

Institutional Review Board (IRB) Policies & Procedures Manual



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IRB Jurisdiction

Purpose

This policy describes the jurisdiction of the Boston Children's Hospital Institutional Review Board.

Policy

The Boston Children's Hospital Institutional Review Board (IRB) is responsible for the oversight of research that involves human subjects (as defined by HHS and FDA regulations) conducted at Boston Children's Hospital. The IRB *will* review all research conducted by members of the Boston Children's Hospital workforce that meets any of the following criteria:

- Research that is performed as part of an individual's academic responsibilities or an individual's employment responsibilities; or
- Research that is conducted during hospital time or with any hospital resources/money/space; or
- Research that is being performed as part of a hospital training program; or
- When the name of Boston Children's Hospital (BCH) will be used as part of an individual's credentials for any type of publication, presentation, or abstract.

Research that meets the criteria set forth above is covered research under this policy.

Work Force

Work Force is defined as medical staff that have appointments as "active staff, research staff or employees" of Boston Children's Hospital or one of the Boston Children's Foundations. The IRB will review all covered research regardless of the location of the research or its source of financial support. This includes research conducted at, schools, institutions, community groups, other hospitals or any other area not owned or controlled by Boston Children's Hospital. If a determination is made that the activity falls under the purview of the BCH IRB, the IRB may choose to rely on another institution's IRB for review through a reliance agreement.

In exercising this oversight, the IRB will permit such research to be conducted on Boston Children's Hospital premises only if the Principal Investigator (PI) is appointed as the appropriate staff of the Hospital or is an employee.

Research that is conducted by the Boston Children's Hospital work force in locations not owned or operated by Boston Children's Hospital, must be approved by the work force member's Chair/Chief or, if not a faculty member, the appropriate Vice President.

It is the responsibility of the Chair/Chief/Vice President to assure that Research is conducted with adequate protection of human subjects, including oversight by an IRB.

Chairs/Chiefs/Vice President are encouraged to contact the IRB administrative Office for guidance when these situations arise.

Although staff members may have appointments at multiple institutions, staff are usually considered "an employee" or a "work force member" of one institution. Staff who are paid by Boston Children's Hospital foundations are considered part of the Boston Children's Hospital work force.

Reliance Agreements

For research that is conducted off Boston Children's Hospital premises, the IRB may:

- Wish to enter into a Reliance Agreement with another institution's IRB for the review of the research.
- May be willing to extend its Federalwide Assurance (FWA) to another entity for the review of research conducted at that institution by a member of Boston Children's Hospital faculty.

It should also be noted that in accordance with the federal regulations, outside locations may need to apply for an assurance of compliance with OHRP if the location is "engaged" in human subject research and there is no IRB available at the site and the project is federally funded.

For information on Reliance Agreements procedures, see below.

Definition of Engaged in Research

The federal guidance document regarding the definitions and associated requirements for institutions/investigators "engaged in research" may be found at:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Procedure

Collaborative Research

Boston Children's Hospital, Chairs/Chiefs/VPs and the IRB recognize that collaborative research programs may originate or be conducted at other institutions and/or at multiple institutions. Investigators are expected to consult with their Chair/Chief/VP regarding these activities. The IRB office is also available to offer the investigator and Chair/Chief/VP thoughts for consideration such as:

- Where there is a question as to whether review by BCH IRB may be necessary in accordance with the federal regulations,
- Whether review by multiple institutions may be necessary,
- Whether an activity constitutes engagement in human subject research,
- Whether a reliance agreement between institutions may be considered, and
- Whether a collaborating institution requires an assurance of compliance when they are engaged in research and receive federal funding.

In these complex situations, factors such as whether the investigator is paid through BCH may be considered to help make the determination. Often consultation with the other organizations may be required to help make this determination.

Research protocols may be submitted for IRB review only by individuals who have a pertinent staff appointment (e.g., as physician, researcher, or nurse) at Boston Children's Hospital and in accordance with the IRB policy: ***Who May Serve as Principal Investigator.***

The records of the Hospital Registrar and Human Resources Department will be considered determinative in establishing the existence and scope of that appointment. Individuals who do not hold such an appointment may participate in the conduct of clinical investigations only when an individual who holds a staff appointment is designated as PI, and is a sufficiently active collaborator in the research to assume full responsibility for the ethical and scientific conduct of the clinical investigation.

Examples

The following are some examples as to when investigators should consult with their Chairs/Chiefs/VP to determine if research activities fall under the purview of the IRB or whether a reliance agreement can be utilized.

1. A work force member:

- Conducts research at a school, day care center, company, community center or another healthcare facility.
- Receives a grant/subcontract through BCH however proposes to conduct the research at another location.
- With a joint appointment receives a grant through another institution to conduct research at an international site.
- Obtains an appointment at another site in order to conduct research at that location and is listed as a co-investigator on the protocol submitted at the other institution.
- Proposes to conduct research in their private practice that is not affiliated with Children's Hospital and will include their Boston Children's Hospital credentials in a publication.

2. Use of BCH data or samples will be used at an offsite location.

Reliance Agreements

To eliminate duplicative IRB review Boston Children's Hospital will consider the use of other reliance agreements, where BCH's IRB agrees to rely on another institution, or another institution chooses to rely on Boston Children's Hospital.

These requests are decided on after regulatory mandates and when applicable on a case by case basis. The decision may be based on factors such as funding, location of research activities, risks of the protocol, expertise and any other factors pertinent to making such a decision. As necessary the IRB Chair and the Institutional Official will be consulted.

Investigators should contact the IRB for any questions pertinent to reliance agreements and whether they may be considered. Reliance agreements can also be terminated at the request of the IRB, IRB chair, or the Institutional Official.

Boston Children's Hospital may determine that it does not have the resources or expertise to serve as a Single IRB.

For detailed information please refer to the IRB policy: ***Reliance Agreements***.

Extension of Federalwide Assurance

In some cases, where the investigator and their employer have significant connections to Boston Children's Hospital, the IRB may be willing to extend its Federalwide Assurance to certain research conducted at another institution. This is considered on a case-by-case basis. The IRB administrative office is available to provide guidance on this issue.

Related Content

IRB Policies

Reliance Agreements

Who May Serve as a Principal Investigator?

Federal Guidance

Engagement: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Document Attributes

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Author	Susan Kornetsky	Dates	4/01/2005

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