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.

Qualifications:

1) **Must be an employee, faculty member, or student.**
    a. Volunteer faculty can lead a study only if they get written approval from a dean or director
    b. If the PI is a student, a faculty advisor must be a secondary investigator (SI).
    c. A student may NOT serve as the PI on a study involving 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 of the PI:

- Design studies that are ethical and scientifically sound
- Get approval from the IRB before starting the study
- Conducts the research in compliance with the protocol, application, and any other IRB-approved documents
- Conducts the research in accordance with the terms of any grant, contract, and/or agreement
- Supervise the research team and make sure everyone is properly trained and qualified
- Make sure risks to subjects and others are minimized
- Ensure participants are selected fairly and treated with respect
- Ensure participant safety and protect their private information
- Receive proper consent from subjects before enrolling them in the study

- Keep accurate records and report any problems, changes to the research, or unexpected events to the IRB
- Submit necessary progress reports and a final report when the study is over
- Keep records safety for at least 7 years after the study ends
- Make sure everyone on the research team:
    - Understands the study drug/device, including the possible risks and side effects, by reading the Investigator's Brochure (IB)
    - Follows the study plan, FDA rules, and any conditions from the FDA or IRB
    - Properly stores and handles all study drugs, biological products, and devices
- Keep documentation for each study showing:
    - Who is doing what tasks,
    - Proof that each person is qualified and trained, and
    - The dates each person worked on the study

There are additional responsibilities for PI-initiated multisite research (sIRB), multicenter research under the oversight of an external IRB (cIRB), and FDA-regulated research. Please see policy 1.26.