



Clinical Research Credential

Policy

Children's Hospital is committed to assuring that all individuals who perform research are appropriately qualified to perform the roles assigned. It is also recognized that collaborative efforts exist among institutions and from time to time, individuals who are not part of the Children's Hospital workforce may be asked to participate in a research protocol under the jurisdiction of the 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 Children's Hospital workforce could be allowed to participate in research conducted under the auspices of 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 Children's Hospital Compliance Officer as deemed necessary.

Research teams consist of different roles and the nature of the research activity will determine the extent of the credentialing process which is required. Those involved with recruiting or consenting research subjects, 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 as Principal Investigators or as part of the research team:

A. Children's Hospital Workforce Members

The following categories are considered to have appropriate appointments and employment status as part of Children's Hospital in order to participate as Principal investigators or research staff on IRB approved research protocols

- Credentialed physicians including foundation physicians or psychologists at CHB (requires appointment as an active medical staff member with appropriate privileges through the medical staff registrar)
- PhDs with appropriate research appointments through the medical staff registrar at CHB
- Nurses credentialed through the CHB nursing department (this includes visiting nurse, faculty and students from institutions who are here under formal agreements).

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- Research coordinators employed by CH or the associated foundations
- CHB Employees from other departments or foundations at Children's (social work, pharmacy, physical therapy)
- Medical students, residents and fellows while rotating or training at CHB are considered part of the workforce. It is also recognized that some institutions have joint training programs that permit activities at multiple locations
- CHB volunteers who have been registered through the Children's Hospital volunteer office.
- CHB Associated Personnel who have been granted a badge and ID number, who have received appropriate training about CHB policies and procedures, and who have been approved for work on the protocol by the PI.

Principal Investigators are responsible for listing all research team members on the research protocol application. The department/division chair's signature on a protocol specifies that all research team members have the appropriate credentials and appointments for the roles assumed in the research protocol.

B. Non Work Force Members

Any non Children's Hospital research team member who is engaged in human subject research under the auspices of the Children's Hospital IRB needs to become appropriately credentialed in order to participate in the research. Situations that require access to hospital information, security systems and CH facilities will require becoming part of the CHB workforce through the Associated Personnel Process. The IRB may also require non work force members to become associated personnel in other situations it deems appropriate. 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.
- 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 non Children's 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.

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When access to hospital information security systems, facilities and other situations deemed necessary by the IRB is required, non-physicians will need to complete an application to become Associated Personnel of Children's Hospital. This process is initiated by the Administrator of the Principal Investigator's Departments or Divisions. In addition the **Unaffiliated Research Team Member** will need to document competence through appropriate credentialing at CHB as described more fully below.

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 Committee on Clinical Investigation has the ability to limit certain activities to 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 Children's Hospital research subjects must receive an appointment through the medical staff privilege process. This requires contact with the appropriate 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 Children's Hospital research subjects must be credentialed through the 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.

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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 complete a form which specifies the role the individuals will play and describe their training and credentials
 - b. The unaffiliated individuals must sign unaffiliated individual agreements (unless there is a reliance agreement with the individual's home institution)
 - c. If access to Children's Hospital security and information systems is required these individuals must become associated personnel with Children's Hospital

- Activities limited to access of identified subject information

For activities that include access to hospital information, security 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 can not intervene or interact with any research subject without such appointments.
2. A 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 CH principal investigator will need to complete a form specifying the role of the medical student in the research and describing his credentials and training in order to assume this role.
 - b. The medical student must sign an unaffiliated individual agreement (unless there is a reliance agreement with the individual's home institution)
 - c. If access to Children's Hospital information systems is required the medical student must become associated personnel

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- d. The 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 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 Children's Hospital clinics and recruit Children's Hospital patients for the study. The 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 CH and recruit research subjects, the following steps need to be taken.
 - a. The Children's Hospital principal investigator will need to complete a form for each non 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 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 unaffiliated individual agreement.
 - d. The 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.

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