UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
COMMUNICATION FROM THE IRB

I. PURPOSE

To document the policy and procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) regarding written communication from the IRB.

II. SCOPE

This SOP applies to the IRB administrative staff and IRB members.

Personnel Responsible:

UTGSM IRB administrative staff and members

III. BACKGROUND

The IRB is required to prepare and maintain adequate documentation of its IRB activities. This includes copies of all correspondence between the IRB and investigators.

In Accordance With:

45 CFR 46.115 and 21 CFR 50, 56

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update located at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126425.htm

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

IV. PROCEDURES

1. Following full board review, expedited review, or determination of exempt status of applications to conduct research, the administrative staff will collect any forms documenting primary and / or secondary reviews, subcommittee or consultant reports, articles or informational documents used in the review.

2. The IRB administrative staff will prepare, review and send correspondence concerning IRB review and actions. The IRB will notify investigators of its decision to approve, disapprove, defer, and/or seek modifications of research activity, submissions or informed consent documents within 10 days of the meeting.

3. If the IRB defers or disapproves a research activity, written correspondence to the PI will include a statement of the decision and give the investigator an opportunity to respond in writing to these concerns.

4. Letters to investigators will include:
   a. The identification number given to the study by the IRB;
   b. The protocol title and number (if available), version dates or designations;
   c. Date and version number of the consent document;
   d. Date of IRB review and determination;
   e. Duration of approval and date of continuing review by the IRB;
   f. If conditionally approved or deferred, a list of provisos that must be met and a statement that the research cannot begin until the investigator receives formal written notification of IRB approval following the response(s) to the provisos.
   g. If deferred, the basis for the IRB's decision and a statement that the investigator may resubmit the protocol.
   h. All paper correspondence will be on UTGSM IRB letterhead. An Email from the Chair, Director or designee may satisfy any requirement for written notice.
   i. A copy of all correspondence will be kept in iMedRIS for the study.