



Standard Operating Procedures		
SOP #207.8 Revision 8	TITLE: IRB Reliance Process	Effective Date: 5/8/2022
Approved By: OIRB Director	Signature 	Date 5/8/2022
Approved By: IRB Chair	Signature 	Date 5/8/2022

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) and for UNM IRB to serve at the IRB of Record.

REVISIONS FROM PREVIOUS VERSION

Update references to electronic research administration (ERA) system

POLICY

UNM researchers may be involved in research that involves multiple organizations, also referred to as cooperative projects. IRB reliance agreements allow one IRB to review and serve as the single IRB of record (sIRB) for human research that is occurring at multiple sites or research that involves personnel from multiple institutions and documents respective authorities, roles, responsibilities, and communication between organizations. For any collaboration, OIRB staff will evaluate the activities of the UNM faculty, staff or student to determine if those activities engage UNM in human research. OIRB staff will refer to the OHRP document “Guidance on Engagement of Institutions in Human Subjects Research” and SOP 209 UNM Policy on Engagement in Human Research in making the determination. If the activities engage UNM in non-exempt human research, the researcher’s involvement in the collaboration may not begin until the UNM IRB has approved the research or until an agreement to rely on another IRB is negotiated and that IRB has granted final approval. The UNM IRB will allow reliance on another IRB’s determination of exemption status without initiation of a reliance agreement.

If a cooperative project is funded by a federal agency that complies with the Common Rule, sites are expected to utilize sIRB. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. Any institution located in the U.S. that is engaged in cooperative research must rely upon approval by a sIRB for that portion of the research that is conducted in the U.S. The sIRB may be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

In certain cases, it may be inappropriate to utilize sIRB. The following research is not subject to sIRB requirements:

1. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
2. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

If a sIRB is utilized, only the IRB review functions will be handled centrally. Awardee organizations are responsible for ensuring authorization agreements are in place and that documentation is maintained. Related local functions (e.g., ancillary committee review, conflict of interest (COI) disclosure, other required institutional approvals) remain with the individual participating institutions. The conduct and reporting of the research remain the project team's responsibility. For federally funded cooperative projects, UNM researchers must contact the OIRB to set up a meeting prior to proposal submission to determine which IRB should serve as the sIRB and to discuss researcher responsibilities (see below).

This SOP discusses the circumstances in IRB reliance may occur and the process by which this is done. An external IRB may also be used to provide oversight of human research that the UNM IRB does not have the appropriate expertise to review.

Criteria for Reliance on an External IRB

1. Decisions on whether to rely on an external IRB or serve as the sIRB for cooperative projects will be based on funding, the location and experience level of the principal investigator, the risk level of the research, the location of the participant population, the extent of the procedures performed at UNM, the IRB policies and procedures 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 project. 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 whose IRB will serve as IRB of record has a current federal-wide assurance (FWA) with OHRP.
 - b. The IRB is in good standing with OHRP (no recent warning letters, no open investigations).
 - c. The IRB conducts its review consistent with applicable ethical standards, laws and regulations. The policies and procedures of the IRB will be reviewed to determine compliance with the regulations, as appropriate.
 - d. IRB Authorization Agreement (IAA) must be in place.
3. The OIRB Director is responsible for facilitating and maintaining IRB reliance agreements, in consultation with the Institutional Official (IO) or designee as needed. Reliance agreements may pertain to individual project or to a defined group of projects.

RESPONSIBILITIES

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

PROCEDURE

Reliance on External IRB

1. Researchers must consult with the OIRB about reliance on an external IRB.
2. To request a deferral, researchers submit a request for external IRB review in the ERA system. The submission should include a *Request for External IRB Review* form and the protocol (or proposal). The protocol or proposal must clearly specify each site's role in the project. Additional documents may be requested.
3. The OIRB Director or designee will perform an administrative review of the research materials. The purpose of the review is to determine exemption status, 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 review and demographics/cultural issues of the local population.

4. UNM will not defer a project to the oversight of an external IRB until all UNM project team members are current with regard to annual UNM COI disclosure requirements and all ancillary institutional reviews, such as biosafety, radiation safety, etc. have been completed.
5. When a project team member has a COI related to the research, 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 record. 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 a Deferral Letter. If necessary, 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. Relevant changes in local policies, laws or requirements will be communicated to the external IRB 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 the project's continued compliance with the IRB requirements and institutional COI requirements related to human research for UNM affiliated researchers. The IAA outlines the duties and responsibilities of both the relying institution and the reviewing institution.
8. UNM retains the right to revoke a reliance agreement at any time in order to conduct its own IRB review.

Reliance on UNM IRB

1. In circumstances when the UNM IRB serves as the sIRB, the UNM PI is responsible for submitting the project to the IRB for review.
2. The protocol must contain a detailed description of each site's proposed activities, any information related to local context for each site and any documentation related to individual site review such as COI management plans, ancillary approvals from the institutions, etc.
3. The UNM IRB is responsible for initial review, reviews of amendments, continuing reviews, adverse events, and other reportable information. When research sites are added to approved projects, UNM IRB will review these requests as amendments according to SOP 306.
4. Individual institutions are responsible for ensuring the project has continued compliance with the UNM IRB requirements and institutional COI requirements related to human research for their researchers. The IAA outlines the duties and responsibilities of both the relying institution and the reviewing institution.

Researcher Responsibilities

1. The UNM researcher is responsible for knowing and complying with the policies and requirements of the sIRB. Responsibilities include, but are not limited to, completing required human protections training, not enrolling participants until the sIRB has approved the project, obtaining and documenting informed consent as required by the sIRB, reporting unanticipated problems or noncompliance, deviations and participant complaints, complying with requirements for project

amendments, continuing reviews, project closure, data security, data monitoring reports and record retention and responding to the sIRB requests in a timely manner.

2. Researchers must also allow the sIRB or OIRB staff to inspect research files for post approval monitoring activities.
3. The UNM researcher must provide the sIRB local contact information for participant complaints and/or injury at local sites and any relevant COI management plans or stipulations.
4. The UNM PI must provide contact information for individual site researchers to obtain answers to questions, express concerns, and convey suggestions regarding the use of the sIRB.
5. The UNM researcher must be aware of any institutional requirements in addition to the approval of the sIRB. The project may not begin until all approvals are obtained. Examples include approvals from ancillary committees, material transfer or data use agreements, or project contracts. Material changes related to COI specific to the project must be submitted according to UNM policy.
6. If the project is deferred, the researcher will provide to the OIRB via the ERA system all IRB related correspondence from the external IRB (including but not limited to approval letters, notices of suspension or termination, reportable events, etc.).
7. Additionally, the UNM PI must submit to the sIRB a written plan in the protocol for the management of information that is relevant to the protection of human participants, such as reporting obligations (e.g. unanticipated problems), protocol modifications, and interim results from all participating sites in addition to documentation from any local ancillary review (e.g. radiation safety, etc.).
8. The IRB will evaluate whether the management of information that is relevant to the protection of human participants is adequate.

Institutional Responsibilities

1. Institutional responsibilities regarding collaborative research are outlined in the IAA signed by the participating parties.
2. In the case of serious and/or continuing noncompliance related to collaborative research, the IO has the authority to suspend the involvement of UNM and its researchers.
3. The institution will notify the sIRB of any changes in local institutional policies or researcher status that impacts IRB review.
4. The UNM signatory official on IRB reliance agreements for projects with federal funding or support will be the IO or designee. The signatory official on agreements without federal funding or support will be the OIRB Director.
5. 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 conducted at UNM. OIRB staff may conduct quality assurance reviews to confirm that the project is being conducted in compliance with the protocol and the requirements of the sIRB.

REFERENCES

OHRP document "Guidance on Engagement of Institutions in Human Subjects Research"

IRB Authorization Agreement (IAA)

45 CFR 46.114

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

AAHRPP Standard I-9