

IRB PROCEDURE STATEMENT

Procedure: Procedures for Responding to Disapproval of a Research Project (Appeal Request)

Procedure ID: 2022-12

Effective: July 1, 2021

Revised: May 2022

A. Background

After review of Exempt, Expedited, or Full Board projects, the Institutional Review Board (IRB) communicates the decision of approval or disapproval in writing to the Principal Investigator (PI). In rare instances, a PI may receive a decision of disapproval for a submitted project. The PI may respond to this disapproval to the Full Board of the IRB by submitting an **Appeal Request**. The Full Board of the IRB will review and vote on the PI's Appeal Request to have the project reviewed again for possible approval.

B. Procedure

1. The PI of a research project that was not approved during review by the IRB, submits written documentation via email or letter to the IRB Office detailing the specifics of the **Appeal Request** to the disapproval. Additional materials may be included as appendices to support statements made in the Appeal Request. This request should be made within 10 business days of the disapproval notification to the PI.
2. The Research Compliance Officer (RCO) assists the IRB Office, IRB Chair and/or Vice-Chair in gathering information about the Appeal Request. The IRB Chair consults with the Vice-President for Research and Economic Engagement (VPREE), RCO, IRB Vice-Chair, and/or IRB Administrator when gathering information about the appeal request.
3. The Appeal Request is referred to the Full Board of the IRB at the next meeting or on-call meeting. The PI presents the Appeal Request to the Full Board, the IRB Chair presents any information from the IRB administrative review, and the Full Board is allocated time for questions to the PI and others involved in this appeal request. The PI is excused from the meeting. The IRB may continue deliberations about the Appeal Request.
4. Unless there is a motion to table the Appeal Request, a vote of all members of the Full Board is taken at the meeting. Votes are tallied and the outcome/action for the Appeal Request is recorded. This review of the Full Board of the IRB is the final decision for support or nonsupport of the Appeal Request.
5. A final summary of the Appeal Request and decision by the IRB is written. The IRB Office notifies the PI, Full Board, the RCO, and VPREE in writing within 5 business days of the outcome of the appeal request. Copies of this final summary are provided to the PI's Director/Chair, Dean, and the Provost.

Note. Adapted from OHRP guidelines and IRB procedures at other academic institutions.