UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
MEMBER EDUCATION

I. PURPOSE

To document the required educational program(s) for University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) members regarding protection for the rights and welfare of human subjects.

II. SCOPE

This SOP applies to the IRB Chairperson, IRB Director or Designee, IRB administrative staff and board members (Full Members, Alternate Members, Ad Hoc Members and Ex Officio Members).

Personnel Responsible:

IRB Director, IRB Staff, IRB Chairperson and members of the UTGSM IRB.

III. BACKGROUND

The primary function of the IRB is to assure that the rights and welfare of human subjects are adequately protected in accord with applicable ethical principles, laws and regulations. In order for IRB staff and members to function effectively in this role, it is essential that they possess a thorough knowledge of the pertinent ethical principles, laws and regulations. The educational programs of the IRB are intended to assure that members possess this knowledge.

These educational programs include provision to staff and members of relevant materials, such as The Belmont Report and applicable laws and regulations that are utilized in IRB review of human subject's research. In addition, new IRB members participate in seminars designed to review the history of the development of ethical principles and regulations for the conduct of human subjects research, as well as the content of these ethical principles and regulations and their application in the review of proposals to conduct research with human subjects. Finally, the UTGSM IRB provides continuing education for its staff and members regarding current ethical and regulatory issues related to the protection of human subjects.

UTGSM IRB members and staff are encouraged to attend local or national seminars related to institutional review boards or human subject protection. As regulations and IRB procedures are developed, they are presented to the staff and board members for review. In addition, the IRB may subscribe to journals or publications of relevance to IRBs.

1. All Board Members and the IRB Administrative Staff will be required to take the CITI

on-line training program. A copy of the certificate of completion will be kept in the training files and will be noted in the iMedRIS system.

2. Orientation may be completed on an individual or group basis.

3. **Continuing Education:**
   a. Any member of the IRB may submit educational materials, articles, and notice of seminars / educational events to the IRB Director for distribution to all members.
   b. The IRB Chairperson or Director will provide an educational article or other educational program to the board as deemed appropriate by Chairperson. During the IRB meeting, the educational material(s) will be discussed.
   c. All Board Members and the IRB Administrative Staff will be required to take the CITI on-line refresher course every 3 years. A copy of the certificate of completion will be kept in the training files and will be noted in the iMedRIS system.

4. The IRB Director will document all members' completion of the above activities in their training files.

UTGSM IRB may maintain membership in the following professional organizations:

- Association of Clinical Research Professionals (ACRP)
- Public Responsibility in Medicine and Research (PRIM&R)

In Accordance With:

38 CFR 16.107(a); 45 CFR 46.107(a); FWA A-7, A-8; OHRP Guidance on Written Procedures, July 11, 2002; ICH GCP 2.8, 4.1; NIH Education Requirement – Clarification of Requirement, September 5, 2001.

OHRP IRB Guidebook located at
http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

FDA Guidance for IRBs and Clinical Investigators 1998 Update located at
http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm113709.htm

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

IV. PROCEDURE

5. Orientation of New Members:

a. The IRB Chairperson and IRB administrative staff is responsible for establishing, reviewing and modifying the IRB SOPs and orientation program as updates are required due to changes in regulations, guidance documents or local policy.

b. The IRB Director or designee will schedule new members for orientation once they are appointed and have signed the Confidentiality Agreement (Appendix 04).

c. Orientation will include the following:
   i. Review of UTGSM IRB Standard Operating Procedures and other relevant administrative documents,
   ii. Review/training of the iMedRIS system with IRB administrative staff,
   iii. Review of The Belmont Report,
   iv. Review of applicable regulations at 45CFR46 and 21CFR50 & 56.
   v. Review of HIPAA Guidelines for clinical investigators

d. The IRB Director will provide new members with documents listed in (b and c) upon their appointment to the Board.

e. The IRB Director will then schedule an orientation session with the new member at a mutually convenient time.

f. At this session, a member of the administrative staff will review the items listed in (b) and (c) above.