UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
MEMBER EDUCATION

I. PURPOSE

To describe educational programs and materials available to members of the University of Tennessee Health Science Center Institutional Review Board regarding protection for the rights and welfare of human subjects.

II. SCOPE

This SOP applies to the IRB Chair, IRB administrative staff and board members.

Personnel Responsible:

IRB Administrative Staff, IRB Chair, and members of the IRB

III. BACKGROUND

In order to maximize the effectiveness of IRB members in protecting the rights and welfare of human subjects, it is crucial that Board members are knowledgeable regarding federal regulations for the protection of human subjects, ethical codes on the conduct of research with human subjects, and local IRB policies and procedures.

This goal is accomplished through a variety of means. Newly appointed committee members review orientation materials on the IRB website intended to introduce them to federal rules for the protection of human subjects, major codes of research ethics, and local IRB policies and procedures. Relevant educational materials and programs regarding current ethical and regulatory issues in the protection of human subjects are provided as continuing education for Board members. IRB members are encouraged to attend local or national seminars related to institutional review boards and human subject protection. In addition, the IRB subscribes to journals and other publications of relevance to the function and activities of IRBs. Finally, the IRB encourages membership in pertinent professional organizations, such as the Association of Clinical Research Professionals (ACRP), Public Responsibility in Medicine and Research (PRIM&R), and the Applied Research Ethics National Association (ARENA).

IV. PROCEDURES

1. **Orientation of New Members**:

a. The IRB Chair, Director and IRB administrative staff are responsible for establishing, reviewing and modifying the IRB orientation program as updates are required due to changes in regulations, guidance documents or local policy and procedures.
b. Orientation materials provided on the IRB website will include the following items:
    i. IRB standard operating procedures and other relevant administrative documents;
    ii. application forms and reviewer forms utilized by the IRB in assessing research applications;
    iii. major ethical codes and guidelines regarding protection for the rights and welfare of human subjects, including the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report;
    iv. federal regulations on the protection of human subjects at 45 CFR 46, 21 CFR 50 and 21 CFR 56;
    v. federal privacy regulations at 45 CFR 160 and 45 CFR 164;
    vi. new drug and new device regulations at 45 CFR 312, 812, and 814;
    vii. ICH Guidelines E-6, E-7, E-8, E-10, E-11, and E-12a.
c. Completion of the on-line training CITI Course in The Protection of Human Research Subjects at http://www.citiprogram.org/ is required. Human protection training documentation from another credible source will be accepted in lieu of the CITI course. A copy of the human protection certificate of completion will be maintained in the electronic iMedRIS system.
d. The IRB administrative staff will schedule the new member for orientation and training in the use of the iMedRIS electronic IRB system.

2. **Continuing Education**:
    a. Any member of the IRB may submit educational materials, articles, and notice of seminars / educational events to the IRB administration for distribution to all members.
    b. Educational articles or other educational programs will be made available to the IRB as deemed appropriate. During the IRB meeting, the educational material(s) will be discussed.

3. The documentation of members' online training will be maintained in the membership files.