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I. PURPOSE

The purpose of this SOP is to define which individuals are qualified to serve as a Principal Investigator (PI) for non-exempt, human subjects research conducted by investigators at the Children's Hospital of Philadelphia.

II. POLICY STATEMENT

Human subjects research studies conducted at the Children's Hospital of Philadelphia must have 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.

III. SCOPE

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

IV. DEFINITIONS

CHOP: Children's Hospital of Philadelphia.

eIRB: The electronic IRB management system.

Principal Investigator (PI): The individual at each institution responsible for the overall conduct of a specified research study or clinical investigation.


V. PROCEDURES

A. Principal Investigator Eligibility Requirements

The PI is responsible for all aspects of IRB-approved research including the responsibility for the oversight of all staff to whom tasks are delegated and for the fiscal management of the research.

To serve as a PI an individual must be qualified under the eligibility requirements enumerated below.

1. The Principal Investigator of a human subjects research study meet all of the following:
 - (a) Employed at CHOP or have an appointment as a member of the CHOP medical staff;
 - (b) Have an appointment or position that meets one or more of the following:
 - (1) Professor, Associate Professor or Assistant Professor at the

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University of Pennsylvania;


- (2) MD with appointment as an Instructor appointment at the University of Pennsylvania or at CHOP;
 - (3) MD or PhD in a scientific field at the CHOP Research Institute in a clinically-related field;
 - (4) PharmD or Masters-prepared or PhD clinician (nurse, pharmacist, audiologist, respiratory therapist, nutritionist, psychologist, etc.) with training or experience in the conduct of human subjects research.
2. Deemed qualified by virtue of training and experience by the PI's department chair, division director or director of their reporting unit to provide oversight for the proposed research and for the required clinical procedures.
 - (a) This requirement should not be construed to mean that the individual is qualified to perform all research procedures. The PI may designate another individual, who is qualified and credentialed, to perform certain procedures.
 3. Individual not qualified under the eligibility requirements 1B and 2 (above) but not ineligible (as outlined in B below) may be deemed qualified by the IRB for a one-time PI status. The single project would have to involve no more than minimal risk human subjects research and the unique qualification of the individual (e.g. IS, Facilities) would have to be demonstrated in the 'PI Eligibility Determination Request' and supported by the individual's department chair, division director or director of their reporting unit.

B. Individuals not qualified to serve as PI

Unless previously qualified, individuals who are trainees, including Fellows, Residents, Masters or Doctoral Candidates, or Postdoctoral Researchers 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. Trainees may serve as a co-investigator under the supervision of an individual qualified to serve as a PI but may not serve as a Principal Investigator.

C. Implementation - Roles and Responsibilities

1. Prior to submission of the protocol in the eIRB 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 eIRB 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.

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3. If the PI changes during an on-going IRB approved research study, the applicable department chair, division chief or other director must certify (e.g. on a PI assurance form or via submission in the electronic system) that the individual designated as PI in the eIRB application, is qualified by virtue of training and experience to serve in that role for the research study.
4. If the IRB member(s) responsible for the review of the protocol is unfamiliar with the PI's qualifications, they will review the PI's CV to ensure that the individual meets the requirements of this policy.


D. Withdrawal of PI Privileges

An individual's status of Principal Investigator may be withdrawn when there is just cause which could include research fraud or misconduct, serious or continuing non-compliance or failure to protect the rights and welfare of research subjects.

1. The IRB may consult with the AVP Research Compliance and Regulatory Affairs, the CHOP Chief Scientific Officer, the AVP & Chief Clinical Research Officer and the individual's supervisor (e.g. Department Chair) before withdrawal of privileges.
2. The decision to withdraw an individual's PI privileges may be appealed to the Chief Scientific Officer.

VI. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.64 and 21 CFR 312.66	21 CFR 812.150
FDA. Guidance for IRBs, Clinical Investigators, and Sponsors. IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed	ICH Harmonised Tripartite Guideline (E6) Guideline For Good Clinical Practice. Section 4.1: Investigator Qualifications and Agreements (this document serves as a guideline for FDA-regulated research)

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VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 106: Research That Must be Reviewed by the IRB	SOP 801: Investigator Responsibilities
SOP 407: Determining When a Proposal Meets the Definition of Human Subjects Research	

VIII. RESPONSIBILITIES

Title	Responsibility
Investigators and Staff	Responsible for ensuring compliance with this SOP.
IRB Members	The primary reviewer is responsible for ensuring that the PI meets the qualifications outlined in this SOP.

IX. ATTACHMENTS

PI Eligibility Determination Request Form

X. REVISIONS:

- 09-08-2014 Initial Approval Date
- 09-25-2018 Revised to update definitions and expand Principal Investigator categories to include psychologists.
- 01-28-2019 Revised to allow for single study exceptions.

XI. APPROVAL

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date