

**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

OHRP IRB Guidebook located at

[http://www.hhs.gov/ohrp/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/irb/irb_guidebook.htm)

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998

Update located at <http://www.fda.gov/oc/ohrt/irbs/appendixc.html>

*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 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. If the IRB disapproves a research activity, the investigator has the right of appeal to the IRB. When necessary, the IRB will seek consultation from nationally recognized experts in the field, other IRB's or the Office for Human Research Protections (OHRP). Every attempt will be made to resolve the identified problem(s). The IRB, however, retains the final authority over whether or not the proposal can be approved.
5. 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. In final approval letters, the IRB must include the following:
    - i. A table as show below detailing the dates of approval and version of consent:

IRB #	
Title	
IRB Action	Initial approval by convened board or Administrative Review & Approval
Informed Consent Version:	
Approval Period	

- ii. At its convened meeting on <date of meeting>, the University of Tennessee Graduate School of Medicine Institutional Review Board reviewed your above-referenced application. The Board voted to approve your application as submitted based upon a finding that the requirements of 45 CFR 46 and/or 21 CFR 56, as well as the policies and procedures of this institution, have been satisfied. Please carefully read the following

- information regarding this approval and your responsibilities with respect to this research.
- iii. **Informed Consent Requirement:** Informed consent and documentation of that consent must be obtained from each participant prior to each participant's involvement in this research. The approved and IRB-stamped informed consent document identified above must be used exclusively. Maintain all signed originals with your research records and provide a copy to each participant.
  - iv. **Modifications:** This approval authorizes you to conduct the research only as described. Except for emergency medical care, IRB review and approval must be obtained prior to making any changes, modifications or alterations to this research. Adverse events and protocol deviations must be reported to the IRB in accordance with our policies posted at <http://gsm.utmck.edu/irb/main.htm>.
  - v. **Renewal:** By federal regulation, all research approved by the IRB must be reviewed not less than once per year. Your approval period is listed above. It is your individual responsibility to submit the appropriate application for continuing review to this office 3-6 weeks prior to the expiration of the approval period if you want to continue your research beyond that date.
- i. All paper correspondence will be on UTGSM IRB letterhead. An Email from the Chairman, Assistant Director or designee may satisfy any requirement for written notice.
  - j. A copy of all correspondence will be kept in the files for the study.