

**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 Chairperson, IRB administrative staff and board members.

**Personnel Responsible:**

IRB Administrative Staff, IRB Chairperson, 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 participate in an orientation session 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 Chairperson 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. New members will be scheduled for orientation once they are appointed and have signed the Confidentiality Agreement.

- c. Orientation will include review of the following items and their provision to new members:
    - 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; and
    - iv. federal regulations on the protection of human subjects at 45CFR46, 21CFR50 and 21CFR56.
  - d. 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 kept in the training files.
  - e. Orientation may be completed on an individual or group basis.
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' completion of orientation and online training will be maintained in the membership files.