

IRB Policy 12: IRB Appeal Process

Effective Date: June 4, 2024

I. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB that human subjects research not approved by the IRB may not be conducted under the auspices of ETSU. However, if an investigator feels that their research proposal was denied or restricted unnecessarily, they may initiate the appeals process. Investigators are encouraged to communicate with the IRB Coordinator to clarify the reasons for deferral or disapproval of applications. Investigators may additionally request an appearance at an IRB meeting to present their views.

II. Overview

The ETSU IRB has the authority to approve, specify modifications required to secure IRB approval, or disapprove any research activity overseen and/or conducted under the auspices of ETSU. The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB policies or approval, or that is associated with unexpected harm to participants or others or comprises the integrity of the Human Research Protection Program.

Research approved by the IRB may be subject to further review by ETSU officials or participating site officials, as appropriate. The institutional official may override the IRB's decision to approve research; however, no university officials may approve research if it has not been approved by the IRB, nor can they overrule other review decisions made by the IRB.

Investigators that disagree with an IRB review determination may appeal:

- Revisions required by the IRB;
- IRB determinations of noncompliance or unanticipated problem involving risks to subjects or others;
- IRB disapproval of research; or
- Termination or suspension of IRB approval.

If the appeal is denied, the investigator's institution cannot override the IRB decision. Documentation of appeal, including all correspondence relating to the

appeal, is retained within the IRB electronic protocol system for the requisite time period.

III. Appeal Process

Investigators who disagree with a written IRB determination and decide to initiate the appeal process should notify the IRB Chair in writing by emailing IRB@etsu.edu within 30 days of the date of the letter. The investigator should provide the rationale and supporting information/material that will aid the IRB in the review of the appeal.

The IRB staff will forward the appeal information to the appropriate IRB Chair immediately and will notify the Institutional Official. The IRB Chair will consult with at least 1 other IRB member to review the basis of the appeal and determine if the appeal warrants further consideration. The appeal may be dismissed without further consideration or proceed through the appeal process below.

The IRB may request additional information to aid in its decision of the appeal. The investigator is expected to provide information as requested in a timely manner. Failure to respond to the IRB request for information may result in dismissal of the appeal at the IRB Chair's discretion.

For research reviewed using the expedited review procedure, the appeal is reviewed by the IRB Chair and designated reviewer(s). They may make a decision on the appeal, or refer the appeal to the convened IRB. If there is a dispute of the decision, the appeal is referred to the convened IRB for final resolution.

For research reviewed by the convened IRB, the appeal is reviewed by the convened IRB. The investigator may be invited to the meeting to present the appeal and provide additional information as requested by the IRB.

The appeal may be denied or accepted for consideration. Acceptance of an appeal does not constitute IRB approval of research, and additional actions may be necessary to receive IRB approval. The IRB may request additional revisions, documentation, or a new protocol submission, as needed, according to the conditions set forth by the IRB in accepting the appeal.

The appeal decision is documented in writing, and the investigator is notified promptly.

If the appeal is denied, the IRB decision is final, and the decision cannot be overruled.

Revision History:

May 15, 2007, revised June 4, 2024