UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA/ INSTITUTIONAL REVIEW BOARD APPEAL OF IRB DECISIONS

I. PURPOSE

To document the procedures for appeals regarding IRB decisions.

II. SCOPE

This SOP applies to all investigators performing research under the auspices of the UTCOMC and EHS and its affiliated institutions.

Personnel Responsible

IRB administrator, Board members and investigators

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.

Under federal regulations at 45 CFR 46.108(a)(4) (previously 45 CFR 46.103(a)(5) under the pre-2018 Common Rule) and 21 CFR 56.108(b), IRBs must also have written procedures for addressing any serious or continuing noncompliance of investigators with federal regulations and local IRB policy. When the IRB determines that serious or continuing noncompliance has occurred, the Board may suspend studies, require implementation of corrective action plans to remedy deficiencies, or terminate research. Investigators may file an appeal requesting that the Board reconsider its action. This process is available to all investigators by written request.

In accordance with:

For studies approved under the revised Common Rule:
45 CFR 46.108(a)(4); 45 CFR 46.109; 45 CFR 46.113;

For studies approved under the Pre-2018 Common Rule:
45 CFR 46.103(b)(5); 45 CFR 46.109

For FDA-regulated studies:
21 CFR 56.108(b)

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 the convened IRB disapproves a new application to conduct research, an application to continue a previously approved project, or a revision application, the letter of notification to the investigator will include a statement of the reason(s) for the Board's decision.

2. The investigator may submit a written response to the action taken by the convened committee. The response must provide adequate reasons for asking the IRB to reconsider its action.

3. At the request of the investigator and with the acquiescence of the Chairperson, the investigator may also present his/her response to the convened Board.

4. The Board will review the response of the investigator and determine whether to uphold or vacate its original action. The results of the Board's deliberation and voting will be conveyed to the investigator.

5. The Board's decision on the appeal is final and no further appeal is permitted.