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**Boston  
Children's  
Hospital**

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Owner Susan Kornetsky:  
Manager  
Department Research  
Applicability Boston Children's  
Hospital- Policies  
& Procedures

## Disapprovals and Appeals Policy/Procedure

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

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

### Definitions

**Disapproval:** 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.

**Appeal:** Request for reconsideration of an Institutional Review Board (IRB) determination in research involving human subjects.

### Policy Statements

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 investigators, in writing, of a decision to disapprove proposed research activity.

If the IRB disapproves an activity, it will send written notification to the Principal Investigator (PI) and to their Department Chair or Division Chief, that includes the reasons for disapproval.

If the submitted research is not approved or if the PI has any concerns about the actions taken, the PI

will have the opportunity to respond in person or in writing to the IRB.

## Procedures

### Disapproval Process

1. If the IRB determines that a study is disapproved, the PI will receive a detailed report of action that includes the rationale for the disapproval.
2. The PI will be informed that they may attend a future meeting to discuss the disapproval.
3. 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 Process

1. The PI may appeal the IRB decision by responding in writing, to the IRB Chair or to the Senior Director of Clinical Research Compliance. This response must:
  - a. State that an appeal is being made **and**
  - b. Describe the rationale for the appeal.
2. Upon receipt of the appeal notification, it will be added to the agenda of the next available convened IRB meeting.
  - a. The PI will have the opportunity to attend the IRB meeting for a discussion.
  - b. All IRB members will receive a copy of the appeal in preparation for the meeting.
3. The IRB will carefully review the appeal and reach a final decision by a formal vote.
4. Final votes are not subject to additional appeals and may not be overridden by any individual, committee, or entity within Boston Children's Hospital.

## References/Citations

[Office of Human Research Protections: 45 CFR 46.109\(d\)](#)

[FDA: 21 CFR 56.109\(e\)](#)

## Related Content

- IRB Policy: Convened IRB: Operational Review Procedures (For more information on the Convened IRB review process)

## Approval Signatures

Step Description

Approver

Date

COPY