Principal Investigator (PI) Qualifications for Conducting Research at UnityPoint Health – Meriter

Definitions

1. **Principal Investigator (PI)** - The single person ultimately responsible for all aspects of a human subjects research protocol.

2. **Site Investigator** – In multi-site research, the site investigator is the single person responsible for all aspects of the human subjects protocol at a specific site.

Who may serve as a PI or Site Investigator at Meriter?

1. **Physician Principal Investigators/Site Investigators**
   The physician PI/Site Investigator must be a member of the UnityPoint Health – Meriter Medical Staff.

2. **Non-Physician Principal Investigators/Site Investigators**
   Examples of PIs that fall in this category are:
   - Advanced-practice providers (e.g. Physician assistants and nurse practitioners) who are on the UPH-Meriter Medical Staff.
   - Nurses with a terminal degree (DNP or PhD)
   - Pharmacists
   - Physical, occupational, and speech therapists
   - Social workers
   - Post-Secondary Educators whose role is to mentor students’ research performance.
   - Other professions

   **Must meet the following requirements.**
   a. Hold a terminal degree including completion of all education and training requirements for their degree and position.
   b. Live and work locally to support executing the research and providing oversight.

Supplemental Information

1. **Principal Investigators and/or Site PIs who do not live/practice in the local community.**
   PIs or Site PIs who no longer practice in the Madison community because they have moved may remain as the PI for one year to complete the research or transition the research to a local PI subject to IRB approval.
2. Exceptions
   a. There are cases when an otherwise qualified individual may be prohibited from serving as PI due to a conflict of interest.

   b. Notwithstanding the above criteria, a reviewing IRB may determine that an individual does not qualify to serve as PI on a study involving human participants.
      i. Examples of this may include when the IRB determines that subject protections may be compromised due to existing circumstances, such as the individual’s lack of training, expertise, past performance or physical location in proximity to research participants.

   c. In rare circumstances, individuals who do not meet the above criteria may be granted permission to serve as PI if they can demonstrate professional experience and qualifications commensurate with leading the study under proposal.