UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
CRITERIA FOR IRB APPROVAL OF NEW RESEARCH APPLICATIONS

I. PURPOSE

This document outlines the criteria for approval of studies reviewed by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB).

II. SCOPE

This SOP applies to all IRB administrative staff and board members.

Personnel Responsible:

UTGSM IRB administrative staff and IRB members

III. BACKGROUND

General criteria for IRB review and approval of research are stipulated in the Common Rule at 45 CFR 46.111. Identical criteria for IRB review and approval of FDA-regulated research are provided at 21 CFR 56.111. Numerous additional guidance documents for interpreting and applying these criteria are provided by the Office for Human Research Protections of the Department of Health and Human Services, the Food and Drug Administration, and other federal departments and agencies involved in conducting or supporting research with human subjects. These guidance documents are supplemented by various codes of research ethics, such as the Declaration of Helsinki of the World Medical Association and the guidelines for biomedical research involving human subjects of the Council for International Organizations of Medical Sciences.

In Accordance With:

45 CFR 46.111; 21 CFR 56.111

OHRP Guidance on Written IRB Procedures
http://www.hhs.gov/ohrp/policy/irbgd107.html

Institutional Review Boards Frequently Asked Questions – Information Sheet
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. The following criteria are utilized by the UTGSM IRB in determining whether applications to conduct research can be approved:
   a. Risk(s) to subjects are minimized.
      i. The study uses procedures that are consistent with sound research design. This includes a review of the scientific validity of the protocol and scientific rationale (including results of previous animal and human studies) for conducting the study.
      ii. The investigators are competent in the area being studied.
      iii. When appropriate, the study uses procedures already being performed on the subjects for diagnostic or treatment purposes.
      iv. Appropriate screening and monitoring procedures are utilized to protect the subjects from harm.
   b. Risk(s) to subjects are reasonable in relation to anticipated benefits.
      i. The risk-benefit profile of any treatment intervention evaluated in the study is not known to be significantly more or less favorable than any available alternative treatment.
      ii. Non-therapeutic interventions used in the study do not involve more than minimal risk or a modest increase over minimal risk.
      iii. The value of the knowledge to be gained in the study justifies any increment of risk to subjects resulting from participation in the research.
      iv. The IRB shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within its responsibility.
   c. Selection of subjects is equitable.
      i. Recruitment will be open to all prospective subjects who may benefit from study participation, without regard to sex, religion or ethnicity.
      ii. Vulnerable populations such as children, fetuses, neonates, pregnant women and prisoners, as well as economically or educationally disadvantaged persons will not be used without scientific justification in research that does not offer the prospect of direct benefit to subjects.
   d. Informed consent is adequate.
      i. The consent form contains the required elements of information as specified in federal regulations.
      ii. The information that is given to the subject or the legally authorized representative shall be in a language understandable to the subject or the representative. The IRB will consider the study population to gauge the readability of the consent disclosure.
      iii. The language of the informed consent form should be one in which the subject or the subject's legally authorized representative is fluent.
      iv. A consent interview will be conducted with prospective subjects that involves presentation of the main elements of information required for informed consent.
      v. When the subject cannot read the consent form, an impartial third party should witness the entire consent process and sign the consent document.
      vi. The consent of the subject or the legally authorized representative will be appropriately documented, as specified in IRB SOP # 6.
   e. Where appropriate, the research plan makes provision for monitoring the data to insure safety of subjects.
      i. The IRB will determine that the plan for monitoring the study data and subject safety is appropriate to the degree of risk associated with participation.

ii. The IRB will determine if a DSMB is required for the study. If so, the IRB will require the investigator or sponsor to submit DSMB reports for the study to the IRB in a timely fashion.
iii. The IRB may ask the investigator for copies of monitoring reports for the investigative sites.
iv. The IRB may perform site audits (See IRB SOP 030).

f. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data
   i. Procedures for protecting the confidentiality of subject data, including the use of coded records, are instituted.
   ii. Procedures, if any, for including research data in the medical record of subjects are specified.
   iii. Investigators will observe the rights of subjects with regard to the use of their protected health information as required under the HIPAA regulations.
   iv. Subjects will not be individually identified in any presentations or publications based on the research.

g. Appropriate safeguards are included in the study to protect the rights and welfare of vulnerable subjects. Additional protections will be considered for protocols involving the enrollment of:
   i. Pregnant women, fetuses, and neonates
   ii. Prisoners
   iii. Children
   iv. Other subjects who are at increased risk of harm or have an impaired ability to decide about research participation.

2. The decision of UTGSM IRB to approve a research protocol may be appealed by the investigator. However, the investigator does not have the authority to overrule the IRB's disapproval or modification of a research protocol. (See SOP 28 Request for Re-review)

3. Institutions in which studies approved by the UTHSC IRB will be conducted have the right to prohibit, suspend, or terminate such studies, or to require alteration of such studies as a condition of their performance at the institution. Any alterations in such studies required by the institution must also be approved by the IRB prior to their implementation.