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.