





Standard Operating Procedures		
SOP #207.2 Revision 2	TITLE: Reliance on External IRBs	Effective Date: 2/1/2017
Approved By: OIRB Director	Signature 	Date 2/10/2017
Approved By: IRB Chair	Signature 	Date 2/10/17

PURPOSE

To describe policies and procedures for deferring oversight of human research studies conducted by UNM faculty or staff to external Institutional Review Boards (IRBs).

REVISIONS FROM PREVIOUS VERSION

Added IO designee, requirements and process for annual review

POLICY

UNM researchers may be involved in research that involves multiple research organizations. An IRB reliance agreement allows one IRB to review research that is occurring at multiple sites or research that involves personnel from multiple institutions. For any collaboration, OIRB staff will evaluate the activities of the UNM researcher to determine if those activities engage our institution in human subjects research. OIRB staff will refer to the OHRP document "Guidance on Engagement of Institutions in Human Subjects Research" in making the determination. If the activities do engage the institution in non-exempt human subject research, the researcher's involvement in the collaboration may not begin until the UNM IRB has approved the research or until an agreement has been negotiated to rely on another IRB. This SOP discusses the circumstances in which UNM may choose to rely on another IRB for oversight of collaborative research and the process by which this is done. An external IRB may also be used to provide oversight of human subjects research that the UNM IRB does not have the appropriate expertise to review.

Criteria for Relying on an External IRB

1. Decisions on whether to rely on an external IRB will be based on funding, the location of the principal investigator, the risk level of the study, the location of the subject population, the extent of the procedures performed at UNM, the IRB resources at the collaborating institution(s) and the scope of existing agreements.
2. The OIRB will confirm that the external IRB has relevant expertise to review the study. When the research is greater than minimal risk, UNM typically requires the external IRB to be AAHRPP-accredited. The following criteria must be met:
 - a. The institution who's IRB will serve as IRB of record has a current federal-wide assurance (FWA) with OHRP.
 - b. The IRB is registered and in good standing with OHRP (no recent warning letters, no open investigations).
 - c. IRB Authorization Agreement (IAA) must be in place.
3. The HRPP Director is responsible for facilitating and maintaining IRB reliance agreements, in consultation with the Institutional Official (IO) or designee. Reliance agreements may pertain to individual studies or to a defined group of studies.

RESPONSIBILITIES

Execution of SOP: OIRB Staff, IO or designee, Researcher



PROCEDURE

Overview of the Reliance Process

1. Researchers are encouraged to consult with the OIRB about reliance on an external IRB. Researchers should submit a request for external IRB review in IRBNet. The submission should include a *Request for External IRB Review* form, the Project Information form, the study protocol, and project team list with current CITI certificates and verification of FCOI disclosure for each project team member. The protocol must clearly specify each site's role in the project. Additional study documents may be requested.
2. The OIRB staff will perform a pre-review to ensure adequate documentation has been provided to determine if the study is eligible for IRB deferral.
3. If the study is eligible for reliance on an external IRB, the HRPP Director or designee will perform an administrative review of the study materials. The purpose of the review is to consider issues of local context and to make a final decision about reliance on the external IRB. Local context issues include, but are not limited to: local and state laws; institutional policies; community standards, researcher credentials; resources to ensure safety and welfare of participants (such as adequate facilities and equipment, staff training, medical or psychosocial resources), tribal IRB review and demographics/cultural issues of the local population.
4. UNM will not defer to the oversight of an external IRB until all UNM study team members are current for human subjects research training and UNM financial conflict of interest (FCOI) disclosure.
5. When a study team member has a COI related to the study, deferral arrangements will not be finalized until a decision memo or management plan has been approved by the UNM COI Committee. This memo and/or plan must be provided to the IRB of oversight. UNM reserves the right not to defer to an external IRB when a COI management plan or other stipulations are required.
6. The UNM researcher will be notified of the decision via the signed Request for External Review form and Deferral Letter in IRBNet. OIRB staff will communicate with the external IRB about any applicable state laws governing the research, local requirements for the informed consent document, approvals by ancillary committees and other topics related to local context as needed.
7. When reliance on the external IRB is approved, the external IRB becomes the IRB of Record and is responsible for initial review, reviews of amendments, continuing reviews, adverse events, and other reportable information. UNM is responsible for ensuring continued compliance with institutional conflict of interest requirements related to human subject research for UNM affiliated researchers.
8. UNM retains the right to revoke a reliance agreement at any time in order to conduct its own review.

Researcher Responsibilities

1. The UNM researcher is responsible for knowing and complying with the requirements of the IRB of Record. Responsibilities include, but are not limited to, obtaining and documenting informed consent as required by the IRB of Record; reporting unanticipated problems or noncompliance; complying with requirements for study amendments, continuing reviews, study closure, data security, and record retention; and allowing the IRB of Record to inspect research files.
2. The UNM researcher must be aware of any UNM requirements in addition to the approval of the IRB of Record. The study may not be initiated at UNM until all approvals have been obtained. Examples include approvals from ancillary committees, material transfer or data use agreements, or study contracts.
3. The researcher will provide to the OIRB, either via IRBNet or by email, all IRB related correspondence from the external IRB (including but not limited to approval letters, notices of



suspension or termination, reportable events, etc.) and will submit a Deferred Projects Annual Report to ensure compliance with institutional policy and federal regulations.

Institutional Responsibilities

1. Institutional responsibilities regarding collaborative research are outlined in the IRB Authorization Agreement signed by the participating parties.
2. In the case of serious and/or continuing non-compliance related to collaborative research, the Institutional Official has the authority to suspend the involvement of UNM and its researchers.
3. The signatory official on IRB reliance agreements for studies with federal funding or support will be the IO. The signatory official on agreements without federal funding or support will be the HRPP Director or IRB Chair.
4. Regardless of whether UNM reviews the research or relies on an external IRB, UNM remains responsible for the safe and appropriate performance of the research. OIRB staff may conduct quality assurance reviews to confirm that the study is being conducted in compliance with the protocol and the requirements of the IRB of Record.

REFERENCES

OHRP document "Guidance on Engagement of Institutions in Human Subjects Research"
IRB Authorization Agreement (IAA)