
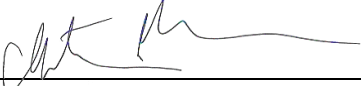


Standard Operating Procedures		
SOP #507.4 Revision 4	TITLE: Principal Investigator Eligibility	Effective Date: 5/8/2022
Approved By: OIRB Director	Signature 	Date 5/8/2022
Approved By: IRB Chair	Signature 	Date 5/8/2022

PURPOSE

This policy applies to human subjects research (HSR) under the oversight of the UNM Institutional Review Board (UNM IRB) which is designated to protect the rights and welfare of research subjects by reviewing and monitoring human research. In order to approve research, the IRB must determine that studies have the resources necessary to protect participants, research staff are appropriately qualified and there is adequate time for the researchers to conduct and complete the research.

The purpose of this policy is to ensure that individuals named as Principal Investigator (PI) on HSR protocols have sufficient authority, appropriate background, accountability and resources for the conduct of the research project in accordance with institutional policy, state and federal regulations, including assumption of fiscal responsibility.

REVISIONS FROM PREVIOUS VERSION

Update references to electronic research administration (ERA) system

POLICY

To be eligible to serve as PI on a HSR protocol submitted to the UNM IRB, an individual must meet one of the following criteria at the time of protocol submission:

- is a UNM faculty employee, defined by the Faculty Handbook B2.2 and B2.3 at an FTE greater than 0.25, or
- is a UNM staff employee with a signed Letter of Academic Title ("LAT") approved by the relevant dean or director, and by the Senior Vice Provost, or
- is a PI approved by an external site utilizing UNM IRB services.

UNM undergraduate and graduate students may serve as student researchers on HSR studies under the mentorship of an appropriately trained, qualified, and authorized faculty research advisor (responsible faculty) serving as PI of Record. The PI is responsible for supervising student research to assure the safety of research procedures and compliance with all relevant IRB requirements, including data security.

Exceptions

In special instances and with the support from the UNM department chair or center director, other members of the university community may request approval from the IRB to serve as PI. These individuals include:

- UNM Main and Branch Campus employee without an LAT when research activities are within the scope of the individual's responsibilities, or
- UNM Main and Branch Campus faculty who are 0.25 FTE or less.

- Unpaid faculty, emeritus faculty or visiting scholars from other institutions conducting UNM engaged research.

Support from the UNM academic department chair or center director must include:

1. **endorsement** that the individual has the chair's or center director's approval to conduct the research **AND**
2. assurance that the department or center **will assume all responsibility** for the conduct of the research project including administrative issues.

RESPONSIBILITIES

Execution of SOP: Researchers, OIRB Staff, Director of OIRB

PI ELIGIBILITY EXCEPTION REQUEST PROCEDURE

To request approval of an exception to serve as PI:

1. Complete the Principal Investigator Eligibility Request Form. This form must be signed by the Department Chair/Center Director or designee to document support and approval. The final file format must be in PDF.
2. Provide a PDF copy of the individual's completed Curriculum Vitae (CV).
3. Provide a copy of documentation evidencing UNM appointment or affiliation (such as LAT, Visiting Scholar appointment letter, etc.)
4. Provide a PDF copy of the individual's valid certification of human subject research protections training in the past three years (e.g. CITI or NIH).
5. Submit to the OIRB the signed request form and CV as part of a New Protocol or Amendment submission.

The Director of the Office of the IRB (OIRB) will review and approve the request. When approved, the PI will receive a signed copy of the form. PI's may be required to attend an in-person orientation with OIRB staff if deemed appropriate.

For additional information regarding Principal Investigator Eligibility for the UNM IRB, please contact the OIRB at IRBMainCampus@unm.edu or (505) 277-2644.