

INSTITUTIONAL REVIEW BOARD
Appeal of IRB Decisions

No./Title: Appeal of IRB Decisions	Resp. Office: Institutional Review Board	Effective Date: 01/15/2005
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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 University of Tennessee Health Science Center IRB and its affiliated institutions.

Personnel responsible:

IRB Compliance Advisor, Director, section chair, administrative staff and IRB 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 chair 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, suspends, terminates, or stipulates corrective actions for submitted studies, the principal investigator (PI) will receive a letter of notification that includes the action and rationale of the Board's decision via an outcome letter in iMedRIS.
2. The principal investigator may appeal the IRB's decision regarding disapproval; study suspension, corrective actions, or termination. Appeals will only be considered if a written request is submitted to the IRB Director within ten (10) business days after formal notification of the PI regarding the action of the IRB. In the correspondence, the PI should identify the action that he or she wishes to appeal, and must explain clearly and completely the basis for the appeal. The IRB Director will confer with the appropriate section chair to determine whether the appeal warrants further consideration. If so, the appeal will be considered at the next meeting of the section of the Board that approved the original action being appealed. At the discretion of the IRB Director and section chair, the PI may be granted the opportunity to make a presentation to the Board regarding the issue. However, the presence of a personal attorney representing the PI will not be permitted.
3. 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 in an outcome letter sent via iMedRIS.
4. The Board's decision on the appeal is final and no further appeal is permitted.