**GUIDANCE 36**

**PRINCIPAL INVESTIGATOR GUIDANCE**

1. **Qualifications of the Principal Investigator (PI)**

Every research protocol will explicitly identify the PI of record. The qualifications of the PI and the investigator’s professional development in relation to the degree of protocol complexity and risk to human subjects are considered in reviewing protocols. IRBs may require less experienced research investigators to be supported by seasoned researchers. Proposals that require skills beyond those held by the PI can be modified by the IRB by requiring additional qualified personnel. Only faculty and staff members may serve as PI. Students, medical research residents, fellows, and post-doctoral fellows are considered co-investigators.

For further guidance on qualification of investigators go to the following links: <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf>. and <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>.

1. **Who may be the Principal Investigator?**

A principal investigator is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research assistants, house staff and students. The Institutional Review Board only recognizes one principal investigator per human subject’s research study, no matter how many research sites may be involved. Other individuals may be named co-investigators. The principal investigator must possess the expertise, time and commitment to conduct and provide the necessary oversight for all aspects of the study, and must be willing to accept full responsibility for the study. In multi-site studies for which Rowan University is the coordinating institution, the principal investigator assumes the responsibility for the conduct of the study at each performance site and by each site-specific principal investigator.

The following classes of individual may serve as principal investigator on human subjects studies conducted at the Institution:

A. Individuals with a paid faculty appointment at the Institution, other than visiting and per-diem faculty, with the approval of the department Chair; unpaid (volunteer) faculty at the Institution with written justification by the Department Chair and Research Dean/Senior Associate Vice Provost for Research, and case-by-case approval by the University Institutional Official.

B. Individuals in permanent, non-faculty staff positions at the Institution, with the approval of the department Chair or Research Dean/Vice President for Research.

C. House staff (interns, residents and clinical fellows), postdoctoral fellows, graduate students and undergraduate students **may not** be principal investigators on human subject studies, but may be named co-investigator under a faculty advisor serving as principal investigator.

D. The faculty advisor, as principal investigator, assumes all of the responsibilities for the conduct of the research and the work of the intern, resident, clinical fellow or postdoctoral fellow. Exceptions for individual house officers or postdoctoral fellows may be requested on a case by case basis by the department Chair to the IRB Director if written procedures are in place to ensure appropriate close- out of the research when the individual leaves the University. However, this cannot be normal practice.