

# Institutional Review Board (IRB) Policies & Procedure Manual



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## Disapprovals and Appeals

### Purpose

This policy describes the process employed by the Institutional Review Board to disapprove a research activity and the process by which an investigator may appeal the decision.

### Policy

In accordance with federal regulations (45 CFR 46.109(d) and 21 CFR 56.109(e)), the Institutional Review Board (IRB) will notify Boston Children's Hospital and investigators, in writing, of a decision to disapprove proposed research activity. If the IRB disapproves an activity, it will send written notification, including a statement of the reasons for disapproval to the investigator and to the Department Chair or Division Chief.

A Principal Investigator (PI) will have an opportunity to respond in person or in writing to the IRB if the submitted research is not approved or if the investigator has any concerns about the actions taken.

### Procedure

**Disapproval:** A disapproval is defined as follows: After consultation with the investigator, the IRB determines that the research places the subjects at a level of risk that far outweighs the benefit or value of the knowledge to be gained or raises such serious ethical questions as to be unacceptable.

#### Disapproval

1. If the IRB determines that a study is disapproved, a detailed report of action that includes the rationale for the disapproval will be sent to the PI.
2. The investigator will also be informed that they may attend a future meeting to discuss the disapproval. In the event the disapproval is foreseen, the IRB Chair may ask that the PI be invited to attend the meeting to discuss the protocol. In rare circumstances this may not be possible, such as when disapprovals cannot be predicted in advance or when the investigator is unavailable.

#### Appeal

3. The PI may appeal the IRB decision by responding, in writing, to the IRB Chair or to the Director of Clinical Research Compliance. This response must:
  - a. State that an appeal is being made and
  - b. Describe the rationale for the appeal.
4. Upon receipt of the appeal notification, it will be added to the agenda of the next available IRB meeting and the PI will have the opportunity to attend the IRB meeting for a discussion. All IRB members will receive a copy of the appeal in preparation for the meeting.
5. The IRB will carefully review the appeal and reach a final decision by a formal vote.

6. Final votes are not subject to additional appeals and may not be overridden by any individual, committee, or entity within Boston Children’s Hospital.

For more information on the convened IRB review, see IRB policy: **Convened IRB: Operational Review Procedures**

**Related Content**

IRB Policy

*Convened IRB: Operational Review Procedures*

**Document Attributes**

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