UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
CONDUCTING INTERNATIONAL RESEARCH

I. PURPOSE

This document outlines the procedures for the University of Tennessee Health Science Center Institutional Review Board concerning the conduct of international research.

II. SCOPE

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

Personnel responsible:

IRB administrative staff, IRB members, and investigators.

III. BACKGROUND

International research poses unique and complex ethical challenges. As a result, the UTHSC Institutional Review Board (IRB) must review all human subject research conducted by UTHSC faculty, staff or students in foreign countries. In addition, the IRB strongly recommends the investigator clearly understand the host country's requirements for reviewing and approving human subject research. Some countries have clear ethical guidelines that must be met for conducting domestic and/or international research. Other countries will not have a formal process but might rely on other neighboring countries to assist with the review.

When international research is conducted, both the UTHSC IRB and the foreign site's IRB/ethics committee must approve the research before the research is initiated. Investigators should consult the resources below, including the International Compilation of Human Subject Protections, which lists over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations.

Resources:

Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries
http://bioethics.georgetown.edu/nbac/pubs.html

International Issues and Codes
http://www.fic.nih.gov/programs/training_grants/bioethics/resources.htm

International IRB's
http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc

International Compilation of Human Subject Protections
http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html

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

IV. PROCEDURES

1. **Submissions to UTHSC IRB**:
   a. Submissions to the UTHSC IRB will be transmitted electronically via iMedRIS.
   b. An IRB Chairperson or designee will determine whether submissions qualify for full board review, expedited review, or exempt status. Full board review will be required for all studies that involve more than minimal risk or do not otherwise qualify for expedited review or exempt status.
   c. For new studies, the principal investigator will submit to the UTHSC IRB the following documents:
      i. Form 1 application prepared according to the IRB instructions, including all required signatures;
      ii. Study protocol (if applicable) including amendments;
      iii. Informed consent document(s) (if applicable);
      iv. Translator's declaration (if applicable);
      v. Grant application (if applicable);
      vi. Subject surveys or questionnaires (if applicable);
      vii. Copy of all proposed advertisement(s) / recruitment materials (if applicable); and
      viii. Copy of the approval from the foreign site's IRB/ethics committee.

2. **Review Process**:
   a. The UTHSC IRB will follow the appropriate review process depending on whether the submission qualifies for full board, expedited or exempt status. For key procedural requirements for IRB review of research, see Full Board Review, Expedited Review, and NHSR or Exempt Status: Determination.

b. See SOP Continuing Review of Research for key procedural requirements for the renewal of a study/project.
c. See SOP Revisions in Approved Studies for key procedural requirements regarding changes/revisions to a study.
d. See SOP Study Closure and Record Retention for key procedural requirements.

3. The findings of the IRB regarding full board, expedited and exempt status including administrative provisos or reasons of deferral are transmitted to the investigator via iMedRIS.

4. Documentation of IRB review and approval, administrative provisos and deferrals will be placed on the electronic meeting agenda and sent electronically to Board members before the Board meeting each applicable week when the agenda is finalized. Also included will be the satisfaction by the investigator of conditions of IRB approval of research reviewed under an expedited or exempt review procedure, including the date when the IRB Chair, Director, or designee determines that all administrative provisos have been satisfied, the date when initial approval becomes effective, and the date by which continuing review (if applicable) must occur.

5. A copy of the finalized agenda is provided to the Vice Chancellor for Research in fulfillment of the regulatory requirement to communicate the IRB's findings and actions to the institution in writing (previously found at 45 CFR 103(a)(4)(i), now found at 45 CFR 46. 108(a)(3)(i) under the revised Common Rule).