Managing Research Subjects/Family Concerns and Complaints

Purpose

The purpose of this policy is to outline the management of research participant/family concerns and complaints.

Policy

Boston Children's Hospital is committed to the protection of research participants and their families. Despite the Hospital's and the investigator's best efforts, concerns or complaints may arise regarding a participant's involvement in a research protocol.

Research participants and their families are encouraged to express their concerns, at any time, directly to the principal investigator (PI) or any other member of the research team. Research participants and their families may also speak with either the Chair of the Institutional Review Board (IRB) or the Director of Clinical Research Compliance to resolve existing concerns.

- All consent documents must contain a telephone number for subjects to call if they wanted to voice concerns or complaints to the research staff, investigator or IRB office.
- All research participants are made aware of the availability of the IRB Chair or the Director for such discussions through the informed consent document.
- All concerns and complaints are to be addressed in a timely and thorough manner.

Procedures

How to Share a Concern or a Complaint

1. The Boston Children's Hospital external website includes information about the IRB and there is a link that invites families to submit comments.
2. A research participant/family member may share a concern or a complaint with the PI, any member of the research team, the IRB Chair, or the Director of Clinical Research Compliance.
3. Subjects may voice a concern or a complaint in person, or by telephone, email, or postal letter. The IRB Chair or the Director of Clinical Research Compliance may be contacted by telephone (617 355-7053) or by email (Susan.Kornetsky@Childrens.Harvard.edu); by mail (Institutional Review Board, 300 Longwood Ave, Boston, MA 02115); or on a walk-in basis. The office is open Monday through Friday, from 8:30 a.m. to 5:00 p.m.

Procedures for Managing a Concern or a Complaint

When Received by Principal Investigator

1. Any PI, member of the research team, or health care provider who receives a research participant/family member complaint must either:
   a. Notify the Director of Clinical Research Compliance by telephone or email, or
   b. Submit a Reportable Event to the IRB, which asks for details regarding the complaint or concern raised.

2. The Director of Clinical Research Compliance is to ascertain the details of the complaint and the course of action thus far and determine whether any additional steps must be taken to resolve the complaint.
   a. This may involve further discussion with the research participant/family member, the PI, other members of the research team, and/or other health care providers, as necessary.
   b. The Director of Clinical Research Compliance and the IRB Chair are to determine whether the issue is adequately resolved or whether further actions must be taken. Members of the IRB are to be informed of this determination.

When Received by Director of Clinical Research Compliance from Other Members of Research Team, Care Providers, or Research Participant/Family Member

1. If a complaint is submitted to anyone other than the PI of the research protocol, the Director of Clinical Research Compliance or the IRB Chair is to contact the PI within 24 hours to ensure that he or she is aware of the concern or complaint.

2. The Director of Clinical Research Compliance is to ascertain the details of the complaint and the course of action thus far and determine whether any additional steps must be taken to resolve the complaint. This may involve further discussion with the PI, other members of the research team, and/or other health care providers, as necessary. Members of the IRB are to be informed of this determination.
   a. If a complaint is received in the IRB directly from a research participant/family member, information regarding the complaint is to be obtained and the participant/family member told that he or she will be contacted within seven or fewer working days with an update on the inquiry into the concern or complaint.
   b. If it takes longer than seven working days to resolve the concern or complaint, the research participant is to be updated on a weekly basis until the concern or complaint is resolved.

Other Potential Actions Pertinent to Concerns and Complaints

If necessary, the research protocol may be suspended by the Department Chair, the Director of Clinical Research Compliance, the IRB chair, the IRB or Institutional Official until the details regarding the concern or complaint are resolved. Any suspension will follow the reporting policy

If the concern or complaint involves possible scientific misconduct, it is to be referred to the Vice President of Research Administration.

Related Content

IRB Form

Informed Consent

Document Attributes

Title	**Managing Research Subjects/Family Concerns and Complaints**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/1/2005 6/20/2005 5/17/2007 5/1/2015
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