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**Boston
Children's
Hospital**

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Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Institutional Review Board (IRB) Jurisdiction - Policy/ Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Work Force is defined as medical staff that have active appointments, scientific staff or employees of Boston Children's Hospital or one of the Boston Children's Foundations.

Policy Statements

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

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 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

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 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.

Procedures

Collaborative Research

Boston Children's Hospital, Chairs/Chiefs/Vice Presidents 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/Vice Presidents regarding these activities.

The IRB office is also available to offer the investigator and Chair/Chief/Vice Presidents thoughts for consideration such as:

1. Where there is a question as to whether review by Boston Children's Hospital IRB may be necessary in accordance with the federal regulations,
2. Whether review by multiple institutions may be necessary,
3. Whether an activity constitutes engagement in human subject research,
4. Whether a reliance agreement between institutions may be considered, and
5. 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 Boston Children's Hospital may be considered to help make the determination. Often consultation with the other organizations may be required to help make this determination.

Reliance Agreements

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

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.

Boston Children's Hospital Staff Appointment

Research protocols may be submitted for IRB review only by individuals who have a pertinent Boston Children's Hospital staff appointment (e.g., physician, scientist, or others who meet criteria to be a PI).

1. The records of the Hospital Registrar and Human Resources Department will be considered determinative in establishing the existence and scope of that appointment.
2. 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 Principal Investigator (PI), and is a sufficiently active collaborator in the research to assume full responsibility for the ethical and scientific conduct of the clinical investigation. Reliance agreements may be required.
3. The following are some examples as to when investigators should consult with their Chairs/Chiefs/Vice Presidents to determine if research activities fall under the purview of the IRB or whether a reliance agreement can be utilized. A work force member:
 - a. Conducts research at a school, day care center, company, community center or another healthcare facility.
 - b. Receives a grant/subcontract through BCH however proposes to conduct the research at another location.
 - c. Holds a joint appointment and receives a grant through another institution to conduct research at another site.
 - d. 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.
 - e. 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.

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.

References/Citations

Office of Human Research Protections (OHRP): Federal guidance regarding the definitions and associated requirements for institutions/investigators "[engaged in research](#)"

Related Content

IRB Policies

- [Single IRB Review \(For more information on Reliance Agreements\)](#)
- [Who May Serve as Principal Investigator \(For more information on pertinent staff appointment\)](#)

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
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Applicability

Boston Children's Hospital- Policies & Procedures

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