Principal Investigator Responsibilities

Purpose

This policy outlines the responsibilities of Principal Investigators who conduct clinical research at Boston Children's Hospital.

Policy

Principal investigators (PIs) at Boston Children's Hospital must understand and assume the overall responsibility for the research study.

Procedure

PI Ethical Standards

The ethical standards of BCH PI's are as follows, PIs:

1. Must acknowledge and accept their responsibility for protecting the rights and welfare of human subjects. Furthermore, they must comply with all applicable provisions of BCH's assurance of compliance with the Office of Human Research Protections, federal regulations, and with all BCH policies pertinent to human subject protections.
2. Are responsible for performing research with sufficient resources to insure appropriate care, oversight, and safety of the research subjects during the course of the study.
3. Are to conduct research only with resources that are appropriate to ensuring research subject safety.
4. When required, are responsible for obtaining the review and approval of the Institutional Review Board (IRB) prior to initiation of human subject research.
5. Are responsible for ensuring that the research is conducted in accordance with IRB-approved protocols, and any conditions that are set in at the time of final approval.

Informed Consent

The expectation of BCH PI's in regard to Informed Consent are as follows, PIs:

1. Are responsible for obtaining and documenting informed consent in accordance with the regulatory requirements, unless otherwise waived by the IRB.
2. Are permitted to delegate to appropriate individuals the authority to obtain consent on their behalf; however, PIs are ultimately responsible.
3. Have an ethical responsibility to ensure that subjects and families understand through the informed consent process: the nature of the research participation, the associated risks and benefits, and any alternatives. PIs must take whatever steps are necessary to ensure this understanding and to facilitate implementation of a bona fide informed consent process.
4. Are to maintain informed consents in a manner approved by the IRB.

Reporting

The reporting standards of BCH PI's are as follows, PIs:

1. Are responsible for promptly reporting to the IRB of record any proposed changes to previously approved human subject protocols. These changes are not to be initiated without IRB review and approval, except when required to avoid apparent immediate harm to the subjects.
2. Are responsible for reporting the progress of the approved research to the IRB of record, in the manner and frequency prescribed by the IRB. This will depend on whether the research is being followed in accordance with the new common rule as of 2018 or is following the old common rule.
3. Are to promptly report to the IRB of record any unanticipated problems that involve risks to the subjects or others.
4. Are responsible for reporting to the IRB of record all actions or processes that deviate from the protocol procedures approved by the IRB.
5. Are responsible for submitting to the IRB of record copies of all external monitoring reports; Data, Safety, and Monitoring Board reports and updates; and FDA annual reviews, if applicable.
6. Are responsible for reporting to the IRB of record any noncompliance with regulations or the institutional policies and procedures under which the research is being conducted.

Protocol Documentation

The protocol documentation standards of BCH PI's are as follows, PIs:

1. Are responsible for maintaining for each study: a current protocol file or binder that contains, at a minimum, the following IRB approved documents: protocol, informed consent form, recruitment materials, study materials (e.g. surveys, questionnaires); IRB Approval Letters, IRB Action Letters (Conditional Approvals, Deferrals), pertinent correspondence with the IRB (and the sponsor, if applicable); investigational brochure for drug and device studies, and Forms 1571 and 1572, if applicable. Note: The electronic protocol system (CHeRP) may serve this purpose.
2. Are responsible for the safe and secure storage of research data (in both paper and electronic formats) and protecting the confidentiality of research data.

Participant/Research Team Concerns

The responsibility of PIs in regard to participant/researcher concerns, are as follows, PIs:

1. Are responsible for immediately addressing any concern or question raised by a research subject before, during, and/or after the completion of a research study.
2. Are responsible for addressing any concerns raised by any member of their research team. The PI responsibilities involving study team oversight include the following:
    a. PIs are to meet frequently with their research teams for the purpose of reviewing the progress of the research and to encourage discussion of any concerns about the research in general and/or about a specific research subject.
    b. PIs are to inform each member of the research team individually of their responsibility to voice any concerns they may have without fear of repercussions.
    c. PIs must take seriously any concern raised. They are to fully investigate each expressed concern and report back to the individual who raised it. No concern is to be dismissed.

d. PIs may not punish an individual who brings a concern to their attention.
e. PIs are responsible for reporting to the IRB of record any expressed concerns that result in findings regarding subject safety, compliance with the research protocol, informed consent violations, and/or the integrity of the research data.

Related Content

IRB Policy

Who May Serve as a Principal Investigator?

Document Attributes

Title	**Principal Investigator Responsibilities**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/01/05 6/20/05 7/17/07 4/28/10 5/01/15
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2020	**Last Modified**	01/01/2020
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance August Cervini, MBA Vice President for Research Administration		