



## Who May Participate on the Clinical Research Team

### Policy

Boston Children's Hospital (BCH) is committed to assuring that all individuals who perform research are appropriately qualified to perform the roles assigned.

BCH also recognizes that collaborative efforts exist among institutions and from time to time individuals who are not part of the Boston Children's Hospital workforce may be asked to participate in a research protocol under the jurisdiction of the Boston Children's Hospital IRB. A reliance agreement may eliminate the need for duplicate reviews at multiple institutions but it does not eliminate the need for credentialing for individuals who intervene or interact with research subjects. In all instances there must be appropriate credentialing and oversight for all members of the research team as a method of minimizing risks to research subjects. The following document summarizes the procedures and process that must take place before any individual who is unaffiliated with the Boston Children's Hospital workforce could be allowed to participate in research conducted under the auspices of Boston Children's Hospital.

While these are general guidelines to be followed, each situation will be individually reviewed by the IRB office and with the Office of General Counsel and Boston Children's Hospital Compliance Office as deemed necessary.

Research teams consist of different roles and the nature of the research activity will determine the extent of the required credentialing process. Those involved with recruiting or consenting research subjects, or conducting research assessments will have more requirements. Individuals who have limited roles such as data abstraction, coding or analysis, with identified information will have fewer requirements. It is important to note that individuals who do not interact with subjects and do not access private identifiable data (such as those who perform data analysis with de-identified data or serve as general consultants) are not considered engaged in human subject research and these guidelines do not apply.

### **I. Credentialing of individuals who participate in human subjects research**

**A. Boston Children's Hospital Workforce Members who may serve as Principal Investigators (PI): Please see the policy "Who May Serve as Principal Investigator" which sets forth the responsibilities of the PI and the requirements for serving as a PI at Boston Children's Hospital.**

**B. Boston Children's Hospital Workforce Members who may serve as Research Team Member**

Research Team Members perform the research under the direction and supervision of the Principal Investigator

- All those who may serve as PI may also serve as Research Team Members.
- Nurses who do not meet the criteria to serve as PI and who are credentialed through the BCH nursing department (this may include visiting nurses, faculty and students from institutions who are here under formal agreements).
- Research coordinators employed by BCH or the associated Foundations.
- BCH employees from other departments or Foundations at Children's (social work, pharmacy, physical therapy).
- Medical students, residents and fellows while rotating or training at BCH. It is also recognized that some institutions have joint training programs that permit activities at multiple locations; these joint trainees may serve on the Research Team.
- BCH volunteers who have been registered through the Boston Children's Hospital volunteer office, who have received the appropriate training and are approved by the PI.
- BCH Associated Personnel (AP) who have been granted a badge and ID number, who have received appropriate training about BCH policies and procedures, and who have been approved for work on the protocol by the PI.

### C. Unaffiliated Individuals who may serve as Research Team Members

Individuals who are not affiliated with Boston Children's Hospital as set forth in the above categories may participate as a Research Team Member. Such individuals must become appropriately credentialed in order to participate in the research. Situations that require access to hospital information, security systems and BCH facilities and other situations determined by the IRB will require that the individual become an Associated Personnel. Each situation will be evaluated individually but in general the steps required could include:

- 1) Providing evidence of competency to perform the assigned role by having appropriate credentials and training.
- 2) Having appropriate knowledge of human research protection regulations as they relate to the roles they will perform, and having provided documentation of human research protections training per IRB policy.
- 3) Documenting a commitment to adhere to the research protocol as approved by the IRB.
- 4) Having an adequate understanding of the specific details of the protocol to perform their tasks.
- 5) Cooperating in any oversight activities, investigations or inquiries regarding the research and the role they have served.

It is acknowledged that some unaffiliated individuals who work in these categories will be physicians.

**The Hospital has established the policy that any physician who intervenes or interacts with research subjects must be appropriately credentialed and appointed through the medical staff registrar. This applies to performing medical assessments and interventions, conducting interviews, questionnaires or obtaining informed consent. This appointment process must be through the medical staff registrar office.**

The following guidelines are meant to enable multi-institutional research activities while still adhering to required institutional oversight and credentialing priorities. The guidelines will be applicable to many situations, however, it is important to note that each case will need to be reviewed on an individual basis and the Institutional Review Board has the ability to limit certain activities to Boston Children's Hospital workforce members as part of its regulatory responsibility to assure that risk to research subjects is minimized.

## **II. Credential and Review Process for Unaffiliated Research Team Members**

### **A. Unaffiliated Physicians**

- Intervene or Interact with Research Subjects  
All physicians who will intervene or interact with Boston Children's Hospital research subjects must receive an appointment through the medical staff privilege process. This requires contact with the appropriate Boston Children's Hospital Department Chair or Division Chief and the medical staff registrar.
- Activities limited to access of identified subject information  
For activities that do not include direct interaction with research subjects but include access to hospital information, security systems, facilities and other situations deemed necessary by the IRB, physicians need to become Associated Personnel only.

### **B. Unaffiliated Nurses and other Patient care Services (Social Work, Nutrition, Pharmacy, etc.)**

- Intervene or Interact with Research Subjects  
All nurses or other members of patient care services who will intervene or interact with Boston Children's Hospital research subjects must be credentialed through the Boston Children's Hospital Nursing Staff Development office and complete and sign the Commitment statement. Marcie Brostoff should be contacted.
- Activities limited to access of identified subject information  
For activities that include access to hospital information, security systems, facilities and other situations deemed necessary by the IRB, nurses and members of health care services need to become Associated Personnel only.

### **C. Unaffiliated other research team members**

Principal Investigators are fully responsible for determining that individuals listed on their protocol meet the appropriate qualifications in order to serve the roles they are assigned. In addition there is an institutional procedure that needs to be followed in order to permit this participation.

- Intervene or Interact with Human Research Subjects
  - a. The PI must specify the role the individual will play and describe their training and credentials.
  - b. The unaffiliated individual must sign unaffiliated investigator agreements (unless there is a reliance agreement with the individual's home institution).
  - c. If access to Boston Children's Hospital security and information systems is required these individuals must become Associated Personnel with Boston Children's Hospital.

- Activities limited to access of identified subject information  
For activities that include access to hospital information, security systems, facilities and other situations deemed necessary by the IRB, other research team members need to become associated personnel only.

Some examples to illustrate these policies:

1. A physician is visiting for a 3 month period and wants to conduct interviews with research subjects. Under this policy this activity would not be permitted unless the physician receives appropriate appointments and credentialing through the medical staff registrar. Physicians and practicing psychologists cannot intervene or interact with any research subject without such appointments.
2. A Boston Children's Hospital investigator wants to have a medical student from a California University recruit patients for a research study. Families will be approached while the families 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. The BCH principal investigator will need to complete a form specifying the role of the medical student in the research and describing his/her credentials and training in order to assume this role.
  - b. The medical student must sign an Individual Investigator Agreement (unless there is a reliance agreement with the individual's home institution).
  - c. If access to Boston Children's Hospital information systems is required the medical student must become Associated Personnel.
  - d. The Boston Children's Hospital IRB will determine whether the medical student may obtain informed consent of behalf of the investigator. This decision may depend on the patient population as well as the complexity and risks of the research.
3. A Boston Children's Hospital investigator is collaborating with an investigator from another Harvard affiliated Hospital (Hospital H). All research related procedures and assessments will occur at Hospital H. It is requested that research coordinators from Hospital H come to Boston Children's Hospital clinics and recruit Boston Children's Hospital patients for the study. The Boston Children's Hospital IRB has agreed to rely on the IRB review of Hospital H, however, in order to allow the coordinators to come on site at BCH and recruit research subjects, the following steps need to be taken.
  - a. The Boston Children's Hospital principal investigator will need to complete a form for each non Boston Children's Hospital research coordinator specifying his/her role and describing his/her credentials and training in order to assume this role.
  - b. Since access to Boston Children's Hospital information systems is required the coordinators must become Associated Personnel.
  - c. Because this work is covered under a reliance agreement the coordinators do not need to sign an Individual Investigator Agreement.
  - d. The Boston Children's Hospital IRB will determine whether these individual may obtain informed consent on behalf of the investigator. This may depend on the patient population as well as the complexity and risks of the research.

## Document Attributes

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