Standard Operating Procedures

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<th>SOP #509.2 Revision 2</th>
<th>TITLE: Researcher Responsibilities, Qualifications and Training</th>
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<tr>
<td>Approved By:</td>
<td>Signature</td>
<td>Date 8/31/2016</td>
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<td>OIRB Director</td>
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<td>Approved By:</td>
<td>Signature</td>
<td>Date 9/1/16</td>
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<td>IRB Chair</td>
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PURPOSE
The purpose of this policy is to ensure that individuals who are conducting human subject 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
Added consequences of unfulfilled training requirements

POLICY
All UNM affiliated researchers and research staff 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 study participants are minimized.

UNM undergraduate and graduate students may serve as student researchers on human subject research studies 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 subjects research
- Knowing under what circumstances approval from the IRB is required
- Acquiring all necessary approvals of research activities before commencing such activities
- 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:
   - Securing authorization (via Departmental Review) to conduct the research from the appropriate department head or equivalent prior to securing approval from the IRB (see details at #3);
• Providing evidence of appropriate training in research related procedures and interventions (such as blood draws), if appropriate;

• Providing evidence of appropriate training in human subject research protections every three (3) years as required by the OIRB (CITI for Social & Behavioral Research Investigators) or (NIH Protecting Human Subject Research Participants); unfulfilled training requirements may result in removal from the research team and/or IRB review for noncompliance with institutional policy;

• Submitting a UNM Financial Conflicts of Interest disclosure (See http://researchcompliance.unm.edu/coi-disclosure-guidelines) and providing a copy of a COI Management Plan, if applicable;

• Maintaining appropriate oversight of each research study, as well as research staff and trainees, and appropriately delegating research responsibilities and functions so as to minimize risks to all participants;

• Following the procedural requirements of the approved research protocol, UNM policies and procedures, and the requirements or directives of the IRB;

• Following continuing review and reporting requirements in accordance with UNM policies and procedures, IRB directives, and applicable laws, regulations, codes, and guidance;

• Notifying sponsors/funding agencies of any lapse, suspension or termination of IRB approval and providing documentation of the notification to the IRB.

2. Researchers who are collaborating with a UNM researcher and who are otherwise unaffiliated with UNM must agree to comply with the directives of the OIRB. 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. Also, should they not have submitted a COI disclosure at their institution, they are required to submit a disclosure to UNM.

3. The IRB may require additional training before approving a researcher to conduct research.

4. The Departmental 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).

   a. Qualified leadership. All researchers must meet the minimum qualifications required by the policies and practices of the department authorizing the research.

   b. 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 or regulatory policies and committee authorizations as relevant to the research.

5. Any proposed changes in research personnel or approved protocols must be in compliance with Review of Changes to Approved Protocols SOP.