Research Team Members

Purpose

This guidance summarizes the criteria and requirements for

1) defining research team members
2) determining when they need to be listed on the BCH protocol ,
3) nonaffiliated research team members

Policy

Boston Children's Hospital (BCH) is committed to assuring that all individuals who perform research under its jurisdiction are appropriately qualified to perform the roles assigned. 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 BCH 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. Individuals who have limited roles such as data abstraction, coding or analysis with identifiable information will have fewer requirements.

BCH also recognizes that collaborative efforts exist among institutions and individuals who are not part of the BCH workforce/staff may be asked to assist in conducting a research protocol under the jurisdiction of the BCH IRB. In most of these situations an established reliance agreement eliminates the need for duplicate IRB reviews at multiple institutions; however, it does not eliminate the need for assuring that applicable hospital training, credentialing, if appropriate, and oversight policies are followed in accordance with the role they play in the research.

Procedures

Research team members are individuals who:

a) 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),
b) collect, report or analyze identifiable and deidentified subject data
c) are administrative contacts for the research activities and protocol application

BCH Research Team Members:

Individuals who serve the above referenced roles and are part of the BCH workforce (which includes both, BCH and foundation staff and employees) must be listed on the BCH protocol as research team members.

If an individual is functioning within his or her regular work practice (e.g., phlebotomist, xray 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 application.

Unaffiliated Research Team Members

Study team members who are not part of the BCH workforce (which includes both BCH and foundation staff and employees) are referred to as unaffiliated study team members.

Unaffiliated study team members who perform the roles referenced above as part of a research protocol reviewed and approved by their IRB should not be listed as research staff on the BCH CHeRP application. Their involvement in the research is 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. When BCH IRB serves as the sIRB each institution relying on the BCH IRB will execute a reliance agreement to formally document that they are relying on BCH IRB for the review and approval of the protocol. As part of this process the relying institution will be added to the approved BCH protocol through a separate action in CHeRP ("Add Reliance on BCH") designed to capture information on the relying institution such as the activities conducted and the name of the relying institution PI. 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. These unaffiliated research team members should not be listed as research team members on the BCH CHeRP application.

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 analyst and will be handled on a case by case basis.

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, if appropriate, at BCH to perform research activities at BCH. Principal Investigators are responsible for assuring compliance with institutional supervisory and/or credentialing policies

If unaffiliated research team members perform activities that require access to hospital information, security systems and/or hospital facilities submission of an Associated Personnel request form may be required through the BCH Human Resources process. Further information about the associated personnel request process may be obtained from Human Resources. It is important to recognize that the associated personnel request process provides badge access to BCH facilities and/or access to BCH systems and services but it does not remove or change the requirement to enter into a reliance agreement. Unaffiliated research team members who complete the associated personal request process should not be added as research staff on BCH CHeRP application.

Examples

1. A physician from another academic institution is a collaborator on a research protocol. 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 BCH and this physician's primary institution.
    b. The BCH approved protocol will be modified through submission of an "Add Reliance on BCH" which will capture information about the relying institution role in the research and the name of the relying institution PI. Keep in mind the unaffiliated physician should not be listed as Research Team on the BCH CHeRP application.
    c. In accordance with BCH medical staff bylaws and credentialing requirements an appointment to the BCH Medical Staff, House Staff or Affiliating House Staff is required because clinical information will be charted in the patient medical record*.
    d. The PI may also need to work with their department to determine if an Associated Personnel request should be submitted

    *Note if this physician were performing a research assessment at BCH that would not be documented in the medical record they may not require credentialing but all other steps would need to be completed.

2. A BCH investigator wants to have a visiting medical student from a California University recruit patients 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 BCH approved protocol will be modified through submission of an "Add Reliance on BCH" which will capture information about the relying institution role in the research and the name of the relying institution PI. Keep in mind the unaffiliated medical student should not be listed as Research Team on the BCH CHeRP application.
    c. The PI may also need to work with their department to determine if an Associated Personnel request should be submitted
    d. The BCH 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.

3. A BCH 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 BCH clinics to recruit BCH patients for the study. BCH has agreed to rely on the BWH IRB. In order to allow the coordinators to come on site at BCH, access records and recruit research subjects, the following steps need to be taken:

    a. A reliance agreement is established between BWH and BCH.
    b. The BCH PI will need to complete and submit an application for Reliance on Another IRB through CHeRP.
    c. The BCH 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

Reliance Agreements

Who May Serve as Principal Investigator?

Single IRB Review

Document Attributes

Title	**Research Team Members**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/05/2010 2/16/2016 1/06/2020
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