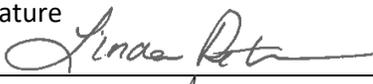


| Standard Operating Procedures | | |
|--------------------------------------|--|-----------------------------|
| SOP #509.3 Revision 3 | TITLE: Researcher Responsibilities, Qualifications and Training | Effective Date: 3/1/2019 |
| Approved By: OIRB Director | Signature  | Date 3/1/2019 |
| Approved By: IRB Chair | Signature  | Date 3/1/2019 |

PURPOSE

The purpose of this policy is to ensure that individuals who are conducting human research have the appropriate training, qualifications and accountability for the conduct of the research project in accordance with institutional, state, and federal regulations.

REVISIONS FROM PREVIOUS VERSION

Clarifying PI responsibilities and administrative corrections

POLICY

All researchers and research staff engaged in human research approved by the UNM IRB must be appropriately qualified by training and experience for their designated research roles including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; competency to conduct research related procedures and interventions such that risks to the safety and welfare of participants are minimized.

UNM undergraduate and graduate students may serve as student researchers on human research projects when an appropriately trained, qualified, and authorized faculty research advisor (Responsible Faculty) serving as Principal Investigator of Record supervises the research to assure the safety of research procedures and compliance with all relevant IRB directed requirements including data security.

Responsibilities of researchers include, but are not limited to:

- Knowing what constitutes [human research](#);
- Knowing under what circumstances approval from the IRB is required;
- Acquiring all necessary approvals of research activities *before* commencing such activities; and
- Knowing their [duties, requirements, and accountability as researchers](#).

RESPONSIBILITIES

Execution of SOP: Researchers.

PROCEDURE

1. Researchers have several obligations which include but are not limited to the following:
 - Providing evidence of appropriate training in research related procedures and interventions (such as blood draws), if appropriate;
 - Providing evidence of appropriate training in human research protections every three (3) years as required by the OIRB (Main Campus Researchers training through [CITI](#)); unfulfilled training requirements may result in removal from the research team and/or IRB review for noncompliance with institutional policy;

- Submitting an annual UNM Conflicts of Interest disclosure (See <http://researchcompliance.unm.edu/coi-disclosure-guidelines>) and providing a copy of a COI Management Plan, if applicable;
 - Following the procedural requirements of the approved research protocol, UNM policies and procedures, and the requirements or directives of the IRB; and
 - Following continuing review, post approval monitoring, and reporting requirements in accordance with UNM policies and procedures, IRB directives, and applicable laws, regulations, codes, and guidance.
2. In addition to the obligations listed above, Principal Investigators (PIs) also have obligations including but not limited to the following:
 - Securing authorization (via Scientific Validity Review) to conduct the research from the appropriate department head or equivalent prior to securing approval from the IRB;
 - Track CITI training, other training in research procedures, and COI decision for all research team members to ensure they have the appropriate training and have made the appropriate disclosure;
 - Maintaining appropriate oversight of each research project, as well as research staff and trainees, and appropriately delegating research responsibilities and functions so as to minimize risks to all participants;
 - Faculty serving as PI of Record on student projects are responsible for maintaining appropriate oversight of the conduct of student research; and
 - Notifying sponsors/funding agencies of any expiration, suspension, or termination of IRB approval and providing documentation of the notification to the IRB.
 3. Researchers who are unaffiliated with UNM must agree to comply with the directives of the OIRB and UNM IRB. In addition, they must provide evidence of appropriate training, experience, or other qualifications to conduct their research related role(s) safely and in compliance with all applicable federal regulations, state laws, research ethics standards, UNM and IRB policies and procedures. External researchers should submit a COI disclosure at their institution & include the decision in the IRB record. Contact the OIRB for information.
 4. The IRB may require additional training before approving a researcher to conduct research.
 5. The Scientific Validity Review shall be understood to attest that each of the following have been considered and determined to meet the requirement standards (also see Review of Scientific Validity and Merit SOP).
 - Qualified leadership. All researchers must meet the minimum qualifications required by the policies and practices of the department authorizing the research.
 - Regulatory compliance. All proposed research activities must undergo a systematic review by the Principal Investigator/Responsible Faculty that is appropriate to the nature of the research before it is initiated. This review should include consideration of and assured compliance with university and regulatory policies and committee authorizations as relevant to the research.