

Series 411 Appeal of IRB Decisions | Institutional Review Board

Appeal of IRB Decisions from Series 411 of the Standard Operating Procedures

I. Authority of the IRB

The Utah State University IRB has the authority to

1. Approve research activity
2. Specify modifications required to secure IRB approval of the research activity
3. Disapprove any research activity overseen and/or conducted by Utah State University or
4. Establish the appropriate site of review for research involving a USU investigator.

The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB policies and/or procedures, is not in compliance with applicable Federal Regulations, or that is associated with unexpected serious harm to participants. Research approved by the IRB may be subject to further review by officials of Utah State University, as appropriate (e.g. Institutional Biosafety, Conflict of Interest, Office of General Counsel, etc.). Such officials may override the IRB's decision to approve research (i.e. not permit a research project that has gained IRB approval to move forward); however, they may not approve the research if it has not been approved by the IRB, nor can they overrule other decisions made by the IRB, such as revisions that were made to gain approval or determining the appropriate site for review.

II. Ability to Appeal

Investigators may appeal, for projects on which they are considered engaged under guidance from OHRP:

- Revisions required by the IRB;
- IRB determinations of noncompliance, serious noncompliance, continuing noncompliance or a reportable event;
- IRB disapproval of research;
- Withdrawal of Investigator and Principal Investigator privileges; and
- Termination of an approved protocol by the IRB.

If the appeal is denied, no part of the investigator's institution can override the IRB decision. Documentation of appeals including all correspondence relating to the appeal is retained with the research protocol in Quali Protocols, or by the IRB in the case of a determination unrelated to a specific protocol.

III. Appeal Procedures

Procedure for Appealing Revisions Required to Gain Initial Approval, a Reliance Determination, Continuing Approval, or Amendment Approval

If an investigator disagrees with a revision requested by the IRB, the investigator may submit a written appeal to irb@usu.edu, clearly identifying the protocol number and revision that is being appealed. The investigator should include information supporting any arguments proffered in support of the appeal. For research reviewed using the expedited review procedure, the appeal is reviewed by the expedited designated reviewer who requested the revisions. The expedited designated reviewer may either

1. Make a decision on the appeal, or
2. Refer the appeal to the IRB Chair.

If the expedited designated reviewer does not sustain the appeal, it shall be directly referred to the IRB Chair (or Vice Chair, in the Chair's absence or incapacity) for a determination. The IRB member whose determination is being appealed shall also explain the reasoning behind the determination under appeal. If the investigator disagrees with the IRB Chair's determination, the matter is referred to the Convened IRB for resolution at the next available meeting (i.e. meeting where an agenda retains space for additional considerations), with the investigator's consent. The investigator may be invited to a meeting of the Convened IRB to provide clarification or additional information to the IRB. The investigator may not be present for the vote on the appeal.

For research initially reviewed by the Convened IRB, the appeal is reviewed by the Convened IRB. The investigator may be invited to a meeting of the Convened IRB to provide clarification or additional information to the IRB. The investigator may not be present for the vote on the appeal.

The expedited reviewer, IRB Chair, or Convened IRB may sustain (accept) the appeal, request different revisions, or deny the appeal. The investigator is notified in writing of the decision. If the appeal is sustained (accepted), the investigator is not required to submit the requested revisions. If different revisions are requested, the investigator must submit those revisions.

If the appeal is denied by the Convened IRB, the IRB decision is final and the revisions must be made prior to approval. Alternatively, the research team may abandon the project.

Procedures for Appealing IRB Withdrawals of Investigator Privileges, Terminations, Suspensions, Disapprovals, or Determinations regarding Reportable Events

If an investigator disagrees with an IRB determination regarding the withdrawal of investigator privileges, protocol terminations, protocol suspensions, or a determination regarding a Reportable Event, the Investigator may submit the appeal and any information supporting the appeal in writing within 10 business days of being notified of the determination. The investigator must submit a written appeal to irb@usu.edu, clearly identifying the protocol number and determination that is being appealed. The investigator should include information supporting any arguments made in the appeal. The information will be provided to the Convened IRB at its next available meeting. The Investigator may also request to be in attendance at a convened meeting to provide clarification or additional information to the IRB. The Investigator may not be present for the vote on the appeal. The Convened IRB may sustain (accept) the appeal, issue a revised directive, and/or deny the appeal. The Investigator is notified in writing of the decision. If the appeal is denied, the IRB decision is final and the original determination stands.

Procedures for Appealing IRB Determinations of Noncompliance

If an investigator disagrees with an IRB Determination related to Noncompliance, the Investigator may submit the appeal and any information supporting the appeal within 10 business days of being notified of the determination. Investigators have ten business days from the receipt of the final findings to submit a written appeal to the IRB, at irb@usu.edu or in hard copy, to **1450 Old Main Hill, Suite 155, Logan, UT 84322**. If hard copy will be utilized, the materials must be received by close of business on the tenth business day. Notice of the intent to appeal must be submitted in writing within five business days of being notified of the determination, using the same delivery mechanisms. The appeal will be reviewed at the next available meeting of the Convened IRB. The written appeal must clearly present:

1. Which finding(s) of the Convened IRB or IRB Chair are being disputed;
2. All evidence supporting the investigator's claim that the finding(s) should be overturned; and
3. All relevant reasoning supporting the investigator's claim that the finding(s) and determination(s) should be overturned.

Investigators are welcome to combine their individual appeals into one written appeal, or may file them separately for separate consideration. The Investigator may also request to be in attendance at a convened meeting to provide

clarification or additional information to the IRB. The Investigator may not be present for the vote on the appeal. The Convened IRB may sustain (accept) the appeal, or deny the appeal. The Investigator is notified in writing of the decision. In the event that the appeal is successful, the IRB will automatically review the Corrective Action plan. If the appeal is denied, the IRB decision is final and the original determination stands.

Notifications of the noncompliance will not be sent to the cognizant Dean, Department Head, or other parties until the period for informing the IRB of the intent to appeal has passed without notice, or until the appeal has been heard by the Convened IRB, whichever occurs first.