



Committee on Clinical Investigation Jurisdiction

Policy

The Committee on Clinical Investigation (CCI) is responsible for the oversight of **research** that involves **human subjects** (as defined by HHS and FDA regulations) conducted at Boston, Children's Hospital (Research). The Committee **will** review all Research conducted by members of the Boston Children's Hospital workforce that meets any of the following criteria.

The research:

- is performed as part of an individual's academic responsibilities or an individual's employment responsibilities; or
- is conducted during hospital time or with any hospital resources/money/space; or
- is being performed as part of a hospital training program; or
- 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 is defined as medical staff that have appointments as "active staff", research staff or employees of Boston Children's Hospital or one of the Children's Foundations. The Committee will review all Covered Research regardless of the location of the research or its source of financial support.

In exercising that oversight, the CCI will permit such research to be conducted on Boston Children's Hospital premises only if the principal investigator (PI) is appointed to the appropriate staff of the Hospital or is an employee.

Research that is conducted by 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.

For Research that is conducted off Boston Children's Hospital premises, the CCI may wish to enter into a Reliance Agreement with another institution's IRB for

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the review of the Research. Please see below for additional information on Reliance Agreements.

For Research that is conducted off Boston Children's Hospital premises, the IRB may be willing to extend its Federal Wide Assurance to another entity for the review of Research conducted at that institution by a member of Boston Children's Hospital faculty. Please see below for information regarding such agreements.

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.

Purpose

To describe the jurisdiction of the Boston Children's Hospital Committee on Clinical Investigation.

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 <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>.

Procedures

Boston Children's Hospital Work Force who conduct Research or Covered Research, whether at Boston Children's Hospital or at any other organization or location owned or controlled by BCH, must inform his/her Department/Division Chief or appropriate Vice President about such activities. It is the responsibility of the Chair/Chief/VP to assure that Research is conducted with adequate protection of human subjects, which includes oversight by the CCI, a reliance agreement with another institution or the extension of Boston Children's Hospital federal wide assurance for the Research Chairs and Chiefs and Vice Presidents are encouraged to contact the CCI 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. Human subject research conducted by an "employee" or "BCH Work Force member" usually falls under the jurisdiction of the Boston Children's Hospital IRB. 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 CCI, the CCI may choose to rely on another IRB for review through the use of a reliance agreement.

Boston Children's Hospital, Chairs/Chiefs/VPs and the CCI recognize that collaborative Research programs may originate or be conducted at other institutions, or be conducted at multiple institutions. Investigators are expected to consult with their Chair/Chief/VP regarding these activities. The CCI 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 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 also be required to help make this determination.

Research protocols may be submitted for CCI review only by individuals who have a pertinent staff appointment (e.g., as physician, researcher, or nurse) at Boston Children's Hospital. 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 and Chiefs/VP to determine if Research activities fall under the purview of the CCI or whether a reliance agreement can be utilized.

- A Work Force member conducts research at a school, day care center, company, community center or another healthcare facility.
- A Work Force member receives a grant/subcontract through BCH however proposes to conduct the research at another location.
- A Work Force member with a joint appointment receives a grant through another institution to conduct research at an international site.
- Use of BCH data or samples will be used at an offsite location.
- A Work Force member 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.
- A Work Force member 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.

Reliance Agreement with DFCI

In accordance with the Harvard Cancer Center grant Boston Children's Hospital has relinquished review of cancer related human subject research to the Dana Farber Cancer Institute through a reliance agreement. A chart which summarizes this arrangement may be found at agreement may be found in a policy titled "Determining Whether a Protocol Requires Boston Children's Hospital or Dana Farber Review"

http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_051_015_DFCI_CH.doc

Harvard CTSA Reliance Agreement (Harvard Catalyst)

The institutional review boards (IRBs) of several Harvard schools and affiliated health care centers have entered into a Common Reciprocal Reliance Agreement under the CTSA awarded to Harvard University Medical School. This agreement creates a framework whereby investigators who wish to conduct a multi-center clinical study can request that the IRBs of the participating centers rely on the review of one center's IRB. In order to request ceded review, investigators must complete and submit a Cede Review Form prior to submitting their IRB application. Each participating IRB makes the decision on a protocol-by-protocol basis whether to rely on the review of another IRB (to cede the review) on a study or to conduct its own full review. The institutions include Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Boston Children's Hospital Boston, Dana-Farber Cancer Institute, Harvard Medical School (includes Harvard school of Dental Medicine), Harvard School of Public Health, Harvard University Faculty of Arts and Sciences*, Joslin Diabetes Center and Massachusetts General Hospital. Other institutions included under the Harvard CTSA may be added in the future

** The IRB of the Harvard University Faculty of Arts and Sciences has regulatory authority for Harvard Business School, Harvard Divinity School, the Harvard Graduate School of Design, the Harvard Graduate School of Education, Harvard Kennedy School of Government, Harvard Law School, the Harvard School of Engineering and Applied Sciences, Harvard University Health Service, and the Radcliffe Institute for Advanced Study*

Other Reliance Agreements

In an effort to eliminate duplicative IRB review Boston Children's Hospital will consider the use of other reliance agreements, where BCH agrees to rely on another institution or another institution chooses to rely on Boston Children's Hospital. These requests are decided on a case by case basis and take into the consideration funding arrangement, location of research activities, risks of the protocol, expertise and any other factor pertinent to making such a decision. As necessary the IRB chair and the Institutional Official will be consulted. As necessary the relying or relinquishing IRB will be contacted as necessary for information. Investigators should contact the Committee on Clinical Investigation office 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 institutional official

Extension of Federal Wide Assurance

In some cases, where the investigator and his/her employer have significant connections to Boston Children's Hospital, the CCI may be willing to extend it federal

wide assurance to certain Research conducted at the other institution. This is considered on a case-by-case basis. The CCI administrative office is available to provide guidance on this issue.

Related Content

“Determining Whether a Protocol Requires Boston Children’s Hospital or Dana Farber Review”

Document Attributes

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