

PERCEPTIONS OF RESEARCH EXPERTS REGARDING
COMPETENCIES NEEDED TO PRACTICE
SAFE RESEARCH WITH
HUMAN SUBJECTS

By

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CHAPTER 1

INTRODUCTION

Research has played a key role in humankind's evolution from caveman to modern humanity. Since the dawn of human existence, research has provided the opportunity to improved the human condition (Belsie, 1999; Benefits of Medical Research, 2000; Geller, 1999; Himmelfarb,1999; Leonard, 2002; Medicine, 2004; Monastersky, 2000; Shaw, 1999; Wong, 2004). Pasteurization, immunizations, X-rays, and medicines are examples of this. However, it has only been in the last 60 years of research that rules and regulations have been formulated for investigators when using human participants in research. The initial establishment of rules governing research involving human subjects was brought about as a result of the injustices that occurred during World War II.

Events That Changed Human Subjects Research

World War II

Following World War II, the world found out about the egregious experiments conducted on humans by Nazi physicians working for the Third Reich. Twenty-three Nazi physicians and bureaucrats were put on trial in Nuremberg, West Germany, and seven of them were executed (Moreno, 1997). The three American judges in this trail formulated what has come to be called The Nuremberg Code (Moreno, 1997). One of the

most important principles that The Nuremberg Code addressed was obtaining consent from the potential research participant. The research participant must consent, or agree, to be included in a research study. The "legal doctrine of informed consent embodies some of the most important ethical and legal principles guiding the conduct of research involving human subjects" (Amdur, Bachir, & Stanton, 2006, p. 222). Ethical consent can only be obtained after the researcher, or someone on the researcher's team, ensures the potential research participant understands what is being asked of them (York, 2003). Thus, the application of the principle of informed consent grants the potential research participant respect and autonomy by giving choice and implies that the researcher is adequately trained in obtaining this consent.

The Tuskegee Study

The problem of unethical research on humans is not limited to regimes like that of Nazi Germany. The United States has not been immune from unethical human experimentation. One glaring example is the Tuskegee Study of Untreated Syphilis. This study, conducted by the United States Public Health Service, was undertaken over the 40 year period from 1932 to 1972 in Tuskegee, Alabama.

The course of the Tuskegee Study of Untreated Syphilis

has been well-documented by a number of researchers (Corbie-Smith, 1999; Freimuth et al., 2001; Satran, 2001; Webster, 1999; White, 2000). The purpose of this study was to follow the natural history of syphilis by allowing syphilis to persist untreated in 399 syphilis positive African-American men. The obvious ethical lapse was that the subjects were made to suffer from the effects of the disease even after penicillin became the standard of care. In retrospect, the most egregious violation of the ethical practice was that these 399 participants were unaware that treatment was being withheld from them, and the subjects did not give consent to participate in the study. The morbidity to these men resulting from the progression of the syphilis is unknown (Freimuth et al., 2001). However, best estimates of the patient mortality is between 28 and 100 men (Freimuth et al., 2001).

The National Research Act of 1974

In reaction to such research scandals, the National Research Act of 1974 (Public Law 93-348) was passed. This act established The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Commission). The persons appointed to The Commission were given the responsibility to "identify the basic ethical principles that should be followed in conducting human

subjects research" (Davis, 2006, p. 130). One of the documents brought into creation by The Commission was The Belmont Report which established the three ethical principles of Respect for Persons, Beneficence, and Justice. These three principles are the ethical basis used to conduct research studies with human participants in the United States (Vanderpool, 2002).

The Commission's findings also facilitated other changes in the regulation of research involving humans. In 1981, the Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects (45 CFR 46) was released (Amdur, 2002). This code is referred to as the Common Rule. These regulations are used by most federal agencies except The Food and Drug Administration (FDA). The FDA did not adopt the Common Rule and has separate research regulations. The differences between the FDA's regulations and the Common Rule are minor (Amdur, 2002). However, together the Common Rule and the FDA regulations provide the philosophical and operational guidelines that establish and govern research practices with human participants and Institutional Review Boards (IRBs). These regulations give IRBs in the United States responsibility for approving and maintaining oversight of any research involving human participants as well as establish procedures for the evaluating and

monitoring of IRBs (Rachlin, 2002).

The FDA's definition of an IRB is "an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects" (FDA, 2007). In accordance with the Code of Federal Regulations (CFR), Title 21, "an IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations" (FDA CFR, Title 21 Part 56, § 56.109(a)). Because the primary duty of an IRB is the protection of people who agree to become research participants, the review of research by the IRB serves an important role in the protection of the rights and welfare of human research subjects.

Since the federal government began this system of federal oversight in the 1980s, refinement of these regulations has continued in such ways as adding specific populations including prisoners and children for special protections. Furthermore, new regulations require IRBs to look at ethical considerations of a conflict of interest when the investigator stands to profit from the research (Kohn, 2002). However, an area that has not been addressed and that does not have guidelines provided is that of research competencies needed by the researcher involved in

research using human participants.

There are a large number of federal regulations which cover hundreds of pages that are meant to protect human participants (Code of Federal Regulations: Title 45, Part 46; Food and Drug Administration, Title 21). Despite the large number of regulations, continued incidences of research misconduct and even research participant's deaths continue to occur. The exact incidence of research transgressions or failure to follow the regulations is unknown although there is strong evidence of under-reporting the occurrences of research transgressions as well as the failure to follow the regulations (Breen, 2003; Komesaroff, 2003).

The incidence of research complaints reported to the FDA increased from 11 in 1994 to 101 in 2000 (Horowitz, 2001). Major universities such as the University of Oklahoma, John Hopkins University, and the University of Pennsylvania had their research programs closed by the FDA for failure to follow research regulations and harm, even death, occurring to research participants in these studies (Ko, 2001; Lemonic, Goldstein, & Park, 2002; Pollack, 2003; Steinbrook, 2003).

The study that was closed at the University of Pennsylvania by the Food and Drug Administration involved

the death of Jesse Gelsinger in September 1999 (Advisory Committee to the Director Working Group on NIH Oversight of Clinical Gene Transfer Research, 2000). Jesse's father, Paul Gelsinger (2000), has spoken out about the research in which Jesse was involved and the circumstances that lead to Jesse's death.

Jesse Gelsinger was an 18-year-old teenager with the genetic disorder of ornithine transcarbamylase deficiency (OTC). OTC is a rare metabolic disorder that prevents the body from appropriately processing nitrogen. Jesse controlled his OTC with a low-protein diet and medications. When Jesse turned 18, he enrolled in a gene transfer clinical protocol at the University of Pennsylvania.

Gelsinger (2000) contends Jesse's death was not a result of his genetic OTC problem but a direct result of the administration of the gene transfer product during the research study. According to Gelsinger, the research study had many major flaws from the beginning, and many cover-ups occurred during the entire process that lead to Jesse's death. Gelsinger discussed how the informed consent process was poorly addressed and not "aboveboard". Gelsinger stated he and his family were not given all the information needed to make an informed decision about participation in the study and even believes they were lied to.

For this research, the gene being studied was carried into the Jesse's body through the use of a virus. The virus apparently gave Jesse a massive liver infection that led to multi-organ failure. An investigation following Jesse's death by the FDA found violations by the principal investigator which included: (a) failure to report to the FDA previous serious adverse events involved with this study; (b) failure to stop the study, as required, when previous patients experienced serious adverse events; (c) failure to disclose to the FDA serious adverse events, including death, that occurred in monkeys given the same experimental treatment; (d) concerns as to Jesse's health and the appropriateness of Jesse's enrollment into the study; and (e) possible financial conflict of interest by the investigator (Advisory Committee to the Director Working Group on NIH Oversight of Clinical Gene Transfer Research, 2000; Baker, 2002; Leiden, 2000; Weiss, 2000a, 2000b, 2000c). While the loss of his son has undoubtedly influenced him, Gelsinger's experiences raise questions about the competencies needed by researchers practicing research with human participants.

Professional Competence

Professional competence is "the habitual and judicious use of communication, knowledge, technical skills, clinical

reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served" (Epstein & Hundert, 2002, p. 226). For the purposes of this research, competence was defined as knowledge, skills, abilities and trait behaviors. Knowledge, skills, abilities and trait behaviors are defined as:

1. Knowledge, which encompasses learning and reasoning related to research rules and regulations as well as knowledge relevant to the researcher's area of professional practice such as medicine, nursing or social sciences
2. Skills, which include tools needed by a researcher such as statistics, research design, and procedures
3. Abilities, which include areas such as time management and inductive and deductive reasoning and
4. Trait behavior which encompass individual tendencies such as rule breaking or keeping. (Ash et al., 2000; Cheetham & Chivers, 1996; Epstein & Hundert, 2002)

Problem Statement

The Problem

Despite reams of federal guidelines, Institutional Review Boards, education of investigators, and monitoring by federal agencies, research participants continue to be harmed and even die when taking part in research studies. One factor that may contribute to this is that there is little in the literature addressing competencies needed by researchers to conduct safe, knowledgeable and effective research while protecting the research participant's well

being. Competencies must be identified before the tasks of teaching and of objective evaluation of those competencies can occur. Until the basic competencies are identified, evaluating an investigator's ability to conduct human research will remain subjective.

Background of the Problem

Since there is little in the literature addressing competencies needed by researchers to conduct safe, knowledgeable and effective research while protecting the research participant's well being and currently there are no federal regulations requiring documentation of human-subjects research competencies by an investigator that uses human subjects in their research, education requirements for investigators are left up to individual institutions or organizations. The National Institutes of Health (NIH) are the only federal agencies requiring documentation of education on human subjects research before allowing a researcher to obtain grant monies for research involving human participants. Many for profit, non-university, and university based Institutional Review Boards have educational requirements for the investigator prior to permitting research, but no standards exist for example: Oklahoma State University (2010), University of Oklahoma (2010), University of Pennsylvania (2010), and University of

Southern California (n.d.). While many educational programs are offered related to conducting research involving humans, no standardization and evaluation of the practices of the researchers can take place until the competencies are identified that are needed for conducting safe, knowledgeable, and effective research while protecting the participant's well being.

Thousands of research projects involving humans are being conducted in the United States today. ClinicalTrials.gov (2010), a registry for clinical trials involving humans, currently registers 95,968 national and international trials. With such a large number of researchers conducting clinical trials and other research involving humans, it is unknown what training these researchers received allowing them to practice safe, knowledgeable, and effective research while protecting the research participants well-being. Some may assume practitioners within their disciplines will have received the proper education and training to conduct human subjects research safely if human subjects research is a part of their profession. However, it is unknown how many practitioners in any given profession have received human subjects research training in the course of their formal education and can safely begin human subject research at

even an entry level in their practice. It is also unknown how many professionals who decide to incorporate human subject research into their practice attain additional education to deepen their knowledge. A major factor hampering both a knowledge of how well trained researchers are related to protecting the rights of human participants and of providing training in this area is that the competencies needed for conducting safe research with human subjects have not been identified.

Purpose of the Study

The purpose of this study was to identify and describe competencies needed by research investigators to practice safe, knowledgeable, and effective research while protecting the research participants well-being. To accomplish this, the Delphi Technique was utilized involving experts in the field of research in order to identify and reach a consensus as to what these competencies are. The Delphi Technique allows the researcher to gather expert opinion and rich details through the experts' voices.

Research Questions

This Delphi Technique involved three rounds of data gathering. Each of the following research questions were used to identify competencies researchers need in order to conduct safe, knowledgeable and effective research while

protecting the research participant's well being round of this study:

1. What competencies do research experts identify as needed by investigators in order to conduct safe, knowledgeable, and effective research while protecting the research participants well being?
2. How do research experts describe the identified competencies?
3. How do research experts rate the identified competencies?

Conceptual Framework

Researchers are professionals who work in real-world situations. A critical component for constant quality improvement in this professional world is ongoing training and development. As participants in this learning, the researchers are in an adult learning environment. Consequently, the background for this study and the training that could result from it is adult learning principles. Within this framework, the specific parts of the conceptual framework can be expressed in a logic model.

Logic Model

The Delphi Technique was developed as a process to produce concrete results "whenever a consensus is needed from persons who are knowledgeable about a particular subject" (Borg & Gall, 1983, p. 413). Consequently, the overall format for a study employing the Delphi Technique can be displayed with a logic model. Logic models can "be

referred to as theory because they describe how a program works and to what end" (W.K. Kellogg Foundation, 2004, p. 2).

Logic models are narrative or graphical depictions of processes in real life that communicate the underlying assumptions upon which an activity is expected to lead to a specific result. Logic models illustrate a sequence of cause-and-effect relationships--a systems approach to communicate the path toward a desired result. (McCawley, 1997, p. 1)

Although the term "logic model" comes from the field of evaluation and although logic models are often used to illustrate a program's operation, logic models can be designed in a variety of approaches (W.K. Kellogg Foundation, 2004, pp. 9-13) and can be used in various formats (Innovation Network, n.d., p. 4) because they are a basic element "that communicates the logic behind a program, its rationale. A logic model's purpose is to communicate the underlying 'theory' or set of assumptions or hypotheses that program components have about why the program will work, or about why it is a good solution to an identified problem" (Schmitz & Parsons, n.d., para. 2). Logic models describe the concepts that need to be considered when seeking outcomes that are linked to a problem and to an intervention (McCawley, 1997, p. 1).

Although many of the materials dealing with logic models refer to program planning, logic models have

widespread use because "logic models help us plan, implement, evaluate, and communicate more effectively" (Taylor-Powell & Henert, 2008, p. 1). In essence, "logic models are useful for all parties involved in an initiative" (Schmitz & Parsons, n.d., para. 4) because they show the importance of the initiative, show the results of the initiative, and show the actions needed to get the desired results.

A logic model describes the sequence of events for bringing about an action by arranging the main elements of the action in a display that shows how things are suppose to work (Butterfoss, 2007, p. 434). It shows how an intervention such as a project, policy, or program is intended to produce specific results (Rogers, 2005, p. 232). The basic components of a logic model are inputs, activities, outputs, and outcomes, and may also include impacts (W. K. Kellogg Foundation, 2004, p. 8). Inputs are the resources that may enable a program or are the barriers that may limit it (p. 8). Activities are the actions that will be conducted to implement the program or initiative (Innovation Network, n.d., p. 10). "Outputs are the measurable, tangible, and direct products or results of program activities. They lead to the desired outcomes...but are not themselves the changes you expect the program to

produce" (p. 12). Outcomes are the specific results "in attitudes, behaviors, knowledge, skills, status, or level of functioning" (W. K. Kellogg Foundation, 2004, p. 8) expected from the program activities. "Outcomes are about change: changes in learning, changes in action, or changes in condition" (Innovation Network, n.d., p. 13). Changes in learning includes new knowledge and increased skills (p. 13). Since outcomes generally occur at the individual level, some logic models include Impacts. Impacts are the broad organizational or system changes that result from carrying out the program activities (W. K. Kellogg Foundation, 2004, p. 8).

In addition to the basic elements, logic models may include other elements such as problem statement, goals, assumptions, and external factors (Innovation Network, n.d.). The problem statement briefly identifies what needs to be changed (p. 7). Goals express the intended results and reflect the priorities that frame the overall logic model (p. 8). Assumptions are conditions that are necessary for program success and are believed to already exist (p. 21). External factors are things that are outside the control of those in the program and that may require program adjustments (p. 19).

Logic models describe the program basics from planning

through its final results and are designed to be read from left to right as a series of "if-then" statements (W.K. Kellogg Foundation, 2004, p. 2). "Reading a logic model means following the chain of reasoning" (p. 2) that connects the sequence of related events from the initial planning to the final desired results for the program (p. 3). "A series of 'if-then' relationships connect the components of the logic model: if resources are available to the program, then program activities can be implemented; if program activities are implemented successfully, then certain outputs and outcomes can be expected" (Innovation Network, n.d., p. 4).

The term "logic model" has been in use since 1979, and the antecedents of the term can be traced to many and varied places: private sector, public sector, nonprofit sector, international area, and evaluation field (Taylor-Powell & Henert, 2008, p. 1). Programs like Total Quality Management and legislation such as The Government Performance and Results Act of 1993 placed an emphasis on results (p. 1). Like the Delphi Technique, the logic model focuses on the explicit, observable, and measurable outputs and outcomes. As such, the philosophical orientation of the logic model is embedded in behavioral principles. "Measures of accountability, behavioral change, behavioral objectives, systems approaches, and programmed instruction are some of

the prevalent manifestations of behaviorism" (Darkenwald & Merriam, 1982, pp. 68-69). This approach makes use of competency-based concepts (p. 65). "Implicit in such an approach is the behavioristic definition of learning as a change in behavior which can be observed and measured" (Elias & Merriam, 1995, p. 94).

Delphi Logic Model

The logic model for this study describes a research process (see Figure 1). The overall problem for the study is the lack of knowledge of the exact competencies needed by researchers in order to conduct safe, knowledgeable, and effective research while protecting the research participant's well being. The goal of the project is to identify the competencies needed by researchers for conducting this research.

While common inputs or resources are concrete entities such as human, financial, or technological resources (W.K. Kellogg Foundation, 2004, p. 2), they are abstract for this research project. They are the history of a concern for the rights of human subjects that dates from World War II, the concept of competencies that identifies explicit and measurable competencies for a behavior, and the principles of adult learning that influences the training of researchers.

The activities for this research project involved the implementation of the Delphi Technique that involved three rounds. If the first round could identify a list of competencies, then the second round could clarify and describe them in more detail. If clear competencies emerged from the second round, then they could be rated in the third and final round. The participants for this process were the experts who were identified to provide the responses in the Delphi Technique.

The output for the project was a list of competencies. If these could be produced, they would do several things. First, they could provide the content that is needed for providing meaningful training that is based on adult learning principles. Second, these competencies would provide an increased knowledge base for the field. Third, these competencies could serve as the initial step in a line of inquiry to further develop and measure the competencies needed for conduct safe and effective research with human subjects. The impact of these outcomes on the overall field is that it could have informed researcher, could have targeted professional development related conducting safe research with human subjects, and could have the actual widespread practice of safe research with human subjects.

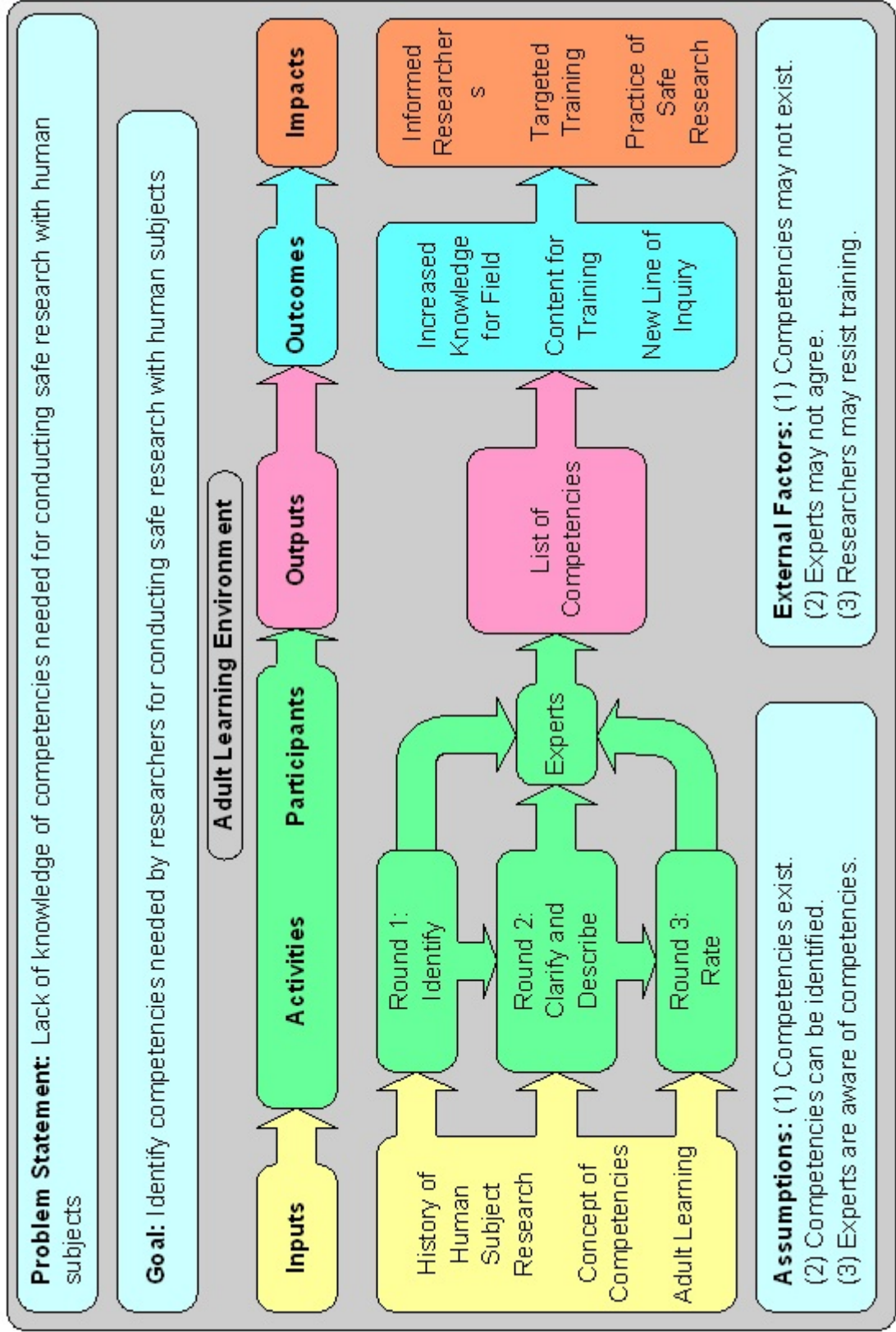
This logic model is based on a set of assumption

implicit in the behaviorist philosophy and rationalistic inquiry. It assumes that there is a single reality and that this reality can be identified (Guba, 1978). This reality is defined in terms of competencies, and it was assumed that the experts who were identified for the study were aware of these competencies and could identify them.

There were three external factors that could potentially hinder the study. One was that the assumption about the existence of the competencies could have been wrong, and specific competencies may not have existed for conducting safe research with human subjects. Another threatening factor was the possibility that the experts may not have been either aware of the needed competencies or able to agree upon what competencies are needed for conducting safe research with human subjects. Finally, the threat exists that researchers may not want training in this area after the competencies have been identified.

Thus, the conceptual framework for this study can be expressed in the form of a logic model that is embedded in an adult learning environment. This model describes the logical or rational relationship of the elements in the study.

Figure 1: Logic Model of Delphi Technique Research Project



Limitations

A Delphi study depends on the expertise of the panel members and therefore the "focus in selecting panelists is not so much their representativeness of a population, but rather their knowledge or expertise in the topic under examination" (Ausburn, 2002, p. 3). In a Delphi study "expertise is deemed more important than representativeness, since accuracy of forecasting is more important than generalizability" (p. 3).

In any research study, issues of reliability and validity must be addressed. Reliability is concerned with how consistently a "procedure produces similar results under constant conditions on all occasions" (Hasson, et al., 2000, p. 1012). As a Delphi study seeks an expert's opinions, a replication of the study using different experts could produce different outcomes, therefore, "there is no evidence of the reliability of the Delphi method" (p. 1012). To overcome the potential reliability problem with a Delphi study, criteria for qualitative studies are used to make certain the interpretations of the data are credible (Lincoln and Guba, 1985). The criteria used address four major issues; "credibility (truthfulness), fittingness (applicability), auditability (consistency) and confirmability" (Hasson, et al., 2000, p. 1013).

The credibility, or validity, of the study refers to the "confidence in the truth of the data and interpretations of them" (Polit & Beck, 2006, p. 332). The credibility of a research study involves two elements; first the research must be accomplished in such a way that believability is enhanced, and second the researcher should conduct the study as to demonstrate credibility (Polit & Beck, 2006). Lincoln and Guba (1985) identify activities the qualitative researcher can do to improve credibility; investing sufficient time in the data collection process, understanding the views of the participants, and the researcher's ability to identify the relevant data being studied (P. 302-304).

Assumptions

The researcher believes the Delphi panel members chosen were truthful, their expertise fit the study questions, they were consistent in their answering and describing, and they confirmed the data that were collected. The panel members were given sufficient time in each round to identify, describe, and confirm the data being collected.

CHAPTER 2

PERSPECTIVES FROM THE LITERATURE

Regulating Research

Regulations Prior to World War II

From the late nineteenth century through the first four and one-half decades in the United States experimentation on human beings had little, if any, governance (Lederer, 1995). As late as just prior to the closing of World War II, development of a formal code of ethics governing human experimentation was rejected by the research community in the United States (Lederer, 1995). However, a formal code of ethics governing experiments on humans was soon to become a reality.

The Nuremberg Code

The German War Trials following the close of World War II revealed to the world the un-consented and horrifying experiments performed on humans in German concentration camps. The following is a synopsis obtained from The Trial of German Major War Criminals: Proceedings of the International Military Tribunal Sitting at Nuremberg Germany (Part 3) 17th December, 1945 to 4th January, 1946 taken from the official transcript (1946). Dr. Sigmund Rascher sent a request to Himmler "for permission to utilise persons in concentration camps as material for experiments with human

beings, in connection with some research he was conducting on behalf of the Luftwaffe" (p 160). Inmates from the concentration camps were readily made available for use in his experiment related to the effects of cold temperatures in high altitudes.

Dr. Rascher began experiments of re-warming persons who had been exposed to extreme cold. The experimental procedure is described as follows:

Persons subjected to experiments were placed in the water, dressed in complete flying uniform, winter or summer combination, and with an aviator's helmet. A life jacket made of rubber or kapok was to prevent submerging. The experiments were carried out at water temperatures varying from 2.5 degrees to 12 degrees. In one experimental series, occiput and brain stem were above the water, while in another series of experiments, the neck (brain stem) and the back of the head were submerged in the water.

Electrical measurement gave low temperature readings of 26.4 degrees in the stomach and 26.5 degrees in the rectum. Fatal casualties occurred only when the brain stem and the back of the head were also chilled. Autopsies of such fatal cases always revealed large amounts of free blood, up to one-half liter, in the cranial cavity. The heart regularly showed extreme dilation of the right chamber. As soon as the temperature reached 28 degrees, the experimental subjects died invariably, despite all reviving attempts. (p 162)

Himmler was very happy with Dr. Rascher and his experiments, and he had Dr. Rascher transferred to his own command, the Schutzstaffel Der National Sozialistischen Deutschen Arbeiterpartei, commonly known as the SS, to assure

continuance of the experiments.

Heinous human experiments did continue. Trials of War Criminals Before the Nuernberg Military Tribunals (1949) notes other experiments included, but were not limited to malaria experiments, Lost (mustard) gas experiments, sulfanilamide experiments, bone, muscle, and nerve regeneration and bone transplantation experiments, sea-water experiments, epidemic jaundice experiments, sterilization experiments, spotted fever (Fleckfieber) experiments, experiments with poison, and the incendiary bomb experiments (p. 175).

Following the close of WWII, the persons conducting these experiments were tried and judged by the Military Tribunal. Powers of the Tribunal were given by "Law No. 10 of the Control Council for Germany" (p. 172) which was established in 1946 by command of the United States Military Government for Germany.

The indictments or charges were structured in four counts. These counts were: "Count One - The Common Design or Conspiracy" (p. 173), "Counts Two and Three - War Crimes and Crimes against Humanity" (p. 174), and Count Four - Membership in Criminal Organization" (p. 180). The trial was conducted by American trial standards. At the trial each defendant entered a plea of not guilty. The trial proceeded

with presentation of evidence and defense of the accused. The judgement on counts two and three following the trial was:

Judged by any standard of proof the record clearly shows the commission of war crimes and crimes against humanity substantially as alleged in counts two and three of the indictment. Beginning with the outbreak of World War II criminal medical experiments on non-German nationals, both prisoners of war and civilians, including Jews and "asocial" persons, were carried out on a large scale in Germany and the occupied countries. These experiments were not isolated and casual acts of individual doctors and scientists working solely on their own responsibility, but were the product of coordinated policy-making and planning at high governmental, military, and Nazi Party levels, conducted as an integral part of the total war effort. They were ordered, sanctioned, permitted, or approved by persons in positions of authority who under all principles of law were under the duty to know about these things and to take steps to terminate or prevent them. (p. 181)

This judgement was followed by 10 basic principles regarding experiments on human beings that have come to be known as The Nuremberg Code. The Nuremberg Code remains the foundation for ethical research involving humans and identified the following 10 standards:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the

subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his/her participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability

- or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. (Trials of War Criminals, 1946, pp. 181-182)

Although the Nuremberg Code continues to be a guiding document in the practice of research involving humans, other documents have been written building on the important principles governing human subjects research identified in the Nuremberg Code.

Declaration of Helsinki

Following the publication of the Nuremberg Code many persons in the research realm believed the Nuremberg Code to be "so absolute in its wording that it excluded large aspects of health research that were considered very important and ethically acceptable by contemporary democratic societies" (Oxford Illustrated, 2001, p. 373). In

the late 1950s and early 1960s more questions arose about research practices which appeared to fail to adequately inform and obtain consent from research participants such as the use of the drug Thalidomide in Europe which caused severe birth defects.

In the late 1950s, thalidomide was approved in Europe to be used during pregnancy. The primary indication for thalidomide was to help control the nausea associated with pregnancy. Thalidomide was also used as a sedative and to help control sleep. Fortunately, thalidomide was not approved in the United States by the Food and Drug Administration (FDA). It was soon discovered in Europe that thalidomide was teratogenic causing severe birth defects and deformities in approximately 12,000 babies. Many of the pregnant women "did not know they were taking a drug that was not approved for use by the FDA, nor did they give informed consent" ("Claremont Graduate University, History of Ethics", 2008). The reaction to the thalidomide outcomes was world wide outcry for furthering the need for research oversight.

The World Medical Association's Committee on Medical Ethics began to develop a new document to guide the ethical practice of research with humans. In 1964, the World Medical Association published the first Declaration of Helsinki

(Oxford Illustrated, p. 373). This was the first truly international document offering research guidance for researchers whose research involved human participants. No one person was responsible for the original text of the Declaration of Helsinki, but rather many national medical associations (Flanagin, 1997). The Declaration of Helsinki underwent the fifth revision in 2000 (Forster, Emanuel, & Grady, 2001).

Prior to approval of the fifth revision there was much controversy and vigorous debate about the direction the Declaration of Helsinki should take regarding use of having a placebo arm in drug studies. A group lead by persons supporting the use of a placebo group before approval, and thus a straightforward scientific method, was opposed by another group who believed that science and societal needs should never trump the well being of the research participant. Thus there were two opposing opinions on the guidance and revision the Declaration of Helsinki should give to researchers, especially those conducting clinical trials.

One fraction believed the new revisions should do more to protect the research participants with the other side supporting a strict scientific method that used a placebo in the research (Rothman, Michels, & Baum, 2000). The first

group believed placing a research participant in a placebo group when there is a treatment available for the disease being researched to be unethical. The group supporting a placebo arm in drug studies believed without the placebo arm the true effect of the new drug could not be measured. The placebo group argued that obtaining informed consent from the participant would ethically allow participation if the research participant was randomized to the placebo arm. The opposing side argued "no investigator or regulatory official has the right to decide how much sacrifice in terms of risk or discomfort a patient should endure in the name of science" (Rothman et al., p. 443) and therefore obtaining informed consent was not enough.

The fifth revision of The Declaration of Helsinki stated in paragraph 29, "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists" (World Health Association, 2008). There was a note of clarification added to paragraph 29 by the World Medical Association General Assembly in Washington, 2002, stating

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-

controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review. (World Medical Association, 2008, p. 1)

The debate over the content of the Declaration of Helsinki and the guidance this document provides continues to be strong on both sides. Goodyear, Krleza-Jeric, and Lemmens (2007) argue the Declaration of Helsinki provides ethical standards, guidance, and basic principles for research with humans. Others argue the Declaration of Helsinki does not provide any of these. Noble (2007) responds to Goodyear et al. with the following comment

The answer to Goodyear et al's question-- "Declaring Helsinki - alive or dead?"--seems to be that the Declaration of Helsinki is dead on the basis of no brain waves, no heart beat, and a rapidly bloating, blow fly infested, stinking cadaver. (p. 736)

Historically, despite the Nuremberg Code and the Declaration of Helsinki that provide guiding principles for

the ethical practice of experimentation on humans, unethical experiments continued and the United States had its share of unethical experiments on humans.

Research Misconduct in the United States

Beecher's Documentation

Beecher's article published in the New England Journal of Medicine in 1966 chronicled 22 unethical experiments performed on humans in the United States since the Nuremberg Code. Examples given by Beecher (1966) included giving 109 service men placebos instead penicillin, the standard of care, for streptococcal respiratory infections. In the placebo group, 2 servicemen developed rheumatic fever and one acute nephritis. No complications occurred in the treatment group. An experiment to determine the period of contagiousness of infectious hepatitis was carried out on institutionalized mentally retarded children with artificial induction of the hepatitis virus. This is one of the two studies Beecher (1966) found of the 50 he reviewed that involved consent issues. Beecher does note that although the parents gave consent for the administration of the virus, "nothing was said regarding what was told them concerning the appreciable hazards involved" (p. 1358). Two of the experiments involved cancer. Twenty-two persons had live cancer cells injected into their bodies and were only

told there were some cells in the injection, "the word cancer was entirely omitted" (p. 1358). The last example cited in this review of Beecher's article (1966) involves the death of a mother and her daughter.

Melanoma was transplanted from a daughter to her volunteering and informed mother, "in the hope of gaining a little better understanding of cancer immunity and in the hope that production of tumor antibodies might be helpful in the treatment of the cancer patient." Since the daughter died on the day after the transplantation of the tumor into her mother, the hope expressed seems to have been more theoretical than practical, and the daughter's condition was described as "terminal" at the time the mother volunteered to be a recipient. The primary implant was widely excised on the twenty-fourth day after it had been placed in the mother. She died from metastatic melanoma on the four hundred and fifty-first day after transplantation. The evidence that this patient died of diffuse melanoma that metastasized from a small piece of transplanted tumor was considered conclusive. (pp. 1358-1359)

Beecher(1966) noted in his article that the final article published was reduced from 50 examples of unethical human research to 22 for reasons of space. Beecher further noted the possibility of examples of hundreds more unethical experiments he found in the literature. A research project, The Tuskegee Study of Untreated Syphilis, possibly the best known unethical human experiment that occurred in the United States, was ongoing at the time of Beecher's publication The Tuskegee Study of Untreated Syphilis

The Tuskegee Study of Untreated Syphilis has been well-

documented by a number of researchers (Corbie-Smith, 1999; Freimuth, Quinn, Thomas, Cole, Zook, & Duncan, 2001; Satran, 2001; Webster, 1999; White, 2000). The purpose of this study was to follow the natural history of syphilis by allowing syphilis to persist untreated in 399 syphilis positive African-American men. The obvious ethical lapse was that the subjects were made to suffer from the effects of the disease even after penicillin became the standard of care. In retrospect, the most egregious violation of the ethical practice was that these 399 participants were unaware that treatment was being withheld from them, and the subjects did not give consent to participate in the study. The morbidity to these men resulting from the progression of the syphilis is unknown (Freimuth et al., 2001). However, best estimates of the patient mortality is between 28 and 100 men (Freimuth et al, 2001). When the news of the Tuskegee Study of Untreated Syphilis broke, the public outrage caused changes in how humans can be involved in research experiments.

The Belmont Report

In retrospect, the year 1971 heralded the beginnings of change in the way research is presently conducted in the United States. In that year, Senator Edward Kennedy was appointed the head of the Senate Health Subcommittee, the Kennedy Institute of Ethics was founded, and Dr. Charles

McCarthy took a job with the Legislative Office of the National Institutes of Health (NIH).

The Belmont Report's 25th Anniversary Symposium (2004) brought together all the living Commissioners and staff persons involved in writing The Belmont Report. At this Symposium these people discussed their perceptions of the events that lead to the seminal document that guides human subject research, The Belmont Report, and the passage of Public Law 93348, the National Research Act. The following account is based on the story McCarthy (2004) provided on his historical perspective and role in the events leading to the passage of Public Law 93348, the National Research Act. This is McCarthy's personal version of how the National Research Act came into being.

McCarthy reflected on his legislative responsibilities at that time. A part of his job was to cover all of the Kennedy hearings. These hearings were held about once every 3 months for over 3 years. It was a Democratic congress and a Republican administration which led to the administrators at NIH being treated with disdain by members of Senator Kennedy's committee. It was difficult to find witnesses to go before Senator Kennedy because they would be "raked over the coals" (McCarthy, 2004). McCarthy attended these meetings and drafted summaries to explain what this

Subcommittee was doing. These summaries were circulated among the administrators at NIH and Public Health Service.

McCarthy recalled that one issue being discussed was birth control research. This research was being carried out, often without proper consent, among lower socioeconomic groups of women. These women were non-English speaking and had little, if any, understanding of the study they were participants in. Other hearings of note were practical and ethical considerations about using prisoners as subjects in research, and psycho surgery. However, the majority of issues were health problems, not research issues. McCarthy reported the administrators at NIH were somewhat complacent and of the attitude that these types of issues dealt with health care. Thus, these hearings did not affect NIH because NIH was a research funding agency. McCarthy believed that the NIH administrators felt they were insulated against any legislation resulting from these hearings. McCarthy reported that Bob Cook, who was working closely with the Kennedy staff, indicated that Senator Kennedy was very serious about moving ahead with legislation that would also affect research.

During this time McCarthy recalled how his boss, came into his office with about 20 pounds of paper. After placing the paper on McCarthy's desk, McCarthy was asked to write

the government's response as to their position on the specific research project addressed in the papers he had just put on McCarthy's desk. The research in question turned out to be the Tuskegee Syphilis Study. McCarthy read and reread the medical documents for days. After studying the papers, McCarthy wrote a memo stating there could be no defense of the Tuskegee Syphilis Study. His recommendation was that the only position the government could take was to say steps would be taken to make sure that this kind of research would never be repeated. McCarthy stated that this was the only memo he ever wrote that no one above him edited. The memo went directly to the Secretary Health, Education, and Welfare who, at that time was Elliot Richardson who later played a role in the Watergate Scandal by opposing Nixon's actions in what became known as the Saturday Night Massacre

Specific to the Tuskegee Syphilis Study memo, Richardson called McCarthy to his office along with some others. McCarthy recollected that this was the first time he had ever been in the Secretary's office. Richardson told McCarthy he agreed with what McCarthy had written in his memo. Richardson then asked McCarthy to draft the testimony which Richardson said he would read when he testified before Kennedy's Subcommittee on Health. Senator Kennedy summoned

Richardson to testify a few days later regarding the Tuskegee Syphilis Study.

Richardson's testimony was only six pages long. McCarthy recalls Richardson delivered his testimony without even reading the text. Richardson delivered it word for word as McCarthy had written it. Following Richardson's "mesmerizing" presentation there were very few questions. Richardson had apologized to the subjects in the Tuskegee study and African Americans in general. Richardson assured the Congress that he would take steps to insure that such abuses of the past would not reoccur. At least for the moment Richardson silenced the critics of the Executive Branch. After the hearing, McCarthy and the others were again summoned to Richardson's office. Richardson said only one thing, "Make it happen." McCarthy felt this was a mandate to do whatever could be done to make sure this type of research tragedy would never be repeated.

Senator Kennedy's Committee drafted a bill requiring that a Commission similar to the Securities and Exchange Commission (SEC) be established. The SEC is responsible for regulating publicly traded stock transactions. Had the Kennedy bill been passed into law there would now be a separate watchdog agency for research. McCarthy reported administrators at NIH were frightened as they did not want a

watchdog agency exercising control over the research they funded.

According to McCarthy, this fear lead to McCarthy's bosses sending him on a number of missions. One was a secret and possibly illegal mission. McCarthy stated he was sent to Pittsburgh to talk to Senator John Heinz. McCarthy's task was to ask him to use his influence with Senator Kennedy to strike the part of the bill establishing a Commission. The other task for McCarthy was to talk with Congressman Paul Rogers, who was known as "Mr. Health" in the House of Representatives.

Initially, Rogers did not want to get into the health research legislative area. Rogers was involved with many health bills on the House side. With pending bills specific to health insurance, health care delivery, the FDA, and other health related issues, Rogers did not want to commit to anything else. However, because of the Tuskegee Study and other studies that had pointed out the need for oversight, Congressman Rogers decided oversight in some form was inevitable. Congressman Rogers introduced a bill draft expanding on Senator Kennedy's Bill, keeping the intent of the language. McCarthy stated that Congressman Rogers changed the language directing the creation of a "Research Commission" that was to be patterned after the Securities

and Exchange Commission to "Advisory Commission". McCarthy met with Congressman Rogers several times to formulate a draft of what would become HR 7724 (Health programs, 1973-1976 legislative overview). McCarthy reported that following his assistance there was a period of silence until one afternoon, a member of Congressman Rogers' staff called McCarthy. The staffer reported that a mission statement for the "Advisory Commission" was needed in order to complete the drafting of the new bill. Senator Kennedy was scheduled to meet with Congressman Rogers the following day and in order to be ready, this mission statement was needed. McCarthy was given the task of drafting the mission statement for the proposed Advisory Commission.

McCarthy stated he "borrowed" a lot of language from the Kennedy Bill and made reference to the scandals that had been discussed in various Congressional hearings over the past 3 years. Also included in McCarthy's draft of the mission statement was Senator Mondale's Bill calling for a Commission to look at how the government could best deal with scientific changes that would have major impacts on society. McCarthy included Senator Javit's Bill proposing a requirement for informed consent. In addition, McCarthy added language that included fetal research. McCarthy added this language because according to McCarthy, a congressman

had falsely accused the NIH of carrying out research with perfused fetal heads derived from abortions. This accusation was untrue but resulted in an outcry from the public. The research with fetal tissue was eventually traced to a Finnish laboratory unrelated to NIH, about a year later.

All of this was poured into the Rogers' Bill. Congressman Rogers' staff told McCarthy they needed the final written Bill by the close of business. McCarthy combined all of the approximately dozen reports with the addition of two or three other reports added by other staff persons later, one of which was the study of the distinction between innovative practice and research. McCarthy finished about four o'clock in the afternoon and ran it by staff members at NIH to correct grammar and punctuation. These reviewers thought the document did capture what the Congress had been concerned about over the past 4 years. Although written in a short time, the document clearly gathered together the pieces that had been dealt with in successive Congressional Hearings over a long period of time, mostly in Senator Kennedy's Hearing Room. Upon rereading the document after finishing it, McCarthy reported he felt the document still lacked something. It was at that point McCarthy wrote the sentence that said, "The Commission must look at and try to identify the principles that underlay biomedical and

behavioral research." McCarthy told the audience that this sentence came to him on the spur of the moment and with no premeditation. This sentence survived various kinds of changes and editorial alterations throughout the legislative process. This is the sentence that originated the Belmont Report. McCarthy continued with his historical recollection.

After reviewing Rogers' Bill, Senator Kennedy had a condition; he would only support the Bill if NIH issued regulations governing research. McCarthy was assigned with Jane Fullerton and Charles Lowe to draft these regulations. The Secretary waved all of the usual required clearances. The regulations were written in 3 weeks. The regulations were published on May 30, 1974. Senator Kennedy then announced that he was satisfied with the regulations and would support the Rodgers' Bill. McCarthy posits that rushing those regulations through made it happen.

McCarthy's accounting of the group of three that wrote the regulations in such a short time was rather humerus. Jane Fullerton was a strong willed woman who did not like Charles Lowe and would not speak to him. Charles Lowe responded in kind and would not speak to Jane Fullerton. Being a three person committee, the committee resembled a sitcom at times. Fullerton would tell McCarthy what she wanted him to say to Lowe and Lowe would tell McCarthy what

he wanted to say to Fullerton. McCarthy reports somehow they managed even under those very difficult circumstances to produce a set of rules that were put in place on May 30. The following week Senator Kennedy expressed satisfaction with the regulations and so Public Law 93348, the National Research Act, was actually passed into law, signed on July 12, 1974.

Contemporary Research Misconduct

Research misconduct in the United States continues today despite the principles of the Belmont Report and federal regulations governing human subjects research. A recent example at the University of Pennsylvania involved Jesse Gelsinger (Advisory Committee to the Director Working Group on NIH Oversight of Clinical Gene Transfer Research, 2000). Jesse Gelsinger was an 18-year-old teenager with the genetic disorder of ornithine transcarbamylase deficiency (OTC), enrolled in a gene transfer clinical protocol at the University of Pennsylvania. OTC is a rare metabolic disorder that prevents the body from appropriately processing nitrogen. Jesse controlled his OTC with a low-protein diet and medications. Jesse died in September 1999; this was not as a result of his genetic problem but apparently was a direct result of the administration of the gene transfer product.

Jesse Gelsinger's father, Paul Gelsinger, has spoken out about the research in which Jesse was involved and the circumstances that lead to Jesse's death. Mr. Gelsinger stated he and his family were not given all the information needed to make a decision about participation in the study and even believes they were lied to by the researchers (Gelsinger, 2000). The informed consent process was poorly addressed and not "aboveboard" according to Gelsinger. Gelsinger contends that many cover-ups occurred during the entire process culminating in Jesse's death.

The vector used to carry the gene that was to be the treatment or cure was a virus. The virus apparently gave Jesse a massive liver infection that lead to multi-organ failure. An investigation following Jesse's death by the FDA found violations by the principal investigator which included: (a) failure to report previous serious adverse events involved with this study to the FDA; (b) failure to stop the study, as required, when previous patients experienced serious adverse events; (c) failure to disclose to the FDA serious adverse events, including death, that occurred in monkeys given the same experimental treatment; (d) questions as to Jesse's health and appropriateness of Jesse's enrollment into the study; and (e) a question of financial conflict of interest by the investigator (Advisory

Committee to the Director Working Group on NIH Oversight of Clinical Gene Transfer Research, 2000; Baker, 2002; Leiden, 2000; Weiss, 2000a, 2000b, 2000c).

Prevention Through Education

While the loss of his son has undoubtedly influenced him, Mr. Gelsinger's experience nevertheless made a compelling case for identifying competencies needed by researchers to help them practice research involving humans, safely. In the absence of known competencies teaching research competencies to both current and future researchers is speculative.

There are many educational programs offered to improve investigator skills in human research. Many universities have such programs, and most federal agencies regulating human research provide educational offerings. Additionally, many of these agencies offer a certificate of completion. However, research has not been conducted to reveal how effective these educational offerings are.

It is estimated that between \$200 and \$210 billion dollars are spent annually on human resource development through education and training (Bunch, 2001; Jacobs, Skillings, & Yu, 2001; Kontoghiorghes, 2001; Kuchinke, 2001). Of this amount, it has been estimated that only 10% of these monies result in knowledge and skills that are

transferred back to the workplace (Kontoghiorghes, 2001). Numbers do not exist estimating the amount of money spent annually on human research training nor the resulting knowledge and skills that occurs following the training. Only 27% of companies routinely perform needs assessments to determine educational and training needs (Tannenbaum & Yuki, 1992). However, "in order to diagnose the causes of performance gaps, practitioners need comprehensive analytical tools to illuminate all possible considerations" (Sanders & Ruggles, 2000, p. 30). Without identifying competencies that researchers need, it is difficult if not altogether impossible to diagnose gaps or develop those analytical tools.

Identifying Competencies Needed by Researchers

It is difficult to define the concept of competency. "It is particularly difficult when it relates to professional occupations where roles can be complex and the knowledge and skills involved many and varied" (Cheetham and Chivers, 1996, p. 20). Competencies needed by a successful chief executive officer include doing, self, managing, developing, and leadership (Zwell, 1998). An effective organizational development consultant needs "contracting, data utilization, implementing the intervention, interpersonal skills, managing group processes, and

maintaining the client relationship" competencies (O'Driscoll & Eubanks, 1993, p. 310). The Accreditation Council for Graduate Medical Education (ACGME) required medical residents to be able to demonstrate competencies which include: "patient care skills, medical knowledge, interpersonal and communication skills, professionalism, practice-based learning, and system-based practice, by using specific knowledge, skills and attitudes" (Accreditation Council for Graduate Medical Education, 2002, p. 1). Competencies needed by nurses identified are: assessment and intervention, communication, critical thinking, teaching, human caring relationships, management, leadership, and knowledge integration (Lenburg, 1999). Given different disciplines value different competencies, identifying competencies needed by researchers to practice safe human subjects research was accomplished by breaking the competencies into elements.

Elements of Competencies

In this research, the constituent elements of competencies are defined as knowledge, skills, abilities, trait behavior, and ethical behavior (Ash et al., 2000; Cheetham & Chivers, 1996; Epstein & Hundert, 2002). Knowledge "refers to a body of information relevant to job performance. It is what people have to know to be able to

perform a job" (Mirabile, 1997, p.75). Skill is the demonstration of an ability such as giving an injection or verbal communication quality. Abilities are talents such as fine motor skills, hearing acuity, or conceptual thinking. Trait behavior is the behavioral expression of a trait. For example, someone that has a trait of being open to new experiences could exhibit trait behaviors of enjoying traveling or learning new things on the job. Ethical behavior is a trait behavior but for this research will be considered as a competency. All of these competencies can be taught and learned.

Andragogy

With any study recommending the adult learning process, it is important to be familiar with the learning model known as andragogy. Knowles defines andragogy as "the art and science of helping adults learn" (Elias & Merriam, 1995, p. 131).

Knowles was first exposed to the concept of andragogy "in the mid 1960s [by] a Yugoslavian adult educator attending a summer workshop at Boston University" (Knowles, et al., 1998, p. 61). Following this exposure, Knowles successfully began his work on developing the theory and model of andragogy (Carlson, 2002; Davenport, 1985; Elias & Merriam, 1995).

The traditional teaching method is known as pedagogy. Pedagogy is passive and is defined as "a systematic body of beliefs that requires loyalty and conformity by its adherents" (Knowles et al., 1998, p. 69) where the learner assumes a "teach me" (p. 65) attitude. In contrast, andragogy is active learning and involves the learner and the learner's life experiences. Adult education's learning focus is based on behavioral principles where learning is "a change in behavior" (Elias & Meriam, 1980, p. 89). Knowles' (1975, 1977, 1980) began his theory development based on four assumptions and by 1990 had added two final assumptions to finish his theory of andragogy. These six assumptions are: (1) the need to know, (2) the learners' self-concept, (3) the role of the learners' experiences, (4) readiness to learn, (5) orientation to learning, and (6) motivation (Knowles et al., 1998, pp. 64-68).

The Need to Know

"Adults need to know why they need to learn something before undertaking to learn it" (Knowles et al., 1998, p. 64). The adult learner needs to perceive how investing personal time in learning will improve some aspect of their life, whether personal or professional. The learner needs to perceive a "need to know" to actively engage in learning.

The Learners' Self-Concept

Andragogy allows the learner to transition from a passive, dependent learner to a self-directed learner. The learner is treated as an adult and actively participates their learning experience. The learner is involved in identifying learning needs and in the development of the learning objectives and plans. Individualized learning gives the learner control over learning needs and ownership which promotes behaviors such as motivation.

Adults have a self-concept of being responsible for their own decisions, for their own lives. Once they have arrived at that self-concept they develop a deep psychological need to be seen by others and treated by others as being capable of self-direction. (Knowles et al., 1998, p. 64)

The Role of the Learners' Experiences

Because adults have such varied experiences in life as compared to youths, "for many kinds of learning, the richest resources for learning reside in the adult learners themselves." (Knowles et al., 1998, p. 66) Andragogy uses techniques that build on this vast bank of experience held by the learners using techniques such as group discussions, problem-solving activities, peer-helping activities, ((Knowles et al., 1998, p. 66) and other activities that cause the learner to engage in critical thinking. Knowles also points out that life experiences become who the adult is and that if these experiences are "ignored or devalued,

adults will perceive this as rejecting not only their experience, but rejecting themselves as persons” (Knowles et al., 1984, p. 67).

Readiness to Learn

“Adults become ready to learn those things they need to know and be able to do in order to cope effectively with their real-life situations.” (Knowles et al., p. 67) This concept addresses the need of the learner to learn at a point in time that coincides with a need for the knowledge to promote progression in life. For instance, earning competencies investigators need to possess in order to conduct safe, knowledgeable and effective research while protecting the research participant’s well being might not be important for an undergraduate who might view learning this information as a waste of time. However, to a graduate student who has to conduct a research study involving humans in order to receive a degree, learning these competencies becomes important. Another example could be a university professor who is on a tenured track and must produce and publish research in order to obtain tenure and continued employment.

Orientation to Learning

Adults need to perceive learning as being useful. Learning provides added value to life when the learning

enhances the experience of living in both personal and professional life roles. The adult learner desiring to learn does so actively and with energy, enjoying the experience.

Adults are motivated to learn to the extent that they perceive that learning will help them perform tasks or deal with problems that they confront in their life situations. Furthermore, they learn new knowledge, understandings, skills, values, and attitudes most effectively when they are presented in the context of application to real-life situations. (Knowles et al., 1998, p. 67)

A scenario in research which occurs can be the education requirements for the researcher which may not take into consideration the difference in the research project and the needs of the researcher. Looking at two different researchers, one researcher who is working in a laboratory with anonymous blood samples and a second researcher who is going to start clinical trials with a potential new cancer therapy where both are required to learn the same information about human subjects research before beginning the respective research projects. This would seem unbalanced. Both researchers have different learning needs. According to Knowles, the first researcher would perceive most of the information as not applying to him and a negative attitude about learning, while the second researcher would value the learning experience as the need to learn would help him effectively perform tasks in a real-life situation.

Motivation

While Knowles identified the importance of internal motivators for adults seeking learning opportunities, there are barriers that can interfere with learning even when the learner is motivated to learn.

While adults are responsive to some external motivators (better jobs, promotions, higher salaries, and the like), the most potent motivators are internal pressures (the desire for increased job satisfaction, self-esteem, quality of life, and the like). (Knowles et al., 1998, p. 68)

Adults that have negative learning experiences in a pedagogical environment or programs that violate principles of adult learning for adults are examples of two such barriers (Tough, 1979).

The andragogical model is clearly different from the pedagogical model. The andragogical model provides the adult learner independence by offering the opportunity to take responsibility for their own learning instead of the pedagogical model where the learner remains dependent on the instructor. Not only are adult learners able to take control of their learning experiences, but andragogy builds on and incorporates life experiences which allows the learner to make sense and apply the knowledge.

The Teaching Role

Teaching using an andragogical model versus a

pedagogical model is a paradigm shift not only for the learner but also for the teacher or facilitator. "There is evidence that adults learn more deeply and permanently on their own initiative than with traditional teacher-oriented classroom approaches." (Knowles, 1984, p. 300). The role of the teacher in an andragogical setting changes to more a role of facilitator or partner (Cervero & Wilson, 1994, pp. 146-148; Ellis & Mirriam, 1995, pp. 125-126; Houle, 1980, pp. 160-164; Knowles et al., 1998, pp. 198-201) instead of a traditional pedagogical model teacher who stands up in front of the class and spews knowledge while the students take notes and want to know what they have to learn for the next test. Many theorist have broken with this traditional pedagogical teaching model to support the andragogical model of the teacher being in a facilitator role. Among those theorist are Dewey (1938, pp. 5-6), Houle (1972, pp. 32-39, 48-56), Rogers (1969, pp. 103 -126, 164-1660,), Tough (1979, pp. 195-197), and Watson (1960, pp. 253-257).

Self-Directed Learning

"To many practitioners, the term self-directed learning conjures up images of isolated individuals busily engaged in determining the form and content of their learning efforts and controlling the execution of these efforts in an autonomous manner" (Brookfield, 1986, p. 56). However,

Knowles (1984) explained that "self-directed learning should be viewed as on a continuum, rather than dichotomous" (p. 301). On one end of the continuum the learner may be encountering a learning situation that is entirely new to the learner which "may be motivated by external pressures" (p.301). This kind of learning "usually takes place in association with various kinds of helpers, such as teachers, tutors, mentors, resource people and peers" (Knowles, 1975, p. 18). Knowles (1984) notes in these situations that if

Self-directed learners recognize that there are occasions on which they will need to be taught, they will enter into those taught-learning situations in a searching, probing frame of mind and will exploit them as resources for learning without losing their self-directedness. (p. 301)

On the other end of the self-directed learning continuum is continuing education. Houle (1980) believes "continuing education must fulfill the promise of its name and be truly continuing-not casual, sporadic, or opportunistic" (p. 13). As each professional evaluates personal learning and training needs for career development, much of the obtainment is left up to the individual and "this fact means essentially that it must be self-directed" (p. 13).

Knowles (1973) developed the following competencies as related to self-directed learning:

1. The ability to develop and be in touch with

curiosities. Perhaps another way of describing this skill would be "the ability to engage in divergent thinking.

2. The ability to formulate questions, based on one's curiosities, that are answerable through inquiry (in contrast to questions that are answerable by authority or faith).
3. The ability to identify the data required to answer the various kinds of questions. The ability to locate the most relevant and reliable sources of the required data.
4. The ability to select and use the most efficient means for collecting the required data from the appropriate sources.
5. The ability to organize, analyze, and evaluate the data so as to get valid answers to questions. The ability to generalize, apply, and communicate the answers to the questions raised. (p. 163)

Self-directed learning can create knowledge and skills "that cannot easily be taught" and can also be "a source of self-confidence in facing a changing world" (Dill, Crowston, & Elton, 1965, p. 130).

CHAPTER 3

METHODOLOGY

Design

Research using formal methods is less than 100 years old. "The first experimental designs were developed in the 1930s by Sir Ronald A. Fisher and published in a book entitled The Design of Experiments" (Burns & Grove, 1997, p. 249). Originally, only research that used an experimental design was considered to have merit. Many even took this a step further and believed only research conducted in a laboratory, which allowed for strict control, had value (Burns et al., 1997). However, experimental designs often do not allow investigators to research social science questions. Thus, new research designs evolved from social science disciplines.

These new research designs included qualitative designs (Burns & Grove, 1997). Qualitative designs allow the perspectives and voices of the participants toward "events, beliefs, or practices" (Gay, 2003, p. 163) to be heard in ways qualitative research methods can not. Qualitative research can answer questions and explain "complex research areas about which little is known" (p. 69).

"Descriptive studies are intended to present new information and to ask questions in order to better

understand a subject" (Portney & Watkins, 1993, p. 233). One type of descriptive design is the Delphi technique. The Delphi technique allows the voices of the experts to be heard.

Delphi Technique

The Delphi technique is a consensus method of a group facilitation process developed by the Rand Corporation in the late 1950s and was used for technological forecasting (Hasson, Keeney, & McKenna 2000). The technique was named after the Oracle at Delphi in ancient Greece (Broad, 2002; Sechrist, 2003; Spiller, 2002). The Pythia, or priestess, at the Temple of Apollo in Delphi, Greece, would answer questions and make predictions for people who came to the Temple (Petraeos, 1971). The Delphi technique research tool makes predictions by using a "panel of experts or high-performance practitioners within a field to gather consensus on future alternatives, expected breakthroughs, and value judgements" (Somers, 1984, p. 26).

The Delphi technique is similar to other consensus methods such as brain storming and nominal group technique. The survey used with the Delphi technique allows the researcher to gather expert opinion and rich details through the experts' voices. The experts have less pressure to conform as all input and feedback remains anonymous (Bowles,

1999).

The Delphi technique uses successive questionnaires to gather the opinions of identified experts. The outcomes of the questionnaires are fed back to the experts so that each expert is made aware of the other experts' opinions. This gives experts the opportunity of changing their opinions in the next round. Competencies not thought of in a previous round may be considered by all of the experts in the following round (Merriam, 1998; Somers, 1984). Each expert must be guaranteed anonymity of their opinions as well as a non-adversarial and non-judgmental environment.

Turoff (1970) identified five possible objectives where use of the Delphi technique is appropriate:

- a. To determine or develop a range of possible alternatives;
 - b. To explore or expose underlying assumptions or information leading to differing judgements;
 - c. To seek out information which may generate a consensus on the part of the respondent group;
 - d. To correlate informed judgements on a topic spanning a wide range of disciplines; and
 - e. To educate the respondent group as to the diverse and interrelated aspects of the topic.
- (p. 149)

This study was based on the third objective of seeking out information for the purpose of generating a consensus on the part of the experts selected to be a part of this study. The consensus of the experts in this study was used to name basic competencies researchers need before practicing

research involving humans.

The Delphi technique was chosen as the research tool of choice for this study in order to obtain information sought from the experts, asking questions and seeking knowledge that had not been sought before. The specific knowledge was sought from the experts in order to identify and define competencies needed by investigators in order to conduct safe, knowledgeable and effective research while protecting the research participants well being.

In the initial phase of this study, experts were asked to identify competencies needed by investigators utilizing humans, to conduct safe, knowledgeable and effective research while protecting the research participants well being. The experts were further asked to define the competencies they identified. Following consensus among the expert participants of these competencies, a Likert-like scale was used to then rate those competencies.

Panel Members

Purposeful sampling was used to obtain the panel of experts. Only from selecting a sample from which the most can be learned can the research "discover, understand, and gain insight into the question being asked" (Merriam, 1998, p. 61).

Each panel member was asked to submit their curriculum

vitae. These indicated the panel members ranged in age from 48 to 71 years old with an average age of 58.6 years. The panel members collectively reported having been involved with human subject research as either a researcher or in a regulatory role in every state in the United States. The panel members were drawn from the private business sectors, government, Office of Veterans Affairs, and academia.

Creating the Panel

When creating a panel "there are no general rules of thumb" (Linstone & Turoff, 1975, p. 68). The ideal size of the panel is from 7 to 18 members (Linstone & Turoff, 1975; Mullen, 2003; Okoli & Pawlowski, 2004). Based on this information the panel size chosen was 10.

The focus of choosing a panel member is their expertise in the field being explored (Ausburn, 2002; Linstone & Turoff, 1975; Mullen, 2003; Okoli & Pawlowski, 2004). An expert includes "any individual with relevant knowledge and experience of a particular topic" (Cantrill et al., 1996, p. 69) with the implication being the more expert a panel member is in the topic being explored, the more knowledge will be generated. For this study an expert was defined by two or more of the following criteria:

1. A minimum of 5 years experience as a member, administrator, or chair of an IRB.
2. One or more articles about research ethics or research clinical practice published in a

- refereed journal or textbook.
3. A minimum of 2 or more years of employment in a regulatory position in either the Office for Human Research Protections or the FDA.
 4. National certification through either the Applied Research Ethics National Association (ARENA) or the National Association of IRB Managers (NAIM).

Shortly after committee approval of the proposal that would guide this research, the Applied Research Ethics National Association (ARENA) meeting occurred. The timing of the ARENA meeting following so closely to approval of the proposal provided the opportunity to begin recruitment of panel members. The first panel member to be recruited was Hammerschmidt. Hammerschmidt has delivered the keynote address at many national and regional research meetings. He is a regular contributor on the IRB Forum, the IRB list serve, responding to IRB problems and issues. The opportunity to ask Dr. Hammerschmidt to be a panel member presented itself on the next-to-the-last day of the meeting. After explaining the proposed research to Hammerschmidt, he immediately agreed to be a panel member. Hammerschmidt also started suggesting other experts. While at the ARENA meeting most of the experts that composed the final panel had agreed to participate. Those that could not be contacted at the ARENA meeting were contacted by telephone or e-mail. Only two persons that were asked to be a panel member declined to participate. Robert Amdur was one of those two, but still

offered help. Amdur had just moved to Florida, had a new job, and reported he was trying to get away from human subject research issues, as well as having time issues. He did however recommend Elizabeth Bankert, a person already under consideration, and offered using his name when contacting her.

Experts that had agreed to be panel members in the study as well as experts that had requested more information were contacted by electronic mail (e-mail). Included in the e-mail was an introduction to myself, a statement of the perceived problem and expectations for the panel members, an overview of the Delphi technique process, the criteria for being a participant in the study, and an informed consent. Five of the experts consented to participate in the study the same day. Two of the 10 persons contacted declined to participate, both citing time issues. It was 2 months from the initial contact of the potential participants before the 10 panel members had been recruited and consented.

Consent to participate in the study was given when the participant e-mailed a copy of his/her curriculum vitae to me. Once the curriculum vitae was received, the participant was directed to a link that collected demographic information. When the participant clicked the submit button on the demographic information, the Round 1 data collection

sheet popped up and the study was underway. Because the credibility of the panel is so important in a Delphi technique study, panel members were asked up front if their names could be used and all panel members agreed. The following is an over-view of each panel member based on information from their curriculum vitae.

Elizabeth Bankert

Elizabeth Bankert received a Bachelor of Arts in Mathematics from New England College in 1984. She earned her Master of Arts in Liberal Studies in 1995 from Dartmouth College. Bankert currently serves as the Assistant Provost at Dartmouth College. While at Dartmouth, Ms Bankert has also served for 7 years as the Director of the Office of the Committee for the Practice of Human Subjects. She has held the position of Assistant Director of the Office of Grants and Contracts as well as the Senior Grants and Contracts Specialist.

Bankert was a collaborator at Children's Hospital of Philadelphia in developing the NIH funded project entitled IRB Net. IRB Net is a tool developed to improve IRB processes including education and communication in multi-site clinical trials.

Bankert is the primary editor for the book Institutional Review Board: Management and Function (2nd

ed.). This book has over 80 expert, contributing authors who provide in depth information on many topics dealing with human subject research. "It has become the a mainstay on the desk of every IRB director, administrator, chair, and most others involved in the oversight or conduct of ethical research, providing education and vital answers to daily questions, and helping to promote ethical research" (2007 Annual Human Research Protection Program Conference Guide, p. 119). Rebecca Wasley, the Associate Marketing Manager at Jones and Bartlett Publishers, reports that the second edition of this book has sold "more than 7,000 copies since 2006" (personal conversation, December 27, 2007).

In December, 2007, Bankert was the recipient of the Applied Research Ethics National Association (ARENA) Legacy Award. "The purpose of the ARENA Legacy Award is to recognize an individual who has made an exemplary contribution to the mission and goals of PRIM&R by significantly promoting the ethical conduct of research through mentoring, teaching, and leadership" (2007 Annual Human Research Protection Program Conference Guide, p. 119).

Jeffrey M. Cohen

Jeffrey Cohen earned his Bachelor of Arts in 1968 from Ithaca College in New York. Cohen received his Master of Arts in Psychology in 1971 and his Doctor of Philosophy in

Experimental Psychology in 1974 from Northern Illinois University.

Cohen's recent publications include two chapters in Institutional Review Board Management and Function (2nd ed.) by Bankert and Amdur (2006). Cohen addresses Federalwide Assurances as well as Internet research in these chapters.

Since 2005, Cohen has been the president of HRP Associates, Inc., a company providing training and consulting in human research protections. The clients for this company include Brown University, Capella University, Cornell University, Harvard University, University of Colorado Denver Health Science Center, University of Miami, and Veterans Administration New York Harbor Health System.

Prior to going into private business, Cohen was the Associate Dean of Research Compliance at Weill Medical College of Cornell University. Cohen served as the Director of the Division of Education at the Office for Human Research Protections, Department of Health and Human Services. He also served as the Associate Director for Education of the Division of Human Subject Protections with the Office for Protection from Research Risks at the National Institutes of Health. Cohen worked for almost 20 years in the Office of Research at the University at Albany in positions responsible for the research compliance

programs for humans as well as animals.

Paul W. Goebel

Paul Goebel received his Bachelor of Science degree from Nebraska State College and did his graduate studies in chemistry at the University of Nebraska. Goebel has over 38 years professional experience with the federal government as a chemist and compliance officer, including management of the human subject protection programs for the Food and Drug Administration (FDA) in the Center for Biologics, the Center for Drugs, and the Office of the Commissioner. Goebel has been the Chair of the FDA's IRB and editor of the FDA Information Sheets for Institutional Review Boards and Clinical Investigators. Goebel worked as a senior member of the education and training team in the Office for Protection from Research Risks (OPRR) in the National Institutes of Health. He then worked in the Office of the Secretary, U.S. Department of Health and Human Services in the Office for Human Research Protections (OHRP), Office of Public Health Science. Goebel was Accreditation Program Surveyor for The Association for the Accreditation of Human Research Protection Programs, Inc (AAHRPP) for 4 years. He has also been a Guest Lecturer at George Washington University and continues in that role at John Hopkins University.

Currently, Goebel is founder and president of Paul W.

Goebel Consulting, Inc. This company provides human subject protections advisory services including consulting, training, and auditing. Since 2005, he has been an alternate member of two IRBs; these are for Chesapeake Research Review, Inc. and the Dana Faber Cancer Institute. He received his Certified IRB Professional (CIP) certification in 2001.

Among Goebel's latest major awards are the Lifetime Achievement Award from the Association of Clinical Research Professionals in 2005 and the President's Award from the Applied Research Ethics National Association in 2002. He also has awards from former Vice President Gore and the FDA.

As well as being the editor for the FDA's FDA Information Sheets for Institutional Review Boards and Clinical Investigators, Goebel has published a dozen times on diverse research topics such as Health Insurance Portability and Accountability Act (HIPAA) and informed consent. Three of these publications are chapters in textbooks. Goebel has been a presenter at many national, state, and local seminars across America.

Dale Hammerschmidt

Dale Hammerschmidt earned his Bachelor of Arts from the University of Minnesota with a major in zoology in 1964. Following this Hammerschmidt studied German literature and

political science as a graduate student at Universitat Wien, Strobl am Wolfgangsee, Oberosterreich, Austria.

Hammerschmidt obtained his Doctor of Medicine degree from the Medical School at the University of Minnesota in 1970. He completed his Internal Medicine Residency in 1974 from the University of Minnesota Affiliated Hospitals. Hammerschmidt worked as an Instructor in Medicine in the Hematology Section at the University of Minnesota Hospitals while completing a Hematology/Oncology Fellowship in 1978. After completion of his Fellowship, Hammerschmidt became an Assistant and then an Associate Professor of Medicine in the Hematology Section at the University of Minnesota Hospitals. He continues to hold this position.

Hammerschmidt served as the Senior Editor for The Journal of Laboratory and Clinical Medicine from 1991 through 1998. Since January of 1999, Hammerschmidt has been the Editor-in-Chief of The Journal of Laboratory and Clinical Medicine.

Grant support obtained by Hammerschmidt includes four National Institutes of Health grants and three privately funded grants. The private grants include a 2 year grant from the Minnesota Medical Foundation titled Readability of "Informed" Consent Documents for Participation in Research and a 3-year grant from the Doris Duke Charitable Foundation

titled Consortium to Evaluate Clinical Research Ethics.

Hammerschmidt lists 407 papers, book chapters, review articles, other publications, brief technical notes and letters, technical position paper and technical manuals, and photography essays in his curriculum vitae. Of the 407 listings, Hammerschmidt is listed as the primary author in 204 of them. Twenty-two of these publications are related to research and deal with various topics such as topics from recruitment, challenges to research findings, cultural issues, the history of research, research ethics, the moral education of scientists, FDA processes, informed consent, conflicts of interest, and race as categorical variables.

Hammerschmidt has been very active in the Applied Research Ethics National Association. Hammerschmidt has twice been elected and served as the elected Midwest Section Councilor for the Applied Research Ethics National Association (ARENA).

Erica Heath

Erica Heath received her Bachelor of Arts from San Jose State University in Speech Therapy. Heath received her Masters in Business Administration in Health Services Administration from Golden Gate University. From 1970 until 1984, Heath was the Principal Administrative Analyst for the Director Human and Environment Protection Committees at

the University of California at San Francisco (UCSF). Since 1984, Heath has been the President of Independent Review Consulting, Inc (IRC). IRC performs IRB consulting that includes being the responsible Institutional Officer for FDA audits and supervising operations of the IRB.

Heath is a Certified IRB Professional (CIP) and has sat on the Public Responsibility in Medicine and Research's (PRIM&R) CIP Council since 2006. Heath was the President of the Bay Area Association of IRBs for 3 years. She served on the Editorial Board of IRB: A Review of Human Subjects Research for 15 years and on the Editorial Advisory Board for Applied Clinical Trials. Since 2003, Heath has been participating with The Association for the Accreditation of Human Research Protection Programs, Inc., a national organization that certifies IRBs.

Heath has provided guidance to persons in the research field in many ways. She has published 12 journal articles as a sole author and has published chapters in two books. She has also contributed her expertise in the development of research guidelines for several research committees at the University of California at San Francisco. Speaking engagements include participation on such programs as the Food and Drug Administration regional conferences on Institutional Review Boards and the Hastings Institute

summer workshops on ethics and research on human subjects. Heath presented an invited paper and testified before the National Bioethics Advisory Commission in 2000.

Howard Mann

Howard Mann was born in South Africa. He obtained his Bachelor of Medicine and Bachelor of Surgery at the University of Witwatersrand in Johannesburg, South Africa. Bachelor of Medicine and Bachelor of Surgery:

are the two degrees awarded after a course of undergraduate study in medicine and surgery at a university in the United Kingdom and other places following its usage, such as medical schools in Australia, Egypt, Hong Kong, Malaysia, Singapore, Myanmar, New Zealand, Jamaica, South Africa, Nigeria, Pakistan, Sri Lanka, Sudan and India. The naming suggests they are two separate degrees; however, in practice, they are usually treated as one. Those holding the degree(s) and practicing medicine are usually referred to as "Doctor" and use the prefix "Dr". The degrees are often used as the Commonwealth equivalent of what is known elsewhere as the degree of Doctor of Medicine (MD). (Wikipedia, 2009, para. 1)

Mann completed his internship was at South Rand Hospital also in Johannesburg. Mann moved to the United States in 1980 and completed a residency in diagnostic radiology at Wilmington Medical Center and Yale New Haven Hospital. Following his residency, he completed a fellowship in thoracic imaging at Yale New Haven Hospital. Since 1985, Mann has worked with the University of Utah School of Medicine in Salt Lake City. He has held joint appointments

since 2002 as Associate Professor at the University of Utah School of Medicine and as Adjunct Associate Professor of Internal Medicine at the University of Utah School of Medicine.

Mann has been on the editorial board for IRB Ethics & Human Research since 2002. In 2006, he was the guest editor for Volume 13, Issue 7 of Accountability in Research. As well as being an editor, he has reviewer experience as a referee for seven peer-reviewed journals, including Lancet. Mann has published 18 times in peer-reviewed journals. For 14 of those publications, he was the primary author, and 9 of these related to research and ethics. He has published three articles in non-peer-reviewed journals as well. Mann has written a book and book chapter as the primary author and a book chapter related to radiology as the second author. He has had many letters to the editor published in peer-reviewed journals including the New England Journal of Medicine and the British Medical Journal. Mann has been a presenter at international, national, regional, and local meetings. He has been an Invited/Visiting Professor at medical centers in multiple states as well as the Department of Clinical Ethics at the University of Chicago in 2007.

Mann was a member of the Bioethics Committee at LDS Hospital in Salt Lake City for 7 years (1992-1999); for 4 of

these years he was the Co-Chair of the Committee. He was a member of the LDS Hospital IRB for 7 years (1994-2001), serving as vice-chair. For 2 years (1999-2001), he was the Chair of the Intermountain Health Care IRB. Since 2006, Mann has been a board member of the National Institutes of Health Specialized Centers for Clinically Orientated Research in Vascular Injury, Repair and Remodeling. Mann is also a member of Data and Safety Monitoring Board (DSMB).

Helen McGough

Helen McGough received a Bachelors of Arts in Anthropology and Sociology from Grinnell College in Iowa in 1967 and a Masters of Arts degree in Anthropology from Michigan State University in 1972. McGough's teaching experiences include instructing at the University of Hong Kong and the University of Vermont.

McGough is a Certified IRB Professional (CIRB). McGough worked at the University of Washington from 1984 until retirement in 2007. While at the University of Washington, McGough served as the Coordinator of the Human Subjects Division as the Director of the Human Subjects Division, and as the Special Assistant for the Office of the Vice Provost for Research.

Jon Merz

Jon Merz received his initial degree, a Bachelor of Science in Nuclear Engineering from Rensselaer Polytechnic Institute. He received a Masters of Business Administration from the University of North Florida. Diversifying his education, he received his Juris Doctor degree from Duquesne University School of Law. His final degree was a Doctor of Philosophy in Engineering and Public Policy from Carnegie Mellon University.

Merz has held many faculty appointments among them are: Research Assistant Professor of Bioethics at the University of Pennsylvania, Associate Scholar, Clinical Epidemiology Unit of the Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Assistant Professor in the Department of Medical Ethics at the University of Pennsylvania, and since 2005 a tenured position of Associate Professor in the Department of Medical Ethics at the University of Pennsylvania. Merz has been Fellow at the Center for Bioethics and Associate Scholar at the Clinical Epidemiology Unit of the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania School of Medicine since 1998 as well as Senior Fellow in International IP Law, Trade and Policy, Consumer Project on Technology. Merz currently is a member of the

Graduate group in the Department of Bioengineering,
University of Pennsylvania and concurrently Associate Chair
for Faculty Affairs in the Department of Medical Ethics at
the University of Pennsylvania.

Major teaching and clinical responsibilities at the
University of Pennsylvania and affiliated hospitals includes
Medical Ethics at the School of Medicine; Research Ethics at
the School of Arts and Sciences as well as the School of
Medicine; Ethics of Human Subjects Research at the School of
Medicine; and Practicing Science and Engineering
Responsibility in the Department of Engineering.

Merz has been on many national committees. Four of
these are National Institutes of Health (NIH) committees and
include the Resource to the Ethical Issues Subcommittee of
the Biological Resources Working Group of the National
Action Plan on Breast Cancer as well as the Working Group on
Informed Consent for Repository Samples, National Heart,
Lung, and Blood Institute. The other two NIH committees Merz
has served on are associated with the National Cancer
Institute (NCI) and include the Research Ethics and
Monitoring Panel for the NCI-funded Cancer Family Registry
for Breast Cancer Studies Consortium as well as the
Bioethics Working Group of the NCI-funded Cancer Genetics
Network.

Merz is a member of two national Data and Safety Monitoring Committees, one related to radiology and one related to allergy, immunology, and transplantation. He is currently a member of two national committees considering biological specimen repositories and lung tissue research. Further committee work in the area of ethics includes contributions to the American Bar Association Committee as a member-at-large for the ABA Coordination Group on Bioethics and the Law.

Merz has been invited to present 69 national and international lectures covering a wide range of topics. Among these are presentations on research history, research ethics, informed consent, cloning, health records, human tissue issues, intellectual property management.

Merz has held six editorial positions. He has been the editor of Penn Bioethics since 2000 and has been the editor and moderator of the IRB Forum since 2003. Merz has conducted scientific journal peer reviews for 28 journals including Accountability in Research, American Journal of Bioethics, IRB: Ethics and Human Research, Journal of the American Medical Association, and Science. Merz has 56 peer-reviewed research publications; he is the primary or sole author of 24 of these. He has also published or presented 17 abstracts. He has contributed to 43 editorials, reviews,

chapters.. Merz is the co-author of Current Controversies in the Biological Sciences: Case Studies of Policy Challenges from New Technologies (2007). Among Merz' professional appointments is Associate Policy Analyst at The Rand Corporation from 1992-1995. No details were given regarding the duties of this position.

John Noble

John Noble received his first two degrees in Philosophy. His Bachelor of Arts from Maryknoll Seminary and his Master of Arts degree from Boston College Graduate School of Philosophy. Noble completed a Masters in Social Work from the Catholic University of America. Noble completed a Doctor of Philosophy from Brandeis University with a major in social welfare in 1966.

Noble held many notable positions before retirement in 2005. For the last 11 years before retirement, he was the Endowed National Catholic School of Social Service Professor for Social Justice at the Catholic University of America. He was also a Professor at the School of Social Work at the State University of New York at Buffalo from August 1995 to retirement and he received emeritus status in January of 1994.

During his professional career, he has also held three national positions. He worked at the U.S. Department of

Education in Washington as a senior program analyst. At the Department of Health, Education, and Welfare (HEW) in Washington he was the Director of the Policy Research and Analysis for Social Services and Human Development for 7 years. He served as the Director, Research and Evaluation, Office of Planning and Policy Development, Rehabilitation services Administration for 3 years which is also at HEW.

Noble has served as a local, state, national, and international consultant for areas including mental retardation, research and statistics, rehabilitation, and special education. Among the consultations of particular note, he served six times as a consultant to the Secretariat, World Health Organization between 1973 and 1982. Noble has been a member of many national committees including the Task Force on Diagnostic Related Groupings with the National Association of State Mental Health Program Directors.

Publications by Noble are numerous. He is co-author of three books related to emergency medical services and workers' compensation reform. Noble is the primary author of 16 publications and a contributing author in 12 more publications in refereed journals. The subject matter of these publications is varied and includes topics such as child abuse, mental illness, employment, social research,

vocational rehabilitation, and detecting bias in biomedical research. Noble has written chapters in 5 books and is a contributing author for 12 other books.

J. Thomas Puglisi

Tom Puglisi received his Bachelor of Arts in Psychology in 1972 from Catholic University of America. He received a Master of Arts in 1975 and a Doctor of Philosophy in the Psychology of Aging and Life Span Development in 1978 from Ohio State University.

Puglisi has been the Chief Research Oversight Officer and Director of Research Oversight (ORO) in the Department of Veterans Affairs (VA) in the Veterans Health Administration since 2006. In this position, he serves as advisor to the Under Secretary for Health on compliance with federal and VA requirements for the protection of human research subjects, research misconduct, and other research related issues. He also manages and coordinates ORO regional offices that conduct compliance reviews in the VA research facilities.

Prior to this current position, Puglisi worked as a senior consultant/manager at Pricewaterhouse Coopers. His responsibilities included evaluating and strengthening client systems for protecting human subjects, managing conflicts of interest, and fostering the responsible conduct

of research.

Procedures

The Delphi technique was chosen as the tool of choice as the study sought knowledge from experts that had not been sought before in order to create new knowledge and, the versatility of the Delphi technique allowed for adapting and adjusting the traditional methods as the study progressed (Linstone and Murray, 1975). Once the decision had been made to use the Delphi technique for this study the next step became creation of the panel.

Defining Competency

For this Delphi technique study, competencies were defined as knowledge, skills, abilities and trait behaviors (Ash et al., 2000; Cheetham & Chivers, 1996; Epstein & Hundert, 2002). Components of this general definition were further defined for the participants. Knowledge encompasses learning and reasoning related to research rules and regulations as well as knowledge relevant to the researcher's area of professional practice such as medicine, nursing, or social sciences. Skills include tools needed by a researcher such as statistics, research design, and procedures. Abilities include areas such as time management and inductive and deductive reasoning. Trait behaviors would encompass individual tendencies such as rule breaking or

keeping.

The Delphi Technique Rounds

This Delphi technique study was divided into three rounds. In Round 1 the panel members were asked the following questions:

1. What competencies do research experts identify as needed by investigators in order to conduct safe, knowledgeable and effective research while protecting the research participants well being?
2. How do research experts define the identified competencies?

The answers to these questions were analyzed and grouped. These competencies were returned to the panel members for (a) confirmation by the panel members that the competencies individual panel members had identified were included in the grouping, (b) validation from the panel members that the named competencies were indeed competencies, (c) confirmation that none of the data had been lost during this initial analysis, and (d) provision of a chance for the panel members to add any competencies they perceived as missing.

In Round 2, the panel members were sent the analyzed and refined list of competencies and asked to vote "Yes", "No", or "No Response" on whether the items listed were indeed competencies needed by researchers to practice safe human subjects research. The panel members were also given

an opportunity to write comments. Analysis of this data was done and based on the panel member's responses, a final list of competencies was developed.

In Round 3, the panel members were sent a list of the final competencies and asked to rate the importance of each competency on safe research practice using a 4-point Likert-like scale.

CHAPTER 4
THE DELPHI PROCEDURE

Introduction

The data collection for this Delphi study was conducted in several rounds. In Round 1 the panel members were asked to name and define the competencies needed by investigators to conduct safe, knowledgeable, and effective research while protecting the well-being of research participants. These competencies that were named and described by the panel members were summarized and sorted by the researcher. The panel members were then sent the summarized and grouped competencies and asked to confirm that the competencies that they had named had not been lost in the summarization, and they were also given the opportunity to add new competencies. The competencies were sent back based very much on the exact words that were submitted. This was to help them see that their ideas were included and to show the panel members exactly what the others were saying. Once confirmation from the panel members that their ideas were contained in the summarization and once they had the opportunity to add any competencies, these responses were analyzed, wording was edited for brevity and clarity, and a new list of competencies developed. This completed Round 1.

In Round 2, the panel members were sent the new list of

competencies and asked to vote "Yes", "No", or "No Response" on whether the items listed were competencies needed by researchers to practice safe human subjects research. The panel members were also given an opportunity to write comments. Once this data were received, panel member's responses were evaluated, and the final competencies were determined.

In Round 3, the panel members were asked to rate the competencies. A Likert-like scale was used.

Round 1

Defining Competencies

This step was similar to brainstorming. "Brainstorming can be an effective method for generating a large volume of creative ideas" (Yoder-Wise, 2007, p. 99). An important element of brainstorming is that all ideas are listed without critiquing or judging. The lack of criticism or judgement allows ideas to be built on each other which enhances the generation of ideas.

A form for defining the competencies was developed and posted on the Internet. The panel members were e-mailed a link to the form. The form had two columns and instructions for completion. The first column asked the panel member to name the competency and was limited to 500 characters. The second column asked the panel member to describe the named

competency, and the panel member had unlimited text space for the response. Upon completion of this form, the panel member was instructed to click on the "submit" button at the bottom of the form. Once the panel member clicked on the "submit" button, the data were sent electronically to the researcher.

Analysis of Responses

Three months after initial contact, all panel members had responded, and 130 competencies were identified and described by the panel members. After competencies that contained the same concept were combined, 72 competencies remained. Three months appeared to be a long time before receiving all of the responses. However, the panel members are very busy professionals, and many spend a large amount of time traveling. One of the panel members e-mailed the following regarding this round, "Well that was a fun exercise. I sat and looked at the screen and remembered the PIs I liked and those I hated and why it was clear that skill in their given field was way down on the list".

One of the most difficult and demanding challenges for the researcher using qualitative methods is to make sense of the data. A method known as constant comparison where "comparing one segment of data with another to determine similarities and differences" (Merriam, 1998, p. 18) to

analysis the data and find patterns was used.

For the initial analysis, the 72 responses were grouped into categories based on the characteristics of the competency. The possibility existed of a competency fitting into more than one category. However, each competency was placed in only a single category based on the competency's strongest characteristic.

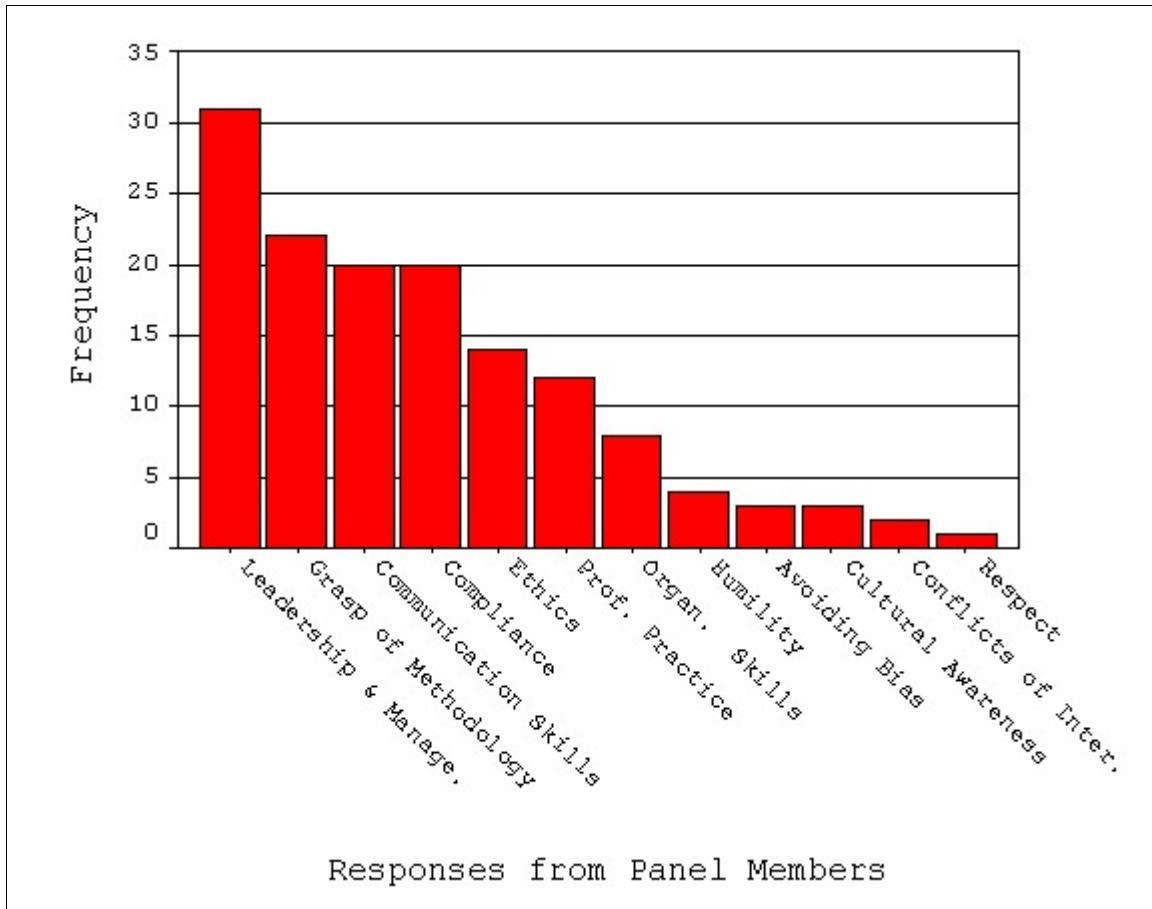
A form was devised to further analyze these categories of competencies. This form had two columns. Each competency named by the panel members was placed in the left column, and the description given of the competency was placed in the right column. When all 72 competencies were thusly entered, a new column was added to the left. Into this new column, a word or phrase such as "compliance" that described each competency was entered. The competencies were then sorted alphabetically using the keyword in this third column.

This process provided for grouping the competencies into major categories. However, to provide for more precise grouping following this major grouping, a fourth column was added to the left, and the categories were further reduced based on predominate characteristics within this grouping of competencies. The competencies in each category were again sorted alphabetically using the keywords in this fourth

column. The competencies were then reduced by analyzing the concepts contained in each competency and summarizing or combining the competencies that were the same.

As a result of this process, the 140 responses fell into 12 competency groups. The 12 groups and the number of competencies in each were as follows: Leadership and Management-31, Grasp of Methodology-22, Compliance--20, Communication Skills-20, Ethics--14, Professional Practice-12, Organizational Skills--8, Humility-4, Avoiding Biases-3, Cultural Awareness-3, Conflicts of Interest-2, and Respect-1 (see Figure 2).

Figure 2: Frequency Count for Responses by Panel Members



Confirmation of Competencies

The summarized and grouped competencies were sent to the panel members. Whenever possible the competencies remained with the exact wording the panel members had used when naming the competency. This was the first time the panel members viewed the responses from other panel members. There were many purposes for this phase. These were (a) confirmation by the panel members that the competencies

individual panel members had identified were included in the grouping, (b) validation from the panel members that the named competencies were indeed competencies, (c) confirmation that none of the data had been lost during this initial analysis, and (d) provision of a chance for the panel members to add any competencies they perceived as missing.

The panel members were then sent a form by e-mail. This form had three columns. The first column listed the competencies named by the panel members, and the competencies were divided into groups. The second column allowed panel members to confirm with a "Yes" or "No" pull-down menu that the named competencies were indeed competencies. A third "comments column" followed and allowed the panel members to make comments on the listed competencies. Blank text boxes were at the bottom of the form to allow panel members to add any additional competencies. Panel members were asked to:

1. Vote either "Yes" or "No" on whether each item was or was not a competency.
2. Add any previously identified competencies which might have been lost in summarization or grouping.
3. Provide any new competencies that they felt were missing.

The panel members were asked to have responses back within 2 weeks.

Panel members took this job very seriously. One of the panel members sent the following e-mail:

The more I looked at this, the more it became difficult. I pretty much liked and agreed with everything that everybody had found to be important. But the more I thought about it, the more there seemed to be three more-or-less distinct universes: 1) Competencies (the abilities to DO something per se), 2) Key knowledge bases, and 3) Key attitudes. There were also a lot of cusp-sitters ... things that were of key importance and would either imply or lead to an important competency, but were not themselves competencies. I found myself wishing for a pull-down menu that had more than "Yes" and "no" as options.

Another panel member wrote, "WOW. I had some trouble with generalizations from one kind of PI to another. You might need to add something about 'across all kinds of PIs' or something like that".

Analysis of Data

The data had been sent to all of the panel members with all of the summarized competencies in order to get a general consensus. However, after 2 months two panel members still had not responded. Therefore a reminder e-mail was sent to each. One of the panel members, Dr. Jon Merz, withdrew from the study. He sent the following e-mail and gave permission to identify him and quote his communication:

Hi Teri

I am at a loss at this stage of the game. I feel my responses would not be very helpful to you, and would be a bit destructive to this process. Can

you proceed to the next stage without my input? I guess I just don't see that much of what has been identified falls within the "necessary" set of core competencies for all researchers. That's why I tried to generalize...at the end of the day, a commitment to truthful inquiry and competence in one's chosen disciplinary arts/skills is all I'd identify as common to all science. Everything else is nice but not necessary, meaning not applicable to all disciplines. Sorry! Its not like I haven't been wracking my brain over this!

A second member never responded despite numerous attempts to contact him. Five weeks later it was decided to proceed with the study without the responses of these two panel members. The second panel member who had not responded to this phase was at the Public Responsibility In Medicine & Research (PRIM&R) meeting 2 months later. He apologized for not responding or communicating at this juncture in the study explaining he had been overwhelmed with other matters. He did agree to participate in Round 3 that was occurring at this point.

Round 2

Analysis of Responses

The panel members were sent the newest list of competencies on a form that was developed and posted on the Internet. The panel members were e-mailed a link to the form. This form had three columns and instructions for completion. The first column listed the competency. The second column was a drop down box giving the panel member

the chance to vote "Yes", "No", or "No Response" for each competency. There was a third column for comments. Upon completion of this form, the panel member was instructed to click on the "submit" button at the bottom of the form. Once the panel member clicked on the "submit" button, the data were sent electronically to the researcher. Analysis of these responses was the final step leading to the identification of competencies needed by researchers in order to conduct safe, knowledgeable and effective research while protecting the research participants well being.

Description of the Competencies

The identified competencies were grouped into four broad conceptual areas: Personal Competencies, Knowledge and Abilities Competencies, Grasp of Methodology, and Situational and Organizational Factors. Personal Competencies include competencies related to Humility, Ethics, Avoiding Biases, and Respect. Knowledge was divided into two areas with one for general knowledge and the other for specific knowledge related to the research process. Knowledge and Skill Competencies include competencies related to Leadership and Management, Organizational Skills, Communication and Communication Skills, and Cultural Competency. Grasp of Methodology includes competencies related to Understanding the Scientific Method, Literature

Review, Hypothesis Development, Protocol Development and Study Design, Protocol Adherence, Analysis of Data, and Transparency. Situational and Organizational Factors include competencies related to Compliance, Professional Practice, Professional Competence and, Conflicts of Interest.

Round 3

In Round 3 the panel members were asked to rate on a form developed for this purpose the importance of the identified competencies. A 4-point Likert-like scale was used with the following values: 1--Not Necessary, 2--Somewhat Necessary, 3--Necessary, and 4--Absolutely Necessary. Once the competencies were identified, it was crucial to obtain the expert's opinions on how important each competency was, thus giving additional meaning to each competency. A Likert-like scale was chosen as it would measure the expert's opinions (Burns & Grove, 1997). A 4-point Likert-like scale was selected to allow elimination of the neutral position. The neutral position could have allowed the panel members to avoid making a clear choice of positive or negative, referred to as a 'forced choice version' (Burns & Grove, 1997, p. 363) in rating the importance of each competency. Nine of the ten panel members completed this rating.

Panel Members Responses

Because a Delphi is based on expert opinions and on getting the voice of the experts to tell the story, the experts in this study were guaranteed their responses would be not identified with them. Therefore, the reader should be aware that all unlabeled quotes in the description of the competencies are the written comments of the experts on this Delphi panel. There are no right answers, single realities, or single correct answers. If a narrower answer had been sought that would have approached a single reality, then each panel member would have been sent only their own information. However, this study recognized that real-world problems are seldom well-structured (Sternberg, 1990). "Problems have to be not only recognized but also defined because the way they are defined will determine how they are solved" (Conti & Fellenz, 1991, p. 11). Therefore, the following chapters use the voice of the panel members to describe each competency.

CHAPTER 5

PERSONAL COMPETENCIES

Personal Competencies are competencies that relate to the personal characteristics of the researcher even though the researcher may or may not be aware of these competencies. Personal Competencies include Humility, Ethics, Avoiding Biases, and Respect.

Humility

Humility is discussed first because this category can influence all others. Humility is "the quality and state of being humble" (Mish, 1997, p. 363). Humble is "unpretentious; unconceited" (p. 363). The presence or absence of humility can affect how the researcher follows the rules or is willing to listen to others as well as to seek input from others.

One panel member simply named "humility" as a needed competency describing it as "other people might have good ideas and this person will listen to them". Humility gives the researcher the "ability to accept input from others". One panel member pointed out that "one of the best defenses against the ability to recognize one's biases is to have input from people whose perspective would be different, especially folks who might just plain disagree with your notion". Humility helps the researcher to "know their

personal limits" by having the "ability to understand the practical applications and limitations of one's abilities and of the context in which one's research takes place".

The researcher with humility can "empathize". Empathy is "the experiencing as one's own of the feelings of another; also: the capacity for this" (Mish, 1997, p. 251). As one panel member pointed out, the researcher with empathy can "have feeling, concern, identification, and understanding of subject's situation, beliefs, motivations, perceptions, and feelings".

Based on their initial input, the following competencies in the subgroup of Humility in the Personal Competencies group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts.

1. Ability to accept input from others by listening to other people who might have good ideas. In addition, one of the best defenses against failing to recognize one's biases is to have input from people whose perspective would be different, especially persons who might disagree with the researcher.
2. Knows personal limits.
3. Ability to understand the practical applications and limitations of one's abilities and of the context in which one's research takes place.
4. Empathy having feeling, concern, identification, and understanding of

subject's situation, beliefs, motivations, perceptions, and feelings.

All panel members but one said numbers 1 and 2 were competencies. One panel member placed both numbers 1 and 2 in the "No" column and commented that they were "too vague".

All panel members but one said number 3 was a competency. One panel member felt that numbers 2 and 3 "are probably lump-able". One panel member placed number 3 in the "No" column and commented this competency was "too vague".

All panel members but two said number 4 was a competency. While agreeing that number 4 was a competency, one of the panel members commented that numbers 1 and 4:

May be lump-able. This section breaks down into two broader concepts for me: Know thyself and Listen to the other guy. Listening to subjects is a special example, but the ability to do it may not be a distinct competency from 1.

Two of the panel members placed number 4 in the "No Response" column. Each wrote a comment. The first expert wrote, "Again, this may be a character trait rather than a competency. Perhaps it could be re-phrased as the experience and ability to empathize". The second expert wrote, "Maybe. Too little empathy is bad. Too much empathy could result in too little protocol adherence".

Based on the panel member's responses, the final Humility category contained four competencies. These are

listed in Table 1.

Table 1: Humility Competencies

1. Ability to accept input from others by listening both to other people who might have good ideas as well as people whose perspective is different and might disagree with that of the researcher.
2. Ability to understand the practical applications and limitations of one's abilities and of the context in which one's research takes place .
3. Ability to understand the subjects by having a feeling and concern for the subject's situation, beliefs, motivations, perceptions, and feelings.
4. Ability to recognize professional limitations.

Ethics

The panel members identified 11 ethical competencies for conducting safe, knowledgeable, and effective research while protecting the research participants well being. Ethics in research is "the application of the steps and modes of ethical reasoning to the problems and situations arising from research involving human beings" (Amdur, 2006, p. 5). Ethics apply to every aspect of a research project.

Research ethics are the guiding principles, based on values that esteem people and the growth of social structures, that promote and safeguard the integrity of all persons involved in the research: participants; gatekeepers; stakeholders; researchers and research consumers, to promote the good of all without sacrificing the interests of any, so that the research outcomes represent a progress worthy of the time and resources expended. (Vallance, 2005, p. 199)

Competencies related to research ethics are invasive and inclusive of all research. While placed in the Ethics

category because the main concepts were ethical, these competencies are related to those in other groups. However, they are included in the Ethics category because without adherence to the competencies in this category, human subject research becomes dangerous and perhaps even worthless. The Ethics competencies consisted of five subgroups. These were (a) Ethical Principles of Research, (b) Protection of Research Participants, (c) Ethical Values and Scientific Principles, (d) Publication Ethics, and (e) Ethical Values Commitment.

Ethical Principles of Research

The three principles of the Belmont Report which are autonomy, justice, and beneficence were reflected in a cluster of competencies in the Ethics category. "Knowledge of ethical principles" means "the researcher must have a sound understanding of ethical principals related to research". More specifically, the "researchers must have a good understanding of the ethical principles governing human subjects research contained in the Belmont Report". Another panel member felt that researchers needed "knowledge of and adherence to relevant ethical principles, including respect for persons, beneficence, justice, and their application in real world contexts".

Based on their initial input, the following competency

in the subgroup of Ethical Principles of Research in the Ethics group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Knowledge of and adherence to relevant ethical principles, including respect for persons, beneficence, justice, and their application in real world contexts.

All panel members but one agreed this was a competency. The panel member disagreeing stated this was not a competency because:

This is a combination of a knowledge base and an attitude, rather than a competency per se. That's a semantic concern, in a sense this is a key attribute of a responsible investigator. For the project, it became a question of whether you want to find a way to put it in words that make it a competency, the ability to do something, or if you want to have three separate lists: key competencies, key knowledge bases, and key attitudes.

Based on the panel members' responses, the final Ethical Principles of Research subgroup of the Ethics group contained one competency. This competency is listed in Table 2.

Table 2: Ethical Principles of Research Subgroup of the Ethics Competencies

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Ability to apply relevant ethical principles (including respect for persons, beneficence, and justice) in real-world contexts. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Protection of Research Participants

Many of the responses in the Ethics category related directly to respect and protection of the people that are the participants in research. The researcher must be able to "recognize and manage subject vulnerability" by having "knowledge of participant characteristics and vulnerabilities" which "maximizes the protections for subjects and scientific outcomes". The researcher cannot control the vulnerabilities of the study participants themselves; however, appropriate researcher knowledge allows recognition and management of participant vulnerabilities and characteristics through study design and the consent process. For example, in a cancer drug study, the design of the study would most likely be a randomized double-blind enrollment of participants. The participants randomized to the control group would get the current standard of care treatment for their cancer. The participants randomized to the experimental group would get the current standard of care treatment as well as the new treatment for their cancer care. Cancer patients can be more vulnerable than those with other illnesses because they are often fearful of dying. The patient could think the best chance for cure would be to have the standard of care treatment combined with the new experimental treatment and not listen as the risks are

explained or consider the possibility of whether the new treatment will even be effective. The informed consent and consent process should make clear to the participants that they may or may not get the experimental drug if they enroll in the study; because of the randomization, they would have an equal chance of getting into either group. Also included in the consent process, the participants should be advised of the known risks associated with the new treatment. When given all of the currently available information about the experimental cancer treatment, some patients could decide not to participate in the study. The persons educating and informing the participant should give the information while remaining neutral and assure the patient has and understands the information needed to make an informed decision, thus allowing autonomy. Being careful not to be coercive when offering enrollment into a research study is another ethical step allowing the patient autonomy.

Humans who agree to participate in research put themselves at risk often for benevolent reasons only. Researchers need to recognize the "gift of self" from people agreeing to participate in research. The idea of "gift of self":

Is a Jay Katz Konzept. Jay said many times that we should always remember that the research subject is a donor to our research and is really giving us a gift--we should treat him that way...with

respect and gratitude.

The researcher can recognize this donation of the gift of self by showing "respect for the subjects" and "respect the rights and welfare of their research subjects" as well as being obliged to keep the "ability to maintain sight of humanity".

Based on their initial input, the following competencies in the subgroup of Protection of Research Participants in the Ethics group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Respect for subjects; this is a Jay Katz Konzept. Jay said many times that we should always remember that the research subject is a donor to our research and is really giving us a gift, we should treat him that way...with respect and gratitude.
2. Knowledge of participant characteristics and vulnerabilities so as to maximize protections for subjects and scientific outcomes.

All but two panel members thought number 1 was a competency. One of the two thought number 1 could be included in number 2. The second comment was from the panel member who originally suggested the competency. The panel member's comment was "Key, key, key attitude, but not a competency per se". A third panel member said this was a

competency but thought "this may be a restatement" of a previous competency "but is nicely said".

All panel members but one said number 2 was a competency needed by researchers using human subjects in research projects. The panel member who said it was not a competency made no comment. However this was the same panel member who made the "Key, key, key attitude, but not a competency per se" comment about number 1. One of the panel members who said it was a competency did comment, "I don't think it belongs in this section".

Based on the panel members' responses, the final competencies for the Protection of Research Participants in the Ethics group contained two competencies. These competencies are listed in Table 3.

Table 3: Protection of Research Participants in the Ethics Competencies

1. Respect for subjects because they are actually donors to the research process.
2. Have knowledge of participant characteristics including vulnerabilities in order to maximize protections for subjects and scientific outcomes.

Ethical Values and Scientific Principles

"Knowledge about research ethics" includes "understanding the universal requirements for the ethical conduct of clinical research: social/scientific value;

scientific validity; a favorable harm-benefit balance; fair subject selection; independent review; informed consent; respect for potential and enrolled subjects". Application of the knowledge of research ethics and "adherence to the principles of scientific integrity" establish the need for the researcher to not only have the knowledge of scientific principles but also to remain faithful to them. The researcher should be aware of and adhere to the standards of research defined in that researcher's discipline. While these are concepts at the most basic level, the implication is that the researcher should have no difficulty in implementing scientific principles.

Based on their initial input, the following competencies in the subgroup of Ethical Values and Scientific Principles in the Ethics group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Knowledge of and adherence to basic principles of integrity, honesty, commitment to truth, avoidance of plagiarism, falsification, fabrication, as well as to standards of one's scientific discipline.
2. Understanding the universal requirements for the ethical conduct of clinical research: social/scientific value; scientific validity; a favorable harm-benefit balance; fair subject selection; independent review; informed consent;

respect for potential and enrolled subjects.

3. The "ability to recognize ethical concerns as focusing on the scientific question and the instrument for addressing it, it's easy to overlook any of a large number of issues that may be important for ethical rather than the primary scientific reasons".

The panel members agreed that these were needed competencies. All but one panel member said number 1 was a competency. No reason or comment was given for the "No" vote.

Number 2 was agreed upon unanimously by the panel members as a needed competency. Even though unanimously agreed upon, two members made comments. The first comment was

I would quibble only with the word "universal". There may be, for example, a cultural context in which experimenting on old people before younger people is counted as "fair subject selection," and another in which this would be considered disrespectful. As a "competence," we might phrase this as "the ability to assure that relevant requirements for scientific value, validity, etc., are implemented.

The second comment suggested that this competency was "repetitive".

All but two panel members thought number 3 was a competency needed by researchers. One panel member said this was not a competency because it was "rather vague". Another panel member put this competency in the "No Response"

category and asked, "Is this a competency separate from the others?"

Based on the panel members' responses, the final competencies for the Ethical Values and Scientific Principles of the Ethics group contained five competencies. These competencies are listed in Table 4.

Table 4: Ethical Values and Scientific Principles in the Ethics Competencies

1. Awareness of ethical values related to both the research itself and the environment in which the research is being conducted.
2. Consistently practice ethical values related to both the research itself and the environment in which the research is being conducted.
3. Have knowledge of basic scientific principles related to integrity, honesty, commitment to truth, avoidance of plagiarism, falsification, fabrication, as well as the standards of one's scientific discipline.
4. Ability to adhere to basic scientific principles related to integrity, honesty, commitment to truth, avoidance of plagiarism, falsification, fabrication, as well as the standards of one's scientific discipline.
5. Ability to recognize ethical concerns focusing on both the scientific question and the instrument(s) used.

Conception of Question to Study Completion

Once a research question or hypothesis has been established, the journey through testing the hypothesis, analyzing the data, and arriving at the conclusion can be long and arduous for the researcher and research team. At

any point in the research process, the risk to the participant could change in a positive or negative direction causing the ethical researcher to stop the study. An example of a change in a positive direction is the study of administering oral penicillin to children with sickle cell anemia started in 1983 (Gaston et al., 1986).

A major cause of death in children with sickle cell disease was infection from the bacteria Streptococcus pneumoniae. There was a high incidence of morbidity and mortality from Streptococcus pneumoniae to children with sickle cell disease under 3-years old. In 1983 a study was started that randomized children with sickle cell disease into two groups. The first group received 125 mg of penicillin by mouth. The second group received a placebo by mouth. The study was stopped 8 months early as "the risk of septicemia from S. pneumoniae was decreased by 84 percent, and no deaths occurred in the group that received penicillin" (p. 1597). Penicillin prophylaxis is now the standard of care for children with sickle cell disease. Stopping this study before its completion is an example of ethical behavior from the researcher. Midway through the study the evidence was so compelling that the study was stopped and the control group started on penicillin because the children in the experimental group receiving the

penicillin prophylaxes were having decreased sickle cell crisis and death.

The Declaration of Helsinki (2008) has a principle that supports the concept of stopping a study when benefits for the participants have been shown to promote health. This principle is:

Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results. (Principle 20)

Based on their initial input, the following competency in the subgroup of Conception of Question to Study Completion in the Ethics group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. The ability to behave in an ethical manner from identifying a research question that needs answering to ending the research before the question is answered, if necessary.

All panel members but one said this was a competency needed by researchers. The panel member who said it was not a competency objected to the wording of it because it was "too vague".

Based on the panel members' responses, the final subgroup of Conception of Question to Study Completion of the Ethics group contained one competency. This competency is listed in Table 5.

Table 5: Conception of Question to Study Completion of the Ethics Competencies

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| <ol style="list-style-type: none">1. Ability to behave in an ethical manner throughout the entire research process which may range from identifying a research question that needs answering to ending the research before the question is answered. |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Publication Ethics

In the past, "non-publication of negative trials and non-reporting of negative outcomes, coupled with redundant publication of positive findings, has led to systematic publication bias, which can undermine the reliability of medical evidence" (Wager, 2006, p. 1). In September, 2004, the Committee of Medical Journal Editors began a policy of publishing only clinical trials that have been registered before the enrollment of the first participant. The registered clinical trials are posted on an online website, ClinicalTrials.gov, and is assessable to anyone with a computer. A researcher can check this website before developing a new research project to see if it has already been done and not published. This limits putting humans at risk for a research study that has already been done. One

panel member commented, "Knowledge about publication ethics including open access publishing and the imperatives for the public dissemination of research results" can prevent repetition of research and thereby prevent humans being put at risk needlessly. Principle 19 of the Declaration of Helsinki (2008) also addresses registration of clinical trials stating that "every clinical trial must be registered in a publicly accessible database before recruitment of the first subject".

Based on their initial input, the following competency in the subgroup of Publication Ethics in the Ethics group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Knowledge about publication ethics including open access publishing and the imperatives for the public dissemination of research results.

All panel members but one thought this was a competency needed by researchers. The panel member who thought it was a competency wrote, "Again not a competency in the strictest sense, but key and re-workable into a competency formulation". One member put this competency in the "No Response" column with the comment "Yes and no. There are good reasons to hold public dissemination".

Based on the panel members' responses, the final Publication Ethics subgroup of the Ethics group contained one competency. This competency is listed in Table 6.

Table 6: Publication Ethics of the Ethics Competencies

1. Have knowledge about publication ethics including open access publishing and the imperatives for the public dissemination of research results.

Ethical Values Commitment

Throughout the written history of human subject's research, a lack of ethical values commitment by a few researchers is documented. In the United States examples of unethical researcher behavior is evidenced by the Tuskegee Syphilis Study and the story of the death of Jesse Gelsinger. A panel wrote that a researcher must have an:

Ethical values commitment as without commitment to ethical values, in and outside of the research domain, what ever other competencies the investigator may possess are up for grabs in situations in which there are competing values. Indeed the ethically challenged individual with all the right stuff is particularly dangerous because he/she can more easily cover his/her tracks.

"Trustworthiness, deserving of one's (colleagues', subjects', and society's) trust" influences the manner in which the study is conducted.

Ethical conduct of research builds on the researcher having the "knowledge of right from wrong". The researcher

with "a moral center but not certitude" allows the researcher to question applications of ethics in research studies.

Based on their initial input, the following competencies in the subgroup of Ethical Values Commitment in the Ethics group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Trustworthiness, deserving of one's (colleagues', subjects', and society's) trust.
2. Knowledge of right from wrong. Having a moral center but not certitude.

All but two thought that number 1 was important and needed. One panel member in this group commented, "The privilege of doing research on humans is granted by society". Another panel member simply commented this was not a competency. Another panel member put this competency in a "No Response" category with the comment, "Again, I think this may be a value rather than a competency".

One panel member placed number 2 in the "No Response" category stating, "I believe this competency is phrased in a way that might backfire in the face of cultural relativism. Is it fair to say that knowing 'right' from 'wrong' is independent of cultural and other contexts?" Two members

thought this was not a competency with the only comment being "too vague". The other panel members said this was a competency. However, one of these thought it was a repeat of a previous competency.

Based on the panel members' responses, the final Ethical Values Commitment in the Ethics group contained one competency. This competency is listed in Table 7.

Table 7: Ethical Values Commitment in the Ethics Competencies

1. Have knowledge of right from wrong in research.

Avoiding Biases

Bias is the "distortion of research data that renders the data suspect or invalid. May occur due to characteristics of the researcher, the respondent, or the research design itself" (Gay & Airasian, 2003, p. 585). As this definition suggests, there are many different types of biases that can influence a study's outcome. The panel members initially identified the following types of biases: cognitive and behavioral biases, one's own biases, and systematic biases. When panel members were able to read all of the responses, additional information was generated clarifying these competencies. By being aware of these potential threats to the validity of the study, the researcher can potentially correct for them.

Panel member's comments recognized many different types of biases and how these biases have the potential to invalidate the results of a research study. An example of the importance of preventing bias on the potential outcome of a research trial is recognized by the concept of clinical equipoise, "a state of genuine open mindedness on the part of the researcher regarding the comparative therapeutic merits of each aspect of the clinical trial" (Freedman, 1987, p. 141). Mann (2008) wrote that "because the concept can be applied to other areas of practice, such as public health or psychology, the term should be broadened" (IRB Forum). The idea behind equipoise is that a researcher negates personal biases by having randomized and controlled studies thereby providing the highest level of research control (Stetler, 2001). Mann's (2008) statement reflects the importance of equipoise or attempting to control personal biases. Some believe equipoise is not possible. One such person is Shamoo (2008) who believed that "the concept of equipoise is a myth, period" (IRB Forum).

As long as researchers attempt to identify biases, they can attempt to have equipoise or to control biases by methods such as study design. Panel members validated the importance of avoiding biases in research by their comments. One panel member began with the thought that researchers

should have "the ability to recognize one's own biases". The panel member defined this ability as:

It's easy (and pretty common) to say: (a) I'll bet that alpha is true (b) I'll therefore bet that, if you did beta, gamma would be the result, then run off and do beta---without carefully analyzing the genuine probative value of beta. It's easy as could be (even accidentally and in all good faith) to construct a study that confirms your own biases rather than one that tests the hypothesis on the table.

Another panel member thought the researcher should have "knowledge about cognitive and behavioral biases". The panel member described this as the "ability to avoid biases in clinical care and research".

A third panel member thought researchers should have "the ability to recognize systemic biases". The panel member defined this as:

A really common failing is the tendency to believe that what's published in a good journal as "true". This requires the researcher to have knowledge usually obtained through formal education. In order to use published information wisely, one needs to be able to recognize publication bias, selection bias, ascertainment bias, and the bias of structuring a research study to be the best test of a specific question, rather than the design that will product the best and most generalizable result.

Based on their initial input, the following competencies in the Avoiding Biases group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional

comments and thoughts:

1. Knowledge about cognitive and behavioral biases.
2. Ability to recognize ones own biases.
3. Ability to recognize systematic biases: A really common failing is the tendency to believe that what is published in a good journal as "true" In order to use published information wisely, one needs to be able to recognize publication bias, ascertainment bias and the bias of structuring a research study to be the best test of a specific question, rather than the design that will produce the best and most generalizable. These biases must be recognized in order to use information well; this is especially true for the person who is looking at published data to decide what should be next be done.
4. Ability to avoid biases in clinical care and research.

All panel members said number 1 was necessary. Two comments were given. The first panel member commented, "Without such knowledge the researcher is naive about the very meaning of the collected data". The second comment was that this "may need more explanation".

All panel members said number 2 was necessary. Two comments were given. The first panel member thought that "the comment in number 1 is equally applicable here". Another panel member believed this competency was "too vague, there are many other biases".

All panel members but one agreed number 3 was a necessary competency. Three comments were given by the panel

members who put this competency in the "Yes" column. One panel member referred back to the work done by a pioneer in research designs, Donald T. Campbell (1966), that addressed correcting for biases by the use of design. This panel member commented, "Donald T. Campbell and his students provide ample knowledge about the kinds of bias that accompany various research designs". A second panel member's comment confirmed how interrelated these research competencies are by stating, "I would put the focus here on the competence of researchers to conduct educated literature reviews as they develop their proposal". Literature review was identified as a separate competency and placed in the subgroup of Literature Review in the Grasp of Methodology group. A third panel member wrote, "I might look at this section as really having two competencies: the ability to recognize biases and the ability to manage them".

One panel member placed number 3 in the "No" column. This panel member thought the competency was too vague and limited and stated, "No, too vague. There are many other biases".

Five panel members thought that number 4 was a competency. Two of the five panel members from this group made comments. One of these two panel member felt that the literature review contributed to preventing biases in

clinical care and research as well as proving evidence for new research and commented, "Not only to avoid but to report what biases the researcher encountered in his/her review of the literature that was used to justify the current research endeavor". Again, this comment reinforces the importance that the literature review should have on influencing research. A second panel member wrote, "I might favor a broader formulation, recognizing that sometimes you cannot avoid bias but can test for it, control for it, correct for it or otherwise manage it".

Two panel members placed number 4 in the "No" column. One of these panel members commented "No. The PI should be biased toward provision of care (being an MD) that comes before research (being a PI). I am not sure that is what was meant, however". This comment does astutely reflect Principle 26 of The Declaration of Helsinki (2008), which states:

When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

A second panel member thought number 4 should not be included because it was "too vague".

One panel member placed this competency in the "No Response" column. However, the following comment given was given: "N/A. I'm not exactly sure what this means. If it is a summary of the above, then I agree that it is a competency required by researchers".

Based on the panel members' responses, the final Avoiding Biases group contained three competencies. These competencies are listed in Table 8.

Table 8: Avoiding Biases Competencies

1. Have knowledge about cognitive and behavioral biases.
2. Ability to recognize one's own biases.
3. Ability to recognize biases in published literature.

Respect

One panel member named "respectful" as a competency without a definition. A moral philosopher, Immanuel Kant, began defining Respect in the late 1700s, and his philosophical theory is still used today. Central to Kant's theory is the belief that all persons are owed respect just because they are people. Kant believed Respect is the recognition in attitude and conduct of the dignity of persons (Caze, 2005).

In the literature of moral and political philosophy, the notion of respect for persons commonly means a kind of respect that all people are owed morally just because they are persons, regardless of social position, individual

characteristics or achievements, or moral merit.
(Dillon, 2009)

The importance of respect is further documented by one of the three principles in the Belmont Report being Respect for Persons.

This competency was unintentionally left out of all of the following Rounds in this study. Respect is however included as a competency.

Table 9: Respect Competency

1. Respect for persons.

CHAPTER 6

KNOWLEDGE AND ABILITIES COMPETENCIES

Knowledge encompasses learning and reasoning related to research rules and regulations as well as knowledge relevant to the researcher's area of professional practice such as medicine, nursing or social sciences. Abilities include areas such as time and staff management as well as inductive and deductive reasoning (Ash et al., 2000; Cheetham & Chivers, 1996; Epstein & Hundert, 2002).

Leadership and Management

United States President Dwight Eisenhower (n.d.) said, "Leadership is the art of getting someone else to do something you want done because he wants to do it." Leadership and management are the major concepts in the operation of organizations. Leadership is "the ability to persuade a group to set aside individual preoccupations in order to pursue a common goal" (Hogan, 1997, p.1). Leaders develop a vision and help others to implement the vision. Leadership also "instills the highest level of integrity in the conduct of research" (Kulakowski & Chronister, 2006, p. 4). Management is defined as "the work of any individual who guides others through a series of routines, procedure, or pre-defined practice guidelines" (Yoder-Wise, 2007, p. 6). Management involves the day-to-day process of getting

things done, organizing, and the oversight of projects.

The largest numbers of competencies clustered into the Leadership and Management group and consisted of six subgroups. The subgroups were (a) Supervision and Hiring, (b) Delegation, (c) Training, (d) Data Management, (e) Budget Management, and (f) Certifications.

Supervision and Hiring

The panel of experts recognized that successful completion of a study can involve many persons. From the conception of a research idea, the researcher may need assistance in the development of the study design and in the analysis of the collected data. Researchers must have the "ability to organize and manage research studies, labs, personnel, budgets, space and equipment, and one must have management and supervisory skills commensurate with the type, size, staffing, and budget of any studies". The importance for researchers to have competencies in leadership and management was evidenced by the Leadership and Management category having the largest cluster of competencies of all the competency groups.

Large research studies can require additional personnel in roles that vary from professional collaborators to people collecting and recording the data. The researcher must have the "ability to hire, train, and evaluate staff". The

"ability to hire and supervise competent and ethical assistants" involves not only the ability of the researcher to recognize expertise and ethical behaviors in others but also the ability to supervise. Supervision is "the active process of directing, guiding, and influencing the outcome of an individual's performance of an activity" (Yoder-Wise, 2007, p. 65). "The researcher must possess the skills to address issues of conduct of research personnel" to assure that the study is conducted as approved. Supervision assures not only regulatory compliance (i.e., "researchers must adequately supervise their research teams in order to ensure regulatory compliance"), but supervision also assures other areas of the study are conducted ethically such as obtaining the consent from the participant. A panel member described the importance of these competencies in the following way:

In research requiring the employment of research assistants or recruitment of professional collaborators, the ability to screen, recruit, and monitor the performance of these extensions of oneself is critical to successful conduct of all aspects of the research.

Based on their initial input, the following competency was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts.

1. Ability to hire and supervise competent and ethical assistants in research requiring

the employment of research assistants or recruitment of professional collaborators.

All but one panel member agreed this was a competency needed by researchers. One panel member placed this competency in the "No Response" column commenting that this was an important part of other competencies in this group.

Based on the panel members' responses the final Supervision and Hiring subgroup of the Leadership and Management group contained two concepts that had been combined into one competency. For clarity the Supervision and Hiring subgroup was divided into two competencies. These are listed in Table 10.

Table 10: Supervision and Hiring Group of Leadership and Management Competencies

1. Ability to hire qualified research staff.
2. Ability to supervise and evaluate research staff.

Delegation

After the qualified staff is hired for the study, the researcher must be able to then delegate responsibilities to this staff. The researcher needs the:

Ability to delegate authority while still leading the research team, keeping them on task and alert to the well-being of research subjects, accuracy and completeness of data collection, compliance issues, while maintaining over-all control of the research project.

While the researcher may delegate some

responsibilities, the overall responsibility of the research study remains with the researcher. Delegation requires that trust be given from the researcher to the delegate. During the hiring process, the researcher has the opportunity to employ someone with the skills, abilities, and trait behaviors needed to fit the job. With time and through the development of a relationship, the researcher learns how much responsibility can be delegated. Regardless of the level of performance of the person receiving delegated responsibilities, the researcher remains responsible for all aspects of the study. A panel member addressed the importance delegation can play in a successful study while noting the responsibility the investigator retains in delegation stating:

The ability to screen, recruit, and monitor the performance of assistants and collaborators, extensions of oneself, is critical to successful conduct of all aspects of the research endeavor, ethical and scientific. The term "latent skepticism" (not paranoia) about the motivation of others may be used to describe this attribute. "Trust but verify" also describes what is needed.

Because of this responsibility, it is important for the researcher to be able to review all aspects of the study for accurateness and appropriateness. It is important for the researcher to have the "ability to establish and implement quality control measures to assure ethical and safe treatment of research subjects, quality of data,

reporting, and compliance”.

When delegation occurs and more than one person is responsible for the study, a team is formed. The researcher should have the “ability to work as a research team member”. The ability of the researcher to work as a collaborator and research colleague can affect how well the team functions. While the researcher retains overall responsibility for the study, delegation of responsibilities without associated authority can prevent team formation.

Based on their initial input, the following competencies were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to delegate authority while still leading the research team, keeping them on task and alert to the well-being of research subjects, accuracy and completeness of data collection, while maintaining overall control of the research project.
2. Ability to delegate authority while maintaining overall control of the research project realizing delegation does not remove the obligation to see that those tasks are well done.
3. Ability to work as a team member.

Panel members all said number 1 was a competency needed by researchers. While agreeing on the competency, one panel member commented that there was “overlap with the

data management section. The theme of proper delegation, and the need to include training and supervision, is a recurrent one". While the panel member's concern was valid, delegation and the need to include training and supervision was often attached with competencies that had a more dominant concept. Because of this a separate category was not added.

All panel members agreed number 2 was a competency. One comment was given: "Over delegation and under delegation are huge issues often found when things have gone wrong".

All panel members agreed number 3 was a needed competency. No comments were made.

Based on the panel members' responses, the final Delegation subgroup of the Leadership and Management group contained one competency. This competencies is listed in Table 11.

Table 11: Delegation Group of Leadership and Management Competencies

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| <ol style="list-style-type: none">1. Ability to delegate authority while maintaining overall control of and responsibility for the research project. |
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Training

In order for the researcher to delegate, the researcher must be assured that the person to whom the

tasks are delegated has the knowledge to perform them. After evaluation of a delegate's skills and before delegating any responsibility, the researcher should be able to provide any needed training either personally or by continuing education. The researcher commonly needs the "ability to train research staff in data collection and analysis techniques" to assure that all data are collected appropriately.

Based on their initial input, the following competency was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to train research staff in data collection and analysis techniques.

All panel members agreed the "ability to train and evaluate research staff" was a needed competency. Their complete agreement was confirmed by not having any comments from the panel related to this competency.

Based on the panel members' responses, the final Training subgroup of the Leadership and Management group contained one competency. This competencies is listed in Table 12.

Table 12: Training Group of Leadership and Management Competencies

1. Ability to train and evaluate research staff.

Data Management

Data management is a critical component of a research study. For the data of a research study to be correctly analyzed, interpreted, and presented, "meticulous recording" of the raw data is absolutely necessary.

The study records have to be good enough that the results are interpretable. If risk to subjects is involved, or if product licensure is involved, particular care in record-keeping is important, and includes the ability to detect and correct errors. Probably a touch of OCD [obsessive-compulsive disorder] is what's needed here, just a notch or two below diagnosable.

If the researcher is going to either delegate responsibility of the data collection or the analysis of the collected data, the researcher must have the ability to train the staff responsible for these tasks assuring whomever is collecting the data has "skill in maintaining study records".

Based on their initial input, the following competencies in the subgroup of Data Management in the Leadership and Management group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments

and thoughts:

1. Skill in maintaining study records assuring that records are adequate and accurate and that confidentiality is maintained. Preparation of the records can be delegated, but the investigator must review the records to assure their completeness and accuracy.
2. Ability to meticulously record data ensuring the results are interpretable. If risks to subjects are involved or if product licensure is involved, particular care in record-keeping is important and includes the ability to detect and correct errors.
3. Ability to train research staff in data collection and analysis techniques.

One of the panel members commented, "I think the three components in this section could be lumped together, and as I reflect on it, I think it almost becomes 'willingness and discipline' rather than 'competency or ability, or skill'". A second panel member thought the "ability to train research staff in data collection and analysis techniques" could be incorporated into the "ability to meticulously record data" but also "clearly rates mention....Training and supervision are part of proper delegation". All panel members agreed all were needed competencies.

The first two competencies were combined as suggested by the panel members while the last competency remained as written. As a result, the final Data Management subgroup of the Leadership and Management group contained two competencies. These are listed in Table 13.

Table 13: Data Management Group of Leadership and Management Competencies

1. Skill either in meticulously recording data or in carefully reviewing records to ensure that the records are adequate, accurate, interpretable by others, and confidentially maintained.
2. Ability to train research staff in data collection and analysis techniques.

Budget Management

Budget Management competencies deal with management of resources allowing the study to be completed in an effective way. Poor budget planning or management could possibly mean not completing the study or could potentially compromise the research. The researcher is responsible for pulling all aspects of the study together, and this often includes having a budget that allows the researcher to obtain qualified personnel and equipment and to address many other potential fiscal needs. The researcher "must have the ability to create a budget for the project to ensure costs are covered adequately" as well have the "ability to maintain oversight of the budget throughout the research". A researcher must "think in a wide range from equipment to knowledge to personnel to subject pool, could even be community resources" when developing a budget. A panel member sent a note stating, "I have heard of too many docs who under-budget and end up angry". A researcher may

need "negotiation skills to negotiate budget, study design, and other aspects of the project". One member commented, "Depends a bit on whether we're talking about competencies of investigators in general, or specifically PIs responsible for funding. This is a required competency for a subset of investigators, but not so important for others". For example, at Oklahoma State University Center for Health Sciences, a system has been developed allowing the researcher to delegate the budget development and continuous resource analysis to the grants and contracts department while still maintaining oversight.

Based on their initial input, the following competencies are in the Budget Management subgroup of Leadership and Management. Competencies were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to develop and manage a budget that allows successful completion of the study from equipment to personnel.
2. Ability to manage the budget to completion of the study and ensure costs are covered adequately.

All of the panel members thought both were competencies needed by researchers. The only comment was as follows: "especially the PI or overall program director;

number 1 and number 2 iterative". Because of the comment, the two competencies were combined.

Based on the panel members' responses, the final Budget Management subgroup of the Leadership and Management group contained one competency. This competency is listed in Table 14.

Table 14: Budget Management Group of Leadership and Management Competencies

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|-------------------------------------------------------------------------------------------|
| 1. Ability to develop and manage a budget that allows successful completion of the study. |
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Certifications

Certification recognizes and measures qualifications thus providing assurance that whatever or whomever is certified is qualified (McGough, 2006). The researcher must have "the ability to recognize and comply with required certifications, licenses, and credentials for self and research staff". An example of the importance of the researcher recognizing and complying with required certifications is Clinical Laboratory Improvement Amendments (CLIA) certification of the laboratory to be used in the research. By using a CLIA certified laboratory, multi-site research studies eliminate a possible confounding variable of inconsistent testing of specimens needed for analysis. Therefore, a pharmaceutical company

will often inquire if a potential research site uses a CLIA certified laboratory before engaging in any further negotiations to possibly include this site in a multi-site research project.

If an investigator is serious about becoming a clinical site in a multiple-site research study, investigators must comply with required certifications, licenses, and credentials for themselves and the research staff. The pharmaceutical company inquires as to the qualifications and licenses of the investigator and all sub-investigators. The pharmaceutical company may also look at not only the licenses of the investigator and all sub-investigators but also the experience each has had participating in research studies. Another important factor in a pharmaceutical company's decision on inclusion of a site could include the employment of a Certified Clinical Research Coordinator to assist in the management of a study. Because of this, many universities as well as medical doctors in private practice who desire to participant in multi-site research studies now employ Certified Clinical Research Coordinators.

Based on their initial input, the following competency in the subgroup of Certifications in the Leadership and Management group was sent to the panel members for

confirmation their ideas had not been lost in the summarizations and for their comments and thoughts:

1. Ability to recognize and comply with required certifications, licenses, and credentials for self and research staff.

All of the panel members agreed this was a necessary competency needed by researchers. This agreement was confirmed by not having any comments from the panel for this competency.

Based on the panel members' responses, the final Certifications subgroup of the Leadership and Management group contained one competency. This competency is listed in Table 15.

Table 15: Certification Subgroup of Leadership and Management Competencies

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Ability to recognize and comply with required certifications, licenses, and credentials for self and research staff. |
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Organizational Skills

Organization of the research begins from the time of inception for the study idea through study closure. Before enrolling a single participant in original research, the researcher must develop a protocol, informed consent form, and data reporting forms; find funding; get IRB approval; possibly get an Investigational New Drug (IND) number from the FDA; file Form 1572 if researching a drug with an IND;

sign agreements; and prepare any other steps.

Once the study has begun, the researcher or delegate must recruit participants and begin the consent process. The researcher or delegate must accurately record not only patient data as specified by the protocol but also record other axillary data including minute details such as the temperature of a refrigerator storing immunizations. Research interventions themselves may be complex, timely, and require many levels of organization. An example of this is mandatory reporting of adverse events that may occur during the course of the research and must be submitted to multiple sources on forms that require minute details and require additional data and time. Also, in the case of pharmaceutical studies, time and personnel must be allotted for the visits by the monitor of the study. The researcher can have many roles during a research study.

The Organizational Skills competencies consisted of two subgroups. These were (a) Time Management and (b) Role Balance.

Time Management

Often researchers have many responsibilities and have to split their time between doing research and other responsibilities. Panel members recognized the importance of researchers being able to manage time during the course

of the study.

One has to manage time wisely, both in the "micro" sense of making sure there is enough time in the day to get the tasks done, and also in the sense of deciding what sort of things have to be done in specific time windows (months or years) in order to stay on track and avoid being derailed by some interesting side issue.

"Time management and organization" are important to successful research. Therefore, the researcher should have the "ability to develop a time-line" as well as the "ability to implement research activities in a timely manner".

Based on their initial input, the following competencies in the subgroup of Time Management in the Organizational Skills group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to develop a time-line.
2. Ability to set and achieve interim goals, implementing research activities in a timely manner both in the "micro" sense of making sure there is enough time in the day to get the tasks done, and also in the sense of deciding what sort of things have to be done in specific time windows (months or years) in order to stay on track and avoid being derailed by some interesting side issue.

All panel members except for one said number 1 was needed by researchers enrolling human participants. No

comments were given.

All panel members except for one said the second point was a competency needed by researchers using human participants. One panel member placed this competency in the "No" column feeling that this was part of number 1.

Based on the panel members' responses, the final Time Management subgroup of the Organizational Skills group contained two competencies. These competencies are listed in Table 16.

Table 16: Time Management Group of Organizational Skills Competencies

1. Ability to develop a time line for project activities.
2. Ability to manage a research project so that it conforms to its stated goals and time-lines.

Role Balance

Many researchers have more than just the researcher role. They may teach, provide patient care, or have academic responsibilities not related to the research. Given these many responsibilities, the researcher may need help in order to be successful with the research project. The researcher should have "skill in organizing the study" including assigning different parts of the process of the research. This could include having a study coordinator. "The study coordinator should be trained in proper

organization and conduct of the study" giving the researcher time for other responsibilities. This also gives the researcher the "ability to balance the need to complete the research with the need to handle emergencies or unanticipated events" that may or may not be related to the research.

Based on their initial input, the following competency in the subgroup of Role Balance in the Organizational Skills group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to balance the need to complete the research with the need to handle emergencies/unanticipated events.

All panel members but one said this was a needed competency. One panel member placed this competency in the "No" column because it was "too vague".

Based on the panel members' responses, the final Role Balance subgroup of the Organizational Skills group contained one competency. This competency is listed in Table 17.

Table 17: Role Balance Group of Organizational Skills Competencies

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Ability to balance the need to complete the research with the need to handle emergencies and unanticipated events. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

CHAPTER 7

GRASP OF METHODOLOGY

Panel members identified 21 competencies for conducting safe, knowledgeable and effective research while protecting the research participants well being related to a research study's methods. Many of these competencies had similar concepts. While placed in the Grasp of Methodology category because of the main concepts, these competencies are related to those in other groups. Without adherence to the competencies in this category, the outcomes of a research study can be worthless. The Grasp of Methodology competencies consisted of seven subgroups. These were (a) Understanding the Scientific Method, (b) Literature Review, (c) Hypothesis Development, (d) Study Design, (e) Adherence to the Approved Protocol, (f) Analysis of Data, and (g) Transparency.

Methodology in research includes study design, data collection, and the analysis of the data. The "purpose of design is to set up a situation that maximizes the possibilities of obtaining accurate answers to objectives, questions, or hypotheses" (Burns & Grove, 1997, p. 235). Accurate collection of the data is necessary as "any deficit in the quality of data collection will diminish the value of the research records" (Kalichman, 2006, p. 492).

In this process, a researcher must "make choices about how data will be selected or rejected, what methods of statistical analysis will be used, and how those results are to be presented" (p. 493) to ensure the correct interpretation and reporting of the data.

Understanding the Scientific Method

A "basic understanding of the philosophy of science" requires the researcher to have a foundation of knowledge generally acquired through formal education and through years of experience to obtain expertise. Research knowledge is built and added to with advancement of education as well as mentoring, coaching, and experience. The researcher begins by obtaining "knowledge of the history and conceptual understandings of the philosophy of science".

Various disciplines tend to approach research differently. Therefore, the importance of a researcher's knowing the history and literature and being familiar with the research of their own discipline is vital. For instance, in educational research, qualitative research is often used and taught during a student's educational process. In medical research, quantitative designs are more frequently used in research. In addition, a discipline often has its own code of ethics including research ethics. Researchers should have "content knowledge" of their

discipline's science philosophy that is "involved in the proposed research".

Based on their initial input, the following competency in the subgroup of Understanding the Scientific Method in the Grasp of Methodology group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Basic understanding of the philosophy of science having knowledge of the history and conceptual understandings of the philosophy of science.

All of the panel members agreed this was a necessary competency needed by researchers. The panel members agreement was confirmed by not having any comments from the panel for this competency.

Even though the panel members had no comments, this competency seemed to have two different concepts; therefore, the final subgroup of Understanding the Scientific Method in the Grasp of Methodology group contained two competencies. These competencies are listed in Table 18.

Table 18: Understanding the Scientific Method in the Grasp of Methodology Group Competencies

1. Understand the scientific method.
2. Basic factual and conceptual understanding of the philosophy of science

Literature Review

After a potential researcher has a research question, the next step is to go to the existing literature to review what knowledge exists on the subject (Gay & Airasian, 2003, p.58). "Content knowledge" or "knowledge of the concept of performing a systematic review of the pertinent literature in support of the proposed research" is a task the researcher must accomplish before moving forward in the research process. The researcher acquires "knowledge of specific research literature" related to the potential question and gains "detailed knowledge of the discipline involved in the proposed research" through reviewing the literature. Thus, the "ability to conduct a thorough and unbiased integrative research review is key to launching new research that builds on all that went before". One panel member suggested that "the principles and techniques of meta-analysis are a meaningful guide to doing an adequate job in this regard". Before a hypothesis can be formed, the "investigator must have a thorough and complete understanding of current scientific literature relevant to

the question under investigation".

Based on their initial input, the following competency in the subgroup of Literature Review in the Grasp of Methodology group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Knowledge of the concept of performing a systematic review of the pertinent literature relevant to the question under investigation in support of the proposed research must be extremely well versed in relevant literatures and background to any studies performed.

All panel members but one said this was a competency needed by researchers. One panel member commented, "Without an adequate job here, the study is likely to miss the mark". Another panel member who thought this to be a needed competency wrote, "This should really be 'ability to' rather than 'knowledge of the concept'". One panel member placed this competency in the "No Response" column stating that "these are Yeses for designers but are barely important for many other PIs where the work is already done for them"; this comment refers to clinical trials.

Based on the panel members' responses, the final competency in the subgroup of Literature Review in the Grasp of Methodology group contained one competency. This

competency is listed in Table 19.

Table 19: Competency in the subgroup of Literature Review in the Grasp of Methodology group Competency

1. Ability to conduct a systematic review of the pertinent literature relevant to the research topic hypothesis.

Hypothesis Development

Following the literature review, the researcher's next step is to form the hypothesis. A "hypothesis is a researcher's tentative prediction of the results of the research findings" (Gay & Airasian, 2003, p. 62). In the research process, "the researcher does not set out to prove a hypothesis, but rather, collects data that either support or do not support it" (p. 62). A researcher must have the "ability to frame a testable hypothesis". Framing a testable hypothesis means "taking an idea and deciding what aspects of it may be liable to challenge in an organized and informative manner, then framing the specific questions to ask. This implies, of course, a basic mastery of the informational universe in which the question arises". The researcher must also have the "ability to distinguish between questions susceptible to empirical investigation and those that relate to values: esthetic, moral, and religious".

Based on their initial input, the following

competencies in the subgroup of Hypothesis Development in the Grasp of Methodology group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. The ability to distinguish between questions susceptible to empirical investigation and those that relate to values: esthetic, moral, and religious is essential.
2. The ability to frame a testable hypothesis by taking an idea and deciding what aspects of it may be liable to challenge in an organized and informative manner, then framing the specific questions to ask, implying a basic mastery of the informational universe in which the question arises.

One panel member placed both competencies in the "No Response" column and made the same comment made for both:

These are all Yeses for a subset of PIs; those that design and frame studies. For the Phase III PI most of this, except the ability to strictly adhere to the protocol, is irrelevant to conducting the study. Most PIs however, should be able to accept well designed studies and reject studies that are bogus.

All other panel members said these were competencies needed by researchers. There were two other comments from panel members on number 1. One stated, "When applicable". A second member thought these were "Lumpable, but key"; this panel member elaborated by commenting that "what I really want to know: what's testable, and what specific

experiments are practical, distinct universes". This comment recognizes the need for researchers to be able to develop a hypothesis that anyone reading the hypothesis, whether for a study approval or when reading the finished research, can evaluate the researcher's "basic mastery of the informational universe in which the question arises" and, thereby, the quality and potential success of the results of the research. No other comments were provided.

Based on the panel members' responses, the subgroup of Hypothesis Development in the Grasp of Methodology group contained two competencies. These competencies are listed in Table 20.

Table 20: Hypothesis Development in the Grasp of Methodology Group Competencies

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| 1. The ability to distinguish between questions susceptible to empirical investigation and those that are not such as values, ethics, morals, and religious. |
| 2. The ability to frame a testable hypothesis which involves the steps of (1) taking an idea and deciding what aspects of it may be liable to challenge in an organized and informative manner and then (2) framing the specific questions to ask in such a way that they imply a basic mastery of the informational universe in which the questions arise. |

Protocol Development and Study Design

Once the researcher has formed a hypothesis, a protocol is developed which includes the study design explaining how the hypothesis is to be tested. Principle 14

of The Declaration of Helsinki addresses a protocol stating:

The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits. (Declaration of Helsinki, 2008, para. 14)

To develop a protocol, the researcher must have the "knowledge of basic research designs". Specifically, "investigators must have a basic understanding of all of the research designs appropriate to their areas of investigation". The researcher must have "detailed knowledge about the architecture of research design (choosing the appropriate research design to answer the research question), including statistical concepts". There are many study designs, and "investigators must have a thorough understanding of the specific research designs they use". The study design tells how the researcher will test the hypothesis.

Usually, the test of an hypothesis is set forth

in a protocol; often, very strict adherence to the protocol is necessary to the reliability with which the test is applied---and in research with substantive risks, it may be necessary to safety.

After development of the protocol, approval by an Institutional Review Board (IRB) is required before the researcher can begin the study if human participants are involved. An IRB must weigh the risks and benefits to the research participant before approving any research. One of the responsibilities of an IRB is to assure that no human participant is unnecessarily put at risk. If the design of a study does not test the hypothesis, then unnecessary risk is not acceptable for the participants of a study because it will not yield usable information. The federal codes address this stating:

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied: (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. (Code of Federal Regulations, 45 CFR 46, para. 46.111)

"Researchers must have sufficient scientific knowledge and experience to design good studies that are likely to result in contributions to the science and, thus, have sufficient benefit to justify the risks to subjects". The study design should also account for and try and prevent or control potential confounding variables.

Once an idea has been found interesting enough to be worth pursuing, and once some testable questions have been identified, one must be able to devise the actual experiment or other data-gathering exercise that will test or extend the hypothesis. This requires clear conceptual grasp of the questions, and ability to recognize and plan for potential biases, and familiarity with the most common types of research designs.

Based on their initial input, the following competencies in the subgroup of Protocol Development and Study Design in the Grasp of Methodology group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Sufficient scientific knowledge and experience to design good studies that are likely to result in contributions to the science and, thus, have sufficient benefit to justify the risks to subjects.
2. Grasp of the scientific method, including the falsificability principle and need for replication to support the advancement of science sets the stage for the design and implementation of internally and externally valid research that is capable of answering relevant empirical research questions.
3. The ability to devise the actual experiment or other data-gathering exercise as a test of the hypotheses requiring a clear conceptual grasp of the questions, and ability to recognize and plan for potential biases, and familiarity with the most common type of research designs.
4. Detailed knowledge about the architecture of research design (choosing the appropriate research design to answer the research question), including methodology and statistical concepts appropriate to the research topic.
5. Knowledge of basic research designs

understanding all of the basic research designs appropriate to their areas of investigation.

6. Knowledge of specific research designs with a thorough understanding of the specific research designs they use.

The panel members grouped comments on numbers 1 through 3. As a group, all panel members but one said all three were competencies. One panel member put all three of them in the "No Response" column with the same comment for all three:

All Yeses for a subset of PIs; those that design and frame studies. For the Phase III PI most of this, except item 7 [the ability to strictly adhere to the protocol], is irrelevant to conducting the study. Most PIs, however, should have enough grasp of the scientific method to be able to accept well designed studies and reject studies that are bogus.

An additional comment on number 1 spoke to its importance:

"Forget everything else without competence in this area!"

There were two additional comments on number 3. One panel member stated, "This appears to be several competencies rolled into one long sentence!" Another panel member wrote of number 3, "Key, and worth separating from the earlier ones".

All but one panel member thought number 4 was a competency. The same panel member who put the first three into the "No Response" column also put this competency in the "No Response" column and commented that this had been

included in previous competencies and that "again, these are Yeses for designers but they are barely important for many".

All panel members but one said that number 5 was a competency. The panel member who put this competency in the "No" column said this had been "mentioned before". Another panel member who said this was a competency commented that this competency had been included previously in this category and that "again this is specific to certain kinds of PIs".

Based on the panel members' responses, the final subgroup of Protocol Development and Study Design in the Grasp of Methodology group contained two competencies. These competencies are listed in Table 21.

Table 21: Protocol Development and Study Design in the Grasp of Methodology Competencies

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| 1. Ability to design the actual research project so that it is a test of the hypothesis by requiring a clear conceptual grasp of the questions to test the hypothesis. |
| 2. Have sufficient scientific knowledge to design good studies that are likely to result in contributions to the knowledge base and, thus, have sufficient benefit to justify the risks to subjects. |

Protocol Adherence

Once approval from the IRB has been given, the researcher may begin the study. Any changes to the protocol

must be approved by the IRB before implementation. Therefore, the researcher must have the "ability to strictly adhere to the protocol". The IRB has the ability to investigate any approved research and the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements (Code of Federal Regulations, §46.113). Two examples of research studies where the researchers did not follow the approved protocols are the University of Pennsylvania's Gene Transfer Study and the University of Oklahoma's Melanoma Study. Both had tragic outcomes for the participants, resulted in closure of all federally-funded IRB-approved studies at the institutions until every study could be reviewed individually, and led to suspension of federal funds for all human research at the institutions occurring at the time (Charatan, 2000; Gelsinger, 2000; Josefson, 2000; Leiden, 2000; Pollack, 2003; Smith & Byers, 2002; Weiss, & Nelson, 2000a, 2000b,2000c).

Based on their initial input, the following competency in the subgroup of Protocol Adherence in the Understanding the Scientific Method group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to strictly adhere to the protocol.

Two members placed this competency in the "No Response" category. The first commented that this was a part of all the competencies in this category. Another panel member was "not sure. There may be instances in which protecting the safety and welfare of subjects over-rides the importance of adhering to the protocol. Perhaps there should be a parenthetical phrase included here". One member placed this competency in the "No" column with the comment that this was "too vague".

All other panel members agreed this was a competency needed by human subject researchers. One panel member agreed that this was a competency but wrote, "Again, I might question whether this were a 'discipline' rather than a competency".

Based on the panel members' responses, the final competency in the subgroup of Protocol Adherence in the Understanding the Scientific Method group contained one competency. This competency is listed in Table 22.

Table 22: Protocol Adherence Subgroup of Understanding the Scientific Method Competencies

1. Ability to strictly adhere to the protocol.

Analysis of Data

Many scientists do not have the necessary training in statistics for their research project and must seek out the needed expertise (Kalichman, 2006) when it is time to analyze the data.

Once one has designed and carried out a study, one has to be able to make sense out of the results. This would encompass a number of types of clear thinking, as well as the ability to construct competitive interpretations of the same data and the ability to conduct and interpret statistical tests.

The "investigators must have a basic understanding of common statistical analysis techniques and a more detailed understanding of the techniques they themselves use". Researchers today have the availability of computer statistical software programs such as SPSS. The researcher can enter collected data and select the type of analysis to perform on the data, and the computer analyzes the data within the given parameters. However, the investigator needs to have "the ability to understand and apply statistical algorithms embedded in the point-and-click statistical software packages to assure appropriate reporting of results and their limitations".

The researcher is responsible for appropriately analyzing the data collected, reaching conclusions based on the analysis, and correctly reporting all of this. The

panel members noted that the consumer of research also has responsibilities in understanding data analysis and that the consumer should be able to confirm the conclusions of the researcher. The consumer of the research "cannot depend on journals, peer reviewed or not, to vet reported statistical findings for their adequacy". The researcher and consumer of the research should have "the ability to analysis multiple complex ideas, ask interesting questions, develop logical investigation strategies, and reach logical conclusions".

Based on their initial input, the following competencies in the subgroup of Protocol Adherence subgroup of Understanding the Scientific Method Competencies group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Analytical skills allowing the researcher to make sense out of the results of the experiment to include the ability to construct competitive interpretation of the same data and the ability to conduct and interpret statistical tests.
2. Understand and apply statistical algorithms not depending on journals, peered reviewed or not, to vet reported statistical findings for their adequacy.
3. The ability to understand and apply statistical algorithms in the point-and-click statistical software packages is needed to assure appropriate reporting of results.
4. Strong analytical skills with the ability to analyze multiple complex ideas, ask interesting

questions, develop logical investigation strategies, and reach logical conclusions.

5. Basic understanding of common statistical analysis techniques and a more detailed understanding of the techniques they themselves use.

All panel members except for one said number 1 was a competency. One panel placed this competency in the "No Response" category. That panel member repeated a previously-made comment:

All Yeses for a subset of PIs; those that design and frame studies. For the Phase III PI most of this, except item 7 [the ability to strictly adhere to the protocol], is irrelevant to conducting the study. Most PIs, however, should have enough grasp of the scientific method to be able to accept well designed studies and reject studies that are bogus.

There were no other comments for this competency.

For number 2, five panel members thought this was a needed competency. One panel member thought it was not a needed competency. This panel member thought this was too "vague" and was addressed in other competencies. Two panel members placed this one in the "No Response" category, and both thought it was included in other competencies in the group. One further commented, "Again, these are Yeses for designers but they are barely important for many other PIs where the work is already done for them".

All panel members but one thought number 3 was valid. One panel member who said this was a competency commented:

This is another one where it seems a bit too pointed and specific. My favorite example of this is a regression line shown on non-number-line data in a New England Journal of Medicine article, immediately adjacent to a statistical review describing the lack of validity of that display. I'd think it better to identify "a conceptual grasp of the statistical methods appropriate to the research being carried out" as the key competency, and regard this as a specific annoying example.

One panel member placed this competency in the "No Response" column. This panel member thought this competency was included in other competencies in this group and that "again, these are Yeses for designers but they are barely important for many other PIs where the work is already done for them".

Number 4 was agreed upon by all panel members but one as a competency. One of the panel members who agreed that it was a competency thought this was included in previous competencies and that "again, this is specific to certain kinds of PIs". One panel member placed this competency in the "No" column stating that this competency was too "vague".

All panel members thought the number 5 was a competency. The only comment for this competency was that one panel member thought this was included in previous competencies and that "again, this is specific to certain kinds of PIs".

Based on the panel members' responses, the final Protocol Adherence subgroup of Understanding the Scientific Method Competencies contained two competencies. These competencies are listed in Table 23.

Table 23: Protocol Adherence Subgroup of Understanding the Scientific Method Competencies

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| 1. Ability to use various analytical skills that will allow the researcher to make sense out of the research results including the ability to construct competitive interpretation of the same data and the ability to conduct and interpret statistical tests. |
| 2. Have a conceptual grasp of the statistical methods appropriate to the research being carried out. |

Transparency

Scientists in greater numbers are demanding researchers share the details of their studies. Evidence of this is the mandatory registration and results reporting for clinical trials of drugs, biologics, and devices included in the Food and Drug Administration Amendments Act of 2007.

Science is a communal enterprise. Even if one individual had the intellect to address all issues relevant to a field of science, no one individual can do all of the work. For this reason, it makes sense that the interest of science would be best served by rapid and unrestricted sharing of findings, insights, and ideas. (Kalichman, 2006, p. 493)

Researchers should have "the willingness to subject one's work to the scrutiny of others, including the

willingness to share data with others who might wish to look at them from a different perspective". This is important because:

The desire for fame, advancement, and monetary rewards are universal and can easily turn the unwary investigator toward bending the ethical and scientific rules, including deception of human subjects, colleagues, IRB reviewers, journals, and peer reviewers. Outright rigging of the data by selective reporting, taking advantage of the vagaries of inferential statistics, or in rare instances fabricating data occur and are the lack of commitment to transparency, full disclosure and accountability.

An example of this happened at the University of Utah with the supposed success of achieving cold fusion in a lab (Broad, 1990; Brown, 1993; Cold Fusion's, 1993; Huizenga 1993; Levi, 1989; Lindley, 1990). Researchers reported achieving cold fusion in the laboratory. The potential of this being true caused international excitement. The researchers were not forth-coming with their methods. As time passed, no one was able to duplicate the experiment. Finally, the researchers were found to have fabricated results. Had these researchers had the "commitment of transparency, full disclosure, and accountability," it would not have been as "easy to be misled by one's own mixed motives when designing, implementing, and reporting the results of research".

Based on their initial input, the following

competencies in the subgroup of Protocol Adherence of Understanding the Scientific Method Competencies group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. The willingness to subject one's work to scrutiny of others, including the willingness to share data with others who might wish to look at them from a different perspective.
2. Commitment of transparency, full disclosure, and accountability as it is easy to be misled by one's own mixed motives when designing, implementing, and reporting the results of research. The desire for fame, advancement, and monetary rewards are universal and can easily turn the unwary investigator toward bending the ethical and scientific rules, including deception of human subjects, colleagues, IRB reviewers, journals, and peer reviewers. Outright rigging of the data by selective reporting, taking advantage of the vagaries of inferential statistics, or in rare instances fabricating data occur and are the lack of commitment to transparency, full disclosure and accountability.

All panel members but one thought number 1 was a competency needed by researchers. One panel member placed this competency in the "No Response" column stating, "I believe this is a character trait, not necessarily a competency".

Only half of the panel members supported number 2. One panel member placed this competency in the "No" column with no comment given. Two members placed number 2 in the "No

Response" column. One stated, "I believe this is a desirable character trait, not necessarily a competency". Another panel member placed this in the "No Response" category commenting that this had been "included in other competencies". This panel member also wrote, "Again, these are Yeses for designers, but they are barely important for many other PIs where the work is already done for them". Only one comment was given from the panel members who placed this competency in the "Yes" column. The comment was that these two competencies could be "combined".

Based on the panel members' responses, the final Transparency subgroup of the Understanding the Scientific Method group contained one competency. This competency is listed in Table 24.

Table 24: Transparency Subgroup of the Understanding the Scientific Method Competencies

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| <ol style="list-style-type: none">1. Commitment to conducting ethical research which has transparency including the willingness to subject one's work to the scrutiny of others and the willingness to share data with others who might wish to look at them from a different perspective. |
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Communication and Communication Skills

Communication is "the process by which information is transmitted and understood between two or more people" (McShane & Von Glinow, 2010, p. 525). "The only thing human beings do more often than communicate is breathe"

(Kowalski, 2003 p. 325). The researcher has the responsibility to communicate a plethora of information to many people on many educational and responsibility levels during the entire research process. Therefore, the researcher should have the:

Ability to present information in a clear manner to the whole panoply of research stakeholders including research subjects, subjects' family members, research staff, co-researchers, IRB and other compliance bodies, and to the public and media; conduct informed consent procedures, re-consent procedures, de-briefing, staff meetings, staff evaluations; prepare progress reports, reports of adverse events or unanticipated problems, follow-up reports, final reports, publications; recognize special requirements of cross- or multi-cultural research.

The Communication and Communication Skills

competencies consisted of four subgroups. These were (a) Language Fluency, (b) Communication with the Research Participant, (c) Ability to Receive Input, and (d) Networking.

Language Fluency

The investigator has to communicate both verbally and in writing with various audiences including the participants, regulatory bodies, peers, and others. The researcher needs to be "literate" and "able to read and write fluently in English, or the language of their country, and in the local languages". The researcher should

have "writing skills" and "oral communication skills" giving the researcher the "ability to express scientific principles, literature, research proposals, research designs, findings, etc. in writing for both professional and lay audiences".

The researcher has the responsibility to communicate with peers the results of the research. The researcher needs the "ability to communicate formally" as "research ain't worth diddly-squat if nobody finds out about it. A successful researcher can present his findings in a way that will be useful to others".

Researchers, especially of large studies, need to communicate with many people on many levels and in many roles; this includes regulatory agencies. Communication occurs before, during, and after the research study is active. Researchers often need to "conduct staff meetings and staff evaluations" as well as "prepare progress reports, follow up reports, final reports and publications". The researcher is required to "report adverse and unanticipated problems" to regulatory bodies communicating the findings of the event. The researcher maintains a responsibility to communicate with research participants any new findings that could affect them.

Based on their initial input, the following

competencies in the subgroup of Certifications in the Leadership and Management group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to express scientific principles, literature, findings, etc. orally and in writing for both professional and lay bodies.
2. Ability to speak, read, and write fluently in the language of the researcher's country and in the local languages.

The large number of comments on these competencies reflect the panel members beliefs of the importance of communication competencies needed by a researcher. All panel members but two said number 1 was needed by researchers. Only one of the two members who placed this competency in the "No" column made a comment. The comment was "no, part of 1". The "part of 1" refers to another competency:

The ability to present information in a clear manner to research subjects and their family members, research staff, co-researchers, compliance bodies such as the IRB, professionals and lay persons and organizations as well as to the media in a way that will be useful.

All panel members but two said number 2 was needed by researchers. However, three of the panel members placing this competency in the "Yes" column made comments reflecting that much thought had been given to this

competency. One of the three stated, "This may need additional information". A second panel member commented applying personal experience from research done in a foreign country where the person did not speak the native language:

This is one of the many items that sits on the cusp of "key competency" versus "useful skill" versus "helpful attitude". The importance of language fluency for an individual researcher hinges on just what his or her role is and with whom he or she has to interact. I don't think I was a bad researcher while on sabbatical in Vienna, but I needed help from a native speaker when doing consent discussions.

The third member's thoughts followed a similar line of thought:

I think what this means is that the PI is literate. If Yes, that should be it. If the researcher's country is India and she is fluent in Hindi but is doing the study here, isn't all that is important is the language at the site?

One panel member placed number 2 in the "No" column commenting that the competency was "too vague". Another panel member placed number 2 in the "No Response" category. The comment given from this panel member reflected the thoughts of other panel members that perhaps it was not as important for the researcher to be fluent in the language as long as someone on the research team was:

I'm not sure I agree that this is a competency required of all researchers. It may be sufficient to have members of the research team be fluent in

local languages, as long as those team members know and accept their enhanced responsibilities for communication.

Based on the panel members' responses, the final Language Fluency subgroup of the Communication and Communication Skills group contained one competency. This competency is listed in Table 25.

Table 25: Language Fluency Subgroup of Communication and Communication Skills

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| <ol style="list-style-type: none">1. Ability to communicate effectively by speaking, reading, and writing fluently in both one's native language and in the local languages where the research is conducted. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Communication with the Research Participant

The importance of communication and communication skills, especially related to the ability to communicate with the research participant, is reflected in the panel member's responses. Many of the communication competencies commented on the importance of giving the potential research participant the information needed to allow a truly informed decision either to participate or not to participate in a research study. Ethical principles stated in The Belmont Report and The Declaration of Helsinki also address the importance of communicating with the research participants regarding obtaining consent to participate in research. One of the three ethical principles of The

Belmont Report (1978) is "Respect for Persons". This principle addresses the autonomy of people and requires research participants to be given the choice to either participate or not participate in a research study after receiving all the information needed to make that decision. The Declaration of Helsinki (2008) also addresses autonomy in several of the Principles: Principle 22 Expressed the idea that participation is voluntary. Principle 24 maintains that each potential participant must be given and understand all of the information needed to make an informed decision on whether to either participate or not participate in a research study.

The only way a person can make the decision to either participate or not participate in a research study is to have all of the relevant information given to them. The participant must not only be given the information, but they should also understand the information. When consent is given, the potential research participant should have made the decision to participate based on information and understanding about the research; thus the consent is "informed consent".

It is not unusual in a pharmaceutical clinical trial for the written informed consent to be approximately 20 pages. The potential participant should be given the

opportunity to ask questions of the research team members, take the consent home and read and discuss it with family members, research the information themselves, or do anything else needed to understand what the researcher is asking of them. Should the potential participant decide to participate in the research, communication should continue with the participants being informed of any new developments in the study that could affect them or their decision to continue in the research or that might make them want to withdraw from the research study. For the researcher to comply with The Belmont principle of Respect for Persons and with The Declaration of Helsinki, the consent of the participant should be informed. This process is not a one time event. Every participant must also be given the opportunity to ask questions and receive any new information as the study progresses and be allowed to either continue or withdraw from the study. Thus consent to participate in a research study is not a one time event, but rather it is a process.

All of the competencies in this category identified by the panel members relate to The Belmont Report's principle of Respect for Persons and to the following principles of The Declaration of Helsinki: Principle 11--to protect the research participant, Principle 22--to obtain consent, and

Principle 24--the consent will be an informed consent. Panel members recognized the importance of communications involved in the informed consent process.

The person consenting the participant should have "skill in conducting the informed consent interview" as "the oral interview is one of the most important parts of the informed consent process. An investigator who is not able to communicate well may need to assign part of the consent process to another team member. The investigator "will listen to others and can get ideas across or can delegate to others who have those skills".

The person seeking consent from the potential participant must "assure the prospective subjects are made aware of the purpose, possible benefits and anticipated risks of participation in the study". The person initiating the conversation about the research with the potential participant should have the "ability to communicate effectively with potential subjects" as well as have the "ability to explain research concepts and procedures to potential subjects".

Based on their initial input, the following competency in the subgroup of Communication With the Research Participant in the Communication and Communication Skills group was sent to the panel members both to confirm that

their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to present information in a clear manner to research subjects and their family members, research staff, co-researchers, compliance bodies such as the IRB, professionals, lay persons, organizations as well as to the media in a way that will be useful.

All panel members thought this was a needed competency for researchers. One panel member referred to the importance of the consent process by pointing out that the researcher needs the "knowledge of deficiency and ability to hire a person who can communicate". If the researcher is not able to communicate appropriately with the potential participant due to a communication deficiency, time limitation, or other problems that might impinge on obtaining informed consent, then having the ability to hire an appropriate person to delegate this responsibility to becomes very important. Often the consent process is more of a team effort rather than being the responsibility of a single person.

Based on the panel members' responses, the final Communication With the Research Participant subgroup of the Communication and Communication Skills group contained one competency. This competency is listed in Table 26.

Table 26: Communication With the Research Participant

Subgroup of Communication and Communication
Skills Competencies

1. Ability to present information in a clear manner to others.

Receiving Input

"Effective communication develops a rhythm in which messages are sent and received in a productive, respectful, and supportive manner" (Wilson, 1999, p. 88). Therefore, communication involves the researcher not only having the ability to send messages but also the ability to receive them in a positive manner. By their responses, panel members placed a great deal of importance on the ability of the researcher to listen. A researcher should have the "ability to accept input from others". Good researchers "will listen to others" because it is important to have "input from people whose perspective would be different, especially folks who might just plain disagree with your notion". Such input could make a difference in the research outcomes through such things as the design, protecting participants, or the many other things involved in research. The presence of humility facilitates listening.

"Listening skills" were listed by three different panel members as a competency. Although three panel members named "listening skills" as a competency, none of the three

described this competency in the same way. The first description addressed the importance of listening to people by having the "ability to listen to research subjects, family members, research staff, etc". The second panel member's description of "listening skills" addressed a different kind of communication. This panel member thought it was important for the researcher to have the "ability to 'read' non-verbal communication and behaviors". The third panel member's description of "listening skills" focused on the communication involved in the peer research process when the researcher needs to "evaluate and corroborate assumptions and conclusions". This competency allows the researcher to be able to network with others.

Based on their initial input, the following competency in the subgroup of Ability to Receive Input in the Communication and Communication Skills group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to listen to others.

All panel members but one thought this was a needed competency for researchers. One of these panel members felt strongly that this was a competency and wrote, "Yes, Yes, Yes". Another supported it as a competency but wrote

"iterative", which meant that it was repetitive of a previous competency. The panel member who disagreed felt that the competency as written was "too vague".

Based on the panel members' responses, the final Ability to Receive Input subgroup of the Communication and Communication Skills group contained one competency. This competency is listed in Table 27.

Table 27: Ability to Receive Input Subgroup of Communication and Communication Skills Competencies

1. Ability to listen to others.

Networking

Researchers need to be able to network with others. It is important for researchers to have "contacts and a social network". The researcher needs to be able to "find a network of people with whom to share research issues and obtain help, support, and answers. [It] is particularly useful in the event of problems".

Based on their initial input, the following competency in the subgroup of Networking in the Communication and Communication Skills group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to network and seek counsel when there is an uncertainty about how to interpret the applicable regulations is part of the requisite ability.

All of the panel members agreed this was a necessary competency needed by researchers. The panel members agreement was confirmed by not having any comments about this competency.

Based on the panel members' responses, the final Networking subgroup of the Communication and Communication Skills group contained one competency. This competency is listed in Table 28.

Table 28: Networking Subgroup of Communication and Communication Skills Competencies

- | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Ability to network and seek counsel when there is an uncertainty about how to interpret the applicable regulations. |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Cultural Competency

The importance of the researcher having cultural competence and the effect with which cultural competence can influence research is evidenced by the many comments made by panel members. Cultural competence is "the process in which the healthcare provider continuously strives to achieve the ability to effectively work within the cultural context of a client (individual, family, or community)" (Campinha-Bacote, 1999, p. 203). To become culturally

competent, one must explore one's own culture, values, and beliefs as well as recognize personal biases, prejudices, and assumptions about other cultures. One must also learn about another's culture in order to provide appropriate health care and health interventions (Campinha-Bacote, 1999, 2002). "Without being aware of the influence of one's own cultural or professional values, there is a risk that the health care provider may engage in cultural imposition" (Campinha-Bacote, 2002, p. 182).

Panel members named several cultural competencies researchers need. A panel member stated that the researcher needs to have "cultural awareness" which is the "ability to recognize and work with the variety of presentations. Think of the book The Spirit Catches You and You Fall Down". The researcher should be able to "recognize special requirements of cross- or multi-cultural research". Another panel member's statement concurred that the researcher should have the "ability to recognize cultural constraints". This panel member noted:

It is easy to design an experiment that seems just fine to you, but is a cultural affront to someone else. This has come out in studies of intercessory prayer, which some people deem blasphemous, and in studies of waste tissue (not considered to be waste by everyone). The humility to ask advice and to admit error is key, as is the willingness to respect and honor cultural conventions different from one's own.

Based on their initial input, the following competencies in the Cultural Competency group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to recognize and work with special requirements of cross- or multi-cultural research.
2. Ability to recognize cultural constraints and design an experiment that is not a cultural affront to someone else.

All panel members agreed number 1 was a competency. However, three comments were given that indicated this competency had limited application and was needed "when applicable", "where applicable", and "if applicable to one's field of research". These comments recognize that not all research involves cross- or multi-cultural populations, and therefore cultural competency would not apply to every research study.

All of the panel members but two thought number 2 was a competency. Two of the panel members that placed number 2 in the "Yes" column also indicated by their comments that this competency was situational. The comments were as follows: "when applicable" and "where applicable; probably expressed more as the attitude of willingness to seek counsel when dealing with other cultures than as a

competency per se". These comments indicate that this competency may only be necessary when enrolling a population with which the researcher is not familiar. The researcher should be willing to consult someone with expertise or competence in the culture before designing and implementing a study. One panel member placed this competency in the "No" column however it was very similar to the first competency and should be included as "part of the first one".

One panel member placed this competency in the "No Response" column. This panel member's comments reflected the same thought as:

I'm not sure I agree that this is a competency required of all researchers. It may be sufficient to have members of the research team be fluent in local languages, as long as those team members know and accept their enhanced responsibilities for communication.

Cross- or multi-cultural research studies have become more common place in the global community. Panel members did, however, recognized that the need for the researcher to have cultural competence is not always necessary. Panel members discerned the researcher should be aware of cultural differences and cognizant of how those differences can distort the research outcomes. If the researcher does not have cross-cultural or multi-cultural abilities,

involvement of someone who does is a necessity for a positive outcome of the research study.

Based on the panel members' responses, the final Cultural Competency group contained four competencies. These competencies are listed in Table 29.

Table 29: Cultural Competency Competencies

1. Ability to work with special requirements of cross-cultural or multi-cultural research.
2. Ability to recognize cultural constraints.
3. Ability to seek counsel to help design an experiment that is not a cultural affront to someone else.
4. Knowledge of participant characteristics including vulnerabilities so as to maximize protections for subjects and scientific outcomes.

CHAPTER 8

SITUATIONAL AND ORGANIZATIONAL FACTORS

The rules and regulations relating to human subjects research were put into place to protect research participants. Whether intended or unintended these rules when followed also protect the researcher, institutions, agencies, and other administrative entities that assume responsibility for human subjects research. Situational and organizational competencies relate to the researchers necessary interactions with bureaucracies, their professional boundaries, and compliance responsibilities.

Compliance

There are international, national, state, and sometimes local laws and regulations governing research with humans. The main purpose of these laws and regulations is to protect persons who are participants in research. The Declaration of Helsinki's Principle 10 addresses compliance with laws and regulations stating:

Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
(<http://www.wma.net/en/30publications/10policies/b3/index.html>)

Researchers are required to comply with these laws and regulations, and without these a strong level of protection for human subjects is lost. The Compliance competencies consisted of four subgroups. These were (a) Education and Knowledge, (b) Interaction Between the Researcher and the Bureaucracy, (c) Good Clinical Practice, and(d) Following the Rules.

Education and Knowledge

In order to practice safe human subjects research, the researcher must learn and understand its rules and standards. "The desire to learn, like every other human characteristic, is not shared equally by everyone" (Houle, 1963, p. 3). However, the importance the panel members placed on a researcher's education and knowledge is reflected in the competencies they named and defined.

Panel members made many comments on the importance of researchers knowing, understanding, and using the federal regulations governing human subjects research. "Researchers must have an adequate knowledge of the federal regulations governing human subjects research to understand and comply with their responsibilities under the regulations". Research "involves rules that need to be known, understood, and followed". The researcher should have the "ability and

willingness to understand and implement applicable regulations and guidance in ethical and safe research”.

The federal regulations governing human subjects research are vast. All rules do not apply to all research. Different researchers with different types of studies have different regulatory requirements. Research studies are governed by different rules “depending upon their areas of research, knowledge of and adherence to the Common Rule (45 CFR part 46), FDA regulations (21 CFR parts 50, 56, 312, 812), and others applicable to their research”. This means the researcher needs the “ability to parse the requirements of relevant federal regulations”.

In depth understanding of the meaning of the relevant federal regulations governing research on human subjects is essential when translated into the researcher's disciplinary commitments. Regulations need interpretation and application to specific cases. The ability to network and seek counsel when there is uncertainty about how to interpret the applicable regulations is part of the requisite ability.

More than federal regulations govern human subjects research and “the researcher must be educated in all regulatory requirements”. There are laws and regulations including international, national, state, and local levels. The researcher must have “knowledge of and adherence to state and local laws and regulations relevant to research”. An unique example of law specific to Oklahoma is a state

statute (63 O.S. § 1-502.2) that governs consent to participate in research and that requires the researcher to inform the participant that it is possible for their medical information to be disclosed to persons outside of the research study. This statute requires all research consent forms involving any health information to tell the participant that the information to be released may include records indicating the presence of a communicable or noncommunicable disease.

Based on their initial input, the following competencies in the subgroup Education and Knowledge in the Compliance group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability and willingness to learn, implement, and comply with applicable research guidance, regulations, and rules.
2. In depth understanding of the meaning of the federal, state, and local regulations and laws governing research on human subjects including professional codes (e.g., APA, ASA, AAA, and local norms).
3. The ability to interpret and apply regulations to specific cases.

All members but one said number 1 was a competency. The only comment from this group was a panel member that noted "unless compliance is by rote and with a sense of duty to

the absolute letter" which as with anyone whose motivation does not involve thinking, but is rote in nature, often will not be open to learning and guidance. One member placed this competency in the "No" column with the comment that "No, I think this is a 'useful attitude' rather than a 'competency'".

All members but two said number 2 was a competency. There were two comments from the panel members who did believe this to be a competency. One member commented, "But not if we use 'competency' narrowly". The second member commented, "As applicable to one's field of research". The two members who placed this competency in the "No" column both made comments. The first said, "No. This is a compound and too in depth. Understanding should be sufficient to know where the problems and traps are". The second panel member thought this competency was included in the first one.

All members but one said number 3 was a competency. One of these stated, "This should follow good teaching". The member who placed this competency in the "No" column thought this competency was included in the first one.

Based on the panel members' responses, the final subgroup Education and Knowledge in the Compliance group contained one competency. This competency is listed in Table 30.

Table 30: Education and Knowledge Subgroup of Compliance Competencies

- | |
|----------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Ability to comply with applicable research requirements by willingly learning about and implementing relevant guidance, regulations, and rules. |
|----------------------------------------------------------------------------------------------------------------------------------------------------|

Interaction Between Researcher and Bureaucracy

Every researcher engaged in human subjects research has to deal with bureaucracy, and usually this is on multiple levels such as with federal government regulations, local regulations, IRB rules, and licensure and professional standards. As the complexity of the research increases, the researcher has to contend with more bureaucracy. Researchers must not only have "knowledge of" but also "adherence to local policies and procedures governing research".

The researcher should have the "ability to work with bureaucracy" as "research involves rules that need to be known, understood and followed". The researcher must be willing and able to "comply with regulatory requirements" and "should be able to work within a framework that allows recognition of the role of other authorities". In every research study involving human participants, the Institutional Review Board (IRB) is a constant and consistent bureaucracy with which the researcher must interact. The "researchers must have a good understanding of the IRB policies and procedures at their institution in

order to understand and comply with their responsibilities" and "have respect for the IRB process".

Even IRBs themselves are not exempt from bureaucracy. IRBs by federal regulation must have "professional competence necessary to review specific research activities" (Code of Federal Regulations, 45 CFR 46 para.46.107(a)).

The bureaucracy of research includes "materials management". Material management in research can include anything from measuring and recording temperatures on refrigerators that are holding medications, recording data, storing data confidentially, calibrating instruments, to complying with regulations that provide guidelines on handling biologics. The types of materials that must be managed would depend on the research study. The researcher should have the "ability to comply with applicable regulations and guidance for licensed tests and data collection instruments, drugs, devices, and biologics".

Another arm of the bureaucracy regulating human subjects research is "information security standards", which is addressed in the Health Information Portability and Accountability Act (Public Law 104-191). This act governs access to a person's protected health information. The Health Information Portability and Accountability Act requires the researcher to have "knowledge of and adherence

to relevant standards for ensuring the confidentiality of sensitive information stored both electronically and in hard copy”.

Based on their initial input, the following competencies in the subgroup of Interaction Between the Researcher and the Bureaucracy in the Compliance group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to work within a framework that allows recognition of the role of other authorities.
2. Understanding and respect of the IRB policies, procedures, and process at their institution in order to understand and comply with their responsibilities.
3. The ability to comply with applicable regulations and guidance for licenced tests and data collection instruments, drugs, devises, and biologics.
4. Knowledge of and adherence to relevant standards for ensuring the confidentiality of sensitive information stored both electronically and in hard copy.

All panel members but one agreed number 1 was a competency needed by researchers practicing research with human participants. The panel member who placed this competency in the "No" column thought this competency was "too vague".

All panel members but two thought number 2 was a competency. One panel member placed this competency in the

"No Response" column. One panel member placed this competency in the "No" column, stating this was part of another competency.

All panel members but two thought number 3 was a competency. One of these panel members wrote, "If applicable to one's field of research". A second member that said it was a competency wrote, "The what to? This is important to those people working with these items". The two panel members who placed this competency in the "No" column each made a comment. One felt it was not a competency while the other thought it had already been included.

All of the panel members agreed number 4 was a necessary competency needed by researchers. The panel members agreement was confirmed by not having any comments from the panel for this competency.

Based on the panel members' responses, the final Interaction Between the Researcher and the Bureaucracy subgroup of the Compliance group contained four competencies. These competencies are listed in Table 31.

Table 31: Interaction Between the Researcher and the Bureaucracy Subgroup of Compliance Competencies

1. Ability to work within a framework that allows recognition of the role of other authorities.
2. Understanding of local institution's IRB policies, procedures, and process in order to comply with them.
3. Ability to comply with required certifications.
4. Practice of relevant standards for ensuring the confidentiality of sensitive information stored both electronically and in hard copy.

Good Clinical Practice

Food and Drug Administration (FDA) regulated research trials that investigate drugs, biologics, and medical devices are commonly referred to as clinical trials. Clinical trials are governed by Code of Federal Regulations number 21 Parts 50, 56, 312, and 812.

Pharmaceutical and device companies recruit appropriately licensed professionals to enroll human subjects and collect data in clinical trials. These professionals do not develop nor have input into the protocol or data analysis for the study.

Good Clinical Practice (GCP) is the term that has been given to the regulations and rules that must be followed by an investigator when participating in clinical trials. "If the researcher is involved with an FDA regulated drug, biologic, or medical device, the researcher must be educated

in GCP and other applicable regulations”.

Based on their initial input, the following competency was in the subgroup of Good Clinical Practice in the Compliance group sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Education in Good Clinical Practices (GCP) if involved with a FDA regulated product.

All panel members but one said this was a competency. The panel member that placed this competency in the "No" column commented that "GCP is biased and self-serving to industry”.

Based on the panel members’ responses, the final Good Clinical Practice in the Compliance group contained one competency. This competency is listed in Table 32.

Table 32: Good Clinical Practice Subgroup of Compliance Competencies

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Knowledge of Good Clinical Practice (GCP) if involved with a Food and Drug Administration (FDA) regulated product. |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Following the Rules

"Investigators [must] understand that they are the leaders of a team of individuals responsible for the conduct of research. Investigators should ensure that the staff understands and acts according to the ethical principles

governing research" (Cooper & Turner, 2006, p. 316).

"Researchers must have sufficient administrative skills to ensure that they are in compliance with regulations and IRB requirements. They must maintain adequate documentation of regulatory compliance". While this concept could have fit in the Leadership and Management group there was such a strong relationship to compliance that it was grouped with the Compliance competencies.

While rules and regulations are the foundation for protecting human participants involved in research, the rules and regulations can not think of nor provide guidance for every possible situation or circumstance that can occur during a research study. Indeed, if that were even possible, the amount of information generated would be overwhelming. One panel member thought "flexibility" to be an important part of working with rules. "Rules must be combined with flexibility to meet the variety of situations that can 'arise'". Another panel member cautioned that the "ability to see past the rules and regulations" was important. The panel member explained:

It's easy to fall into the trap of believing that, if all the rules are followed, all is well. It's important to remember that rules are (often imperfect) attempts to make important ideas--often ethical principles--operative. Treating the rules as mere encumbrances is ignoring what they are trying to do; treating them as the final answer is equally so.

Based on their initial input, the following competency in the subgroup of Following the Rules in the Compliance group was sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to see past rules and regulations as it is easy to fall into the trap of believing that, if all the rules are followed, all is well. It's important to remember that rules are (often imperfect) attempts to make important ideas, often ethical principles, operative. Treating the rules as mere encumbrances is ignoring what they are trying to do; treating them as the final answer is equally so. Rules must be combined with flexibility to meet the variety of situations that can arise.

All panel members said this was a competency needed by researchers practicing research with human participants. Two panel members wrote comments. The first comment indicated this was "on the cusp of 'competency' and 'attitude'". The second indicated that this reflected the seriousness and personal interest that the panel member put into their responsibilities as a panel member: "Must have been my comment. Yeah".

Based on the panel members' responses, the final Following the Rules subgroup of the Compliance group contained one competency. This competency is listed in Table 33.

Table 33: Following the Rules Subgroup of Compliance Competencies

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|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Ability to see the comprehensive "big picture" related to the research that is greater than simply complying with the rules regulating the research |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|

Professional Practice

Houle (1980), defines profession not with a stagnant definition, but rather in terms of continuous learning and calls this ongoing process "professionalization" (p.34). Houle (1980) includes fourteen characteristics of professionalization. The first he calls the "conceptual characteristic" (p. 35). The purpose of conceptual characteristic is to define what the function of the profession is. The second, third, and fourth characteristics he groups under "performance characteristics" (p. 40). These three characteristics describe the profession as based on theory and are "mastery of theoretical knowledge" (p. 40) for the profession including a profession's knowledge base of theory and information of the profession, the "capacity to solve problems" (p. 42) giving responsibility to member practitioners to deal with problems using theory, and the "use of "practical knowledge" (p. 45) which grows out of the history and application of the professional practice as well as theory. Practical knowledge explains and challenges current knowledge with research which causes change within

the profession.

The fifth characteristic of professionalization is "self-enhancement" (Houle, 1980, p. 47). Houle believed general education and learning related to self-fulfillment in areas of interest outside of a profession as well as areas such as home and community gives professionals insights and prevents a "stunted mind" (p. 48) as well as prevents "boredom and routine often produced by professional practice" (p. 48).

Houle (1980) grouped the next nine characteristics of professionalization in a category he called the "Collective Identity Characteristics" (p. 49). Collective identity characteristics require those who seek professionalization to "establish its collective identity by building systems and structures that foster and maintain conceptual and competency characteristics" (p. 49). Collective identity characteristics make the occupation unique and different from other occupations by such things as licensure to enable practice, imposing restrictions for membership in associations, collective identity, accreditation of educational programs, standards of practice based on knowledge, and by "building systems and structures that foster and maintain conceptual and competency characteristics" (Houle, 1980, p. 49).

As Houle (1980) describes professionalization, advancement of the profession relies on research and theory development. An example of advancement of nursing practice through research was the development of a pain scale allowing evaluation of pain in patients with severe dementia (Horgas & Miller, 2008) that are unable to communicate with the nurse. This scale allows the nurse to objectively evaluate pain in patients who can be noncommunicative and respond appropriately to provide comfort interventions.

In addition, a professional has another responsibility related to research. According to Houle's (1980) "performance characteristics" (p. 40) the professional is a consumer of research, using research to enhance the profession and the people the profession serves. As a consumer, the professional should have the knowledge to appropriately evaluate the results of someone else's research and decide whether to incorporate the new knowledge into their personal practice.

Professionals should be able to (1) know where and how to find the best possible sources of evidence, (2) formulate clear questions, (3) search for relevant answers to those questions from the best possible sources, including those that evaluate or appraise evidence for its usefulness with respect to a particular patient or population, and (4) determine when and how to integrate those findings into practice. (Greiner & Knebel, 2003, p. 415)

Research Related to the Professional Discipline

Panel members identified competencies that grouped into professional practice relating to the researcher's discipline. A panel member named "knowledge of scientific discipline" as a competency. The description for this competency was that "investigators must have a thorough understanding of the basic principles and shared knowledge of their scientific discipline". Another panel member echoed this by stating, "Investigators must have a thorough detailed knowledge and understanding of the basic principles, shared knowledge, and ethics of their scientific discipline". Another panel member agreed that "it goes without saying in our world....knowledge in the field, has the book-learning, can use the book-learning, and skill in the field". The researcher should have "detailed knowledge of the discipline involved in the proposed research". In addition, a researcher should have "intellectual curiosity motivating the desire to learn something new, to contribute to the corpus of scientific knowledge" in the field.

Based on their initial input, the following competencies in the subgroup of Research Related to the Professional Discipline in the Communication and Communication Skills group were sent to the panel members both to confirm that their ideas had not been lost in the

summarizations and for providing additional comments and thoughts:

1. Intellectual curiosity motivating the desire to learn something new and to contribute to the corpus of scientific knowledge.
2. Content knowledge: investigators must have a thorough detailed knowledge and understanding of the basic principles, shared knowledge, and ethics of their scientific discipline.
3. Knowledge in the field; has the book-learning, skill in the field, can use the book-learning, one must be expert in the substantive field in which one works.

All panel members but two thought number 1 was an appropriate competency needed by researchers practicing human subjects research. One of these panel members commented, "Curiosity might be in inverse relation to phase. Phase 1, Yes, but phase III, just follow the rules".

Pharmaceutical studies have 4 phases. Phase 1 is the first phase in human subjects research. It is preceded by bench studies followed by animal studies documenting safety. Principle 12 of the Declaration of Helsinki established that:

Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. (Declaration of Helsinki, para. 12).

The purpose of phase 1 is to establish safety for humans who could be enrolled in the study. Generally, a

small number of healthy subjects are enrolled in the study and the drug is given to them until the toxicity of the drug can be established and dosages worked out. The researcher in this phase is evaluating whether the drug is safe enough to continue the research. This researcher is "intellectually curious", as well as desiring to develop a potentially new drug for treatment of a disease process as well as "contribute to the corpus of scientific knowledge". If the drug is deemed safe, the study continues to phase 2 where a small group of subjects with the disease the drug is targeting are enrolled. This phase looks not only at the safety but also the efficacy of the drug. While the purpose of phase 3 in a pharmaceutical study is still safety and efficacy, this phase generally expands the number of subjects involved in the study. In phase 3, the pharmaceutical companies are trying to recruit clinical sites that would be able to enroll patients into the clinical trial of this drug. An example of this could be if the clinical trial is testing a drug to fight a certain type of cancer, then the clinical sights would most likely be oncologist offices and clinics. At this point in a clinical trial, the protocols are established and the doctors who agree to become a part of the study must follow the protocol exactly; that is, they need to "just follow the rules". In

the sense the doctors must strictly follow the established protocol and have no voice in the development of the study nor the interpretation of the data, "intellectual curiosity" nor "the desire to learn" are a large part of what might influence the decision to participate and run a clinical site. However, a motivating factor such as "contributing to the corpus of scientific knowledge" could positively influence the decision for the doctor to participate and agree to run a clinical site for the study.

One panel member placed this competency in the "No" column. This panel member stated, "I don't think curiosity is a competency. I certainly agree it is a desirable feature".

One panel member marked this competency in the "No Response" column. Like the panel member who did not feel this was a competency, this panel member believed that "this is a desirable character trait, not necessarily a competency".

All of the panel members agreed numbers 2 and 3 were necessary competencies needed by researchers. The panel members agreement was confirmed by not having any comments about this competency.

Based on the panel members' responses, the final Research Related to the Professional Discipline subgroup of

the Communication and Communication Skills group contained three competencies. These competencies are listed in Table 34.

Table 34: Research Related to the Professional Discipline
Subgroup of Communication and Communication Skills
Competencies

1. Ability to conditionally question findings in order to stimulate alternative and reflective thinking.
2. Have a thorough, detailed and knowledgeable understanding of the basic principles, shared knowledge, and ethics of one's scientific discipline.
3. Have expert knowledge in the substantive field in which one works.

Professional Competence

The Professional Competence competencies consisted of two subgroups. These were (a) General Professional Competence and (b) Biomedical Research.

General Professional Competence

A researcher should have basic knowledge, or competence, in the field in which the research is being conducted. For instance, a person with a degree in horticulture would not be able to do research evaluating the efficacy of one cardiac splint over another while a medical doctor would not be able to research how much calcium is needed for the optimal growth of bulb plants. This is because neither has the appropriate content knowledge, or competency, to develop research outside their disciplines.

This is addressed in Principle 16 of the Declaration of Helsinki.

Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent. (Declaration of Helsinki, para. 16).

One panel member reported "depending on the nature of the research, the researcher must have an appropriate level of expertise in the subject area" as well as have "expert knowledge of the specific area under study. For example, different levels of knowledge are needed for specialties in medicine; studies done with children should have pediatric clinical investigators, social and behavioral studies should be conducted by qualified psychologists". Disciplines often have ethical codes unique to their field, and "researchers must have a good understanding of the ethical standards of their field".

Many professions recognize competence by certification or licensure within their discipline. A panel member named a competency that addressed the need for certification or licensure stating "recognize and comply with required

certifications, licenses, and credentials for self and research staff". Often procedures or techniques used in research require specialized training and can be restricted by laws to professions or practitioners holding specific certifications and licensure.

An investigator has to know the techniques well enough to perform them well or supervise them well...else he knows not whether the research has been competently carried out. Just which techniques, of course, will vary widely from study to study.

This is important because "the researchers' knowledge of their own abilities and limitations provides a measure of safety for the participant". One of an IRB's charges is to confirm a researcher is qualified to perform the proposed research. The researcher's licensure and experience provide ways for IRBs to confirm a researcher's qualifications.

Based on their initial input, the following competencies in the subgroup of General Professional Competence in the Professional Competence group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Expert knowledge of the specific area under study. For example, the many specialties in medicine. Studies done with children should have pediatric clinical investigators. Social and behavioral studies should be conducted by qualified psychologists.

2. Ability to perform techniques well or supervise them well assuring the research has been completely carried out.
3. Ability to conduct research procedures in a safe manner, in compliance with community practices and standards.
4. Ability to manage adverse outcomes (physiological, political, economic, social).

All panel members said number 1 was needed by researchers. Two panel members made comments. Two panel members thought this competency was similar to another. One also wrote:

I don't know that this is a required competency, but it MAY be in certain types of research. It may be a competency that could rest with a consultant rather than with the investigator per se. Sometimes 'qualified psychologists' are exactly the wrong people to conduct social studies, but their input may be invaluable.

All panel members agreed number 2 was a competency. The only comment was "again, iterative", meaning it had already been named.

All panel members but one agreed number 3 was a competency. One panel member placed this competency in the "No" column with the comment that it had been "included before".

All panel members but two agreed number 4 was a competency. Two panel members placed this competency in the "No" column, and one of these commented, "I believe it is not realistic to expect researchers to manage ALL adverse

outcomes, particularly unanticipated problems”.

Based on the panel members’ responses, the final General Professional Competence subgroup of the Professional Competence group contained two competencies. These competencies are listed in Table 35.

Table 35: General Professional Competence Subgroup of Professional Competence Competencies

1. Ability to assure quality by either performing techniques well or supervising them well in order to assure that the research has been completely carried out.
2. Ability to manage adverse outcomes.

Biomedical Research

Several professional practice competencies and comments were specific to biomedical research. One panel member identified “clinical expertise” as a competency with a definition that “the biomedical researcher must have an appropriate level of medical expertise in the specific area of the research”. Although some researchers may have certification or licensure in their field, one panel member perceived the “ability to recognize limitations” as a professional practice competency. An example of this could be a general pediatrician trying to conduct research in the pediatric oncology area. The researcher should have the “ability to conduct research procedures in a safe manner, in

compliance with community practices and standards”.

A panel member also listed “logic” as a competency. This was described as the researcher “should be able to compartmentalize work so that research & practice are distinguishable to self and to recruits”. In clinical research, this can be especially true because established patients in a professional practice generally have developed a trust with the health care provider. In these situations, the researcher needs to clearly define to the potential participant the difference in roles between being a researcher and a care giver. The researcher also needs to define the difference in roles to self and clearly present the change in roles to the potential participant trying to avoid trust as a care giver being coercive. This extra precaution is necessary to ensure the potential research participant is truly making an informed decision based on information.

Based on their initial input, the following competencies in the subgroup of Biomedical Research in the Professional Competence group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. The biomedical researcher must have an appropriate level of medical expertise in the

specific area of the research.

2. Ability to recognize professional limitations

All panel members but one agreed number 1 was a competency. A panel member that agreed said that "any researcher must have an appropriate level of any expertise". The panel member who disagreed wrote that "'No' may be a bit harsh, but I think this is pretty strong, 'it depends'. Lots of biomedical researchers have no medical expertise at all. I'd limit this one to the conduct of certain specific clinical research".

All panel members but two agreed number 2 was a competency. One of these agreeing panel members commented that "this is iterative of an item under humility; may not need both". One panel member placed this competency in the "No" column and one placed it in the "No Response" column. Neither gave comments. This competency was moved to the Humility category.

Based on the panel members' responses, the final Biomedical Research subgroup of the Professional Competence group contained one competency. This competency is listed in Table 36.

Table 36: Biomedical Research Subgroup of Professional Competence Competencies

- | |
|--------------------------------------------------------------------------------------------|
| 1. The researcher must have an appropriate level of expertise in the area of the research. |
|--------------------------------------------------------------------------------------------|

Conflict of Interest

A conflict of interest is "a set of conditions in which an investigator's judgement concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain)" (Nelson, 2006, p.167). The problem researchers are trying to avoid is bias in judgement. Thus,

Conflict of interest occurs when there is a conflict between an individual's private interests and his or her professional obligations to another entity such that an independent observer might reasonably question whether the individual's professional actions or decisions are affected by his or her private interest. (Chinn & Kulakowski, 2006, p. 514)

In order to manage conflicts of interest the researcher needs to have "knowledge about the notion of conflict of interest". The panel member defined this knowledge as "appreciation of the difference between research in the public interest and research in the private interest". The researcher should have the "ability to recognize and manage potential and real conflicts of interest in self, research staff, research subjects, and sponsors".

Based on their initial input, the following

competencies in the Conflict of Interest group were sent to the panel members both to confirm that their ideas had not been lost in the summarizations and for providing additional comments and thoughts:

1. Ability to recognize and manage potential and real conflicts of interest in self, research staff, research subjects, and sponsors.
2. Knowledge and appreciation of the difference between research in the public interest and research in the private interest.

The panel members all agreed the number 1 was a competency needed by researchers. There was one comment for this competency: "Unfortunately, conflicts of interests are so ubiquitous that rationalization about how little they affect findings abound!"

Five panel members thought number 2 was a competency. One panel member in this group commented that this competency "may need additional information". Two panel members placed this competency in the "No" column. One of these panelist wrote, "The purpose of research doesn't affect methodology for obtaining valid answers and thus affords the distinction between public vs. private interest makes no difference in this regard". A second panel member in this group wrote, "I don't understand this one. Research either public or private must still have the same standards. Sounds like a bias expressed but perhaps not".

One panel member checked the "No Response" column on this competency and wrote the following comment:

Wow! This is one I had not thought about. I am not sure what these differences are, myself, and if such knowledge and appreciation is a necessary competency. Does this mean that researchers conducting research in the public interest (presumably meaning that the research is federally funded) think and behave differently than those conducting research in the private interest (presumably privately and presumably for-profit funded)?

All panel members agreed that the researcher needs to have the ability to recognize and manage potential and real conflicts of interest within themselves and with research staff, research subjects, and sponsors. An example of how a researcher could have a conflict of interest between private interests, professional interests, and public interests can be demonstrated using phase 3 and 4 clinical trials. A doctor in private practice who is receiving thousands of dollars for each participant enrolled in a research study could have a conflict between the desire for obtaining money and the professional obligation to the patient and the potential utilitarian good to the public that an honest outcome of the research study could have for society.

Based on the panel members' responses, the final Conflicts of Interest group contained three competencies. These competencies are listed in Table 37.

Table 37: Conflicts of Interest Competencies

1. Ability to recognize potential and real conflicts of interest in research.
2. Ability to manage potential and real conflicts of interest so it does not influence the research.
3. Ability to differentiate between private interests and public interests in research.

CHAPTER 9

RATING OF COMPETENCIES

Introduction

The final round of the Delphi Technique for this study consisted of having the panel members rate the importance of how necessary they felt each competency is for conducting safe, knowledgeable, and effective research while protecting the research participant's well being. A 4-point scale was used for the ratings. The even number of points on the scale did not "allow respondents the opportunity to be neutral on the topic" (Pearson Education, n.d., para. 20). Also, since "the percentage of overlap in adjacent judgment increases as the number of anchor points increases" (Bass, Cascio, & O'Connor, 1974, p. 320) in a scale, the 4-point scale was used because the overlap is lowest with this number of anchors among all scales in the generally recommended range of 4 to 9 points on a scale (p. 319). The anchor points on this survey related to how necessary the experts felt the competencies were: 1 = Not Necessary, 2 = Somewhat Necessary, 3 = Necessary, and 4 = Absolutely Necessary.

The survey for this rating had the competencies arranged by categories with the categories in alphabetical order. This form was posted on the Internet. The panel members were sent the link to this form via an e-mail. The

responses of panel members to the rating survey were sent electronically to the research team and were downloaded into an Excel file for analysis using SPSS. Nine panel members participated in the rating.

Personal Competencies

Personal Competencies included the categories of Humility, Ethics, Avoiding Biases, and Respect. The area of Respect was not included in this rating. The area of Humility contained four competencies (see Table 1). The mean rating for the competencies in the category ranged from 2.78 to 3.00. The grand mean for these was 2.81; thus, the overall rating for competencies in the category was between Sometimes Necessary and Necessary with a tendency toward Necessary.

Table 38: Distribution of Rating of Experts on Humility Competencies

Competency	Necessary				Mean
	Not	Some	Nec.	Abs.	
1. Ability to accept input from others by listening both to other people who might have good ideas as well as people whose perspective is different and might disagree with that of the researcher	1	1	6	1	2.78
2. Ability to understand the practical applications and limitations of one's abilities and of the context in which one's research takes place	0	3	5	1	2.78
3. Ability to understand the subjects by having a feeling and concern for the subject's situation	0	4	4	1	2.67
4. Ability to recognize professional limitations	0	1	7	1	3.00

The area of Ethics contained 11 competencies (see Tables 2, 3, 4, 5, 6, and 7). The mean rating for the competencies in the category ranged from 2.78 to 3.67. The grand mean for these was 3.31; thus, the overall rating was between Necessary and Absolutely Necessary with a tendency toward Necessary.

Table 39: Distribution of Rating of Experts on Ethics Competencies

Competency	Necessary				Mean
	Not	Some	Nec.	Abs.	
1. Ability to apply relevant ethical principles (including respect for persons, beneficence, and justice) in real world contexts	0	0	5	4	3.44
2. Respect for subjects because they are actually donors to the research process	0	1	3	5	3.44
3. Have knowledge of participant char. including vulnerabilities in order to maximize protections for subjects and scientific outcomes	0	1	6	2	3.11
4. Awareness of ethical values related to both the research itself and the environment in which the research is being conducted	0	0	5	4	3.44
5. Consistently practice ethical values related to both the research itself and the environment in which the research is being conducted	0	0	6	3	3.33
6. Have knowledge of basic scientific principles related to integrity, honesty, commitment to truth, avoidance of plagiarism, falsification, fabrication, as well as the standards of one's scientific discipline	0	0	3	6	3.67
7. Ability to adhere to basic scientific principles related to integrity, honesty, commitment to truth, avoidance of plagiarism, falsification, fabrication, as well as the standards of one's scientific discipline	0	0	4	5	3.56
8. Ability to behave in an ethical manner from identifying a research question that needs answering to the potential ending of the research before the question is answered	1	0	6	6	3.00
9. Ability to recognize ethical concerns focusing on both the scientific question and the instrument(s) used.	0	2	7	0	2.78
10. Have knowledge about publication ethics including open access publishing and the imperatives for the public dissemination of research results	0	1	7	1	3.00

11. Have knowledge of right from wrong in research	0	0	3	6	3.67
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The area of Avoiding Biases contained three competencies (see Table 8). The mean rating for the competencies in the category ranged from 3.11 to 3.56. The grand mean for these was 3.45; thus, the overall rating was between Necessary and Absolutely Necessary.

Table 40: Distribution of Rating of Experts on Avoiding Biases Competencies

Competency	Necessary				Mean
	Not	Some	Nec.	Abs.	
1. Have knowledge about cognitive and behavioral biases	0	2	4	3	3.11
2. Ability to recognize one's own biases	0	1	2	6	3.56
3. Ability to recognize biases in published literature	0	0	4	5	3.56

Knowledge and Abilities Competencies

Knowledge and Abilities Competencies included the categories of Leadership and Management, Organizational Skills, Communication and Communication Skills, and Cultural Competency. The area of Leadership and Management contained eight competencies (see Tables 9, 10, 11, 12, 13, 14, and 15). The mean rating for the competencies in the category ranged from 2.67 to 3.33. The grand mean for these was 2.99; thus, the overall rating for competencies in the category was Necessary.

Table 41: Distribution of Rating of Experts on Leadership and Management Competencies

Competency	Necessary				Mean
	Not	Some	Nec .	Abs .	
1. Ability to hire qualified research staff	0	0	6	3	3.33
2. Ability to supervise and evaluate research staff	0	0	6	3	3.33
3. Ability to delegate authority while maintaining overall control of and responsibility for the research project	0	3	5	1	2.78
4. Ability to train and evaluate research staff.	0	3	6	2	2.67
5. Skill in either meticulously in recording data or in carefully reviewing records to ensure that the records are adequate, accurate, interpretable by others, and confidentially maintained	0	3	3	3	3.00
6. Ability to train research staff in data collection and analysis techniques	0	3	6	0	2.67
7. Ability to develop and manage a budget that allows successful completion of the study	0	4	4	1	2.67
8. Ability to recognize and comply with required certifications, licenses, and credentials for self and research staff	0	1	8	0	2.89

The area of Organizational Skills contained three competencies (see Tables 15 and 16). The mean rating for the competencies in the category ranged from 2.78 to 3.22. The grand mean for these was 3.04; thus, the overall rating was Necessary.

Table 42: Distribution of Rating of Experts on Organizational Skills Competencies

Competency	Necessary				Mean
	Not	Some	Nec .	Abs .	
1. Ability to develop a time-line for project activities	0	3	5	1	2.78
2. Ability to manage a research project so that it conforms to its stated goals and time-lines	0	0	8	1	3.11
3. Ability to balance the need to complete the research with the need to handle emergencies and unanticipated events	0	0	7	2	3.22

The area of Communication and Communication Skills contained four competencies (see Tables 17, 18, 19, and 20). The mean rating for the competencies in the category ranged from 2.56 to 3.33. The grand mean for these was 3.06; thus, the overall rating was Necessary.

Table 43: Distribution of Rating of Experts on Communication and Communication Skills Competencies

Competency	Necessary				Means
	Not	Some	Nec .	Abs .	
1. Ability to communicate effectively by speaking, reading, and writing fluently in both one's native language and in the local languages where the research is conducted	0	1	2	6	2.56
2. Ability to present information in a clear manner to others	0	0	8	1	3.11
3. Ability to listen to others	0	1	5	3	3.22
4. Ability to network and seek counsel when there is an uncertainty about how to interpret the applicable regulations	0	0	6	3	3.33

The area of Cultural Competency contained four competencies (see Table 21). The mean rating for the competencies in the category ranged from 2.67 to 3.22. The grand mean for these was 2.97; thus, the overall rating was Necessary.

Table 44: Distribution of Rating of Experts on Cultural-Competency Competencies

Competency	Necessary				Mean
	Not	Some	Nec.	Abs.	
1. Ability to work with special requirements of cross-cultural or multi-cultural research	1	2	5	1	2.67
2. Ability to recognize cultural constraints	0	2	6	1	2.89
3. Ability to seek counsel to help design an experiment that is not a cultural affront to someone else	0	1	5	3	3.22
4. Knowledge of participant characteristics including vulnerabilities so as to maximize protections for subjects and scientific outcomes	0	1	6	2	3.11

Grasp of Methodology Competencies

Grasp of Methodology Competencies did not include any separate categories. The total competency area contained 11 competencies (see Table 22, 23, 24, 25, 26, 27, 28). The mean rating for the competencies in the category ranged from 2.67 to 3.56. The grand mean for these was 3.24; thus, the overall rating for competencies in the category was between Necessary and Absolutely Necessary with a tendency toward Necessary.

Table 45: Distribution of Rating of Experts on Grasp of Methodology Competencies

Competency	Necessary				Mean
	Not	Some	Nec .	Abs .	
1. Understand the scientific method	0	1	3	5	3.44
2. Basic factual and conceptual understanding of the philosophy of science	0	4	4	1	2.67
3. Ability to conduct a systematic review of the pertinent literature relevant to the research topic	0	1	5	3	3.22
4. Ability to distinguish between questions susceptible to empirical investigation and those that are not such as those dealing with values, esthetics, morals, and religion	0	2	3	4	3.22
5. Ability to frame a testable hypothesis which involves the steps of (1) taking an idea and deciding what aspects of it may be liable to challenge in an organized and informative manner and then (2) framing the specific questions to be asked in such a way that they imply a basic mastery of the informational universe in which the questions arise	0	2	4	3	3.11
6. Ability to design the actual research project so that it is a test of the hypothesis by requiring a clear conceptual grasp of the questions to test the hypothesis	0	1	5	3	3.22
7. Have sufficient scientific knowledge to design good studies that are likely to result in contributions to the knowledge base and, thus, have sufficient benefit to justify the risks to subjects	0	0	2	7	3.56
8. Ability to strictly adhere to the research protocol	0	1	3	5	3.44
9. Ability to use various analytical skills that will allow the researcher to make sense out of the research results including the ability to construct competitive interpretation of the same data and the ability to conduct and interpret statistical tests	0	1	5	3	3.22
10. Have a conceptual grasp of the	0	2	5	2	3.00

statistical methods appropriate to the research being carried out					
11. Commitment to conducting ethical research which has transparency including the willingness to subject one's work to the scrutiny of others and the willingness to share data with others who might wish to look at them from a different perspective	0	0	4	5	3.56

Situational and Organizational Factor Competencies

Situational and Organizational Factor Competencies

included the categories of Compliance, Professional Competence, and Conflict of Interest. The area of Compliance contained seven competencies (see Tables 29, 30, 31, 32, and 33). The mean rating for the competencies in the category ranged from 2.89 to 3.78. The grand mean for these was 3.41; thus, the overall rating for competencies in the category was between Necessary and Absolutely Necessary with a slight tendency toward Necessary.

Table 46: Distribution of Rating of Experts on Compliance Competencies

Competency	Necessary				Mean
	Not	Some	Nec.	Abs.	
1. Ability to comply with applicable research requirements by willingly learning about and implementing relevant guidance, regulations, and rules	0	0	4	5	3.56
2. Ability to work within a framework that allows recognition of the role of other authorities	0	0	7	2	3.22
3. Understand of local institution's IRB policies, procedures, and process in order to comply with them	0	0	4	5	3.56
4. Ability to comply with required certifications	0	1	4	3	3.25
5. Practice of relevant standards for ensuring the confidentiality of sensitive information stored both electronically and in hard copy	0	0	5	4	3.44
6. Knowledge of Good Clinical Practices (GCP) if involved with a Food and Drug Administration (FDA) regulated product	0	1	4	4	3.33
7. Ability to see the comprehensive "big picture" related to the research that is greater than simply complying with the rules regulating the research	0	0	6	3	3.33

The area of Professional Competence contained six competencies (see Tables 34 and 35). The mean rating for the competencies in the category ranged from 3.00 to 3.89. The grand mean for these was 3.57; thus, the overall rating was between Necessary and Absolutely Necessary with a slight tendency toward Absolutely Necessary.

Table 47: Distribution of Rating of Experts on Professional-Competence Competencies

Competency	Necessary				Mean
	Not	Some	Nec .	Abs .	
1. Ability to conditionally question findings in order to stimulate alternative and reflective thinking	0	2	5	2	3.00
3. Have expert knowledge in the substantive field in which one works	0	0	4	5	3.56
4. Ability to assure quality by either performing techniques well or supervising them well in order to assure that the research has been completely carried out	0	0	3	6	3.67
5. Ability to manage adverse outcomes	0	0	3	6	3.67
6. Have an appropriate level of expertise in the area of the research	0	0	2	7	3.78

The area of Conflict of Interest contained three competencies (see Table 36). The mean rating for the competencies in the category ranged from 2.89 to 3.78. The grand mean for these was 3.41; thus, the overall rating was between Necessary and Absolutely Necessary with a slight tendency toward Necessary.

Table 48: Distribution of Rating of Experts on Conflict of Interest Competencies

Competency	Necessary				Mean
	Not	Some	Nec .	Abs .	
1. Ability to recognize potential and real conflicts of interest in research	0	0	2	7	3.78
2. Ability to manage potential and real conflicts of interest so it does not influence the research	0	1	2	6	3.56
3. Ability to differentiate between private interests and public interests in research	0	2	6	1	2.89

Summary

The panel members rated the importance of how necessary they felt each competency is for conducting safe, knowledgeable, and effective research while protecting the research participant's well being on a 4-point scale: 1 = Not Necessary, 2 = Somewhat Necessary, 3 = Necessary, and 4 = Absolutely Necessary. The means for the competencies ranged from a low of 2.56 for Communication and Communication Skills to a high of 3.89 for Professional Competencies. The grand mean for the competencies ranged from a low of 2.81 for Humility to a high of 3.57 for Professional Competence. Consistently, the panel members rated the competencies as Necessary to Absolutely Necessary with the tendency toward Necessary.

CHAPTER 10

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary of the Study

The competencies needed to practice, teach, and monitor human subjects research are complex and have a specialized set of rules and ethics. Whether planning to conduct or currently carrying out research with human participants, researchers in the United States are expected to conduct research ethically and competently, knowing and following the rules, regulations, ethics, and discipline-related knowledge that govern human subject research. For the researcher this can mean knowing, understanding, and applying guidelines from the Office for Human Research Protections, the Food and Drug Administration, state and local laws and regulations, Institutional Review Board requirements, professional guidelines specific to disciplines and ethical guidance from the Belmont Report, the Nuremberg Codes, and the Declaration of Helsinki.

Despite the importance of protecting the rights of participants in research, competencies researchers need to in order to conduct safe, knowledgeable, and effective research while protecting the research participant's well being have not been identified. Therefore, the purpose of this study was to identify competencies researchers need in

order to conduct safe, knowledgeable, and effective research while protecting the research participant's well being.

This study used a Delphi technique design. The Delphi design is a descriptive study technique used to gather expert's opinions. The study utilized a panel of 10 experts. This Delphi study was divided into three rounds. In Round 1, expert panel members were asked to identify and define competencies needed by investigators utilizing humans subjects. In Round 2, a consensus of the competencies among the expert panel members was reached. In Round 3, the panel members were sent a list of the final competencies and asked to rate the importance of each competency using a 4-point Likert-like scale.

Summary of Findings

The Delphi technique uncovered four broad categories: Personal Competencies, Knowledge and Abilities Competencies, Grasp of Methodology Competencies, and Situational and Organizational Factor Competencies. Personal Competencies contained the four subcategories of Humility, Respect, Ethics, and Avoiding Biases. Humility contained four competencies. Respect contained one competency, Ethics contained eleven competencies, and Avoiding Biases contained three competencies.

Knowledge and Abilities Competencies was the largest

category. It was divided into five subcategories which were Leadership and Management, Organizational Skills, Communication and Communication Skills, and Cultural Competency. Leadership and management contained eight competencies. Organizational skills contained three competencies, Communication and Communication Skills contained four competencies, and Cultural Competency contained four competencies.

Grasp of Methodology Competencies had no subcategories. However, Grasp of Methodology Competencies contained 11 competencies.

Situational and Organizational Factor Competencies had the subcategories of Compliance, Professional Competence, and Conflict of Interest. Compliance contained seven competencies. Professional competence contained six competencies. Conflict of interest competence contained three competencies.

The panel members were also asked to rate the individual competencies. Overwhelmingly the panel members rated the competencies high with a grand mean of 2.81 out of a 4-point scale for all of the competencies.

Conclusions

The panel of experts identified a complex set of competencies needed to conduct safe, knowledgeable, and

effective research while protecting the research participants well being. The identification of these competencies suggests the following conclusions:

1. Competencies can be identified that investigators need for conducting safe, knowledgeable, and effective research while protecting the research participant's well being.
2. These competencies can be divided into the following four areas: Personal Competencies, Knowledge and Skill Competencies, Situational and Organizational Competencies, and Grasp of Methodology Competencies.
3. There is a dedicated core group of leaders in the field of research who are aware of and can articulate competencies that investigators need to conduct safe, knowledgeable, and effective research while protecting the research participant's well being.

Increased Knowledge for the Field

Foundational Competencies

Professionals can decide to become involved in contributing to the profession's knowledge by conducting research at many points in a professional career. Beginning researchers can be on a professional experience continuum ranging from a student to a well-established practicing professional. However, no matter how many years of professional practice, any new researcher begins at the novice level when learning how to conduct research. Without the humility to accept the role of being a novice learner as

well as respecting other research expert's knowledge, learning is likely not to be collegial for the novice researcher nor any expert providing mentoring or oversight of the study such as an IRB. Having humility that a novice learner needs can sometimes be more difficult for an experienced practitioner who is no longer accustomed to being in the role of novice.

Humility is intricately related to respect. Without humility and respect the researcher increases the risk to the research participant. The researcher with humility will listen to what others in the study, whether the participant, team member, or mentor, and respect the knowledge being shared. Humility and respect work synergistically to protect the research participant's vulnerabilities and produce quality research. Consequently, respect and humility are the two most important competencies.

The researcher is also extended respect from the research community with the expectation that the researcher will practice ethically. Ethics competencies are in all that researchers do. For example, the ethical researcher develops a protocol that starts with equipoise, reflects the discipline's ideologies, and protects the participant's well being to the utmost possible.

Ethics extends past the researcher into the research

community. As a group, the research community has recognized the ethical responsibility for researchers and professional journals to publish research that did not support the hypothesis being tested. Publication and sharing knowledge of failed studies can prevent putting humans at risk in a study that has already been shown not to be the answer sought. Other researchers interested in the same subject might review the study with non-significant results and build a better study or at least not put other humans at risk by repeating the same study.

Once a researcher has knowledge of what ethical research practice is, the researcher makes the personal decision of whether to practice ethically or not. Negative consequences incurred if ethical principles are breeched help to reinforce ethical research practice. However, a researcher must learn ethical principles and their application whether through formal education, continuing education, or mentoring before ethical research practice can occur.

Avoiding Bias

Avoiding biases is important in the outcome of research studies and in protecting the research participant. Biases can be cognitive and behavioral. To avoid biases, the

researcher has to have knowledge of all the different types of biases, be able to recognize bias, be able to do a self-assessment to recognize this potential bias, and have the humility to listen to objective experts who review the research and may identify biases. This is achieved by providing researchers with adequate training in research methodologies.

The researcher should learn to discriminate and recognize that biases can exist in all aspects of research such as in the published literature, in proposals based on the literature, in conducting the research, and in the interpretation of the results of a research study. Expertise in methodologies and application of that knowledge can help prevent biases from skewing the data in all phases of the research. By learning about methodologies, expertise can be obtained at recognizing and preventing biases. Consequently, the researcher is more likely to be able to control for those biases in a research study. From conception to interpreting and reporting the data, the researcher should be continually vigilant about recognizing biases.

The ability to identify biases also assists a professional in evaluating and interpreting published reports. This in turn gives the professional the ability not to take the results at face value and not to believe that

just because it is published the information in the study, it is the truth. As consumers of published research, professionals need to learn how to read research critically with conditioned acceptance while developing the ability to evaluate for biases in the published studies.

Other biases that can affect research are personal biases. Study design can allow personal biases to be managed and controlled to prevent those biases from influencing the outcome of the research. Thus, a research study with clinical equipoise helps ensure the outcomes of the research are more likely to reflect accurate results.

Unrecognized personal biases can also lead to a conflict of interest. An example of this is the gene transfer study in which Jessie Gelsinger participated. In this study, the principle investigator's bias led to a false confidence that the research would prove to be an effective treatment for the genetic disorder of ornithine transcarbamylase deficiency. While this study may have started out with clinical equipoise, biases contributed to the failure to follow the protocol and to the death of Jesse Gelsinger. A researcher who does not recognize personal biases has the likelihood of failing to follow the rules and be blinded to what the data is saying thereby putting people who volunteer to be research participants needlessly at

risk.

The researcher with the ability to be able to self-assess for personal biases provides additional protection to participants and reliable study outcomes. The researcher who is able to recognize biases can prevent them from influencing the study outcomes by use of appropriate methodologies in the study design. As well, the researcher who continually self-assesses throughout the study is better able to recognize, evaluate, and correct unanticipated problems that can occur and that can put participants at risk and also skew study outcomes. While self-assessment is at the Analysis level or higher of Bloom's Taxonomy, others such as the Institutional Review Board (IRB) members also assist in assessing for biases in studies.

Because the primary responsibility of Institutional Review Board members is to protect human subjects, the researcher has the advantage of having the research study evaluated by a group of research experts. During the review of the proposed research, the IRB will also look for biases and conflicts of interest that can cause increased risks to research participants.

Personal Competencies

Research studies can add additional roles to the researcher's professional practice. Large research studies

can place principal investigators in a management role in which they have to supervise, hire, delegate, budget and ensure appropriate training for themselves and the research staff. Delegation with the principal investigator retaining the overall responsibility for the research study is one way a researcher can manage professional practice while adding research into that practice. By delegating, the researcher is able to assign parts of the research study to other persons with expertise in areas such as data collection, reporting, and budgeting. However, successful practice in a discipline does not ensure leadership and management knowledge, skills, and abilities. Opportunities for researchers who need to obtain leadership and management competence could be provided through many avenues such as formal education, continuing education, and mentoring.

Researchers need organizational skills to successfully complete a research study. These skills include the ability of a researcher to be able to set goals and develop a timeline for the research project and to conform to these. Most researchers wear many hats and must be able to balance the need to complete the research by having the ability to organize personal time with other roles such as teaching or providing direct patient care. Again, however, successful practice in a discipline does not ensure a professional will

intuitively have these skills.

The researcher should be competent in communicating. In all aspects of a research study from conception to disseminating the results of the study, the researcher must be able to present information in a clear manner to others. For example, the protocol and informed consent must clearly give the readers the information needed to make decisions whether it be the members of an Institutional Review Board reviewing the study or a participant making a decision of whether to participate in the study.

The principal investigator as a manager is responsible for communicating information to those having delegated responsibilities in the research study as well as assuring all study participants are kept informed of any additional needed information. Additionally in today's global settings, this could include the need to communicate in a language that is not the researcher's native tongue.

In today's complex research environment, communication includes the ability of a researcher to be able to network with others. Networking provides opportunities for the researcher to seek help when there is doubt about how to interpret the applicable regulations or to share research issues both as a mentee and mentor. Having the opportunity to attend both formal and informal meetings is important for

the researcher. Today's electronic communications also provide an opportunity for the researcher to network with others through such avenues as IRB Forum, a list serve for researchers and IRB members.

The researcher should also have the ability to listen. The researcher who does not listen to peers, participants, communities, mentors, experts, or others involved in research has an increase likelihood of taking action that can potentially harm participants.

Because of today's global environment, a researcher could be conducting research in a culture that is unfamiliar. Cultures can include not only ethnic backgrounds but variables such as gender and age. The more heterogeneous a study population is the more generalizable the results of the research will be. Because of this many studies attempt to include culturally diverse populations.

As the cultural diversity of study participants increases, so does the responsibility of researcher to become familiar with participant characteristics including vulnerabilities. In order to protect the study participants and have valid scientific outcomes, the researcher must be able to design and conduct the research project in such a way as to account for participant variables that can be affected by cultural beliefs.

Methodology

There are many established methodology rules for research. Some of these are general while some are discipline specific. Professional formal education generally includes research courses that are both general and discipline specific. The importance of researchers understanding the scientific method as related to the professional discipline is often reflected in the formal curriculum of a profession. For instance, programs in nursing at the bachelor's degree level and beyond require students to take research courses. These courses are mandated to be included in the curriculum by the National League of Nursing Accrediting Commission, which is the accrediting organization for nursing education. Medicine may require the student to complete a formal research project before graduating from medical school or a residency program.

Professional disciplines hope that the practicing members will participate in research which may vary in form such as developing new research or being a consumer of published research. The hope is that professionals will either practice the profession based on evidence provided by peer research or add to the discipline's knowledge base by doing research. The competencies needed to participate in research depend on the purpose of the research in which the

professional is involved.

Certain competencies such as the ethical competencies are needed by all researchers. However, research competencies cover a wide range of different types of research. For instance, the researcher's knowledge of research methodologies is on a continuum. On the near end of the continuum is the research consumer. The consumer should have enough knowledge to be able to recognize bias in published literature, interpret, and evaluate published research. Further down the continuum would be the researcher participating in clinical trials as a site principle investigator. This investigator has no responsibilities in the overall design nor statistical interpretation of the massed collected data. However, before agreeing to become an investigator in the study and to enroll participants, the researcher should have the knowledge to evaluate the quality of the study and the risks to the participants. In order to make this judgement, the investigator needs to know research methodologies which allow evaluation of the protocol and the potential risks for the participant. This researcher must also have enough general research design and statistical knowledge and skills to be able to interpret local outcomes such as adverse events. On the far end of this continuum is the researcher who is doing original research. This

researcher should understand and grasp most of the competencies related to research including ones that are discipline specific.

Professional Practice

Historically one way to assure quality of research has been publication in peer reviewed journals. In order for peers to review submissions of research before publication, transparency of the study is required. Once accepted and published, discipline-wide scrutiny of the research follows. The researcher when submitting for publication is sharing new knowledge. Without transparency of methods the research cannot be evaluated by others. An example of this was the publication from the researchers at the University of Utah reporting discovery of a solution to cold fusion in a laboratory. The immediate response from the public and peers included headlines in news reports internationally and grants pouring into the university. The publication lacked transparency as to the methods that achieved the cold fusion. Only after peers tried to replicate the study was it discovered the researchers had published fraudulent information.

Transparency can also mean the sharing of data from a study. Others who might have a different perspective could further use the data to develop additional new knowledge.

Any research involving human participants has many levels of rules, regulations, federal codes, state statues, and regulatory bodies with which the researcher must comply. The main purpose of these rules and regulations is to protect human participants in research studies. The researcher has to have knowledge of, understand, and practice research using these guidelines. In addition to the general rules and regulations that govern human subject's research, there are added discipline specific guidelines. This means professional competence has a dual role for the researcher practicing human subject research. There is an obligation for the researcher not only to have knowledge of, understand, and apply general research principles but also to have expert knowledge that is discipline specific. Examples of this are research procedures such as deception studies in psychology or invasive procedures in medicine. Because adverse events or outcomes are defined differently by different disciplines, the researcher must be able to identify and manage adverse events related to the research being done. To do this, the researcher needs expert knowledge of all techniques that might be used during any research involving humans.

Professional relationships tend to have a trust factor between the professional and the client. The researcher

within a profession has to guard against coerciveness when enrolling potential research participants into research studies. When professionals recruit their clients into a research study, clear distinctions need to be made for the potential research participant between the professional as a care-giver and the professional as a researcher. The researcher must recognize the potential conflict of interest between the professional relationship and the researcher relationship with a client.

As long as the researcher has the ability to recognize potential and real conflicts of interest, then these conflicts can be managed to protect not only the research participant but also the research outcomes. The researcher has several tools to help in managing these conflicts. These include a grasp of methodology and the review of the research study by an Institutional Review Board.

Research Training

This study has identified and defined competencies investigators need to conduct safe, knowledgeable, and effective research while protecting the research participant's well being. Because no prior research had identified competencies needed by researchers in order to conduct this type of research, teaching and learning in this area had to be based on research rules, regulations, and

observations of what went wrong and on trying to correct the wrongs by learning not to repeat the behaviors. Some researchers have had formal research education opportunities and mentors that were willing to teach and guide the research mentee. Other researchers have been self-directed learners that wanted to be successful and were willing to commit to learning with the personal purpose to do so. Many researchers go to meetings such as the Applied Research Ethics National Association or attend other research education offerings. Still others complete some type of training because of organizational rules that require the training before they will be allowed to conduct research involving human participants.

One major online training source is the Collaborative Institutional Training Initiative (CITI).

As of May 2010, the CITI Program is used by over 1,130 participating institutions and facilities from around the world. Over 1,300,000 people have registered and completed a CITI course since September 2000 and now more than 35,000 new learners complete a CITI Program course every month. (Collaborative Institutional Training Initiative, 2010, para. 5)

While many researchers have taken CITI training, it is only on the Knowledge level of Bloom's taxonomy and, therefore, is only a beginning that needs to be built upon.

In addition, not all competencies apply to all research

situations. Once a student has graduated and is in practice, the opportunities to gain the competencies needed to practice safe, knowledgeable, and effective research while protecting the research participant's well being will be influenced by personal motivation to learn, mentoring, and continuing education. The degree to which these competencies are learned will be affected by the desire to learn and by the way the knowledge can be applied.

Adult Learning Principles

Knowles' first assumption and the core principle in the andragogical model addresses adult learners' need to know. It is important for adults to understand why they need to learn something before they start the task of learning (Knowles et al., 1998, p. 64). Until an adult learner understands and perceives the need to learn, little commitment from the learner will be given, and, therefore, little learning will occur. However, the researcher who perceives a need to know will learn and begin applying the information, moving up Bloom's taxonomy.

As a learner progresses from Bloom's lowest level, Acquisition of Knowledge, to the highest level, Evaluation, the type of learning is different. Acquisition of Knowledge means the learner can remember and recall the information. CITI training is an example of this type of learning. The

next step in Bloom's taxonomy is Comprehension where the learner is able to make sense out of and understand the meaning of the research knowledge. As the researcher continues to learn, the next level in Bloom's Taxonomy is Application. At this level the researcher is able to use previously learned research information and apply it to new situations to solve problems. For instance, a practitioner reviewing research notes the unexpected occurrence of an event in a study. In a similar study the same unexpected event occurred. This practitioner could deduce the possibility of a relationship in both studies causing the event.

The next level in Bloom's taxonomy is Analysis. When functioning at this level the researcher is able to break down and examine new information, find evidence to support the information, and draw independent conclusions. The researcher who has moved up to the Synthesis level is ready to produce original research. At this level the researcher can combine prior knowledge and skills to hypothesize, construct, and generate new research. When the researcher reaches last level in Bloom's Taxonomy, Evaluation, judgement and evaluation of the research occurs. The researcher submits the study for peer review and is able to defend the work.

Knowles' second assumption in the andragogy model relates to the learners' self-concept:

Adults have a self-concept of being responsible for their own decisions, for their own lives. Once they have arrived at that self-concept they develop a deep psychological need to be seen by others and treated by others as being capable of self-direction. They resent and resist situations in which they feel others are imposing their wills on them. (Knowles et al., 1998, p. 65)

Using Bloom's taxonomy is one way to assess the researchers needs and then provide appropriate education and training. With no assessment of the researcher's actual needs, the researcher loses control over personal training and is being treated more as a dependent child who is told what must be learned. This researcher can develop a negative attitude towards research in general when forced to spend hours on training that is not seen as helpful. The researcher may fail to recognize any value in such research education and training if it does not address immediate and personal needs.

Knowles' third assumption in the andragogical model relates to recognizing the role of experiences the adult learner brings into an educational activity (Knowles et al., 1998, pp. 65-67). "The richest resources for learning reside in the adult learners themselves" (p.66), and adults learn best from "techniques that tap into the experience of the

learners, such as group discussion, simulation exercises, problem-solving activities, case method and laboratory methods instead of transmittal techniques" (p. 66). These allow the learner to build on the education and life experiences already learned. Because learners have different life experiences, the learners can also be teachers. In any interactive learning activity involving research, there will be various levels of experiences. Some learners could have been fortunate enough to be mentored by an experienced researcher, another may have had a family member who participated in a research trial, and yet another may be completely novice. By being interactive, each learner can contribute to the learning experience based on life experiences and can gain insights and understanding of research competencies from others. When an adult learner is presented with information and has no experience nor anyone to interact with that has experience, gaining meaning from the information is not always successful nor is the information valued.

Knowles' fourth assumption in the andragogical model pertains to adult learners' readiness to learn. Adults become "ready to learn those things they need to know and need to be able to do in order to cope effectively with their real-life situations" (Knowles et al., 1998, p. 67). A

faculty member of a university seeking tenure may need to do research involving humans in order to obtain tenure. As an adult learner, the faculty member will pursue learning the competencies necessary to achieve this goal to progress professionally (Knowles et al., 1998, p. 67).

Knowles final two assumptions in the andragogy model relate to adults orientation to learning and motivation. As adults are "life-centered (or task-centered or problem-centered) in their orientation to learning" (Knowles et al., 1998, p. 67), adults learn more effectively "when they [learning opportunities] are presented in the context of application to real-life situations" (p. 67). When learning is presented in the context of addressing the learning needs of the adult and the learner can apply the knowledge, adults "learn new knowledge, understandings, skills, values, and attitudes most effectively" (p. 67). This information from Knowles is important for educators to help develop training for researchers at all levels. As professionals begin to engage in research, educators have the opportunity to assess the researcher's learning needs and develop training based on those needs.

There is not a one-size-fits-all training opportunity for researchers because researchers come from different disciplines and have different research interests, goals,

and individual needs. In order to change research education, training organizations such as professional organizations, accrediting bodies, and universities have to support the change and provide appropriate training opportunities. Curriculum changes and continuing education offerings should be developed at institutions conducting human subjects research based on a needs assessment which can use multiple tools such as nominal group technique and surveys to identify and address the needs of researchers. This information should then be used to plan training activities that implements adult learning principles.

Change by Curriculum

Research competencies need to be incorporated and taught as part of the curriculum for those students who will enter into a profession in which they will be involved in performing human subject research. However, a major barrier to adding any additional requirements such as this to an existing curriculum is that curricula are already overcrowded. Not only could the addition of coursework to develop competencies related to conducting research be difficult, but also the timing of the additional course work is of paramount importance. Because adult learning principles support the need for learners to recognize the need to know why they should learn new things and how to

apply the learning in the real world (Knowles, et al., 1998), the students are less likely to view the information as valuable and desire to learn it if the timing of the presentation of this information is not correct.

Houle (1974) identified a developmental period in learning he called "occupational preparation" (p. 436) where a student evolving into a profession not only has learning occur but also has cultururation. Based on this, the addition of research competencies into a curriculum combined with the opportunity for mentoring and participating in research at a novice level could influence the future professional's view and attitude about the personal benefit and the benefit to the profession of incorporating research into practice.

Institutional Change

An institution or organization should have a process of institutional self-reflection supporting institutional values. If institutional values include human subject research, then the educational needs of the researchers should be assessed and supported promoting professional growth and validating the institutional values. Research can add to an institution's reputation and thereby attract a higher caliber faculty, increase grants, and in turn attract a higher quality student. Institutional support for research can be shown in such ways as appropriate educational

support, dedicated time provided to researchers, and support of the IRB.

Organizational Accreditation

“Organizational accreditation serves to accredit practice institutions and health plans, but has some impact on the continuing competence of practicing professionals through standards imposed” (Greiner & Knebel, 2004, p. 97). Many professions such as nursing and medicine have accrediting bodies that approve or can withhold approval from educational programs. Among other things, accreditation assures students that their program meets the basic standards needed for entry into the profession. Accreditation allows a profession to change and improve on existing minimum standards (pp. 98-99). This makes accrediting bodies very influential and powerful.

Educational organizations cannot afford to lose accreditation. Therefore, when accrediting bodies for a profession require inclusion of a subject matter in the curriculum, educational organizations comply by adding this new requirement to their curriculum. If members of a profession feel it is important that the membership be competent in human subject research, then they could advocate with the profession’s accrediting organization to require inclusion of research competencies being taught into

the curriculum. Accreditation standards change the culture of the profession by having the membership value these competencies (Houle, 1974, p. 436); therefore, teaching these research competencies has the potential to change the field. For instance, in academic settings where students and graduates of a profession are expected to conduct research that involves human participants, the competencies identified in this study could be included in the curriculum, and students would be expected to demonstrate competency in these areas.

Mentoring

Interaction with other expert researchers can provide the learner an excellent opportunity to gain research competencies, including application of the competencies. The panel members who were very busy professionals in their own disciplines and internationally known for their research knowledge and experience were willing to participate in this study. The panel members spent a lot of time and responded to every part of this study with a great amount of thought. The panel members demonstrated the willingness of experts to mentor and help other researchers.

The research community is full of expert researchers who are willing to mentor and teach if the mentee has the willingness to listen and learn. An example of the generous

mentoring can be seen on the IRB list serve, IRB Forum.

People with research questions post the questions and get thoughtful responses from all over the world from people who are willing to mentor. IRB members are very often willing to offer expert help to a researcher. Expert research mentors are available to researchers who want to learn.

Mentoring is especially helpful in applying the methodology competencies. While research methodologies may be taught as part of a professional's formal education, application of these methodologies are learned through use. Mentoring provides interactive learning and can "provide for enhanced forms of experiential opportunity, learner initiative, evaluative mechanism, and supervisory authority" (Houle, 1980, p. 223). Because mentoring can support new opportunities for learning as the "mentor may treat the learner as a colleague, teaching by nuance and serving as a sophisticated role model" (p. 22), mentoring allows novice researchers to exchange ideas with expert researchers, to improve research competency through feedback on their performance, and thereby to create new knowledge. As evidenced by the panel members for this study, experienced researchers are often willing to teach.

Certification

To acquire certification, a person must have the

knowledge to meet the requirements for certification. However, certification cannot guarantee that the person holding the certification will practice ethically or appropriately. Most professions offer certifications in areas related to practice. For instance, most states require a nurse practitioner to hold certification from a nursing organization that the State Board of Nursing recognizes in order to practice as a nurse practitioner. In medicine, physicians obtain certification to practice in speciality areas such as dermatology or cardiology. In research, the organization of Public Responsibility in Medicine and Research (PRIM&R) offers a certification for researchers and members of institutional review boards; this certification is called a Certified Institutional Review Board Professional. While much of the knowledge that was identified and reflected by the panel of experts as research competencies in this study are included in this certificate; the panel members also recognized that not all competencies are needed by all researchers. Currently PRIM&R does not offer different levels of certification for research competencies.

Researcher skills are also on a continuum from novice to expert. Ways of becoming an expert researcher include education, practice, and mentoring. This study identified

competencies needed by researchers to practice safe human subjects research. Education for researchers is in major need of change. The opportunity to incorporate adult learning principles and to allow the learner to participate in their learning would change not only what and how the learner learns about research but the also learner's attitude about research.

Recommendations for Further Inquiry

The identification of these competencies opens up a whole new line of inquiry. The two groups most affected by this new knowledge are educators and researchers. However, organizations play an important role in the success of research by supporting the needs of the researcher.

Implications for Educators

Novice researchers who want to add a research component to their practice should be able to rely on educators to assist them. Using the research competencies that have now been identified, educators need to develop methods and tools for assisting the researcher in assessing their research learning needs. One such method for doing this in a group setting is the nominal group technique.

Nominal group technique is a form of brainstorming. A group of people interested in the subject are asked to silently think about and write down perceived needs, which

in this case is the research needs of the researcher. In smaller groups these ideas are shared, written down, and agreed on by the group members perception of the importance of the research need. In turn each smaller group presents their ideas which are written down and discussed among the entire group. The entire group then identifies what the research needs are.

A nominal group technique was used at Oklahoma State University Center for Health Sciences to find out what researchers there perceived as their research needs. Researchers were invited to participate during lunch and were lead through the process. At the end of the nominal group technique exercise, several training needs were identified. Among the needs were more education on methodologies, release time from practice to do research, and help in understanding the IRB process.

Once research needs have been assessed, learning objectives need to be developed by the educator and the researcher that are connected to the competencies. This gives the learner and educator a map for the direction in which the researcher needs to go. By developing these objectives, the researcher now has a direction, specific destinations, and control the learning experience.

The objectives need to be measurable. This holds the

researcher responsible for arriving at the correct destination and makes the learner accountable for the learning. The educator and researcher should agree on how the competency will be measured.

Many professional disciplines are evidence-based, and change occurs only when members of that profession conduct research. Because of this, curriculum changes in those disciplines should include research competency training during the formal education process.

The timing of the research training in a curriculum is critical. Adult learning principles teach educators that if the student does not perceive the need to know the information nor understands how important to their practice and profession research is, then learning is less likely to occur. Because of this, research opportunities and teaching of research competencies need to be placed in upper-level courses. The addition to curricula that gives the student the opportunity to participate in actual research projects and apply research competencies reinforces the need to learn research competencies for the student. Research projects during school also provide the opportunity for experienced faculty to mentor the novice research student.

As students participate in more research experiences, they will gain more research competencies. With greater

research competencies, the graduate professional will be better prepared to base professional practice on evidence and to add to the profession's knowledge through research.

Implications for Researchers

Novice researchers have a responsibility to self-assess or seek help from others such as experienced researchers, educators, or other sources such as IRB members to help them evaluate their research competency. Now that research competencies needed for human subject research have been identified and described, obtaining these competencies before practicing research with human participants should be the responsibility of the researcher. The novice researcher should recognize that moving forward requires learning which should be approached with humility, respect for teachers, and collegiality.

Expert researchers have a responsibility to mentor novice researchers. Real-life experiences through mentoring is a powerful tool in learning and teaching. Mentoring can help propagate professional standards in research. The expert mentor should also approach mentoring with humility, respect for the learner, and collegiality.

Researchers within a profession should advocate for the inclusion of research competencies being taught during the formal education process of the profession. This can be done

in two ways: through the education accrediting organization and through the professional organization. For example, in nursing, the National League of Nursing Accrediting Commission (NLNAC) is the education accrediting body and can be used to lobby for the inclusion of teaching research competencies in the curriculum. Researchers can also promote teaching research competencies through professional organizations such as the American Nurses Association (ANA) which can lobby accrediting bodies speaking as the voice that represents nursing.

Recommendations for Organizations

Many professions have professional bodies that already offer certifications of competence in many areas as in nursing and medicine. Both offer certifications in such areas as pediatrics and geriatrics. Professional organizations such as ANA and the American Medical Association can promote research competencies by providing levels of certifications in human subject research competencies.

Institutions and organizations that value research should support, encourage, and value members efforts to become competent in human subjects research. This can be done by hiring educators that can access research needs and help provide training. Organizations can also provide

researchers dedicated time for research. Professional release time can be given for activities such as research conferences and peer meetings.

Recommendations for Further Inquiry

The identification of these competencies opens up new lines of inquiry. Now that this study has identified the competencies researchers need to conduct safe human subject research, additional research should be conducted to see if other research experts agree with these competencies. Surveys could be sent to experts in the field of research to test how complete they believe the competencies are. As research competencies have no borders, focus groups could be done internationally to further describe each one of the categories.

Specific groups such as methodology experts could be brought together to look at how teaching research methods could be improved. Other investors in human subject research such as educators, administrators, and researchers could also benefit from similar groups.

Once there is agreement among experts on what the competencies are, more specific research can be done. An example is curricula could be studied to see if implemented changes impact the safety of human participants in research and improves the quality and amount of human subject

research being done.

This research has identified the broad competency areas needed for conducting safe human subjects research. However, the competency areas have not yet been expressed with the specificity expressed by experts in the competency field such as Mager. Therefore, further research is needed to write each competency in such behavioral and measurable terms.

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Oklahoma State University Institutional Review Board

Date: Wednesday, May 23, 2007 Protocol Expires: 5/22/2008
IRB Application No: ED0613
Proposal Title: The Perception of Research Experts Regarding Competencies Needed to Practice Human Subject Research
Reviewed and Processed as: Expedited
Continuation

Status Recommended by Reviewer(s): **Approved**

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Approvals are valid for one calendar year, after which time a request for continuation must be submitted. Any modifications to the research project approved by the IRB must be submitted for approval with the advisor's signature. The IRB office **MUST** be notified in writing when a project is complete. Approved projects are subject to monitoring by the IRB. Expedited and exempt projects may be reviewed by the full Institutional Review Board.

- The final versions of any printed recruitment, consent and assent documents bearing the IRB approval stamp are attached to this letter. These are the versions that must be used during the study.

Signature :



Sue C. Jacobs, Chair, Institutional Review Board

Wednesday, May 23, 2007

Date

VITA

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