

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-003-001-who-may-serve-principal-investigator.docx

Who May Serve as a Principal Investigator?

Purpose

This policy defines which individuals are qualified to serve as a Principal Investigator (PI) for non-exempt human subjects research conducted at Boston Children's Hospital. Furthermore, it seeks to implement a mechanism of accountability and continuity for human subject protections.

It 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

Principal Investigator (PI): A PI is defined as 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.

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.

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 IRB 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.

Procedure

Criteria

Individuals qualified to serve as PI

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

1. Physicians, Podiatrists, Dentists, Psychologists, and Optometrists or Advanced Practice Registered Nurses (APRN), Certified Registered Nurse Anesthetist (CRNA), Physician Assistant (PA), or Pharmacist engaged in Collaborative Drug Therapy Management (CDTM) that have been credentialed and appointed to the Boston Children's Hospital Active Medical Staff or Associate Clinical Staff by the Board of Trustees and have an appointment of Instructor or higher at Harvard Medical School

It is acknowledged that there may be BCH Medical Staff or Associate Clinical Staff 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/Division Chief.

2. Individuals who possess a degree of Doctor of Medicine, Philosophy or Science, or comparable academic or scientific attainment whose activities are limited to science and research, but whose activities do not involve direct patient care, and are appointed to the Scientific Staff by the relevant Department Chief subject to appropriate verification of their credentials through the BCH Human Resources process.
3. Other patient service professionals (e.g. 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:
 - a. Research is part of their scope of employment responsibility and not to meet a training or degree requirement
 - b. They have training and experience and confirmed clinical research competencies
 - c. 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 a 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/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/Division Chief or other Director's approval is required before the completed application is submitted to the IRB. This approval is designated in CHERP as part of a protocol submission process.

3. If the PI changes during an on-going IRB approved research study, the applicable Department/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/Division Chiefs, Directors or other institutional officials to restrict or limit the ability of an individual to serve as a PI on a research protocol.

5. Related Content

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IRB Policy

Required Credentialing of Individuals Who Conduct Human Subjects Research

Document Attributes

Title	Who May Serve as a Principal Investigator		
Author	Susan Kornetsky	Dates	6/29/2015
Reviewed/ Revised by	Susan Kornetsky	Reviewed/ Revised	2/18/2016 2/11/2020
Copyright	©Boston Children’s Hospital, 2020	Last Modified	4/29/2022
Approved	<hr/> Susan Kornetsky, MPH Director of Clinical Research Compliance <hr/> August Cervini, MBA Vice President for Research Administration		