

PI Qualifications and Responsibilities (HRPP 1.26)

Description:

This policy describes the qualifications and responsibilities of the Principal Investigator (PI) during the conduct of research within UNMC and at external sites under the PI's protocol.

Qualifications:

- 1) **Must be an employee, faculty member, or student.**
 - a. Volunteer faculty may serve as the PI only with written permission from the appropriate UNMC Dean.
 - b. Individuals other than who are listed may serve as the PI only if a special memorandum of understanding exists.
 - c. If the PI is a student, a faculty advisor must be a secondary investigator (SI).
 - d. A student may NOT serve as the PI on a study involving administration or use of an FDA regulated drug, device, or biologic.
- 2) **The PI must be qualified by education, training, experience, and licensure** (as applicable) to assume overall responsibility.

Responsibilities:

- Will **conduct and monitor the research** from start to finish.
- Will make sure the **research complies** with all HRPP policies & procedures, HIPAA requirements, FDA guidelines, protocol and related documents, IRB of record's policies and procedures, grants/contracts/agreements, etc. (*all as applicable*).
- Is **responsible for all study personnel**, including their involvement, their qualifications, keeping them informed, communicating changes, conflicts of interest, etc.
- Is **responsible for all IRB paperwork**: application, change requests, adverse events, continuing review, study completion report etc.
- Is **responsible for reporting to the IRB** any conflicts of interest, unanticipated problems, adverse events, noncompliance, etc.
- Is **responsible for overall safety and welfare of subjects**.
- Is **responsible for proper monitoring and storage of** all research-related **data**.
- Is **responsible for all study communication** via RSS.