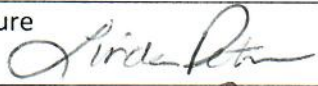
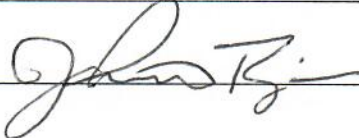




Standard Operating Procedures		
SOP #508.0 Revision 0	TITLE: External and Multi-Site Research	Effective Date: 3/31/2016
Approved By: OIRB Director	Signature 	Date 3/31/2016
Approved By: IRB Chair	Signature 	Date 3/31/16

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 in accordance with institutional, state, and federal regulations.

REVISIONS FROM PREVIOUS VERSION

None

POLICY

Multi-site research activities 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 human subjects. In coordinating multiple research reviews, the Office of the IRB (OIRB) staff, in consultation with the OIRB Director, take into consideration the source of funding for the research activity, federal regulations, specific sponsor regulations governing human research protections, and institutional policy.

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) and/or research that meets the definition of multi-site research. 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 Reliance on External IRBs SOP), 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 in a multi-site study or UNM faculty is the PI or 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, the project may require a reliance agreement with the site to provide IRB review.
2. Additionally, the UNM PI must submit to the IRB a written plan in the protocol for the management of information that is relevant to the protection of human subjects, such as reporting obligations (e.g. unanticipated problems), protocol modifications, and interim results from all participating sites.
3. The IRB will evaluate whether the management of information that is relevant to the protection of human subjects is adequate.