

Oklahoma State University
Center for Health Sciences
College of Osteopathic Medicine

Institutional Review Board
FWA # 00005037

Memo


To: Jarrad Wagner, Ph.D.
Forensics

From: Johnny Stephens, Pharm. D.
Chairman, Institutional Review Board

Date: June 24, 2009

Re: Exempt Approval of Protocol – IRB # 2009012

Titled: Quantitative Analysis of Acetone in Blood via HS-GC/FID



Board members of the OSU-CHS, Institutional Review Board (IRB), reviewed the above-named protocol and determined Protocol – IRB # 2009012 meets exempted criteria under federal guidelines, 45CFR 46.101 (b); therefore, you are free to begin the study.

If you plan to publish the results of your research, The International Committee of Medical Journal Editors (ICMJE) now requires trial registration at www.ClinicalTrials.gov as a condition for publication of research results.

The ICMJE's definition of a **clinical trial** is: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome."

The ICMJE's definition of **medical intervention** is: "Any intervention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like."

YOU MUST REGISTER YOUR TRIAL BEFORE YOU RECRUIT ANY PARTICIPANTS. This registration includes retrospective chart reviews, but does not include single case studies.

As principal investigator of this protocol, it is your responsibility to insure that this study is conducted as approved. When your study is completed, please notify the IRB.

If you have any questions, please contact Teri Bycroft, Associate Director of Human Subjects Research, at 586-4609 or teri.bycroft@okstate.edu .