

Institutional Review Board (IRB) Policies & Procedures Manual



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Research Related Injury

Purpose

The purpose of this policy is to define what treatment and compensation will be provided to research subjects as a result of a research-related injury. This policy is required to conform with federal regulations pertaining to informed consent and pertinent accreditation standards.

Policy

Boston Children's Hospital (BCH) is dedicated to the protection of persons who participate in research as human subjects. Protecting subjects requires respecting and enforcing regulations that prohibit requiring subjects to waive their rights to compensation, and proactively using methods reasonably calculated to provide for direct medical care of a subject without any need for legal recourse by a subject.

Federal regulations require that one of the provisions of consent is that prospective subjects be provided with information "for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments will be provided if an injury occurs and if so, what they consist of, or where further information may be obtained."

Those regulations also prohibit any informed consent, oral or written, from including "any exculpatory language through which the subject or their representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence" (21 CFR 50.20; 45 CFR 46.116).

Procedure

Medical Treatment for Injuries Sustained During Human Subject Research

Industry-Sponsored Research

As part of the clinical trial agreement negotiations, the Sponsor will be required to pay for treatment of illness or injury suffered by a research subject that directly results from participation in the research. These terms are negotiated as part of the clinical trial agreement.

Sample clauses from Boston Children's Hospital's clinical trial contract template are as follows:

In addition to its obligations under Article 8 ("Indemnification") of this Agreement, Sponsor agrees to reimburse any research subject, or BCH as applicable, for the costs of medical care provided to address, diagnose and/or treat adverse events and other injuries resulting from a subject's participation in the Study, including medically appropriate follow-up. The Sponsor shall not delay or withhold reimbursement from any such subject based upon the belief that an adverse event or resultant medical care was

due to the negligence of BCH or Investigator, or their failure to follow the Protocol. In that event, Sponsor's sole remedy shall be with respect to BCH under the Indemnification provisions of this Agreement.

The parties recognize that research subjects' participation in clinical studies may require additional testing or clinical care that is not covered by the subjects insurance, managed care, or governmental payers on the grounds that the testing or care is experimental or related to research. The parties also agree that it is ethically imperative, as well as practically appropriate in reducing Sponsor's potential liabilities for indemnification as provided in section 8 of this Agreement, that BCH and/or Principal Investigator may provide such additional testing and care in appropriate cases. Therefore, both BCH and Principal Investigator (in his or her clinical capacity) reserve the right to invoice Sponsor for the cost of such additional testing or care, provided in connection with or as a consequence of the subject's participation in the Study, provided that such care is in their reasonable judgment medically indicated; that it is or would be excluded by the subject's health care coverage, if any; provided that the condition requiring care is not caused by the negligence or willful malfeasance of the Principal Investigator or BCH; and provided that BCH and/or Principal Investigator document(s) the condition and the charges. Sponsor agrees that it shall pay such charges in addition to any other payments required in this Agreement.

In addition, it is the policy of BCH that, other than what is set forth in the above-mentioned template language, no clinical trial contract shall permit the Sponsor to limit its own indemnification, or shift to subjects its indemnification risk with respect to claims or causes of action that arise from the conduct of the Sponsor, whether related to the manufacturing, distribution or quality of a test article, or with respect to the actions of the Sponsor in design, conduct and reporting of the research.

Governmentally or Philanthropically Funded Research

In situations where the funding source is the government or a philanthropic institution or foundation, BCH will provide reasonable necessary treatment for an injury or illness suffered by a human subject which is directly related to participation in the study, provided that the IRB has approved the study and the investigator has performed it in the manner in which the IRB has approved it.

- In situations where the cost of research-related treatments could be covered by a subject's insurance, insurance may be billed consistent with applicable laws, agreements, and regulations.
- In situations where insurance will not cover treatment for research-related injuries or illness, BCH will provide treatment at no cost to the subject, but will not cover costs at another facility except in an emergency directly related to the research, or if special arrangements were made and approved by BCH in advance.

Internally Funded Studies

Studies which have no external funding should provide medical care to subjects on the same terms as governmentally or philanthropically funded studies.

Protocol Application: Chair's/Chief's Approval

Approval of a proposed study will depend on the investigator having determined and disclosed how the expenses of such care would be covered, and the pertinent Chief having approved. The protocol application will include this as a specific question to be addressed by the investigator with clear options. The source of funding may include the department/foundation, medical insurance (depending on the nature of reasonably predicted adverse events), a Sponsor, or some other specified arrangement. The signature is not intended to make the Chief's foundation the guarantor for BCH's charges.

Scope and Conditions of Care

For government-funded, philanthropically funded, and internally funded research, coverage is limited by the following terms:

- The injury or illness must be a direct result of the subject's participation in a research study. (The determination of whether the illness or injury is the direct result of the research activity is not limited to events resulting from study drugs, biologics or devices, but includes events resulting from tests, procedures and evaluations required by the protocol.)
- The subject must have notified BCH within a reasonable time period after discovering the injury or illness.
- The injury or illness must not be simply the normal progression of the subject's disease or underlying illness.

In situations where a third party is not obligated to cover treatment for research-related injuries or illness, BCH and associated foundations may agree to provide treatment at no cost to the subject, but will not cover costs at another facility except in an emergency directly related to the research, or if special arrangements have been made and approved by BCH.

BCH reserves the right to bill the patient's insurance or the patient themselves for the costs of routine items and services provided to the patient that would typically be covered by the patient and/or his or her insurance plan if not enrolled in a clinical study. BCH has a free care policy to cover those unable to cover their medical expenses.

Compensation

Compensation for claims in connection to research-related injuries, such as lost wages, pain and suffering, and other types of additional expenses beyond medical treatment related to the research-related injury, will be handled under the supervision of the Office of General Counsel.

The IRB will not be responsible for the oversight of such claims, but the Office of General Counsel may receive confidential information from time-to-time about such cases as necessary to comply with pertinent laws, regulations, and policies affecting the research during which the injury arose.

Procedures to Follow

1. Coverage for Research-Related injury.

The IRB application will request the PI to indicate how research-related injuries will be covered, in the following language or language that is substantially similar:

Medical Expenses for Research-Related Adverse Events

How will the cost of reasonably foreseeable medical care in the event of a research related adverse event be covered?

- Corporate sponsor agreement
- Likely to be covered by insurance
- Philanthropic or other grant
- Foundation or Departmental Funds
- Interdepartmental arrangements
- Other (Explain):
- Not applicable

2. Availability of Resources

The protocol application certifications by the PI and Chief will address the availability of resources, and coverage for research-related injuries as follows (pertinent language is italicized):

- **PI:**
The undersigned accepts responsibility for assuming adherence to DHHS, FDA, and Boston Children's Hospital's policies relative to the protection of the rights and welfare of patients/subjects participating in this study. I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other Purposes or disclose the information to other individuals or entity I will seek approval by the Institutional Review Board. *I assure the Committee that there are appropriate resources (equipment, space, support services) to conduct this research safely and in accordance with all required human subject protection policies.*

Signature of Principal Investigator

Date

- **Chief:**
This protocol has been approved for submission to the [IRB](#). The PI and associated staff have:
 - i) The appropriate resources (equipment, space, support services) to perform the research.
 - ii) The time necessary to oversee the conduct of the research.
 - iii) The appropriate qualifications, training, credentials/licensure to perform the associated research procedures.

I have reviewed and approved the investigator’s plans for covering the expenses associated with providing medical care in the event of a research related adverse incident.

Department Chair or Division Chief Signature [if the PI is within the Department of Medicine]
 (if PI is a Department Chair, signature of August Cervini, MBA is required)

 Date

3. Informing Subjects

All consent forms that involve research with greater than minimal risk will contain the statement:

“In the event of an injury resulting directly from your participation in this research study, medical treatment will be provided if the injury is reported in a timely manner. Provision of such medical care does not imply any negligence or other wrongdoing on the part of the Hospital or any of the physicians or other personnel involved in the study. Where applicable, the Hospital reserves the right to seek payment from third-party payors for any medical care or services rendered. The Hospital has no program to provide you with any additional compensation as a result of any such injuries.”

Investigators are also responsible for discussing obligations for research related injuries as part of the informed consent process.

4. Determination of Injury

The PI of the study is responsible for evaluating a subject that claims to have a research-related injury or illness in accordance with this policy and reporting this to the IRB, the Program for Patient Quality and Safety (PPSQ) and Office of General Counsel.

Investigators should report all claims and outcomes to the IRB, PPSQ and Office of General Counsel regardless of whether it is determined to be research-related or not.

If it is determined to be research-related, a meeting will be held with the PI, IRB representatives, PPSQ and Office of General Counsel to determine the additional steps which need to be taken and to designate a point of contact for the research subject.

Related Content

BCH Form

Clinical Trial Contract Template

Document Attributes

Title	Research Related Injury		
Author	Susan Kornetsky	Dates Reviewed/ Revised	4/1/2005
Reviewed/ Revised by	Susan Kornetsky		6/20/2005 5/1/2015
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Approved	<hr/> <p>Susan Kornetsky, MPH Director of Clinical Research Compliance</p> <hr/> <p>August Cervini, MBA Vice President for Research Administration</p>
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