

1.27 Research Personnel Qualifications and Responsibilities

1.0 Purpose

The purpose of this policy and procedure is to describe the qualifications and responsibilities of personnel conducting research within the Organization and at external sites under the jurisdiction of the UNMC IRB.

2.0 Policy

It is the policy of the Organization that personnel involved in the conduct of research must possess the required experience, skill, education and (as appropriate) licensure to safely conduct the research in full compliance with all applicable regulatory and Organizational requirements specified in [HRPP policy 1.1](#) (Human Research Protection Program).

3.0 General Requirements

- **3.1.** Research personnel who are Responsible Personnel per [HRPP policy 1.25](#) (Financial Conflicts of Interest) must comply with the Organizational Conflict of Interest Policy as described in that policy.
 - **3.2.** Research personnel who (a) participate in the process of consent, (b) have contact with subjects, or (c) have access to identifiable private information or identifiable biospecimens, and Faculty Advisors of student investigators, are required to comply with HSP subject protection training as described in [HRPP policy 1.23](#) (HRPP Training Requirements and Opportunities for Research Personnel)
 - **3.3.** For FDA regulated research, research personnel must comply with applicable FDA requirements, including completion and submission of FDA Form 1572 to the sponsor if applicable.
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4.0 Definitions of Research Personnel and Specific Requirements

- **4.1.** Principal Investigator (PI):
 - **4.1.1.** The PI assumes overall responsibility for the conduct of the research. Specific responsibilities are described in [HRPP policy 1.26](#) (PI Qualifications & Responsibilities).
 - **4.1.2.** Only one PI can be named on the IRB application. Co-PIs (for example, on NIH grants) must be listed as Secondary Investigators.
 - **4.1.3.** The PI must be an employee, faculty, or student associated with the Organization.
 - **4.1.4.** The PI must be qualified by education, training, experience and licensure (as applicable) to assume overall responsibility for the safe and proper conduct of the research in full compliance with all applicable regulations and UNMC HRPP policies.
 - **4.1.5.** If the PI is a student, resident, or house officer, a faculty advisor or program director must be identified on the IRB application. The faculty advisor/program director assumes responsibility for overall supervision of the student's research and must sign off on the IRB application before submission to the IRB.
- **4.2.** Secondary Investigator(s) (SI):
 - **4.2.1.** Secondary Investigator(s) responsibilities may include (but are not limited to):
 - **4.2.1.1.** Development of the research plan (in conjunction with the PI and other investigators)
 - **4.2.1.2.** Obtainment of legally effective informed consent/assent from prospective subjects.
 - **4.2.1.3.** Performance of research interventions or tests, or analysis of data or biospecimens
 - **4.2.1.4.** Presentation or publication of the data (in conjunction with the PI and other investigators).
 - **4.2.2.** The SI shares responsibility with the PI for assure safe conduct of the research in full compliance with the protocol, HRPP policies, IRB requirements, HHS or other Federal regulations, applicable FDA regulations and state law.
 - **4.2.3.** More than one SI may be named on the IRB application.
 - **4.2.4.** The SI is not required to be associated with the Organization; however an unaffiliated investigator must sign an external investigator agreement unless he/she does not have access to subjects or identifiable private information or identifiable biospecimens

- **4.2.5.** The SI must be qualified by education, training, experience and licensure (as applicable) to perform the specific responsibilities described above.
- **4.3. Participating Personnel:**
 - **4.3.1.** Participating Personnel are not involved in the development and submission of the Application to the IRB.
 - **4.3.2.** Participating Personnel responsibilities may include (but are not limited to):
 - **4.3.2.1.** Obtainment of legally effective informed consent/assent from prospective subjects, if authorized by the PI in accordance with [HRPP policy 5.1](#) (Obtaining Informed Consent from Research Subjects).
 - **4.3.2.2.** Performance of research interventions or tests in the course of providing clinical care or routine services to the patient/subject, or analysis of data or biospecimens
 - **4.3.2.3.** Presentation or publication of the data (in conjunction with the PI and other investigators).
 - **4.3.3.** More than one PP may be named on the IRB application.
 - **4.3.4.** Participating personnel are not required to be associated with the Organization; however unaffiliated personnel must sign an External Investigator Agreement unless they do not have access to subjects or identifiable private information or identifiable biospecimens
 - **4.3.5.** Participating personnel must be qualified by education, training, experience and licensure (as applicable) to perform the specific responsibilities described above.
- **4.4. Lead Coordinator:**
 - **4.4.1.** The Lead Coordinator is directly involved with working with the PI in the submission of all applications and reports to the IRB.
 - **4.4.2.** The Lead Coordinator serves as the primary regulatory contact point for the ORA. All correspondence from the IRB will be directed to both the PI and Lead Coordinator.
 - **4.4.3.** The Lead Coordinator may be authorized by the IRB to obtain informed consent/assent in accordance with [HRPP policy 5.1](#) (Obtaining Informed Consent from Research Subjects).
 - **4.4.4.** Performance of research interventions or tests in the course of providing clinical care or routine services to the patient/subject, or analysis of data or biospecimens.
 - **4.4.5.** Only one Lead Coordinator may be named in a study.
 - **4.4.6.** A Lead Coordinator is not required for all research. The PI will serve as the single contact when a Lead Coordinator is not identified.
- **4.5. Coordinator**
 - **4.5.1.** Coordinators may be authorized to obtain informed consent/assent in accordance with [HRPP policy 5.1](#) (Obtaining Informed Consent from Research Subjects).
 - **4.5.2.** Coordinators may be involved with performance of research interventions or tests in the course of providing clinical care or routine services to the patient/subject, or analysis of data or biospecimens.
 - **4.5.3.** More than one coordinator may be named on the IRB application.
 - **4.5.4.** Coordinators must be qualified by education, training, experience and licensure (as applicable) to perform the specific responsibilities described above.
- **4.6. Administrative and Data Management Personnel:**
 - **4.6.1.** Administrative and Data Management Personnel generally handle the data collected during the course of the research.
 - **4.6.2.** Administrative and Data Management Personnel may be involved in preparation of IRB applications and required paperwork under the direction of the Lead Coordinator and PI.
 - **4.6.3.** Administrative and Data Management Personnel do not have direct subject contact, but may have access to subject's identifiable private information, or protected health information (PHI).

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