



Who May Serve as a Principal Investigator

Purpose

The purpose of this policy is to define which individuals are qualified to serve as a Principal Investigator (PI) for nonexempt human subjects research conducted at Boston Children's Hospital. The policy seeks to implement a mechanism of accountability and continuity for human subject protections and is not intended to restrict academic productivity or leadership. Individuals who do not meet the criteria to be a PI may still participate as a Co-Investigator.

Policy

All human subjects research studies conducted at Boston Children's Hospital (BCH) must designate an individual, qualified by training and experience, to serve as the Principal Investigator (PI). The PI must have sufficient authority, relevant scientific knowledge, and the requisite training to personally carry out or supervise all aspects of the project. This individual is responsible for all aspects of the protocol, as approved by the IRB.

Scope

This policy applies to investigators who are eligible to conduct non-exempt human subject research at Boston Children's Hospital. In addition to research reviewed by the BCH IRB, this policy applies to research where BCH enters into an IRB Reliance Agreement to have an external IRB serve as the Reviewing IRB.

The policy "Who May Participate on the Clinical Research Team" addresses who is eligible to conduct the research at BCH under the direction of the Principal Investigator.

Definition

Principal Investigator (PI): is the individual responsible for ensuring that the research is conducted in accordance with the human subject federal and state laws and regulations as well as institutional policies and procedures. The PI is responsible for ensuring that all requirements established by the study sponsor or the funding agency for the proper programmatic, scientific, and technical conduct of the project are met, and the research is conducted in compliance with the terms and conditions of the award and relevant BCH and sponsor policies. The PI is responsible for supervising and directing all members of the clinical research team.

Criteria

Individuals qualified to serve as PI

To serve as a PI an individual must be qualified under one of the following eligibility requirements:

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- a. Physicians, Dentists, and Psychologists that are credentialed through the hospital with the BCH medical staff registrar as an active medical staff member and have an appointment of Instructor or higher at Harvard Medical School *
- b. PhDs with appropriate research appointments through the medical staff registrar at BCH

* It is acknowledged that there may be BCH staff physicians with only clinical responsibilities and no Harvard appointment. The decision as to whether they can be a PI will be made on a case by case basis by the Department Chair/Division Chief.

- c. Other patient service professionals (Registered nurses and clinicians with doctoral preparation, masters -prepared clinicians nurse, pharmacist, audiologist, respiratory therapist and other employees of the hospital or foundations) must meet all the following criteria for consideration to be a PI:
 - o research is part of their scope of employment responsibility and not to meet a training or degree requirement
 - o they have training and experience and confirmed clinical research competencies
 - o they receive approval from the Vice President of Patient Services or designee.

Individuals not qualified to serve as PI

Individuals who are trainees, including Fellows, Residents, Masters or Doctoral Candidates, Postdoctoral Researchers or any other patient services professionals may not serve as the PI. Trainees may not serve as the PI for research conducted as part of their thesis or dissertation to support an academic degree. The restriction of trainees applies equally to physicians, dentists, PhDs and other patient services professionals. Trainees may serve as a Co-Investigator under the supervision of an individual qualified to serve as a PI. It is recognized this is an additional responsibility for faculty and others who mentor residents, interns, fellows and post docs; and other patient services professionals however, appropriate oversight is required to assure human subject protections while enhancing the educational process and supervision of those learning to conduct clinical research.

Implementation- Roles and Responsibilities

1. Prior to submission of the protocol in the Children's Hospital Electronic Research Portal (CHERP) system, the individual designated as PI must ensure that they meet the requirements of this policy.
2. The applicable Department Chair, Division Chief or other Director must certify that the individual designated as PI in the CHERP application is qualified by virtue of training and experience to serve in that role for the proposed research study. The Department Chair, Division Chief or other Director's approval is required before the completed application is submitted to the IRB.
3. If the PI changes during an on-going IRB approved research study, the applicable department chair, division chief or other director must certify that the individual designated as PI in the CHERP application meets the criteria and is qualified by virtue of training and experience to serve in that role for the research study.
4. The IRB may make recommendations to the Department Chairs/ Chiefs, Director or other institutional officials to restrict or limit the ability of an individual to serve as a PI on a research protocol.

Document Attributes

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