



## **SOP 410: APPEAL OF IRB DECISIONS**

### **POLICY**

The University of Utah IRB has the authority to a) approve research activity, b) specify modifications required to secure IRB approval of the research activity or c) disapprove any research activity overseen and/or conducted by the University of Utah. The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB policies, is not in compliance with applicable Federal Regulations, or that is associated with unexpected serious harm to participants (see SOP 904: Administrative Hold, Suspension and Termination of Research).

Research approved by the IRB may be subject to further review by officials of the University of Utah as part of the Human Research Protection Program (HRPP), as appropriate. HRPP officials may override the IRB's decision to approve research; however, they may not approve the research if it has not been approved by the IRB or overrule other decisions made by the IRB.

Investigators may appeal:

- revisions required by the IRB;
- IRB determinations of non-compliance, serious non-compliance, continuing non-compliance or an unanticipated problem involving risks to participants or others;
- IRB disapproval of research; and
- termination of an approved protocol by the IRB.

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 with the research protocol in the ERICA system.

### **PROCEDURES**

#### **1. Procedures for Appealing Revisions Required by the IRB**

- 1.1. If an investigator disagrees with a revision requested by the IRB, the investigator may submit a written appeal to the IRB administrator or coordinator who was responsible for issuing the request. The investigator should include information supporting any arguments made in the appeal.
- 1.2. For research reviewed using the expedited review procedure, the appeal is reviewed by the expedited reviewer who requested the revisions. The expedited reviewer may either (a) make a decision on the appeal, or (b) refer the appeal to the convened board. If the investigator disputes the decision of the expedited reviewer, the appeal is then referred to the convened board for resolution.
- 1.3. For research reviewed by the convened IRB, the appeal is reviewed by the convened IRB. The investigator may be invited to a convened meeting to provide clarification or additional

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information to the IRB. 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.

- 1.4. The expedited reviewer or convened IRB may accept the appeal, request different revisions, or deny the appeal. The investigator is notified in writing of the decision.
  - 1.4.1. If the appeal is accepted, the investigator is not required to submit the requested revisions.
  - 1.4.2. If different revisions are requested, the investigator must submit those revisions.
  - 1.4.3. If the appeal is denied, the IRB decision is final and the revisions must be made prior to approval.

## **2. Procedures for Appealing Determinations made by the IRB**

For the purposes of this policy, the term “IRB determination” means a determination of non-compliance, serious non-compliance, continuing non-compliance or an unanticipated problem involving risks to participants or others.

- 2.1. If an investigator disagrees with an IRB determination, the Investigator may submit the appeal and any information supporting the appeal in a new Report Form in the ERICA system within 60 days of being notified of the determination.
- 2.2. For IRB determinations made through administrative review (review conducted by an IRB administrator or the IRB Chair or his/her designee), the appeal is reviewed by the individual who made the determination. The administrative reviewer makes a decision on the appeal. If the investigator disputes the decision of the administrative reviewer, the appeal is then referred to the convened board for resolution.
- 2.3. For IRB determinations made by the convened IRB, the appeal is reviewed by the convened IRB. The investigator may be invited to a convened meeting to provide clarification or additional information to the convened IRB. 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.
- 2.4. The administrative reviewer or convened IRB may accept the appeal or deny the appeal. The investigator is notified in writing of the decision.
  - 2.4.1. If the appeal is accepted, a new determination is made using the information provided in the new Report Form.
  - 2.4.2. If the appeal is denied, the IRB decision is final, and the original determination stands.

## **3. Procedures for Appealing the IRB Decision to Disapprove or Terminate a Study**

- 3.1. If an investigator disagrees with the IRB decision to disapprove or terminate a study, the investigator may submit a written appeal of the decision to disapprove to the IRB Chair and IRB Director within 60 days of being notified of the decision. The appeal should address the specific concerns of the IRB and the IRB basis for disapproval.
- 3.2. The appeal is reviewed by the convened IRB. The investigator may be invited to the convened meeting to provide clarification or additional information to the IRB. The investigator may also

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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.

3.3. The convened IRB votes to accept or deny the appeal. The investigator is notified in writing of the decision.

3.3.1. If the appeal to the decision to disapprove a study is accepted, the investigator is invited to submit a new study application to the IRB for review and approval, according to the conditions set forth by the IRB in accepting the appeal.

3.3.2. If the appeal to the decision to terminate a study is accepted, the investigator may resume research activities after any conditions set forth by the IRB are met. In some cases, the IRB may require the investigator to submit a new study application for review and approval prior to resuming research activities.

3.3.3. If the appeal is denied, the IRB decision is final, and the study may not be approved or resume.

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