Principal Investigator Responsibilities

Policy

- Principal investigators (PIs) at Children's Hospital must understand and accept their responsibilities.

Purpose

To outline the responsibilities of the PIs who conduct clinical research at Children's Hospital.

Procedure

Ethical Standards

1. Research investigators are to acknowledge and accept their responsibility for protecting the rights and welfare of human subjects, and for complying with all applicable provisions of Children's Hospital's assurance of compliance with the Office of Human Research Protections; with federal regulations; and with all Hospital policies.
2. Research investigators are responsible for performing research with sufficient resources to insure appropriate care, oversight and safety of the research subjects during the course of research
3. Research investigators are to conduct research only with resources that are appropriate to ensuring research subject safety.
4. When required, research investigators who intend to use human subjects are responsible for obtaining the review and approval of the Committee on Clinical Investigation (CCI) prior to initiation of the research.
5. Research investigators are responsible for ensuring that the research is conducted in accordance with CCI-approved protocols, and any conditions that are set in order to receive final approval.

Informed Consent

1. Research investigators are responsible for obtaining and documenting ***informed consent*** in accordance with the regulatory requirements unless otherwise authorized by the CCI. Investigators are permitted to delegate to appropriate individuals the authority to obtain consent on their behalf; however, they are ultimately responsible.
2. Research investigators have an ethical responsibility to ensure that subjects and families understand, through the informed consent process, the nature of the

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research, the requirements of participation, the associated risks and benefits, and any alternatives. Research investigators must take whatever steps are necessary to ensure this understanding and to facilitate implementation of a bona fide informed consent process.

3. Research investigators are responsible for providing a signed copy of the CCI-approved informed consent to each subject at the time of consent, unless the CCI has specifically waived this requirement. All informed consent documents are to be maintained in a manner approved by the CCI.

Reporting

4. Research investigators are responsible for promptly reporting to the CCI any proposed changes to previously approved human subject protocols. These changes are not to be initiated without CCI review and approval, except when required to avoid apparent immediate harm to the subjects.
5. Research investigators are responsible for reporting the progress of the approved research to the CCI, in the manner and frequency prescribed by the CCI (based on the risk to subjects), but not less than once per year.
6. Research investigators are to promptly report to the CCI any unanticipated and serious events, or other unanticipated problems, that involve risks to the subjects or others.
7. Research investigators are responsible for reporting to the CCI all actions or processes that deviate from the protocol procedures approved by the Committee.
8. Research investigators are responsible for submitting to the CCI copies of all external monitoring reports; Data, Safety, and Monitoring Board reports and updates; and FDA annual reviews, if applicable,
9. Research investigators are responsible for reporting to the CCI any noncompliance with regulations or Hospital policies and procedures.

Protocol Documentation

10. Research investigators are responsible for maintaining for each study a current protocol file or binder that contains, at a minimum, the following documents: approved CCI protocol; approved informed consent form; approved recruitment materials; approved study materials (e.g., surveys, questionnaires); CCI Approval Letters; CCI Action Letters (Conditional Approvals, Deferrals); pertinent correspondence with the CCI (and the sponsor, if applicable); investigational brochure for drug and device studies; and Forms 1571 and 1572, if applicable. Investigators are encouraged to document and file all CCI (and sponsor, if applicable) submissions, responses, and pertinent correspondence.
11. Research investigators are responsible for the safe and secure storage of research data (in both paper and electronic formats) and protecting the confidentiality of the data.

Participant / Researcher Concerns

12. Research investigators are responsible for immediately addressing any concern or question raised by a research subject before, during, or after the conduct of a research study.
13. Research investigators are responsible for addressing any concerns raised by any member of their research team. This responsibility includes the following:

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- Investigators 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, or about a specific research subject.
- Investigators are to inform each member of the research team, individually, of his or her responsibility to voice any concerns he or she may have, without fear of repercussions.
- Investigators 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.
- Investigators may not punish an individual who brings a concern to their attention.
- Investigators are responsible for reporting to the CCI any expressed concerns that result in findings regarding subject safety, compliance with the research protocol, informed consent violations, or the integrity of the research data.

Related Content

Clinical Investigation Policy: ***Informed Consent***

Document Attributes

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