

Effective Date: 3/15/20	Original Issue Date: 7/1/11	Revision No.: 02	SOP No.: 210	Page 1 of 2
Who May Serve as a Principal Investigator				

## 1.0 Purpose:

- 1.1 To define who may serve as a Principal Investigator (PI) for research studies conducted within Hartford HealthCare (HHC).

## 2.0 Definitions:

- 2.1 **Principal Investigator** - The PI is the person who is ultimately responsible for the conduct of research and ensures it is conducted in compliance with all applicable laws, regulations and hospital policies. The PI may delegate research tasks. However, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate tasks.
- 2.2 **Co-Investigator (Co-I)** – An individual responsible for assisting the Principal Investigator with the conception, implementation and conduct of the study.

## 3.0 Procedure:

- 3.1 The PI of a research study is someone who:
  - 3.1.1 Is an employee of HHC or a member of the Medical Staff Office
  - 3.1.2 Is in good standing with the HRPP
- 3.2 Medical residents may NOT serve as a PI. They may serve as the Co-I provided that the protocol design and conduct is appropriate for the trainee's level of knowledge, training and skill and that they perform the research under the oversight of a designated employee or Medical Staff member who serves as PI and supervises the conduct of the research.
  - 3.2.1 Because residents are in training and have schedules that require rotational work at several institutions (i.e. other cover entities), they must ensure proper storage, protections, and retention of HHC data. Subject/patient private, identifiable health information must not leave the premises. Electronic data must be stored on secured network drives.
  - 3.2.2 Because residents are in training, their tenure at HHC is finite. The PI is responsible for closing all studies by submitting the appropriate paperwork to the IRB or making arrangements for a transfer of Co-I for studies that are continuing after their graduation.
  - 3.2.3 Resident Co-Is must assist the PI with making arrangements for long-term storage of original research records (including IRB approval letters, data collection sheets, informed consent forms) at HHC.
- 3.3 Clinical Fellows may serve as the PI provided that the protocol design and conduct is appropriate for the trainee's level of knowledge, training and skill and that they perform the research under the oversight of a designated employee or Medical Staff member who serves as Co-I and supervises the conduct of the research.

Effective Date: 3/15/20	Original Issue Date: 7/1/11	Revision No.: 02	SOP No.: 210	Page 2 of 2
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3.4 Students wishing to conduct research at HHC must identify an employee or Medical Staff member at HHC who is willing to mentor him/her, and serve as the PI for the project.

3.4.1 Before submitting an application to the IRB for a research project, the student (if not a HHC employee) must register with Volunteer Services. Once he/she is registered as a HHC Volunteer, a research application can be submitted. Again, the student will be identified as the Co-I, and the mentor will be identified as the PI.

3.4.2 The IRB will not grant final approval for the study until verification has been received from the Volunteer Services Department that the individual has fully met the requirements and has received an ID badge.

**4.0 Documentation:**

4.1 N/A

**5.0 References:**

5.1 N/A

**6.0 Revision History:**

Rev #	Initials	Effective Date	Description of Change(s)
00	CLG	7/1/11	New Issue
01	CLB	3/1/15	Residents and fellows may no longer serve as PI
02	CLB	3/15/20	General review. Clarification that Fellows may serve as PI.