

Research Personnel Qualifications and Responsibilities (HRPP 1.27)

Description:

This policy describes the qualifications and responsibilities of personnel conducting research within UNMC and at external sites under the jurisdiction of the UNMC IRB. Specific responsibilities of the Principal Investigator (PI) are described in [HRPP Policy 1.26](#).

Principal Investigator (PI):

- Must only be ONE
- See [HRPP Policy 1.26](#) (PI Qualifications and Responsibilities)

Secondary Investigator (SI):

- May be one or more, but is not required
- Shared responsibility with PI for safe, compliant research conduct
- **May contribute to:**
 - Research plan development
 - Informed consent/assent
 - Research intervention/tests
 - Data/biospecimen analysis
 - Data presentation/publication
- Not required to be affiliated with UNMC/NM, **but** if they have access to subjects or identifiable data, they must sign an agreement

Faculty Advisor (FA):

- Shares responsibility with student PI
- Assumes PI role if student departs
- **Responsibilities include:**
 - Research plan development
 - IRB and ancillary application support
 - Communication with IRB/ORI
 - Informed consent/assent
 - Research intervention/tests
 - Data/biospecimen analysis

- Data presentation/publication
- Must meet PI qualifications described in [HRPP Policy 1.26](#)

Participating Personnel (PP):

- May be one or more, but is not required
- **May assist with:**
 - Informed consent/assent (if authorized)
 - Research interventions/tests during clinical care
- Not required to be affiliated with UNMC/NM, **but** if they have access to subjects or identifiable data, they must sign an agreement

Research Point of Contact (POC) (formerly Lead Coordinator):

NOTE: the position of Lead Coordinator is being phased out and replaced with Point of Contact. Some applications may not have been changed yet.

- **May be only ONE** but it is not required
 - PI serves as POC if no POC is named
- **Primary contact** for IRB/ORR communications along with PI
- May also serve as SI, PP, coordinator, or data personnel, or hold no other role

Lead Coordinator:

NOTE: the position of Lead Coordinator is being phased out and replaced with Point of Contact. Some applications may not have been changed yet.

- **May be only ONE** but it is not required
- Works closely with the PI to submit the IRB application and all other pertinent documents
- **The main contact** for study communications via RSS
 - If there is no lead coordinator designated, the PI serves as the main point of contact
- Same responsibilities as a coordinator

Coordinator:

- May be one or more, but is not required
- **May assist with:**
 - Informed consent/assent (if authorized)
 - Research interventions/tests
 - Data/biospecimen analysis

Data/Administrative Personnel:

- May be one or more, but is not required
- May manage research data
- May assist with IRB applications, reports, and sponsor communications under PI direction
- No direct subject contact, but may access identifiable data or PHI