Investigator Responsibilities - overview

Qualifications to serve as a PI are set by UCLA Policy
• UCLA Policy 900

PI Duties and Responsibilities are set by UCLA Policy
• UCLA Policy 991

OHRPP guidance and procedure
• PI Responsibilities
Investigator Responsibilities - highlights

• As PI, have **sufficient training/qualifications** to safely oversee this specific type of research project:
  - Clinical medical expertise to oversee biomedical clinical trial
  - Cultural expertise to oversee research in specific communities (such as in foreign countries, with indigenous communities, etc...)
Investigator Responsibilities - highlights

• Ensure that all staff on the research team are:
  ✓ Qualified to do the tasks they are assigned
  ✓ Have completed all required training (as directed by IRB, other UCLA entities, and as required by the funding agency/Sponsor, if applicable)
  ✓ Are appropriately supervised
     ➢ To successfully conduct the tasks they are qualified to do
     ➢ To not conduct tasks for which they are not qualified
Investigator Responsibilities - highlights

• Design the study to
  ◦ maximize benefits and minimize risks
  ◦ ensure equitable subject selection
  ◦ Obtain legally effective consent or waiver from the IRB
  ◦ Obtain HIPAA authorization or waiver from the IRB (acting as the privacy board for research), if applicable
Investigator Responsibilities - highlights

• Begin research only after IRB and all other institutional/regulatory requirements are met. Other approvals/reviews might include:
  ◦ Research Advisory Panel of the CA Attorney General’s Office (for schedule 1 or 2 drug research)
  ◦ CIRC
  ◦ ISPRC
  ◦ MRSC
  ◦ Etc...
Investigator Responsibilities - highlights

• Conduct the research as described in the IRB-approved application

• Submit **Amendment applications** and receive approval before implementing changes to the protocol
  ➢ Except for deviations from the approved protocol to prevent immediate hazards to participants

• Submit **PAR applications** as required per the **PAR Guidance**

• Submit **continuing review applications** or complete **annual PI assurances** to continue the research
When in doubt about IRB requirements, *ask OHRPP directly*
“Investigator Responsibilities for single site (UCLA) and central/lead site (UCLA + other sites) under a reliance agreement: best practices and how to avoid pitfalls”

Presenter: Moore Rhys, OHRPP

Date/time: September 24, noon-1pm

Register in advance
OHRPP’s “Office Hours”

- OHRPP Quality Improvement Unit staff are hosting **half-hour open Q/A sessions every other week** to answer your questions

- **Upcoming sessions**
  - Tuesday, September 15, 2020 8:30am
  - Tuesday, September 29, 2020 8:30am

Register once and you can join any session.
To be in the know when OHRPP releases updated guidance and offers training opportunities, please subscribe to Human Research News

➢ To subscribe, visit [ORA news subscription](#)
Any Questions?

Contact Information

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