



Disapprovals and Appeals

Policy

- In accordance with federal regulations (45 CFR 46.109(d) and 21 CFR 56.109(e)), the Committee on Clinical Investigation (CIC) will notify Children's Hospital and investigators, in writing, of a decision to disapprove a proposed research activity. If the CCI 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 CIC 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 Committee on Clinical Investigation 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 CIC 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 CIC 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 CIC decision by responding, in writing, to the CCI 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 CCI meeting, and the PI will have the opportunity to attend the CIC

meeting at which it is being discussed. All CIC members will receive a copy of the appeal in preparation for the meeting.

4. The CCI will carefully review the appeal and reach a final decision by a formal vote.
5. Final votes are not subject to additional appeals and may not be overridden by any individual, committee, or entity within Children's Hospital.

Related Content

None identified

Document Attributes

Title	Disapprovals and Appeals		
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