and 202 herein; also GAO, 2001; AAUP, 2001). Along with every layer of federal regulation also come the attendant local interpretations, often described as (virtuously) "more rigorous."[256]

The treatments qualitative researchers ask for permission to inflict include observing people in their natural world, asking people questions in conversation, or recalling relevant aspects of one's own life in what might be called retro-observation,[257] reflexive methods (Alvesson & Sköldberg, 2000) and other activities. This is maybe the central reason for the unmanageability, the "unregulat-ability" of qualitative research, the lack of *a priori* knowledge of what will be data, who might supply it, when the data may become useful or how long it may remain so (see concerns about IRB rules requiring the destruction of anthropological and other data in AAUP, 2001), or even what the point of the studies might ultimately be.

These treatments are at least as innocuous as survey research. However, quantitative and survey protocols are perhaps more familiar to IRB members, and meet

[256] This was mentioned by a local IRB chair several times in an open forum in Fall 2001. The chair used the words "more rigorous" and, in this context, that means more restrictive and rigid.

[257] It can be argued that as an ethnographer " ... one never really leaves the field because the experience itself may be elaborated and experienced throughout the ethnographer's life" (Crawford, 1996, p. 163). This is "real" life, and impossible to control, "regula-torily" or otherwise. As Klockars (1979) and others have suggested, researchers should be skeptical of well-meaning bureaucrats and their (inevitable)

with less apprehension, resistance, or scrutiny.[258] Perhaps IRB members (most of whom demonstrate more familiarity with quantitative methods than qualitative ones[259]) are more comfortable with the quantitative researchers standardized, formulaic, and precise specification of the procedures in step-by-step and moment-to-moment detail all rendered in an explicit, articulated (if unmakeable) promise. For example, a researcher's local experiences, accurately remembered, reported, and rendered relevant, are not only adequate for use as data (see Hayano, 1979; Foucault, 1980; Crawford, 1996; Denzin & Lincoln, 2000), but often highly desirable. And these particular activities, along with many other qualitative research endeavors, "need" no regulation. (Of course, having a higher ratio of qualitative researchers on IRBs would most likely help everyone involved.)

Some of the problems with trying to regulate qualitative research are apparent in the application form (see application form analysis in Chapter Six, p. 174-185, herein). For example, the methods in the qualitative approach are developed (as are the questions) as the process continues. This "reality" considerably confounds any attempt to describe the study in advance.[260] When a researcher is looking *at*, rather than looking *for*, it is impossible to be precise in the same way as in a clinical trial or other

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attempts to make rules and guidelines. We should all be wary of them, and of our own tendencies to follow them.

[258] Qualitative methods may be disorienting to those who are unfamiliar with them, because "they require stepping out of one's usual framework for making sense of daily life and stepping into the unfamiliar world of others. Consequently, the results of qualitative research may require reconceptualization of mainstream values and perspectives or the examination of the underlying reasons for those perspectives" (Denzin & Lincoln, 2000, p. 11).

[259] The numbers of each would tend to support this as well. NBAC (2001) reported that 75 percent of current research reviewed by IRBs is clinical and biomedical in nature.

[260] Field observation differs from some other models of observation in that it is not only a data-collecting activity. Frequently, perhaps typically, it is a theory-generating activity as well (see Lofland & Lofland, 1995; Denzin & Lincoln, 2000).

hypothesis-driven approach in an application process. Regulation makes this type of study "undoable" (or the regulation is undoable, as is the point here) whether it is the *intent* of regulators (to be impossible) or not. The processes related to regulation corrupt "real world" data whether that is acknowledged by regulators and researchers or not.

Given the rules that have been in place for more than 25 years, I argue that many "natural" settings have been (historically and continue to be) "altered" rather than "natural," and the degree to which this may be true is largely dependent upon the affiliation (or lack) of the researcher and the associated IRB regulations or lack of them, and (perhaps most important) the interpretations of the regulations by local IRBs, *i.e.*, what the IRBs required that particular researcher at that particular time to do that may have altered the natural ("real") environment. Even though the treatment may not have changed significantly, if at all, the environment did (because of the rules), and therefore the results did. Maybe significantly. Maybe not. These rules have and continue to work against what are perhaps the least risky forms of research (see also Geertz, 1988). It doesn't seem possible that qualitative researchers can both do adequate work *and* follow the rules (Geertz, 1988, p. 133, who speaks of the right to write ethnography being at risk).

Many qualitative methods involve no activity that is of any greater risk than that found in ordinary everyday life. In many qualitative endeavors, nothing resembling "treatment" is involved. This, I argue, is the *prima facie* case for abdicating the system. Where can there be risk if there is no treatment?[261] And where there is no risk, there

[261] If researchers find it necessary to reveal the identities of private individuals who are participants, they can make that judgment and proceed to get permission or have their asses sued off if they don't.

should be no IRB involvement by definition. Regulations may be (legitimately) viewed as required but unnecessary by many qualitative researchers (and government researchers, see GAO 2001, p. 6).

Concession, Circumvention, Contamination

Researcher concession. That qualitative research is not easy to regulate is not the biggest problem. That no one has established the need for regulation in the first place, and that very few have openly challenged a system that doesn't work are bigger problems, in my view.

As the AAUP (2001) suggests, social scientists were co-opted into the regulatory system "from the beginning," but how did it happen? Why? And why is it that some social scientists aren't? I believe social scientists opted in themselves, in part, to enhance the "scientificity" of their work, *i.e.*, to appear more legitimate in scientific terms by succumbing to the same scrutiny as the positivists. (Somewhat as several Indian tribes have become "nations" to, perhaps, "appear" more valid, more sovereign. Also, see Flyvbjerg, 2001 re: the scientificity issue.)

Some individuals (I would argue students are an especially relevant group in this situation) are susceptible to manipulation, which can lead to domination by a group or (an automated) structure. Given power by individuals, driven by (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS,

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Additional rules seem—are—redundant. If researchers don't need to use identities, then it is the case that the researcher owns his/her own experience and the IRB process becomes absurd (unless signing one's

SIMULATIONS including the anthem that conflict is negative, and fueled by tendencies toward compliance and obedience, researchers in the IRB system allow at least two forms of domination, *i.e.*, localized "parental" control of the IRB itself, as well as big-picture peer pressure, *i.e.*, researchers are dominated by the behavior of other researchers. So, in this case of IRB regulation, what works to constrain and subordinate researchers may be their own concession, based on the desire, following Schutz' thinking, to maintain a "focus on non-everyday problems" and to take advantage of the "stock of knowledge" as presented by regulators (what might be called "unacknowledged knowledge"). Relieving vital risk and responsibility, one can take solace and defense, if necessary, in "I was just following rules" mentality.

In workplace structures, conflicts are minimized and eliminated with managerial tactics; (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS of the "don't rock the boat," "be a team player," "follow the leader" (even if over the cliff) variety help create there's-no-problem-here illusions. Certain SINS are reinforced (notions that conflict and rebellion are good are rarely among them, even if it is said that they are welcomed) with doctrines including job enrichment programs, TQM, organization as family, and dress-for-success formulas,[262] and even research methods classes/seminars, when the leaders advocate/require participation in an unreasonable system, and describe it as "inevitable" and, simultaneously, unreasonable. These models often contribute to illusions (*i.e.*,

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own consent form seems reasonable).

[262] Some may use different equations on purpose (I say dress for comfort, plan for success, for example) and some (researchers) do things differently (or wrong, in the IRB view) because of the *way* they were

simulations) of well being, development, progress, happiness, satisfaction, "rightness," etc. More bars.

"Most members of culted organizations may have choices, but organizational coercion keeps them from being exercised" (Arnott, 2000, p. 93). Culted employees (or conditioned researchers, I suggest) "have turned over their right to make decisions" (p. 93; see also Schutz & Luckmann, 1973, who says, " ... the prevailing social stock of knowledge frees every individual from finding 'independent' solutions to broad provinces of typical everyday problems ..." p. 298; see also Adorno, 1989a; Horkheimer & Adorno, 1944/1972; and Habermas, 1971).

Qualitative researchers, in particular, have conceded too much for too long. They have conceded so much in fact that they can no longer do their work under the rules. Perhaps inventing circumventions is somehow better, easier, involves less conflict, causes less trouble, etc. than casting off an impotent system. I would agree that in the short term, it is. But not overall. Eventually the "real" world must be "really" encountered, *i.e.*, experienced.

However, in the IRB system, researcher assimilation, in a sense meant by both Baudrillard and Rand, is nearly complete in that *compliance* is held as equal to *protection* and as virtuous, or at least inevitable. Compliance, though itself often difficult, remains the path of least resistance, and the need for regulation is too rarely, nearly never questioned. There is no whying. Assimilation into the regulatory system *seems* inevitable, adding to the likelihood it will be. Baudrillard (1983) makes a similar

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indoctrinated rather than a lack of indoctrination. Left to our own instincts, we might, perhaps, dress "better" and "protect" more.

case about U.S. colonization, "At the beginning [of the process], a moment of stupor and amazement before the very possibility of escaping the universal law of the Gospel. There were two possible responses: either to admit that this law was not universal, or to exterminate the Indians so as to remove the evidence. In general, it was enough to convert them, or simply to discover them, to ensure their slow extermination" (p. 20). So it goes with thinkers, as with Rand's "[people] of the mind" (Rand, 1957/1992, particularly John Galt's speech, p. 923).

Researcher circumvention. Circumvention, public, private, and corporate[263], occurs frequently in the face of "required but unnecessary" regulation. Being required to gain informed consent when employing no treatment (observations and/or involvement of non-identified [and therefore non-] participants) is an example of the problem and informal "local" solution, *i.e.*, circumvention.

Informed consent provisions require a form that specifies, among other things, that the subject may withdraw from the research project at any time. How does this work in research involving participant observation, for example? And issues of sampling, *i.e.*, people who "wish" to participate may vary substantially from those who are simply observed. As Weppner (1977) observes, this threatens the continued existence of much "street-style" ethnography (p. 41). When Powdermaker (1966, and recalled in Punch, 1998) was confronted with a lynch mob, was she supposed to ask the

[263] See Overland, 2002, Feb 19, regarding pharmaceutical company plans to conduct trials in India, "at a time when such research is facing increasingly tough oversight in the United States" (Daily News). This activity would appear to support Deetz (1995) who states "Global economies weaken all state units" (p. 27).

participants to stop the proceedings while she delivered informed consent forms? Or, worse in my view, was she simply to avoid writing about her experience? Gaining consent is inappropriate because activity is taking place that cannot be interrupted. Researchers (especially qualitative ones, the primary focus of this analysis) may (of necessity, in order to do the kinds of work they do and preserve the study environment) circumvent the *process*, but, much more rarely, the *purpose*. Even if one doesn't trust researchers themselves to do what is "right," there are already laws against abusing others (research participants or not). And, there is very little risk, if any, *inherently* in observational/survey/interview methods; even if researchers using these methods *wanted* to, there is little they could to do actually harm people.

Contamination of the natural world. In much fieldwork there seems to be no way around the predicament that informed consent—divulging one's identity and research purpose—will "kill many a project stone dead" (Punch, 1998, p. 171). And if it doesn't kill the project, as it can be argued it did in my case and countless others,[264] it can drastically skew the data and results. And it causes in my estimation, a loss of "spirit" for this kind of research. As I have argued, the study is no longer of the natural world, but of an altered research environment. Data becomes contaminated, often with socially desirable behaviors and explanations, accounts and attributions of participants. The natural world becomes a much more contrived one. IRB requirements so

[264] I had the audacity to *try* it. Many, I surmise, would argue based on the response of the OUIRB to my applications, there is little reason to try, and this is evidence of the level of self-regulation, or "unacknowledged knowledge" that operates in this system.

contaminate data that to gather it would be pointless. It could be likened to adding a 50 percent margin of error to a quantitative venture, or finding significance at .0000001.

Even when/if the natural world can be preserved as a place of study, sometimes (as in my case) researchers are simply regulated out of business, *i.e.*, the process becomes impossible to accomplish and/or permission is simply never granted; the application is ignored. "One need not always be brutally honest, direct, and explicit about one's research purpose, but one should not normally engage in disguise. One should not steal documents. One should not directly lie to people. And, although one may disguise identity to a certain extent, one should not break promises made to people" (Punch, 1998, p.172). I ask, how does this differ from "ordinary life" values? There is no need, indeed no *way* to regulate these values. People, including researchers, who have these values use them, and those who don't have or use them aren't affected by rules in the way the rules were designed to affect them.[265]

Gans (1982) expresses:

> The social scientist attempts to describe the world as it is, and he must therefore observe people in their normal, everyday ways. Should he hide his purpose, either by not telling them of his participant-observation role, or by asking interview questions which get at more than they seem to on the surface, he does so because he has no other alternative. If he bares all his research purposes, he may be denied access to the very society he wants to study. If he forswears participant-observation and gathers his data solely by interviewing, he can get only reports of behavior, but not behavior itself. If he is completely open about his participant-observation or interview questions, his respondents are likely to hide information from him—not necessarily by intention—by giving him access not to

[265] Though these values are "teachable" and guidelines and the experiences of other researchers would be useful for new researchers, regulation of these matters is not possible or reasonable, I am suggesting.

> behavior but to appearances; not to what people do, but how they would like their doings to appear publicly. (p. 405)[266]

It is "not ethically necessary, nor methodologically sound to make known specific hypotheses, background assumptions, or particular areas of interest" (Van Maanen, 1978, p. 334).[267] Further, quantitative researchers aren't required to reveal their hypotheses to participants. As a senior American academic at an ASA seminar on field methods put it bluntly, "You do lie through your teeth" (quoted by Punch, 1998, p. 173). The process of regulating qualitative non-treatment, minimal/no risk research must be revealed as the façade (simulation) it is. Why haven't we abandoned it before now? SINS.

Too much regulation contributes to another "real" world phenomenon. Unnecessary yet required rules (somewhat like "fascinating but unpublishable" manuscripts; see Wax, 1971, p. *ix*) and processes create a sort of underground arena of research activity, (what I call) "the invention of circumvention" techniques. Researchers engaged in fieldwork often confess to professional misdemeanors, namely the ones

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[266] This adds to the argument about the appropriateness of texts as "constitutive" data in studying organizations (Foucault, 1972, and others).

[267] Perhaps a good example of this is a study I proposed to do for my dissertation. I proposed to study the informed consent process, touted in several government and other reports as "needed." But, in order to "really" study the "real" informed consent process, the study would *have to be done covertly* for two reasons. First, it would be unduly confusing for participants to be told about a "study of the informed consent process" they are going to undergo for the "original" study in which they have agreed to participate. These participants would have to undergo my explanation, and be asked to sign the informed consent form for my study, and then would receive similar explanations and forms from the researcher conducting the "original" study. As established, often one such form or process is confusing enough (even this explanation is confusing!). Second, the researcher administering informed consent for the "real" study would very likely alter their behavior (knowing they are being watched, and specifically which behavior is being watched) with respect to administering informed consent forms and provisions. It appears, therefore, that even though the study is clearly "minimal risk" under the federal definition, and that the topic can be approached scientifically, and has been described by many people and groups as a process that needs to be studied, *under the rules*, it can't be done in the way it must be done to yield

mentioned by Wax (1971, p. 168-170) and Gans (1982, p. 405). Punch (1998) asks "what sanctions should we impose for these breaches of professional standards? Should we drum these miscreants out of the profession? That seems a rather severe punishment for coming clean on their predicaments in the field" (p. 171)[268]. As I asked earlier, what are researchers to do? A similar situation is explored by Manning, 1978, who discusses *situationally justified actions* (*i.e.*, what I call liquid and local) in the field of policing, this situation being similar to what researchers (and all of us, I would argue) face in the lifeworld. Regulations will never be able to account for every situation, and oversight can never be complete. It must be recognized that people must (and therefore do) *decide* what to do. Again, guidelines and shared experiences, *i.e., learning* how to do things is different (and preferable and possible) from acting as if we can control them.

Abusive institutional interpretations. As Forester (1983) states:

> When organizations or polities are structured so that their members have no protected recourse to checking the truth, legitimacy, sincerity, or clarity claims made on them by established structures of authority and production, we may find conditions of dogmatism rather than of social learning, tyranny rather than authority, manipulation rather than cooperation, and distraction rather than sensitivity. (p. 239-40)

The abyss between federal rules and local institutional interpretations is often huge. For example, the federal system *exempts from the process* much research that institutional interpretations *make impossible under the process* (the contamination of the

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useable data. Informed consent rules prevent (legitimate, needed, and non-risky) observation of the informed consent process.

[268] And it is important to remember what we may be doing "wrong" is not "really" wrong, but is wrong *only* under the rules.

natural world, for example.[269] Lengthy application processes even when studies are exempt under institutional rules on *prima facie* conditions are an example. Such *prima facie* conditions might include requests to interview public officials or to involve participants in observational situations in which the identities of the "observed" (somehow labeled "participants" by authors of the OUIRB handbook, Section 4.4) are not *known*, and obviously therefore, cannot be recorded. Institutional interpretations do not always accommodate federal rules.[270] Lawful or not, many IRB rules are created and/or followed by 10s of organizations, 100s of regulators, 1000s of institutions (IRBs), 10s of 1000s of researchers, and 100s of 1000s of two-legged research participants for, often, many years (also see p. 72 herein). Regardless of legality or level or duration of conformity, it seems foolish to ask people to sign a form that says they are being interviewed, or that they are completing a survey. These things are obvious. It

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[269] Federal regulators, as was mentioned, operate with a Theory Y (McGregor, 1960) mentality toward institutions (see Grob and Ellis testimony, cited as U.S. House, 1998, Jun 11; and Human Research Subject Protections Act of 2002, where "research" is defined as "clinical"). Institutional regulators on the other hand operate *à la* Taylor, assuming a Theory X (as described by McGregor, 1960) posture with researchers.

[270] According to the AAUP (2001), "Whether, in a particular instance, the risk is more than minimal is for an IRB to decide. The IRB can, and usually does, require that the researcher submit documentation to verify that the project is indeed exempt from review, and the quantity submitted can rival in bulk what is required for research that is not exempt. At the University of Nevada, Reno, the 'statement of Exemption from Review by [the] Human Subjects Committee' asked the researcher to send along with the completed statement the "informed consent form and instruments, *i.e.*, questionnaire, test, interview transcripts, stimulus material, letters of permission form sites of performance, etc." (p. 7; also see University of Nevada entry in bibliography). And the University of Oklahoma IRB policy and procedure, Section 4 provides (emphasis in original)"**THE DETERMINATION OF WHETHER OR NOT RESEARCH WOULD BE CONSIDERED EXEMPT FROM REVIEW WILL BE MADE BY THE [OUIRB].** However, 45 CFR §46.101 is clear about the categories of research (six in all) that are explicitly exempt from the policy, even when human subjects or government funding are involved. The six categories are research in education settings on instruction techniques, curricula, or classroom-management methods; research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, unless the subject can be identified and disclosure of the subject's responses could put the individual at risk of criminal or civil liability or could damage the subject's financial standing, employability, or reputation; research involving elected or appointed officials or candidates for public office; research using existing data, documents, or records, as long as these resources are publicly

seems foolish that we as researchers have to prepare a document that has to be scrutinized by a board, the members of which have perhaps never participated in, much less conducted, qualitative research. These requirements seem foolish because they *are* foolish. Many rules are inadequate, ill-fitting, and/or irrelevant when translated from medical science to social science. Some argue that informed consent procedures are unnecessary even in some clinical trials, and inconsistent in others (see Truog, Robinson, Randolph, & Morris, 1999; see also GAO, 2001, p. 3, regarding inconsistencies produced at the federal level).

In my own experience, I have seen the rules constituting the process restrict the view of the process. This is a very serious matter, and contrary to informed interpretations of relevant law.[271] Legally, administrative rules are based on several tenets. Among them, at least two are locally relevant. First, administrative rules should not contradict higher-level law such as state and federal constitutions and statutes.[272] It is in no one's best interest for local IRBs to restrict researchers' First Amendment privileges.

A second tenet of administrative law is that people subjected to the law are to be treated "the same way," however, similar to the notions of "a greater good" or

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available or the human subject cannot be identified; studies of public benefit or service programs; and research focusing on consumer consumption of food and the taste and quality of food.

[271] In the Human Research Subject Protections Act of 2002, social science, it appears, isn't considered research. In the act, "research" is *defined* as "clinical" studies, see Section 491A, Part 3(a).

[272] Such contradictory rules may be made, and in fact, may be followed for decades by thousands. However, if just one litigious dissenter (i.e., whyer, activist, troublemaker, etc.) comes along and challenges the rule, it is likely to be found "unconstitutional" and sometimes the agency that made the rule is punished. Given that "avoiding litigation" may be the strongest pursuit of many such agencies, it appears to be in everyone's best interest (regulators and the regulated) in the long term to avoid making such contradictory rules. One way the IRB system could accomplish this is for local IRBs to adopt federal rules *as they are written*. This may not completely eliminate local interpretation of the federal rules, but it

"universals in human behavior," this is an idea with very low correspondence to conditions in the "real" world. Even in the face of this system flaw, many regulators persist in attempts to write "comprehensive" rules (that pretend) to cover any situation (clinical or social) that might arise, *ensuring* (in their imagination, perhaps) that the abstract system is the "same" for any participant. Rules added to existent ones (ones that were not the "same for all" and that did not prevent crimes or atrocities) won't help. Next, nothing can be done "comprehensively" and attempts to standardize the lifeworld in such a way is often of no great consequence in meeting the purpose for "comprehensive" policies, rules, etc. (Attempts to be "comprehensive" similar to looking for universals in human behavior.) Additionally, as demonstrated in at least two situations, those with very similar proposals and requests are not treated "the same way" by the OUIRB (student exemptions and other situations described herein, including the lack of disposition of my own applications). This speaks, in my opinion, more to the nature of life than the (in)competence of the OUIRB (or others). In this regard most administrative law is set for failure. The extent to which we *ignore* this failure is the extent to which these systems work. We first build the bars, and then put ourselves on the restricted side of them. And then, we just sit there in Schutzian relief. An Adornological sanctuary.

The American Anthropological Association (2001, Feb 15), in addressing proposals made by the National Bioethics Advisory Commission in their draft report (see NBAC, 2001) states that "proposed rule changes ... could jeopardize the future of

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reduces the number of *layers* of local interpretation, and the tendency to make "more rigorous than federal" a virtue in the minds of local yokels.

anthropological research" (p. 1). A lawyer who represents academic-research institutions and who sits on the National Human Research Protections Advisory Committee, said, referring to a Maryland Court of Appeals decision regarding the use of children in studies, that all research involves some amount of risk, and that the court's decision effectively raised safety requirements for research involving children to unprecedented heights. "It's a no-risk standard," he said. "That's certainly farther than they need to go" (quoted in Curry, 2001, Sep 7, p. A32)[273]. Currently the Bush administration is requiring "agencies to ensure than any scientific results they release be "capable of being substantially reproduced" (Brainard, 2001, Sep 28, Daily News; also see description of Bush's plan, p. 2-3, herein). This of course is not a goal of many social science pursuits, and, many researchers who conduct social science research do not believe it is possible, desirable, or (as in my case) desirable to believe it is possible (critical theorists and other anti-positivists for example).

In many ways, the regulations don't fit, *i.e.*, they don't fulfill their intended purpose, and the process often produces negative affects associated with under- and over-regulation in a given context, and is very prominently featured in the regulation of social science research, and elsewhere.

IRBs, and regulatory entities generally, operate in a closed fashion (most IRB meetings are closed, for example, and local IRBs don't usually solicit input when considering rule changes, we don't vote for IRB members, etc.). These boards issue statements rather than provide explanations, and they do so according to their own time

[273] "Really," and we must hope, obviously, it is further than they are *capable* of going.

frame. Local IRBs are in no *regulated* way accountable to the people they serve, participants nor researchers.

For example, the OUIRB makes no commitments about how long the approval process takes (as the University of Texas at Austin does, see p. 134, herein), the board often answers correspondence aggregately, *i.e.*, "facelessly," without a specific voice, does not demonstrate an attitude of service to (many) students, and provides no adequate form of appeal (see OU Policies and Procedures, Section 10, Part 5; see also p. 225, herein).

So, here and now, what are qualitative researchers to do? They are marginalized and dominated, much like faculty members are by administrators, doctors by insurance companies, and lots of other "real world" horrors. I argue that qualitative researchers are a muted group, particularly students. Muted group theory (Kramarae, 1981) utilizes interpretivist/interactionist notion, based on Mead's (1934) theory of objects, that the power belongs to those who label (and not inconsistent with Foucault's ideas).[274]

Label Power

Quantitative exemption-by-label. Speaking to inconsistency in IRB regulation, given that much qualitative work takes places before quantitative instruments are used, *i.e.*, during the development of instruments, much of the "real" research conducted by quantitative researchers is not acknowledged as research, and therefore "gets past the

[274] Somewhat like the ratio of disparaging terms used to describe women to the number of similar terms available to describe men, I believe if we looked, we would find more disparaging terms (and connotations) for "rebel" than for "conformist." I might call this the troublemaker/team player dialectic. For example, on the negative side there are terms such as troublemaker, boat rocker, being difficult, or a

IRB." This is in spite of the fact that much of what quantitative researchers are doing (when developing instruments, for example), treats people as "subjects" in that they are subjected to more than being watched. This way of treating the developments of instruments constitutes what might be called an "exemption-by-label." In the "real" world, human subjects are involved, but they are not labeled as subjects because the (often very similar) activities are not *labeled* as research. Positivists often do not acknowledge that asking people questions about instrument clarity, pre-testing survey instruments, etc., is human subjects data. I'm not advocating these activities *should* be regulated, but to exempt by label rather than by treatment is a troublesome inconsistency in the system, and, of course, evidence to support a *reduction* of regulatory interference in these types of work at least as much as it provides evidence to support an *increase* in scrutiny.

Because of the lack of clarity in rules, many times researchers in the newer social sciences have not opted into the system (*i.e.*, they don't realize they are "researchers") and have not been forced to participate thus far. I have learned in conversations with people that certain departments doing very similar "treatments" are much less aware of IRB regulation. Cultural geography, civil engineering, and film studies in particular have come into my awareness in conversations during the past few years.[275] These departments have not labeled the IRB as necessary or relevant; nor, it

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critic, or a renegade, or dissenter, even "outlaw." On the other side, terms such as "supportive" and "team player" are used to describe those who conform (especially without whying).

[275] It may seem creepy, *i.e.*, SINSful, to advocate the study of people who don't know they are being studied. But, as discussed, these methods don't provide the researcher with advance warning. Anybody may say or do something important (*i.e.*, something that might become data) at anytime, and the importance might be recognized at still different times. This situation is very conducive to a blanket approach, but impossible to ask for permission specifically in advance, *i.e.*, people, time, place, etc. It

appears, has the IRB, in this case, labeled cultural geography, civil engineering, or film studies as non-compliant.

Student exemption-by-label. With respect to student exemptions, and just as institutions have opted in to IRB scrutiny for all subjects, whether the study they are involved in involves federal funds or not, where is the logic in suspending the process based on whether or not the researcher is earning course credit, *i.e.*, is a student? Aren't all human subjects of research equal in terms of deserving protection? Don't researchers have the right to pursue questions of interest without unreasonable interference? We must acknowledge the dialectic between participant rights and researcher rights exists, and there are limits to what rules of any kind can do with respect to that tension.

Assurance-by-label. In terms of providing assurances, we cannot predict to what uses research will be put. Who can define "undeserved harm," "greater than minimal risk," even "somewhat greater than minimal risk" and other equally vague terms often used in guidelines[276]. For example, when graduate students refer to a dissertation, do they mention it will be housed in a library, indexed in a variety of places, and open to all? The more sensitive the activity being studied, the more likely it is that participants will fear consequences, and the "single most likely source of harm in social science inquiry (*i.e.*, non-medical) is that the disclosure of private knowledge can

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may be years before a relevancy is established, before a little chunk of the past-lifeworld becomes data. The idea that people, when in public, are observe-able, *i.e.*, can be photographed and their actions written about, is consistent with the rules for reporters. And all of this is in addition to the need to avoid contaminating the natural environment.

be damaging" (Reiss, 1979, p. 73). Professional codes (rules) and what is considered sound advice (norms) may not be at all clear in the field, given that the "real" world is highly liquid and local. "Real life" and, therefore, the research environment must accommodate various degrees of impression management, manipulation, concealment, deception, etc. It is the job of many qualitative researchers to determine ways these activities operate (along with other SINS). And hardly can a researcher "explain" to a participant first what the study is about, and then gather meaningful (unaffected) data about these same phenomena. To even explain that "research" is being conducted adds to the level of impression management, enhanced use of socially desirable (*i.e.*, altered) behaviors and other "affectations" described. There is no process and no assurance that can make "real life" conform, no more than we can control the weather or other aspects of the natural (*i.e.*, "real") world. We can offer our own personal assurances to do the best we can. That should not be confused with absolute assurance, and certainly not with a written form, regardless of the title of that form, who demands it, or who signs it. It may be the best we can do, or it may not be, but it is not *assurance*, regardless.

Questions as labels. Basic political issues, *i.e.*, issues that many would advocate should be argued "happily ever after," are in this way transformed into (labeled as) technical problem-solving issues, according to Alvesson and Deetz (1996). For example in the IRB system, attempts to regulate how people *should* take care of other people via standardized handbooks, forms, codes of conduct, etc., are not productive. Qualitative

[276] "Minimal risk" is somewhat clear (in the federal definition) but further distinctions are more comedic than clear.

researchers and many others should be asking "*Why* am I doing this?" (*i.e.*, the application procedure, for example) rather than the technical (non) problem solving activity of asking, "*How* do I do this?" The differences in the questions posed serve to frame (*à la* Goffman) a bad system as inevitable.

Rules Aren't Values

In the context of the protection of human subjects, procedural rules do not replace nor work in lieu of values. As procedural rules are substantially less salient than values, rules are most often unnecessary (often not even known). If people have values, these procedural rules don't matter. Circumvention of rules may become the norm when the rules are not tied to a purpose, have no value, cannot be understood, etc. If people don't have values, these procedural rules don't matter, either.[277] The system—since its development, through all the debates, changes, chances to change not taken, and under the (current and past) rules—remains only as good as the conscience of researchers. (And sometimes rules become tools used to perpetuate harmful situations. See Solomon, 1985, regarding Tuskegee syphilis study; see Morley & Shockley-Zalabak, 1991, for discussion about mature organizations and constraint on innovation.)

[277] Regulation, I contend, is not "creatively" developed, *i.e.*, if I become a manager or regulator, I don't just go to the mountains to think up a policy book. Regulations are rooted in what people already *do*. That behavior is subsequently standardized into codes of conduct. We watch what we are doing, and write it down and send it to others who are thinking of developing programs like ours, for example. Rules thereby reflect the values we are using in "real" life. Rules are in this way *subsequent and subordinate* to values, rules are not an *a priori* condition of values. The reverse is more likely. Compliance to the code of federal (or other) regulation is *incidental*; it is the *moral* code of the individual that guides behavior. "Scientists, not university review boards, bear primary responsibility for protecting human subjects," Greg Koski, director of OHRP, acknowledges (as quoted in Brainard, 2000, Jul 21, p. A21).

Researchers are, as are people in general, usually (even overwhelmingly) humane and ethical. It seems pointless to ask them to write about their ethical stance in dozens of nearly identical IRB applications. Ethics are relatively stable over time, therefore this application activity is a form of redundantly inappropriate penance (and based on SINS). The system has *produced* risk in certain research areas. Especially risky to researchers. To research. To free inquiry.

Alternatives[278]

IRB members' and researchers' preconceived and perpetuated (SINS-ful) notions of research and regulation must be altered. "Social structure should grow from the bottom rather than be enforced from the top" Deetz (1995, p. 170) concludes. The irrelevant, overly restricting, often justifiably circumvented, ill-fitting, debilitating system as it relates to qualitative methods in particular must be decentered and disprivileged, from within or outside or both. Regulators (bureaucrats and other cultists), who operate in deeply entrenched systems, may be "unmeltable ethnics" (Denzin & Lincoln, 2000, p. 68), *i.e.*, maybe they cannot change. Where that is the case, the system's dismantling must begin from the outside.[279]

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[278] In presenting both critical theory and postmodern approaches, I recognize the inherent fallacy of making (overt) recommendations. By labeling recommendations "alternatives," I hope to create an important distinction. In making the suggestion (recommendation veiled as alternative) to adopt blanket assurance for researchers, I contradict basic tenets of postmodernism (*i.e.*, the future can't be planned, and who is to say one dogma is any better than another; see Huspek, 1991). I find myself in a dilemma: I can't seem to resist the urge to make suggestions I feel might improve the system, even if doing so creates the aforementioned philosophical explosion. However, because what I advocate essentially constitutes abandonment of (especially the application-parading-as-exemption) process, I feel less tension in my argument, via these relatively simple rationalizations.

[279] See "Call for overhaul" section, p. 21, and discussion about diverse voices making similar calls for change, p. 227.

The contemporary common-sense credo "It's easier to beg forgiveness than ask for permission" implies two pervasive ideas: first, *prima facie*, permission is (at least perceived as) difficult to obtain; people experience some degree of apprehension and/or anxiety about it. Second, forgiveness is (again, perceived as) easier to obtain, perhaps because the acts for which one might seek absolution (if not salvation) were great, pretty good, worked out all right, were reasonable, at least defendable, somehow understandable. Justifiable. As I have argued, researchers (and others dominated unnecessarily and unreasonably), circumvent (justifiably) *processes*, as distinguished from *purposes*.

Rather than attempting to fix the process (by abandoning rather large portions of it in some cases), researchers have tended to avoid making changes in the rules, as reported in GAO (2001), and DHHS OIG reports (in particular 2000b).[280] In considering the IRB system (and other regulatory entities) we may regularly see (then quickly look the other way) violations of the process (rules), for example reports may be late and paperwork backdated, bids may be split, etc. Much more rarely do we see violations of the purpose (people). Even more rarely do we look away from harmful situations. This is supported by the talk surrounding sanctions, *i.e.*, federal sanctions were (in no way to minimize the exceptions) overwhelmingly for non-compliance with rules rather than "harming" people (Brainard, 2000, Mar 17; see footnote # 136, p. 117, about U. of Virginia, Duke, and Chicago). Notably, the sanctions were nearly the same

[280] "Minimal progress" has been made in overall reform of federal regulations, according to DHHS OIG (2000b). IRBs have no more flexibility nor are they more accountable for results. Too much IRB attention remains focused on review responsibilities of "questionable protective value" according to this report and others cited herein.

in terms of breadth, depth, and duration, whether non-compliance with processes was alleged, or a death reported. In other words, federal regulators don't seem to consider the severity of the (sometimes actual) "crime" when assessing punishment, much like the institutional regulators don't appear to consider treatment types when assessing protocols (though I have heard it said that while the OUIRB makes little distinction between asking questions and injecting drugs, they do make a Big Deal about the details of questions, occasionally raising opposition to questions about occupation, marital status, and general income level on questionnaires). This opens the door to the argument that the focus of local IRBs is the maintenance of the flow of funding or the avoidance of litigation long before any issues of human protections. This is, I argue, in large part to the acknowledgement on the part of regulators including Koski, Ellis, Grob, and others quoted extensively herein who have said even though sanctions are issued, rarely is the problem abuse of a patient (and never in what I've learned has an interview or survey participant claimed damages, certainly substantially more rare than the already rare abuse of patients in medical trials); it is almost always a paperwork (*i.e.*, a process) deficiency. If, on the other hand, abuses were frequent and severe, I do believe IRB members would be focused on those participant concerns related to the problems (not to imply they would devise relevant rules, but they would most likely be talking about the problems as they relate to the abuse as they see it). And once again, if the government or an IRB defines something as "NO RISK BEYOND THAT FOUND IN ORDINARY LIFE" then what is it they see themselves "protecting" against?

Alternative One: Blanket Assurance for Researchers

Because there is (virtually) no direct regulatory oversight of the research process, a blanket assurance system for researchers would more accurately reflect what is "really" going on in the research environment (*i.e.*, perpetuating a less abstract simulation, perhaps).[281] Researchers, on their honor, carry out their protocols as approved, or they don't. Only the researcher and the participant, in a liquid and local negotiation, directly oversee (or undersee or see at all) the process. Researchers, including (if not *in particular*) students, *should* be able to readily explain how they handle issues involving privacy and confidentiality, and one "blanket" explanation of the researcher's policy, adequately ambiguous, is adequate. Even researchers, because of the liquid and local nature of the world, cannot predict every situation that might occur, and subsequently ask and gain approval for each situation, each new idea that emerges along the course of the study. Researchers (those who interact with participants) must be able to explain their intentions to specific participants at specific times using their own values as guidance. Participants are not without their own abilities, specifically the ability to use their own values in agreeing to participate or not, or to continue participation, etc. In other words, the notion of "needing to be protected" is patronizing in many cases. Finally, it must be acknowledged that that law itself is a liquid and local phenomenon.

[281] This would appear to have another benefit: reducing the size of the local IRB workload. Somewhat similar to unsupervised probation, the rules that must be followed for the structure to be successful are (mostly) clear, and (again, mostly) no force or coercion is (or has been for some time) necessary. If we as a society can make simplified systems for unemployed persons and convicted felons, it "seems right" to do it for graduate students and faculty researchers. And, the precedent exists at the federal level. With no formal oversight system in place and few assessments made about oversight activities, adherence to federal regulations is based more on trust than on other forms of evidence (see DHHS OIG, 2000b).

Prominent in the federal rules is the requirement that the informed consent of participants be obtained and a record of that consent maintained. I support this part of the process. Informed consent may or may not be a written form. Allowing researchers to develop the consent *process* to suit the needs of the particular participants balanced with the needs of the researcher is the only sensible, "doable" process based on the nature of life. A blanket "oath" is the best (and only) way to go about this.

Alternative Two: Making Important Distinctions

Researchers must counter the labeling power of regulators, making clear the distinctions between patients and non-patients (participants), doctors and researchers, therapy and research, and (see below, Alternative three) exempt vs. exemption process. Further, these terms must be used as specifically as possible, and new labels developed as needed. Researchers themselves have much power to label, and it should be used. If a coalition of professional organizations[282] (such as the AAUP, anthropology groups, oral historians, and others joining each other) encourages their membership to label their studies "NO RISK" and "EXEMPT UNDER FEDERAL RULES" regardless of whether an application form has a space for it or not, is an example. All of these alternatives are especially important for social scientists, and most of all for qualitative researchers employing unobtrusive methods.

[282] *i.e.*, an actual coalition of groups, involving many individuals

Alternative Three: Avoid Attempts to Regulate Liquid and Local Phenomena

We must avoid the pretense that regulators can successfully define for the world (and for participants in particular) what constitutes protected and non-protected classes, sensitive and non-sensitive topics, and obtrusive and unobtrusive research and other phenomena too slippery to standardize. Whether an organism is a fetus, a child, or a prisoner is generally discernable (pregnant women are somewhat less so). Researchers, overwhelmingly, would not have difficulty distinguishing these classes. However, what an individual may consider sensitive or obtrusive is not regulate-able.

What exemptions are is not necessarily the problem, but *the interpretation of what can be done in the process of exempting* ("the process of exempting" is an apparent oxymoron, but it is literal in this situation) is problematic, *i.e.*, it doesn't work *as an exemption*. One may consider just the time to make the application to "real"-ize it is not an exemption, for example. Exemption, if not left to the fine devices of the researchers themselves (this system is in lieu of admission that this is "really" the case, of course), should be post-card simple: Will participants be identifiable? Any kids? Anybody who's incarcerated? Any feti involved? Neither researchers nor regulators should be troubled by anything more and federal law allows for such a system.

In fact, to do more than "really" exempt, when that is the label used, produces at least one problem. Both students and their professors new to the area of regulation may misinterpret the label used with the widespread meaning of the word "exempt." That is, student researchers and their advisors may take the word literally, and this would be acceptable if they were reading/operating under the federal regulations, but taking the

word "exempt" at face value in local interpretations is not acceptable. (Students can be thrown into a "research misconduct" inbox and have their projects, including dissertations, held up until the "problem" is settled, for example.) If a student or faculty advisor or researcher finds the local policy unclear, a logical place to seek clarification would be to read the federal rules on which the local interpretations are based. The federal exemptions might lead a student or other researcher to conclude they are exempt and fail to make an application to the local IRB. In this case, potentially, a very costly mistake. What "seems right" (in this case following federal law) is "locally" wrong. Federal exemption is not local exemption is not exemption in the common definition of the word; the word then becomes a very slippery, if not meaningless, term. And, how are the readers of these texts to know words don't mean what they "usually" mean?

Alternative Four: Insist Treatment be the Focus of IRB Consideration

Somewhere along the way, science lost to politics. Faculty lost to administrators.[283] Researchers lost to regulators. Doctors lost to the insurance industry. And so on and on we see the victories of capitalism. Scientists, doctors, faculty members, and researchers are required to do things that don't "seem right." Things that don't "make sense." (For example, preparing syllabi before meeting a class, prescribing or failing to prescribe certain medications or treatments, etc.). These losses are alarming, but not as alarming as the fact that scientists, doctors, faculty, and researchers

[283] See Snyder (2000; AAUP's *Footnotes* Fall 2000's cover story), in which Charles Osgood of Princeton University is quoted as having said in 1914, "perhaps no more important question could be investigated now than that of the faculty's power to govern the purely academic functions of the college or university"

are mostly conceding. There seems to be no "fight" on the part of researchers. Maybe we just don't have time. Productivity is winning over possibility (see Lyotard, 1984, re: performativity). Research is losing to regulation, via concession, circumvention, and contamination.

Micro-management of minutiae: A reason to live. Debates in IRBs too often focus on minutiae. "Oftentimes, IRBs get very mired in consent forms," Jeffrey P. Kahn, director of the Center for Bioethics at the University of Minnesota-Twin Cities. "That should not be their main focus. They need to keep their eyes on the prize, which is the protection of subjects of research." Federal rules require consent forms to contain many details, "so that's an easy place to spend time," Kahn said. "To try to assess risks and benefits is a more difficult and ongoing challenge" (as quoted in Brainard, 2000, Mar 17, p. A-31; see also list serve postings from University of Pittsburgh Medical Center[284] and University of Utah's online handbook which includes a five-page consent template, and a 25-page assurance document (MPA), the University of Texas at Austin's consent template has grown from less than two pages to more than 10 pages in two years and the Texas MPA from 19 to now 23 pages long; OUIRB doesn't have one available online (as of May 2002), but the University of Oklahoma Health Science

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(p. 1). Osgood states that this power "declines in many institutions to almost nothing" and is "more gravely menaced every year" (p. 1).

[284] For example, a message from the operations manager at the IRB at the University of Pittsburgh Medical Center, dated August 30, 2001, broadcasts "After reviewing the standard language in the template consent form in the IRB Reference Manual, it was determined that it is inappropriate for a research participant to contact the Institutional Review Board in the event of a research-related injury. A change has been made under the Compensation for Injury section to remove the reference to the IRB as well as the telephone number. Please refer to the Sample Consent Form in Chapter 8 for further information."

Center does (see entry in bibliography for website); it is 10 pages long (see University of Utah listings in bibliography, and also University of Texas, University of Oklahoma, etc.).

The number of research proposals that review boards assess each year has at least tripled in the past 20 years (in part due to the "inclusionary" definitions of who "must" participate), while the number of boards has remained about the same, says Charles R. MacKay, an NIH scientist studying the effectiveness of review boards for the agency (quoted in Walker, 1996, Nov 8). The GAO (General Accounting Office) reported in March that in some cases, panel members spent only one to two minutes on each proposal[285] (Walker, 1996, Nov 8). Brainard (2000, Mar 17) concluded the IRB members operated more like manuscript editors than researchers. This situation also illustrates Foucault's ideas about texts as constitutive of organization.

Campbell (1998, Apr 3) quotes Milton Goldberg, president of the Council on Governmental Relations, representing 140 universities that account for 90 per cent of the federal research grants to academe was quoted, "IRB time is precious; regulatory refinement of the type suggested here [loosening rules for expedited reviews of some kinds of research] allows the IRB to focus more attention on research in which the risks to human subjects are greatest." I would agree that there are surely more important matters for consideration than the wording of a form for a study that should be exempt under federal rules.

[285] Of course, this is two minutes too many in many cases.

Alternative Five: Passive Rebellion (Researcher Self-exemption)

Engaging in passive rebellion (in this case, ignoring the local IRB system in favor of following federal rules), and encouraging others to do so is the kind of dissent that is dis-allowed by managerial domination (Alvesson & Deetz, 1996; Willmott, 1993, and the works of Marx, Horkheimer, Adorno, and others). These are the debates that are silenced by "following rules is best even when rules are bad" (SINSful) mentality (though I argue it isn't "really" *thinking*).[286]

(Regulators) allowing researchers to exempt themselves (if researchers *choose not* to take their entitlement to exemption under federal rules) would represent a shift on the part of local IRBs from a Theory X to a Theory Y (McGregor, 1960) stance. Researchers are capable of reading and interpreting rules; they are capable of exempting themselves from the process. If or when they have questions about exemption, they can always choose to go to the IRB for clarification (making IRB "really" useful). Many federal government agencies (including the FDA and NIH) seem to agree, saying that IRB time is precious and should focus more attention on research involving the greatest risks to humans (see Campbell, 1998, Apr 3, ACHRE, 1995). Researchers conducting no-harm studies should for the benefit of the researchers and regulators, (and "no-harm" being what it is, the regulated, too) should be *exempted* from the application process. The American Political Science Association (APSA, 2001, Feb 14) states "expedited reviews [are found] to be expeditious in name only" and that "to insist that [research

[286] In other words, it is frightening to think that we ask "Who would ignore the rules? That would be crazy" rather than asking "Who would follow crazy rules?"

posing no threat to participants] should be subject to even administrative review unnecessarily burdens both investigators and the review process" (p. 2).

A blanket assurance document from the researcher could certainly include a commitment that informed consent will be obtained and records of it maintained (this is also reasonable for the researcher's own self interest), that the researcher would comply with all federal and state laws as they pertain to the treatment of others. If the researcher is in doubt as to whether a class of people is protected, or whether an issue is considered sensitive (although, as I have argued this can only be decided locally, by the person actually answering the questions, or refusing to) the researcher can make a formal request for a ruling (interpretation) to the local IRB (and rendering another benefit: IRB members can have a focus on more substantive protection issues, thereby better serving researchers and the researched). Questions such as treatment and class of participants does not require a lengthy application for the researchers, nor any review on the part of the IRB. Further, a (truly expedited) process would also reduce the tension between what the local IRB typically considers "expedited" and "exempt" to mean, and what researchers consider the meanings to be. Further, the long stream of applications could be greatly reduced if the researchers were "really" exempted, the provisions for which are already in place at the federal level (OHRP Human Subjects Policy specifically states institutions *may* review studies which are exempted under federal provisions, but that the review process is not required. See http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc95-02.htm, accessed May 25, 2002. Also see Campbell, 1997, Oct 24, for an example).

Additionally and significantly, the "need" for this regulation has not been established. The process is debilitating in the rather obvious ways just mentioned, *i.e.*, burdening both regulators and researchers, as mentioned, by contributing to self-censorship of ideas and draining the energy from researchers. Not just the physical energy the process requires, but the system drains enthusiasm from researchers. Most seem to agree the process is not needed, yet we allow it to persist.

It is important to point out that *everyone* was exempt until about 25 years ago (with the passing of the National Research Act in 1974). And, the rules that were put into place in the 1970s were limited in scope. These rules were only expanded to include *nearly everyone* in 1991, barely more than a decade ago. And it is also important to note that before the rules were put into place, the biggest atrocities by far were perpetuated by researchers working for the federal government (see ACHRE, 1995). This "inclusionary" trend (now invasionary) on the part of regulators does not work and is not needed.

Miscellaneous and Mostly Missed Opportunities to Address "Real" Needs

The following ideas may be useful attempts to change the system. First, a registry of projects that are exempted might be useful to universities, for statistical purposes and decision and labeling practices. Next, local IRBs might dismantle portions of their oversight mechanisms that are unneeded in order to invest in re-directing efforts to situations involving risk to participants such as conflicts of interest, as mentioned. And, IRBs might become more concerned with other "problems" such as hammering

out policies to protect researchers who (boldly) report findings that anger drug companies or other researchers, etc. (see Blumenstyk, 1999, Apr 9). There are pressing issues (perhaps), but these are not the issues consuming the energy of the system.

Finally

I advocate these alternatives, and want to make one more point about the centrality of treatment in regulation. As stated, if there is no treatment, there "needs to be" no regulation. The language here is important, *i.e.*, there is a difference between "regulation is not needed" and "there needs to be no regulation." Government, including institutional IRBs, is obligated to create the least restrictive environments rather than the most invasive and impotent policies.

Social Darwinists feel government should intervene only when necessary to remove barriers that limit *laissez-faire* practices. Progressives on the other hand, hold that government should accommodate—ideologically, legally, and financially—the pursuit of social progress (Hamilton, 1998). These ideas are apparent in current IRB regulatory debates, and progressives are ahead in defining what the IRB system of regulation "should" be doing. The (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS of positivistic, progressive dogma are operating, demonstrated by researchers' self-censoring, conforming, compromising convolution of their programs of research and their rights to free academic inquiry. These compromises may be much more severe and costly than the researchers wish to or even can acknowledge. Many, apparently, don't see the bars.

The pretense of value-free inquiry for the human disciplines is over, and researchers now struggle to develop situational and transsituational ethics that apply to any given research act, or across similar acts. This doesn't "standardize" the system, though; ethics can only be applied in more limited ways than (perhaps) we wish, *i.e.*, we might be able to "bridge" across a farm pond, but not the Pacific. We must make our expectations more realistic. Neither regulators nor regulations are suited for or to this task. Researchers themselves, in conjunction with their participants, are the most qualified—morally, intellectually, politically, and practically—to decide *exactly* what to do in a particular situation.

Who could be opposed to reducing oppression? (Or apple pie, moms, or libraries?) Who would oppose lessening the workload on both IRB members and researchers? Being able to devote more time (researchers, professors, *and* regulators) to the consideration of protection issues surrounding research that carries greater risks to humans?

Maybe qualitative researchers themselves (as mentioned earlier) have concerns about how "scientific" their work "appears" to be. I argue that abandoning an impotent IRB system does not lessen the scientific nature of qualitative research. If anything, it works to energize the field, currently demoralized by watching free inquiry going the way of (dripping into the same sewer as) academic freedom and rights to intellectual property[287].

[287] In my case, as an example, denial of permission to conduct inquiry at all, *i.e.*, my applications were "essentially" ignored. Further, I was prohibited from interviewing *public officials*—a particularly egregious, probably unlawful, certainly unreasonable local interpretation of rules.

It appears promises born during The Enlightenment and continued during the reign of positivism just haven't been kept. There is plenty that "positivism" can't do. Absolutism and standardization are flawed concepts. SINS-ful perpetuation of these regulations and practices obscure important alternatives and silence important debates (for example, use of the term "radical" when terms such as "practical" or "reasonable" are at least as appropriate).

Developments in medical science during the past 30 years are nothing short of amazing, yet many diseases remain. Life goes on; death goes on. There is plenty regulators can't do; and even more they shouldn't attempt. And, plenty that researchers shouldn't *allow* them to attempt.

We have become more diverse in the way we study human behavior. To maintain a "real" qualitative/quantitative dichotomy is no longer, if it ever was, reasonable.[288] The art is matching the right method with the right question rather than determining, with an absolutist, dogmatic, hegemonic mentality what the right method is. Questions should lead the researcher, rather than a philosophical allegiance to a way of answering (or as in the present study, describing and whying).

The case is similar for regulation. Matching the right regulation with the right treatment (the right risk), speaks to the *purpose* for regulation, rather than declaring The Process, entrenching it, and maintaining it, all the while begging the questions "Who is

[288] I have defined qualitative research very broadly with the intent that no "real" dichotomy exists in the present study. Essentially I have used the labels to indicate a continuum of research, methods, perspectives, and most importantly, treatments.

being harmed?" and "Where is the need?" "What is the *point* of this?" "HOW CAN THIS BE?"

As mentioned elsewhere, in the world of regulation eventually almost all parties to a particular regulatory system will admit it contains ambiguities and absurdities. That we have become conditioned to accept this as "natural" or "the best we can do" is a manifestation, as described, of (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS. Sometimes, regulators should do (and "really" can do) nothing. I support acknowledging rather than ignoring the limitations of rules and rule makers.

Values guide rather than rules; humanity is more basic than is compliance. The local situation, *i.e.*, the treatment, the topic, the situation, and the "needs" of the study, and a researcher's own values are parts of the formula. Generalized, and thereby often irrelevant, rules are numerators totaling zero. And, we know the effect of that on denominators. Nothing remains nothing.

The values of research participants should be acknowledged, as well. Research participation in the past may have been more altruistic. Many participants were willing to participate in studies that might benefit others, even when the potential benefit for them personally was negligible or nil. And, that might be true today (see CNN.com, 2002, May 26), except participants aren't often given that chance. Contemporary (local) clinical research is marketed, packaged, spun. Participants, particularly sick ones (because medicine is where the money is), are taunted with "potential treatment benefits" and "hopeful preliminary results." And of course, before results can be

produced and sold (published), patients (or healthy participants) must be found and convinced. This spin creates further ambiguity in the therapy-research dialectic, and contributes more to "spoiling the field" than any contribution a qualitative researcher could muster. These are concerns that should be the focus of IRB attention.[289] More and more frequently doctors own stock in companies that are "interested" in the scientific data. In earlier times, we perhaps had over-zealous doctors (or more precisely, *research* doctors) to fear. Now we have greedy, over-zealous research doctors to fear. Medical journals are in a similar predicament, the debate presented in a variety of media and especially prominent in the past decade.

Interview or survey participation will never be as risky as giving a person a drug or installing a medical device. The line between therapy and research conflict will never be as convoluted for interview and survey participants. How-to questions about the IRB application process remain, often asked by researchers in "minimal," "no treatment," and/or "no risk" situations (in methods classes and on user lists, for example). But more important by far, yet too rarely asked, are the questions about *why*.

Difficult but necessary versus required but unnecessary. Changing systems is difficult, but desirable, (and for certain kinds of minimal risk research) necessary. Opposition to existing structures occurs, according to Foucault (1980), not through assumption of the role of the universal intellectual but through that of the specific

[289] IRBs which currently review mostly social science protocols could certainly be utilized for considering the privacy aspects of medical trial proposals for example. The obvious benefit would be reducing IRB workload, in turn producing faster (even more thorough and helpful, useful) responses to researchers.

intellectual. (Earning respect on one's own terms for example, or the demonstration of one person making a difference, of being the one who "gets the cheese;" see footnote # 292, p. 293.) Foucault (1980) describes "specific intellectuals" as ordinary people who understand their circumstances and have the ability to express themselves independently of the "universal theorizing intellectual" (a "life is local and liquid" perspective). "Not in the modality of the 'universal,' the 'exemplary,' and the 'just-and-true-for-all,' rather within specific sectors, at the precise points where their own conditions of life or work situate them" (p. 126). We are too often discouraged from engaging in selective ethics, situational leadership, anecdotal evidence, gut feelings, even merit raises, seeming to prefer dogma to thought. Why? In our simulation, it is easier. We've made it "safer" to go along. Why? Even where we see the simulation, it is, sadly but evidently, more acceptable than change for most. Apathy wins.

(SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS related to the belief that interpretation is not scientific, and that leaving things to people's own judgment is bad or risky, and other "matters of subjectivity" are too often demonized, one of several somewhat obvious SINS of positivism and Taylorism. This demonizes humans (at least doubts them, *a priori*, yet we give trust, *a priori* and in perpetuity it seems, to rules, systems, and officials). Disturbingly, during manual recounts of ballots in Florida in 2000, strong insinuations were made that machines were more reliable, more accurate, and more neutral[290] than the humans making and operating them, for example.

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[290] Republican Party representatives in particular seemed to cross the line from appreciation of machines to reverence for them. And something else: Because the undercounted votes were strongly in favor of Al

Foucault (1980) says this specificity is the level at which criminals challenge prison conditions, welfare workers and clients seek to change the bureaucracy, consumers organize against corporations, and, I would add, the regulated challenge the regulators, faculty challenge administrators, doctors challenge insurance companies, people (individuals) challenge (local) (SINS) STRUCTURES, INSTITUTIONALIZATIONS, NATURALIZATIONS, SIMULATIONS. Whying should become more prominent in every discourse, according to my dogma.

I do not subscribe to the notion that some*thing* called "the greater good" exists or that standardization is possible or desirable (Nietzsche, 1968). Regulatory processes, which are purported to operate in (even *ensure* in the vernacular of some) the "greater good" cannot. Regulations *might* have a *tendency* to work *some*what for *some* people *some*times. To acknowledge this is not nihilistic, rather it is a prerequisite to better regulation.[291]

It might be at this moment in a dissertation that an "Ideas for future study" section "should be" forthcoming. However, I feel in this, and similar cases of qualitative research, that it is inappropriately risky to do so. It might be later said, given the local interpretation of federal rules, that I gathered data in a premeditated fashion (via living and talking about issues relevant to that life) rather "authentically" recalling "data."

Gore, I disagree with many assessments made that machines are not Republican or Democrat. Inexplicably, (perhaps) these *particular* machines seemed to be Republican.

[291] Postmodernism and Baudrillard's simulations have this in common: the most common critique of both is that they are nihilistic. If postmodernism says "no one can know anything" and Baudrillard says that "nothing is real," one might ask, what is the point? The point is that without an acknowledgment that the world is full of viable ideas if not absolute "positive" knowledge, and that we have the ability to alter our simulated lives, it is, I maintain, the *failure to acknowledge* that is nihilistic. Not to mention tedious. And scary.

No matter how many times we may say it, write it, read it, or hear it, most of the time regulatory systems are not "the best we can do." But they will remain "all that we have" until we acknowledge we don't want (to tolerate) what we have anymore. And that acknowledgement will only be the beginning of deconstructing the IRB system.[292] "What can *we* do?" should not, in this case, be asked rhetorically. It is time to realize the "games of power" are, or have already become, "states of domination" (Foucault, 1988, as quoted in Hindess, 1996, p. 99). There has been too a long period of contortional, conformiating compliatorianism. It is now time for, at the least, some new definitions. Perhaps a new dictionary will be next.

Who will be the Hundredth Monkey (Schell, 1982)? At what point will those for whom systems do not work stop contributing to the "requisite level of mass loyalty" to those systems (Habermas, 1975)? When will we openly, publicly, recognize the legitimation crisis in the regulation described here? When will we begin to act in public ways to change rather than conform to bad policy?

If we keep quiet about what is wrong, we are part of what is wrong.

[292] Arnott's (2000) Internet-era proverb suggests "The early bird gets the worm, but the second mouse gets the cheese" stating "culted organizations 'cut off the head' of innovators in an attempt to keep the organization under strict control ... It's the second, third, or fourth person to try a new method that finally 'gets the cheese,'" he concludes (p. 99). So far, no one has accounted for what happened to the hapless early worm.

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Appendix A

Foucault's questions and examples of analysis

Table 1

Foucauldian Analytical Framework (Adapted from *The Archaeology of Knowledge*, 1972)

Foucault's critical scheme consists of a set of questions designed to uncover potential discursive formations and, thereby, systems of knowledge, power, and ethics. He provides a heuristic system of 12 questions grouped in threes under four headings, implying that discursive formations may appear in four functional areas: objects, enunciative modalities, concepts, or strategies.
(Some examples of these phenomena that appear in this dissertation appear in bold print.)

Category (Functional Areas)	**1** Object—Determine how something becomes an object of discourse **(Development of vernacular used in IRB system)**	**2** Enunciative modality—Explore speaker roles in discursive events **(Who has knowledge & expertise?)**	**3** Concept—Explore the operative system of knowledge in closer detail **(Who defines things?)**	**4** Strategy—Confront the pragmatic functions of discursive acts **(Who do they serve?)**
Question 1	**1-a** "Surfaces of Emergence," aimed at discovering where discourse occurs	**2-a** Who is speaking, societal role or position required to speak **(Presidents, federal & local regulators, legislators, researchers)**	**3-a** Concerns the order of discursive acts; internal organization of particular groups of statements, patterns of interaction, reasoning, and expression	**4-a** Determination of what is and is not consistent with the discourse under study **(IRB's differing responses to similar protocols)**
Question 2	**1-b** "Authorities of delimitation," concerned with who has the power to *name* and define the subject of discourse	**2-b** Determination of the arenas in which discourse obtains legitimacy, the institutional sites of discourse **(Congress, handbooks, media)**	**3-b** Examines types and patterns of statements that are or are not sanctioned in or knowledge systems **(Voices of students & scientists)**	**4-b** Investigation of the relationship that one set of discourse has with another set **(Institutions' renditions of federal rules)**
Question 3	**1-c** "Grids of specification," description of the systems by which the object is defined and categorized	**2-c** Relationship of speakers to other groups and domains of objects, status of speakers in the web of human relations & objects they have legitimacy to speak about	**3-c** "Procedures of intervention," the ways in which statements are transferred from one domain to another **(Federal register, statutes, handbooks)**	**4-c** Assessment of the function the discourse serves for nondiscursive practice **(Maintenance of the status quo; Following process without regard for purpose)**

Examples of Foucauldian analysis

Example 1 (from p. 151, above)

Foucault's questions are useful in considering Glenn's text. First we may consider that Glenn is the person arguing (addressing Foucault's questions 1-a, 1-b, 2-a, 2-b, and 2-c). Next, there is *what* Glenn uses (the evidence) to make a case and then *how he structures* the argument (addressing Foucault's questions 1-c, 3-b, 3-a, 3-b, 3-c, 4-a, and 4-b). And finally, the argument about *why* Glenn may be making the argument, *i.e.*, the balance between politics and protection, the *appearance* of the safety of science and *actual, unmeasurable, unforeseeable* safety of science (Foucault's question 4-c).

Example 2 (from p. 151 and 154, above)

In the several incidents Glenn uses to support his contention that there "really [is] a problem out there," (the ACHRE report in1995 and his examples: the use of homeless alcoholics by a pharmaceutical company, psychiatric experiments on children and mentally ill in New York, FDA approval of the use of human growth hormone, implantation of fertilized embryos in patients without the consent of the donor, and unapproved use of drugs) in only the case of the implantation of embryos is one of the main provisions of the Common Rule (informed consent) addressed. And, none of the situations Glenn describes involve the two agencies (Department of Labor and the Nuclear Regulatory Commission) he mentioned as not having adopted the Common Rule, central to supporting his "problem" thesis, specifically that the gap in Common

Rule adoption matters. Foucault's question 2-a, *i.e.*, accepting who can say there's a problem, and 1-b, *i.e.*, how "problem" is defined are addressed here. Also notable in this situation is that Glenn had been an actual research participant and it is likely assumed that his experience adds to his expertise, though this too may be a SINSful assumption

Example 3 (from p. 155, above)

The following observations "answer" several of Foucault's questions, including 3-a, 3-b, 2-c, 4-b, and 4-c. First, the "results" of Glenn's research and his "legitimizing discourse" are based on the use of the GAO (1996), which was reliant in substantial part on ACHRE (1995), and both then used to build the case for Glenn's Act of 1997. Included in the series of political discourse are President Clinton's apology for the Tuskegee incident later in 1997, the series of DHHS OIG reports issued between 1998 and 2000 from the executive branch, along with the various congressional hearings conducted in close temporal proximity (and, it could be argued, in response) to each other. These activities constitute essentially a debate between the executive and legislative branches of the federal government, designed around a topic that allows politicians to show concern about "innocent victims" of research, to assume moral high ground, appear busy doing something good, important, and effective, etc.

Example 4 (from p. 155, above)

That the events listed flow from each other, *i.e.*, are temporally located near each other, is an important consideration: The release of the ACHRE final report in 1995, the establishment of the NBAC and production of interim reports by the Commission, the

introduction of S. 193 in 1997 and H.R. 3569 in 2000, release of the DHHS OIG reports between 1998 and 2000, fueled by the Tuskegee apology in 1997, and Gelsinger's death in 1999, culminated in very minor changes in the process. This series of events addresses Foucault's questions 3-a and 4-b.

Example 5 (from p. 156, above)

The section "Other political observations" addresses Foucault's questions 3-a, 3-b, and 4-b related to the order of discursive acts, patterns of statements, and relationships among groups of statements.

Example 6 (from p. 162, above)

This paragraph focuses on Foucault's questions 2-a, 2-b, and 2-c: The changes [to the IRB system at the federal level] that actually made a difference in the "real" world of research involved moving the OPRR essentially up two hierarchical steps in the organizational chart. The organizational structure, prior to the change, was: at the top, the Secretary of DHHS, then DHHS director, then director of the Office of Extramural Research, then OPRR. The change placed the OHRP directly under the Secretary of DHHS (Federal Register, 2000, Jun 13; Brainard, 2000, May 26b). A new director was named, which is significant as mentioned previously, because more sanctions had been issued by Ellis than all other previous directors combined (and only one sanction has been issued since, that against Johns Hopkins in July 2001).

Appendix B

Resource list of documents related to human subjects protection
(Websites accessed June 1, 2002)

Legal Citations

(Note: All website addresses in this appendix were accessed June 1, 2002)

The primary laws guiding use of human subjects in social science research are found at:

45 CFR §46.101 to §46.409

Text of 45 CFR §46 online:
http://ohsr.od.nih.gov/mpa/45cfr46.php3

Those laws guiding medical trials and substances or devices for use by humans include:

21 CFR §56.101 to §56.124
21 CFR §10.1 to §10.206
21 CFR §50.1 to §50.48
21 CFR §312.1 (Drug research)
21 CFR §812.1 (Device research)

In addition, The Common Rule (Federal Policy) is also codified, according to NIH, at:

7 CFR §1c	(Department of Agriculture)
10 CFR §745	(Department of Energy)
14 CFR §1230	(National Aeronautics and Space Administration)
15 CFR §27	(Department of Commerce)
16 CFR §1028	(Consumer Product Safety Commission)
22 CFR §225	(International Development Cooperation Agency, Agency for International Development)
24 CFR §60	(Department of Housing and Urban Development)
28 CFR §46	(Department of Justice)
32 CFR §219	(Department of Defense)
34 CFR §97	(Department of Education)
38 CFR §16	(Department of Veterans Affairs)
40 CFR §26	(Environmental Protection Agency)
45 CFR §690	(National Science Foundation)
49 CFR §11	(Department of Transportation)

Websites of the agencies within the purview of the
Department of Health and Human Services (DHHS) and the
National Institutes of Health (NIH) and other resources
(All websites listed were accessed June 1, 2002)

Nuremberg Code
http://ohsr.od.nih.gov/nuremberg.php3

Declaration of Helsinki
http://ohsr.od.nih.gov/helsinki.php3

Belmont Report
http://ohsr.od.nih.gov/mpa/belmont.php3

Department of Health and Human Services Websites

DHHS Topics in Human Research Protections
http://www.hhs.gov/topics/humanresearch.html

Office of Human Research Protections (formerly OPRR)
http://ohrp.osophs.dhhs.gov/

Bioethics Resources on the Web
http://www.nih.gov/sigs/bioethics/IRB.html

NIH Websites

(NOTE: NIH is comprised of 27 separate institutes and centers, and is itself one of eight health agencies that is part of the U.S. Department of Health and Human Services. For a brief program summary for each institute and center, go to **http://www.nih.gov/icd/)**

NIH, Office of the Director
http://www.nih.gov/icd/od/

Center for Information Technology
http://www.cit.nih.gov/home.asp
Center for Scientific Review
http://www.csr.nih.gov/
National Cancer Institute
http://www.nci.nih.gov/
National Center for Complementary and Alternative Medicine (NCCAM)
http://nccam.nih.gov/

National Center on Minority Health and Health Disparities (NCMHD)
http://www.ncmhd.nih.gov/
National Center for Research Resources (NCRR)
http://www.ncrr.nih.gov/
National Institute on Aging (NIA)
http://www.nih.gov/nia/
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
http://www.niaaa.nih.gov/
National Institute of Allergy and Infectious Diseases (NIAID)
http://www.niaid.nih.gov/default.htm
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
http://www.niams.nih.gov/
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
http://www.nibib.nih.gov/
National Institute of Child Health and Human Development (NICHD)
http://www.nichd.nih.gov/
National Institute on Deafness and other Communication Disorders (NIDCD)
http://www.nidcd.nih.gov/
National Institute of Dental and Craniofacial Research (NIDCR)
http://www.nidcr.nih.gov/
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
http://www.niddk.nih.gov/
National Institute on Drug Abuse (NIDA)
http://www.nida.nih.gov/
National Institute of Environmental Health Sciences (NIEHS)
http://www.niehs.nih.gov/
National Eye Institute (NEI)
http://www.nei.nih.gov/
National Institute of General Medical Sciences
http://www.nigms.nih.gov/
National Heart, Lung, and Blood Institute (NHLBI)
http://www.nhlbi.nih.gov/index.htm
National Human Genome Research Institute (NHGRI)
http://www.nhgri.nih.gov/
National Library of Medicine
http://www.nlm.nih.gov/
National Institute of Mental Health (NIMH)
http://www.nimh.nih.gov/
National Institute of Neurological Disorders and Stroke (NINDS)
http://www.ninds.nih.gov/
National Institute of Nursing Research (NINR)
http://www.nih.gov/ninr/

Warren Grant Magnuson Clinical Center (NIH Hospital)
http://www.cc.nih.gov/
John E. Fogarty International Center
http://www.nih.gov/fic/

Other Government Websites (General Information/Search Engines)

Search engine for identifying and retrieving federal and state government information
http://www.google.com/unclesam

Official government search engine; more than 47 million pages of government information
http://www.firstgov.gov

FDA home page provides information on all aspects of the drug and device approval processes, including human subjects protection
http://www.fda.gov

FDA regulations on human subject protection addressing informed consent (21 CFR 50)
http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr50_99.html

FDA regulations on the composition and activities of Institutional Review Boards
http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr56_99.html

FDA Information Sheets
http://www.fda.gov/oc/ohrt/irbs/default.htm

NIH site designed to assist researchers in recruiting human subjects for clinical trials
clinicaltrials.gov

Sites related to social science research

Protection of Participants in Behavioral and Social Sciences Research
http://obssr.od.nih.gov/IRB/protect.pdf

NIH. Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health (Revised 3/2/95)
http://ohsr.od.nih.gov/guidelines.php3

National Library of Medicine, Current Bibliographies in Medicine, "Ethical Issues In Research Involving Human Participants" (Jan. 1989 to Nov. 1998; 4650 Citations)
http://www.nlm.nih.gov/pubs/cbm/hum_exp.html

NIH. Analyses of Epidemiologic and **Ethnographic Study Data**, NIH Guide, Volume 22, Number 8, February 26, 1993
http://grants.nih.gov/grants/guide/notice-files/not93-073.html

National Institute of **Mental Health, Effort** designed to find opportunities to apply basic **behavioral science** in an effort contribute to improved clinical practice.
http://www.nimh.nih.gov/tbsia/priority.cfm

NIH. Instructions to Reviewer for Evaluating Research Involving Hunan Subjects in Grant and Cooperative Agreement Applications (April 25, 2001)
http://grants.nih.gov/grants/peer/hs_review_inst.pdf

NIH. Regulatory Burden, Human Subjects Protections, Workgroups report (Web posting 12/11/2000)
http://grants.nih.gov/grants/policy/regulatoryburden/humansubjectsprotection.htm

NIH. Report of the Advisory Committee to the Director, NIH from the Office for Protection from Research Risks Review Panel (June 3, 1999)
http://www.nih.gov/about/director/060399b.htm

Answers to questions frequently asked of NIH's Office of Human Subjects Research (OHSR) and Responsibilities of the OHSR (Revised August 2000)
http://ohsr.od.nih.gov/info/ainfo_1.php3
http://ohsr.od.nih.gov/info/hinfo_8.php3

Examples of guideline documents/administrative activities

NIH Guidelines on the Inclusion of **Women and Minorities as Subjects** in Clinical Research (NIH Guide, Vol. 23, No. 11; March 18, 1994)
http://grants.nih.gov/grants/guide/notice-files/not94-100.html

National Institute of **Allergy and Infections Diseases, Guide to Requirements** for Research Grants Involving Human Subjects (August 29, 2001)
http://www.niaid.nih.gov/ncn/tools/humansubjects/guidereq.htm

NIH, Office of Extramural Research, **Ethical and Safe Conduct in Science** and Organizational Operations
http://grants.nih.gov/grants/policy/nihgps/part_ii_2.htm

Enhancing the Protection of Human Subjects in Gene Transfer Research at NIH, Advisory Committee to the Director, Working Group on NIH Oversight of Clinical Gene Transfer Research (July 12, 2000)
http://www.nih.gov/about/director/07122000.htm

NIH **Council of Public Representatives, Minutes of Meetings**
http://www.nih.gov/about/publicliaison/COPR.htm#minutes

NIH Policy and Guidelines on the inclusion of **Children as Participants** in Research involving Human Subjects (Release Date: March 6, 1998)
http://www4.od.nih.gov/ocm/contracts/rfps/childpol.htm

National Institute of Mental Health, **Board of Scientific Counselors, Minutes of Meetings**
http://intramural.nimh.nih.gov/bsc/minutes1-99.htm
http://intramural.nimh.nih.gov/bsc/minutes10-00.htm

National Human Subjects Protections Advisory Committee
http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm

FDA, Clinical Trials and Institutional Review Boards
http://www.fda.gov/oc/oha/default.htm#clinical

Entries about grant solicitations are offered as examples of where such solicitations can be found. The specific grant solicitations included here may, obviously, have expired since publication of the present study.

Websites related to U.S. Congress

Bills:
http://thomas.loc.gov

Committees:
http://www.house.gov/house/CommitteeWWW.html
http://www.access.gpo.gov/congress/senate/

Hearings:
http://www.access.gpo.gov/congress/cong017.html

Congressional hearings (http://www.access.gpo.gov/congress/cong017.html)

Do current federal regulations adequately protect people who participate in medical research? Hearing before the Subcommittee On Criminal Justice, Drug Policy, And Human Resources, of the House Committee On Government Reform, 106th Cong., 1st Sess. (December 9, 1999).

Human subjects research: Radiation experimentation: Hearing before the Senate Committee on Labor and Human Resources, 103rd Cong., 2nd Sess. (January 13, 1994).

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Endnotes

[i] Organizational communication scholars and critical theorists often conduct studies about power. Marx, who provided the basis for critical theory, concluded that religion is the "opium of the masses" and encouraged workers to "shed their chains," indicating the not-too-underlying motives of critical theorists. Marx suggests that the superstructures of politics, religion, and culture were driven by economics (a deeper structure). These structures are often invisible, and that is often by design. Loyalty, patriotism, devoutness, and various virtues are established by the "ruling" class, and in the name of money. This has many implications for regulatory activities, including issues related to ethics, morals, and values, and more recently prevalent, profit. In postmodernism, power is treated differently. Foucault has been explicit (Foucault 1977/1995; 1980). The power that is of interest is not that one possesses or acquires, that is simply the appearance of power. Power is in the discursive formation itself – the combination of linguistic distinctions and ways of reasoning that, together with other aspects, organize social institutions. (See Alvesson & Deetz, 1996, p. 209).

[ii] Differences between critical theory and postmodernism are important. According to Alvesson and Deetz (1996), critical theory works toward individual autonomy and better social choices, hope for social agreements that better fulfill human needs. Postmodernism rejects this as simple replacement of one dogma with another, creating perhaps new elites and new forms of marginalization. In response to that, Alvesson and Deetz (1996) suggest, critical theorists respond that "without reflection, consensus and rationality, there is no politics, no agenda for a constructive alternative." Postmodernism counters: "Politics are by necessity local and situational; responsiveness is more important than systematic planning." Critical theory answers: "Local politics are too weak to confront system-wide gender and class dominations as well as global poverty and environmental problems." Postmodernism maintains: "Organizing against domination both props up and solidifies dominant groups; it creates its own forms of domination." Critical theory "wants us to act and provides direction and orchestration; postmodernism believes that such a move will be limited by the force of our own subjective domination and encourages us to get out of the way and allow the world to pull us to feelings and thought heretofore unknown; but critical theory does not have enough faith to let go. And so on" (p. 211-12)

[iii] Frederick Suppe (1977) divided the development in the philosophy of science (or paradigm shifts, in Kuhnian) into five phases, starting with the philosophy of Ernst Mach and the Vienna circle in the 1920s. (The Vienna Circle was first known as "The Ernst Mach Society.") During this phase it was proposed that science should limit its statements to descriptions of the regularities that held in observations. During the second phase, beginning in the 1940s, the philosophy of science was expanded to include theoretical statements that referred to nonobservable entities and the construction of an axiom-based network of universal statements. The third phase, in the 1960s, consisted of the critique of the assumptions of logical positivism and was paralleled by the fourth phase, which proposed alternative systems for science based on an analysis of the history of science. The contemporary or fifth phase (historical realism) is a deconstruction of science based on pragmatic reason and an acceptance of the influence of historical conditions on scientific inquiry. In contrast, Jacob (1989) outlines a fivefold division of "qualitative research traditions" (ecological psychology, holistic ethnography, ethnography of communication, cognitive anthropology, symbolic interaction). She also distinguishes between the "paradigms of social sciences:" which she considers a "disciplinary matrix used as a heuristic framework" and says she uses the term "tradition," saying "If the sciences operate with paradigms, the social sciences are steered by traditions" (p. 229). However, Shils (1981) suggests that realistic social scientists don't mention tradition (see p. 93, herein).

[iv] Qualitative research is described as crosscutting five "historical moments," all of which operate simultaneously operate in the present. Denzin and Lincoln (2000) describe them as the traditional (1900-1950), the modernist or golden age (1950-1970), blurred genres (1970-1986), the crisis of representation (1986-1990), and postmodern or present moments (1990-present). The traditional period is associated with the positivist movement; modernist and blurred genres are connected to postpositivist arguments and a new variety of interpretive, qualitative perspectives emerged, including hermeneutics, structuralism, semiotics, phenomenology, cultural studies, and feminism. The crisis of representation occurred when researchers struggled with how to locate themselves and their subjects in reflexive texts, and the postmodern moment is characterized by a new sensibility that doubts all previous paradigms. "Qualitative research means different things in each of these moments" (p. 3). "The present moment is defined," Richardson (1991) argues, by a new sensibility, the core of which is "doubt that any discourse has a privileged place, any method or theory a universal and general claim to authoritative knowledge" (p. 173).

[v] In 1974, Congress passed the National Research Act that would profoundly affect research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the Act. The Commission's charge was to examine the protections of the rights, welfare, and well-being of human research subjects, which many observers feared had slipped from the expectations set forth after World War II in the Nuremberg Code (and in the face of the Tuskegee atrocity). Their work would lead, during the decade, to the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1979. In the same year, the Department of Health, Education, and Welfare (HEW) began revising the 1974 rules on protecting subjects (set forth in the National Research Act) and the NIH policies (which had been developed and released in 1966). (It wasn't until 1981 that the Department of Health and Human Services (HEW changed to this in 1979) gave its final approval to 45 CFR 46. In 1976, DOE's predecessor agency, the Energy Research and Development Administration (ERDA), published similar policies to HEW on the protection of subjects in research. DOE adopted the Common Rule as Part 745 of Title 10 of the Code of Federal Regulations (10 CFR 745). By 1991, 16 Federal agencies had adopted the Federal Policy for the Protection of Human Subjects, known as the "Common Rule" in the form of regulations applicable to all human subjects research these agencies conduct or sponsor.