

**UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
APPEAL OF IRB DECISIONS / REQUEST FOR RE-REVIEW**

I. PURPOSE

To document the procedures for appeals regarding IRB decisions.

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members, investigators and sponsors.

Personnel Responsible:

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) administrative staff and members

III. BACKGROUND

Under federal regulations for the protection of human subjects, applications to conduct research studies may not be implemented without prior approval of the IRB under whose auspices the research will occur. Moreover, officials of the institution(s) in which the proposed might occur may not approve research if it has been disapproved by the IRB. Applications that are reviewed on an expedited basis by the Chairperson or designee may not be disapproved without review by the convened IRB. If the full Board disapproves a new application to conduct research, an application to continue a previously approved project, or a revision application, investigators may file an appeal requesting that the Board reconsider its action. This process is available to all investigators by written request.

Should UTGSM IRB disapprove a submission, there is a written process whereby investigators can file an appeal. This process is available to all investigators and Sponsors/ CROs by request.

In Accordance With:

45 CFR 46, 21 CFR 56

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

IV. PROCEDURES

1. If UTGSM IRB disapproves or modifies a research activity, or disqualifies the credentials of an investigator, the document forwarded to the investigator will include the notification and a statement of the reason(s) for the board's decision, and give the investigator opportunity to respond in person or in writing.
2. The investigator may submit a written response to the action recommended by the board. The response must provide adequate reasons or data for asking the IRB to reconsider its recommendations.
3. The response will be submitted to the full board, and the reviewers may vote to accept the appeal or reject the appeal.
4. The Board's decision on the appeal is final and no further appeal is permitted.