



## Disapprovals and Appeals

### 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 a 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.

### Purpose

To describe the process employed by the Institutional Review Board to disapprove a research activity, and the process by which an investigator may appeal the decision.

### Procedure

#### Definition

Disapproval is defined as follows: After consultation with the investigator, the committee 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.

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1. If the IRB determines that a study is not approved, a detailed report of action that includes the rationale for the disapproval will be sent to the investigator. The investigator will also be informed that he or she may attend a future meeting to discuss the disapproval. In the event the disapproval is foreseen, the Chair of the IRB may ask that the investigator 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.
2. The investigator may appeal the IRB decision by responding, in writing, to the IRB Chair or to the Director of Clinical Research Compliance. This response must state that an appeal is being made, and describe the rationale for the appeal.
3. Upon receipt of the appeal notification, it will be added to the docket of the next available IRB meeting, and the PI will have the opportunity to attend the IRB meeting at which it is being discussed. All IRB members will receive a copy of the appeal in preparation for the meeting.
4. The IRB will carefully review the appeal and reach a final decision by a formal vote.

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

## Related Content

## Document Attributes

Title	Disapprovals and Appeals		
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