

Standard Operating Procedures		
SOP #508.1 Revision 1	TITLE: Research at External Sites	Effective Date: 5/18/2018
Approved By: OIRB Director	Signature 	Date 6/27/2018
Approved By: IRB Chair	Signature 	Date 6/27/2018

PURPOSE

The purpose of this policy is to describe requirements for IRB review of projects conducted at an external site or at multiple sites for which UNM is the lead site or a UNM researcher is the Principal Investigator (PI) to ensure the conduct of the project is in accordance with institutional, state, and federal regulations.

REVISIONS FROM PREVIOUS VERSION

Modified title and added clarifications related to NIH sIRB policy and reference to SOP 207

POLICY

Research activities conducted at sites external to UNM are subject to special procedures for coordination of research review and may involve more than one IRB responsible for research oversight. In these cases, UNM has established additional procedures to define the responsibilities of the UNM IRB, coordinate communication among responsible IRB committees, and manage information obtained in multi-site research to ensure protection of research participants. In coordinating multiple research reviews, the Office of the IRB (OIRB) staff, in consultation with the HRPP Director, take into consideration the source of funding for the research activity, federal regulations, specific sponsor regulations governing human research protections, and institutional policy.

If the project is multi-site and funded by the National Institutes of Health (NIH), all sites in the United States must utilize a single IRB of record (sIRB). This does not apply to organizations/sites outside of the U.S. The prime awardee organization(s) is responsible for ensuring IRB Authorization Agreements (IAAs) are in place and that documentation is maintained. If UNM is a participating site, it will rely on the sIRB in accordance with NIH policy. See SOP 207 IRB Reliance Process for more information.

The UNM IRB requires additional information and documentation for research that is conducted at an external site (a site that is not owned or operated by UNM or UNM affiliates). For research conducted at external sites, the UNM IRB requires a Letter of Support (LOS) from each site, indicating knowledge and support of the conduct of the research at that organization. For multi-site research, the UNM IRB requires documentation of IRB review for all research sites. UNM may enter into formal agreements with external sites to provide IRB review (see SOP 207 IRB Reliance Process), to rely on other institutions for research review, or to cooperate in review.

RESPONSIBILITIES

Execution of SOP: Researchers

PROCEDURE

1. If UNM is the lead site or if the research is being conducted at an external site, the PI provides additional information to the UNM IRB to ensure ongoing communication among the participating IRBs and sites. The UNM PI submits the following information along with the IRB application for each external site:
 - For sites with an IRB, a contact name and contact information (e.g. phone or e-mail) for the IRB and appropriate documentation (if joint review, a copy of the IRB approval letter);
 - For sites with an approved FWA, the site's FWA number;
 - For sites without an IRB, a LOS from an appropriate administrator as determined by the site that includes: a statement granting permission for the researcher to conduct the research at the site, a description of the involvement of the site, and a description of the research activities to be conducted at the site. If the external site is engaged in the research, UNM may require a reliance agreement with the site to provide IRB review;
 - For sites on Native American reservations, relevant tribal IRB or council approval.

REFERENCES

Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research NOT-OD-16-094