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**Boston
Children's
Hospital**

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

Research Team Members Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy summarizes the criteria and requirements for:

1. defining research team members
2. determining when they need to be listed on the Boston Children's Hospital research protocol
3. nonaffiliated research team members

Definitions

Research team members are individuals who:

1. interact with human subjects (e.g. recruitment, informed consent process, manipulating subject's environment for research purposes, conduct invasive or non-invasive research assessments and procedures
2. collect, report or analyze identifiable and deidentified subject data
3. are administrative contacts for the research activities and protocol application

Affiliated Individuals of Boston Children's Hospital: Individuals part of the Boston Children's Hospital workforce. This includes Foundation staff and employees.

Unaffiliated Individuals: Individuals who are not part of the Boston Children's Hospital workforce (this includes both Boston Children's Hospital Foundation staff and employees).

Policy Statements

Boston Children's Hospital is committed to assuring that all individuals who perform research under its jurisdiction are appropriately qualified to perform the roles assigned.

All human subjects research studies conducted at Boston Children's Hospital must designate an individual, qualified by training and experience, to serve as the Principal Investigator (PI). Principal Investigators are responsible for assuring that individuals listed on their research protocols are appropriately qualified, trained, supervised and credentialed, if appropriate, in accordance with Boston Children's Hospital institutional credentialing requirements.

Research teams consist of different roles and the nature of the research activity will determine the extent of the training, expertise, and credentialing required. Those involved with recruiting or obtaining consent from research subjects or conducting research assessments may have more requirements. For example, individuals who have limited roles such as data abstraction, coding or analysis with identifiable information will have fewer requirements.

Boston Children's Hospital also recognizes that collaborative efforts exist among institutions and individuals who are not part of the Boston Children's Hospital workforce/staff may be asked to assist in conducting a research protocol under the jurisdiction of the Boston Children's Hospital Institutional Review Board (IRB). In most of these situations an established Reliance Agreement eliminates the need for duplicate IRB review at multiple institutions; however, it does not eliminate the need for assuring that applicable hospital policies concerning training, credentialing, and oversight are followed in accordance with the role individuals play in the research.

Procedures

Affiliated Individuals of Boston Children's Hospital

Affiliated Individuals must be listed on the Boston Children's Hospital protocol as research team members.

1. If an individual is functioning within their regular work practice (e.g. phlebotomist, x-ray technician, pharmacist, floor nurses) and involvement in the research is limited to only those work responsibilities without further contribution to the research, then such individuals do not need to be listed on the protocol application.

Unaffiliated Research Team Members

Unaffiliated study team members who serve as research team members and are part of a research protocol reviewed and approved by their institution/organization's IRB should not be listed as research staff on the Boston Children's Hospital research protocol (within CHeRP). Their involvement in the research should be covered under a protocol at their own institution.

Increasingly the use of single IRBs (sIRBs) reduces the need for each site to review a protocol that is conducted at multiple institutions.

1. When Boston Children's Hospital IRB serves as the sIRB each institution relying on the Boston Children's Hospital IRB will execute a Reliance Agreement to formally document that they are relying on Boston Children's Hospital IRB for the review and approval of the protocol. As part of this process the Relying Institution will be added to the approved Boston Children's Hospital protocol through a separate action in CHERP ("Add Reliance on Boston Children's Hospital").
 - a. This is designed to capture information on the Relying institution such as the activities conducted and the name of the Relying Institution PI.
 - b. In these situations, the Relying Institution will be responsible for tracking the involvement of their staff/employees/students as part of the research team and Reliance Agreement process.
2. Unaffiliated research team members covered either by their own institution's IRB approval or more commonly through a Reliance Agreement may also need to be supervised and/or credentialed at Boston Children's Hospital to perform research activities at Boston Children's Hospital.
 - a. Principal Investigators are responsible for assuring compliance with institutional supervisory and/or credentialing policies.
 - b. If unaffiliated research team members perform activities that require access to hospital information, security systems and/or hospital facilities submission an Associated Personnel request form may be required through the Boston Children's Hospital Human Resources process.
 - i. Further information about the associated personnel request process may be obtained from Human Resources.
 - ii. It is important to recognize that the Associated Personnel request process provides badge access to Boston Children's Hospital facilities and/or access to Boston Children's Hospital systems and services, but it does not remove or change the requirement to enter into a Reliance Agreement.
 - iii. Unaffiliated research team members who complete the associated personal request process should not be added as research staff on Boston Children's Hospital CHERP research protocol application.
3. In some limited situations, a protocol may involve working with unaffiliated research team members from institutions or organizations that do not conduct human subject research. This may limit the ability to use a traditional Reliance Agreement. These situations should be referred to the IRB Reliance Specialist and will be handled on a case-by-case basis.

Examples

1. A physician from another academic institution is a collaborator on a research protocol at Boston Children's Hospital. He will conduct a specialized clinical test for research purposes and the results will be entered in the medical record of the research subject. In this situation:
 - a. A Reliance Agreement should be established between Boston Children's Hospital and this physician's primary institution.
 - b. The Boston Children's Hospital protocol will be modified through submission of an "Add Reliance on Boston Children's Hospital" which will capture information about

- the Relying institution role in the research and the name of the Relying Institution PI.
- i. The unaffiliated physician should not be listed as Research Team on the Boston Children's Hospital CHERP application.
 - c. In accordance with Boston Children's Hospital medical staff bylaws and credentialing requirements, an appointment to the Boston Children's Hospital Medical Staff, House Staff, or Affiliating House Staff is required because clinical information will be charted in the patient medical record.
 - i. if the physician was performing a research assessment at Boston Children's Hospital that would not be documented in the medical record they may not require credentialing but all other steps would need to be completed.
 - d. The PI may also need to work with their department to determine if an Associated Personnel request should be submitted
2. A Boston Children's Hospital investigator wants to have a visiting medical student from a California University recruit patient for a research study. Families will be approached while they are waiting in the emergency room. The investigator also asks that the medical student obtain informed consent. In order to consider permitting this arrangement, the following steps need to be taken:
- a. A Reliance Agreement with the individual's home institution may be required.
 - b. The Boston Children's Hospital approved protocol will be modified through submission of an "Add Reliance on Boston Children's Hospital" which will capture information about the Relying institution's research role and the name of the Relying institution's PI.
 - c. The PI may also need to work with their department to determine if an Associated Personnel request should be submitted
 - d. The Boston Children's Hospital IRB will determine whether the medical student may obtain informed consent on behalf of the investigator. This decision may depend on the patient population as well as the complexity and risks of the research.
 - e. The unaffiliated medical student should not be listed as Research Team on the Boston Children's Hospital CHERP research protocol.
3. A Boston Children's Hospital investigator is collaborating with an investigator from Brigham Women's Hospital (BWH). All research related procedures and assessments will occur at BWH. Research coordinators from BWH will come to Boston Children's Hospital clinics to recruit Boston Children's Hospital patients for the study. Boston Children's Hospital has agreed to rely on the BWH IRB. In order to allow the BWH coordinators to come on site at Boston Children's Hospital and access records and recruit research subjects, the following steps need to be taken:
- a. A Reliance Agreement is established between BWH and Boston Children's Hospital.
 - b. The Boston Children's Hospital PI will need to apply for "Reliance on Another IRB" through CHERP.
 - c. The Boston Children's Hospital PI may also need to work with their department to

determine if an Associated Personnel request should be submitted to allow for the BWH research coordinators to come on site and access medical records.

Related Content

- IRB Policies
 - Principle Investigator Responsibilities (For more information on the role of the PI)
 - Single IRB Review (For more information on non-Boston Children's Hospital research team members)
 - Who May Serve as Principal Investigator (For more information on PI eligibility)

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures

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