OFFICE OF THE INSTITUTIONAL REVIEW BOARD

UNM IRB Researcher Handbook

Office of the Institutional Review Board
Office of Research Integrity and Compliance

University of New Mexico

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UNM IRB Researcher Handbook

Purpose of the Handbook

The purpose of this document is to provide guidance to UNM Main and Branch campus researchers who conduct human subjects research (HSR). This document provides information about federal regulations as well as UNM policies supporting and interpreting research regulations.

Department Resources

Office of the IRB

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Visit UNM IRB website for:

- Submission Forms
- IRB Submission Checklist (for comprehensive list of required documents based on submission type)
- Templates (consent forms, protocol, HIPAA Authorization, recruitment)
- Study tools to use when conducting your research
- Policies and Guidance documents
- Consultation Requests
- Streamlyne Resources (instructions and resources for using the submission software)
- Links to required human research protections training (i.e. CITI)
- Upcoming educational outreach events, training workshops
- IRB review metrics
- FAQs

Human Research Protections 101 – Why is the IRB important?

Role of the IRB

The primary role of the UNM Institutional Review Board (IRB) is to ensure that the safety, rights, and welfare of research participants are protected. This is done through the initial and continuing review of HSR and monitoring of approved projects. The IRB also has the responsibility to ensure that UNM remains in compliance with relevant federal regulations regarding HSR.

Ethical Foundation for Human Research Protections

The Belmont Report (1978) provides the foundation of three basic ethical principles for conducting HSR. These principles are important considerations for researchers, IRBs, institutions, and sponsors involved in human research.

- **Respect for persons**: Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. Research participants should understand as completely as possible what is to be done to them, what information will be gathered about them, and what the potential risks and benefits are of participating in research. Participants must give their consent freely without pressure or coercion.
- **Beneficence**: The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules have been formulated as complementary expressions of beneficent actions in research: first, do not harm, and second, maximize possible benefits and minimize possible harms. An appropriate balance must exist between potential benefits to the participant and/or society and the risks assumed by the individual.
- **Justice**: The principle of justice holds that particular individuals, groups, or communities neither should bear an unfair share of the direct burdens of participating in research, nor be unfairly excluded from the potential benefits of research participation. Inclusiveness in research and fair distribution of benefits and burdens are important considerations for researchers, IRBs, research institutions and sponsors. Issues of fair and equitable treatment arise in deciding whether and how to include individuals, groups or communities in research, and the basis for the exclusion of some.

Regulations for Federally Funded Human Subjects Research

The Department of Health and Human Services (HHS) provides federal regulations (45 CFR part 46), referred to as the “Common Rule”, for the conduct of HSR funded by the federal government. Any institution receiving federal funding for research must have a Federalwide Assurance (FWA) and is required to adhere to the Common Rule and additional relevant federal regulations such as those listed below as they pertain to federally funded research. Through this assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human participants at 45 CFR part 46.

Codes of Federal Regulations for Human Subject Research

Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Department of Defense (DOD)
Department of Justice (DOJ)
Department of Education (ED)

Equivalent Protections

Federal regulations allow institutions to reduce IRB requirements for minimal risk non-federally funded research by committing to provide equivalent protections (EP). EP apply only to research that is neither federally funded nor will be submitted for federal funding. UNM IRB policies have incorporated certain EP for minimal risk research. UNM IRB will determine which projects meet criteria for EP upon initial review. For more information, refer to Standard Operating Procedure (SOP) 205 “Review Standards for Minimal Risk Research Not Covered by FWA”.

UNM IRB and the OIRB

History of UNM IRB

The UNM IRB has been in operation for several decades. The IRB oversees all Main and Branch campus affiliated HSR projects. From 2008-2013, the administration of the IRB was transferred to the Human Research Protections Office on the UNM Health Sciences Center campus. In 2013, the IRB support office was reestablished on Main Campus as the Office of the IRB (OIRB). All UNM Main and Branch campus faculty, students, and staff are required to submit human research protocols to the UNM IRB. Additionally, the UNM IRB provides IRB services for external partners, see the OIRB website for more information. The UNM IRB maintains its own FWA number, IRB registration number, Institutional Official, and the ability to defer oversight to other IRBs as appropriate. This information is required when submitting proposals for federal funding.

UNM IRB FWA Number:

FWA00004690

UNM IRB Registration Number:

IRB00000431

Institutional Official

The Institutional Official (IO) is UNM's signatory official on the FWA and on all IRB authorization agreements involving federal funding. The IO has the authority to review decisions of the IRB. In the case of an approval decision, if the IO determines that a project does not fully comply with policies or obligations of the university, the IO may disapprove, suspend, or terminate the project on behalf of UNM. However, the IO does not have the authority to approve research disapproved by the IRB. The IO is also the person at UNM that the IRB notifies when it finds a project that does not receive federal funding to be in serious or continuing noncompliance, or when there is an unanticipated problem involving risks to participants or others.

UNM Institutional Official
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Overview of Regulations and IRB Authority

- The IRB shall review and have authority to approve, require modifications (to secure approval) or disapprove all research activities (45 CFR 46.109(a); 21 CFR 56.109(a)).
- The IRB shall conduct continuing review of research covered by the Common Rule (i.e. federally funded) at intervals appropriate to the degree of risk, but no less than once per year for projects that are greater than minimal risk, and shall have the authority to observe or have a third party observe the consent process (45 CFR 46.109(e); 21 CFR 56.109(g)).
- Research covered by the Common Rule approved by the IRB may be subject to further appropriate review, approval, and disapproval by officials of the institution. However, those officials may not approve the research if not approved by the IRB (46 CFR 46.112; 21 CFR 56.112).
- The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants (45 CFR 46.113; 21 CFR 56.113).

Composition of the IRB

IRB Members: Federal regulations require that membership of the IRB have at least five members with varying background to promote complete and adequate review of research activities commonly conducted by the institution. The full board composition must include, at a minimum: one member whose primary concerns are scientific areas, one member whose primary concerns are nonscientific areas, and at least one member not affiliated (or whose immediate family member is not affiliated) with UNM. The UNM IRB maintains a modest full board roster responsible for reviewing human research at the convened meeting and a roster of minimal risk reviewers.

IRB Chair and Vice Chair: The IO appoints the IRB Chair and Vice Chair. Chairs have the knowledge to enforce consistent application of the ethical principles of the Belmont Report, federal regulations, and IRB policies governing human research protections. Chairs are responsible for managing the efficient and effective conduct of IRB meetings and have standard voting privileges as members of the IRB. The IO and IRB Director review Chair performance and renew appointments annually.

Consultants: On occasion, the IRB may request that a topic expert consult on a specific protocol. The consultant is not a replacement for departmental representation on the IRB. Rather, the IRB utilizes a consultant if the IRB membership lacks knowledge about a specific issue or experience in a specific area such as a new, specialized technology or a novel participant population. Consultants may be internal or external to UNM, are sought based on their expertise and must not have a conflict of interest with the protocol under review. Consultants serve an advisory role and do not vote with IRB.

Office of the IRB

The OIRB is a support office that serves the IRB, researchers and study personnel, and participants. Staff members conduct intake on all submissions, including verification of training and conflict of interest disclosures, verifying all documents required for review are present and enter it in the queue for review. Once entered into the queue, it is assigned to an IRB Analyst on a first come, first serve basis. The Analyst will conduct a preliminary review (pre-review) ensuring that all required documents are present, information is consistent throughout all documents, and critical regulatory and ethical requirements are addressed. The Analyst will also make an initial determination as to whether the project requires IRB review (i.e. meets the definition of HSR), and the risk level of the project. If any issues are noted, the Analyst will return the submission to the PI listing the issues to address prior to IRB review. Researchers must address issues within 30 days to continue the review process. Additionally, the Analyst will ensure that all required regulatory determinations are properly documented and will communicate the decision to the researcher. OIRB staff are also responsible for educational outreach related to HSR protections, post-approval monitoring of approved research, and continuous quality improvement activities within the OIRB. With regard to research participants, the OIRB serves as an information resource for human research protections requirements, as well as a contact point if participants have questions, concerns or complaints regarding their experience as a research participant.

The UNM Human Research Protections Program

UNM maintains an integrated Human Research Protections Program (HRPP) under the oversight of the Institutional Official. The HRPP includes the IRB, the OIRB, Office of University Counsel, Office of Sponsored Projects and the Conflict of Interest (COI) Committee. Other components include the UNM Privacy (HIPAA) Office, Institutional Biosafety Committee, Radiation Safety Office and the Research Pharmacy, researchers and research participants. The HRPP works together to promote the safety and protection of people participating in research by establishing and encouraging high ethical standards and facilitating communication across

departments. The HRPP is responsible for ensuring compliance with the requirements of the FWA even when projects are under the oversight of an external IRB.

UNM joins an elite group of organizations in achieving full accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). In achieving full AAHRPP accreditation, UNM has demonstrated its commitment to rigorous standards that help protect research participants while ensuring that society continues to realize the benefits of scientific research.

Defining Human Subjects Research

IRB policies define the activities that the institution considers to be HSR. A **decision tree** and **guidance document** are available on the website to help the researcher determine whether an activity meets either the HHS or FDA definition of HSR, keeping in mind that the IRB has the authority to make the ultimate determination if an activity is subject to IRB oversight.

The researcher may not conduct HSR without prior IRB approval. If you have questions about whether an activity is HSR, contact the OIRB, who will provide you with a determination. If you wish to receive a formal determination, you must submit documentation via Streamlyne as described in the **IRB Submission Checklist**.

Researcher's Responsibilities All researchers and research staff engaged in human research approved by the UNM IRB must be appropriately qualified by training and experience for their designated research roles including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; competency to conduct research related procedures and interventions such that risks to the safety and welfare of participants are minimized.

Principal Investigator (PI) Eligibility

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

- Is a UNM faculty employee, defined by the Faculty Handbook B2.2 and B2.3 at an FTE > 0.25, or
- Is a UNM staff employee with a Letter of Academic Title (LAT) approved by the relevant dean or director, or 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 projects under the mentorship of an appropriately trained, qualified, and authorized faculty research advisor (responsible faculty) serving as the **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.

Staff, part-time or retired faculty, or visiting scholars from other institutions conducting research at UNM must have support from a UNM academic Department Chair or Center Director to serve as the PI of Record. The PI of Record will assume responsibility for the conduct of the research project in accordance with institutional policy,

state and federal laws, and regulations. For more information on how to request eligibility to serve as PI on a human research project, see SOP 507 "Principal Investigator Eligibility."

Researcher Training

For the purpose of the IRB, **study personnel** are those individuals who either interact or intervene with individuals for the purpose of research, who have access to private identifiable information, and/or are the PI of Record for a student project. Prior to becoming study personnel, individuals must:

- Complete required human research protections training (renewed every three (3) years). This requirement is satisfied by completing the CITI Program's "UNM Main Campus Researchers" course (must affiliate with UNM Main Campus in CITI) (https://www.citiprogram.org/). Note that community-based researchers may consult OIRB staff regarding alternative training possibilities for community researchers.
- UNM faculty, staff, and students who can influence the design, conduct, or reporting of research must complete an annual Conflicts of Interest Disclosure. Additionally, ALL UNM study personnel must complete project-specific Conflicts of Interest Disclosures. External partners may alternatively provide documentation of COI disclosure and review from their home institutions.

Faculty Responsibility in Student Research

UNM undergraduate and graduate students may serve as student researchers on human research projects when an appropriately trained, qualified, and authorized faculty research advisor (Responsible Faculty) serving as Principal Investigator of Record supervises the research to assure the safety of research procedures and compliance with all relevant IRB directed requirements including data security.

A faculty member assigning research projects involving human participants must take an active role in assuring that the participants of student research are adequately protected. The University expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research, and assisting in the preparation of IRB applications. After IRB approval, the advisor should meet regularly with the student in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of human participants. By completing a new project questionnaire in Streamlyne and submitting the protocol, the faculty member indicates their willingness to comply with all administrative and federal regulations (University Policy on the Involvement of Human Participants in Research). To comply with this policy, the faculty member who is acting as the Principal Investigator is required to educate and mentor the research team, and is also responsible for maintaining research records as required by law and University policy.

Submitting to the IRB

IRB Library

The most current versions of IRB submission forms, templates, and research tools are located on the IRB website in the submission forms and templates tab: https://irb.unm.edu/library/index.html.

We recommend that all researchers become familiar with the **IRB Submission Checklist** and the **Streamlyne Researcher Manual**. The IRB Submission Checklist specifies documents required for submitting new projects, amendments, renewals/continuing reviews, response to modifications, HSR determinations, and IRB deferrals. The **Streamlyne Researcher Manual** provides systematic details on how to navigate the online submission database.

We strongly encourage researchers to use the most current protocol, consent, and recruitment templates when drafting project documents.

Consults

We strongly encourage researchers to schedule a consult with an OIRB staff member prior to submitting documents for IRB review. This provides the researcher an opportunity to ask project-specific questions and review documents with staff to ensure everything is in order for submission. To schedule a consult, complete the consult request form on the OIRB website.

Streamlyne

Streamlyne is an online submission platform used by the UNM IRB to conduct reviews. Researchers submitting protocols to the UNM IRB must use Streamlyne, which is a repository for all determinations, communications, and documents reviewed by the UNM IRB over the life of a study and archives documents after a study has closed. UNM faculty, staff and students log into Streamlyne using their UNM NetID and password. External users can request and receive an account by submitting a request HERE. For assistance with using Streamlyne, see the instructional video and Tip Sheets on the Streamlyne webpage.

Submitting Conflict of Interest Disclosures through Streamlyne

All Conflict of Interest Disclosures must be submitted through Streamlyne. These can be accessed by logging into Streamlyne, selecting the "Main Menu" drop-down menu, hovering over the "Conflict of Interest" option and then selecting the appropriate disclosure type from the menu that populates to the right. Specific instructions for annual disclosures can be found here while specific instructions for project-specific disclosures can be found here.

IRB Protocol

The IRB Protocol is the most important document submitted to the IRB. It provides detailed information about the study, which allows the IRB to review and evaluate it according to the federal criteria for approval.

Use the **Protocol Template** as a starting point for drafting a new IRB Protocol and use the bullet points as a guide to what the IRB looks for when reviewing research. Here are some key points to remember when developing a protocol:

- Always keep a version-dated electronic copy. This is also available in Streamlyne. You will need to modify this copy when making changes or updates to the protocol.
- If you believe your activity may not be HSR, contact the OIRB prior to developing your protocol.
- Inclusion criteria should be specific for any vulnerable populations that may be included in the research. These populations may have regulatory implications and may require additional protections. Provide justification if your project includes any vulnerable populations as listed in the Protocol Template.

Informed Consent: Discussion and Documentation

Informed Consent is a Process, Not Just a Form

It is the researcher's responsibility to educate prospective participants about the purpose of the project and its risks and benefits, to obtain their consent before involving them in research, and to keep them informed as the research proceeds. This is the informed consent process. Information may be provided to the potential participant as a document that may or may not require a signature, a script that is read to the participant prior to proceeding with a telephone survey, a paragraph to be read prior to completing an online survey or a hybrid of the above.

It is essential that informed consent discussions are conducted and documents are written in plain language that participants can understand. UNM IRB has specific policies regarding the recruitment and informed consent of **non-English speaking** and **child** participants (see *Special Considerations* section below). The consent document(s) should always be revised if there are changes in the project that might affect the participant or when additional information will improve the consent process. If appropriate, participants who have previously provided informed consent may need to be notified of changes in the protocol and/or consent document(s).

The consent form(s) should not contain any exculpatory language. That is, participants should not be asked to waive (or appear to waive) any of their legal rights, nor should they be asked to release the researcher, sponsor, or institution (or its agents) from liability for negligence. Federal regulations and University policy also require that researchers seek informed consent only under circumstances that provide the prospective participant (or representative) **sufficient opportunity** to consider whether or not to participate and that **minimize the possibility of coercion or undue influence**, defined as any act of persuasion that over-comes the free will and judgement of another.

Consent Forms

Obtaining a participant's signature and date on a consent form is important, but it is just one step in the continuous process of informed consent. Informed consent is about people's understanding and willingness to participate in your project; signing a form is the most common way to document that participants understand and are willing. Prospective participants in your research must understand the purpose, the procedures, the potential risks and benefits of their involvement, and their alternatives to participation. While a consent document that gives this information, and more, is a vital part of the process, the opportunity to discuss any questions or concerns with a knowledgeable research team member is also necessary.

Use one of the **Consent and/or Assent Form templates** in the IRB Library to create a consent form. Note that consent forms must contain all of the required elements of consent as provided in the template. Template language for additional elements of consent that may be required for various projects can be found in the **Additional Elements of Consent**. Consent forms that are longer than 4 pages must include key information as presented in the consent template. All consent forms should also include a version date. **Use only the IRB approved consent form to enroll participants.**

Informed Consent Not Needed for Screening

An IRB may approve a research proposal in which a researcher will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant (or LAR), if either of the following conditions are met:

1) The researcher will obtain information through oral or written communication with the prospective participant or LAR, or
2) The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Alteration and Waiver of Informed Consent Processes

An IRB may waive the requirement to obtain informed consent (in most cases, this occurs when, the participant is not directly involved in the research procedures (e.g. record review, secondary data analysis) or can approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, provided the researcher justifies the waiver using the criteria in 45 CFR 46.116(f) (see below).

The IRB must find and document that the research meets the requirements for a general waiver or alteration of consent in 45 CFR 46.116(f). These include:

i. The research involves no more than minimal risk to the participants;
ii. The research could not practicably be carried out without the requested waiver or alteration;
iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
iv. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
v. Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation

Waiver of parental or guardian permission

See Special considerations section.

Wavier of consent for research involving public benefit and service programs

The IRB may waive the requirement to obtain informed consent if the research involves public benefit and service programs conducted by or subject to the approval of state or local officials. The IRB must find and document that the research meets the requirements in 45 CFR 46.116 (e) These include:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

a. Public benefit or service programs;
b. Procedures for obtaining benefits or services under those programs;
c. Possible changes in or alternatives to those programs or procedures; or
d. Possible changes in methods or levels of payment for benefits or services under those programs; AND

(ii) The research could not practicably be carried out without the waiver or alteration.

Waiver of consent documentation (signature)

In most cases, informed consent must be documented (obtain signature and date from participant). However, in some cases, waiver of documentation (signature) is appropriate and allowed. In order for the IRB to waive the requirement of a participant's signature, one of the following conditions must be justified in the IRB protocol:

1) That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or LAR) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; OR
2) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; OR
3) If the participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If the documentation requirement is waived, the IRB may require the researcher to provide participants with a written statement regarding the research (i.e. a consent form with no signature lines).

Note: If requesting any type of waiver from the IRB, justifications must be provided in the IRB Protocol with direct reference to the criteria listed above.

Criteria for IRB Approval of Research

In order to approve a HSR project, the IRB must determine all of the following requirements are met:

1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes (such as a blood draw, or diagnostic behavioral interview).
2) Risks to participants are reasonable in relation to both the anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably result.
3) Selection of participants is equitable. In making this assessment the IRB will consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the unique problems of research that involves vulnerable populations.
4) Informed consent is sought from each prospective participant or the participant's legally authorized representative, in accordance with relevant policies or federal regulations (all required elements, ongoing consent, in a language understandable to the participants, etc.).
5) Informed consent is appropriately documented, in accordance with relevant policies and federal regulations, unless there is a credible justification to waive such documentation.
6) When appropriate, the research plan makes adequate provision for monitoring data collected to ensure the safety of participants.
7) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the research to protect the rights and welfare of these participants

Types of IRB review

HSR Determination

Activities that meet the definition of HSR require IRB review. Activities that do not meet the definition of HSR (e.g. journalism, creative writing, etc.) do not require IRB review. Tools are available on the website to help researchers with this determination. If you want a written determination from the IRB of whether a project is HSR, you must submit documentation via Streamlyne as described in the **Requesting IRB review not required determination Tip Sheet and the IRB Submission checklist.**

Minimal Risk Review of Non-Federally Funded Research

Research that is not funded by the federal government and that involves no greater than minimal risk can undergo minimal risk review. *This is a determination made by the IRB upon review of the project.* Minimal risk review procedures allow an individual IRB member to review and approve projects on behalf of the full IRB. Projects that qualify for minimal risk review are reviewed on a weekly basis. Although not required, the IRB may determine that these projects require continuing review or post approval monitoring, depending on the type of research and participant population.

Exempt and Expedited Review of Federally Funded Research

Certain categories of federally funded HSR can be determined to be exempt from IRB oversight as long as they fall within certain categories and meet prescribed ethical criteria including the requirement for informed

consent, minimal risk procedures and considerations for participant privacy and data confidentiality. Any significant changes to an exempt project will need to be submitted to the IRB to ensure that the exempt determination still applies. *This is a determination made by the OIRB or IRB; researchers are not authorized to make exempt determinations.* Examples of exempt projects include online anonymous surveys, classroom curriculum evaluations, interviews on non-sensitive topics, review of existing academic, medical or other records without recording identifiers, etc. See SOP 302 "Exempt Review of Federally Funded Research" for a complete list of exemption categories.

Certain research that involves no greater than minimal risk and only includes procedures listed in the Federal Register expedited review categories can undergo expedited review. *This is a determination made by the IRB upon review of the project.* Expedited review procedures allow an individual IRB member to review and approve projects on behalf of the full IRB. Projects that qualify for expedited review are reviewed on a weekly basis. Although not required, the IRB may determine that these projects require continuing review or post approval monitoring, depending on the type of research and participant population. Some full board projects may eventually qualify for expedited review, for example, once the project is limited to data analysis. Examples of expedited projects include identifiable surveys, interviews and focus groups on potentially sensitive topics, projects that access identifiable health or educational records, projects collecting biological specimens by noninvasive means, etc.

Full Board Review

Projects that do not qualify for any of the above and/or present greater than minimal risk to participants must be reviewed at a fully convened IRB meeting. The full board meets once per month. Due to the frequency of full board meetings, the OIRB website lists deadlines for submission in order for items to be added to the meeting agenda. Submissions that complete pre-review after the deadline will be reviewed at the following month's meeting. A majority of the board including at least one non-scientific member must be present at the meeting in order for quorum to be established. If protocols include research with prisoners, then an IRB member with that expertise must be present in full board meetings that review such research. Examples of full board projects include research in prisons, projects administering drugs or alcohol, research using investigational devices, research involving invasive interventions (e.g. biopsies), or high risk or vulnerable populations (e.g. maximal aerobic capacity testing on frail populations), etc.

Administrative Review

Minor changes to already approved documents, including but not limited to, project team changes, grammar corrections, recruitment phone number or format changes, project closures and HSR determinations are reviewed administratively by OIRB staff. For more information please see SOP 306. Submissions that qualify for administrative review are done on a daily, first come first serve basis.

IRB Review Outcomes

Upon review of a project, the IRB makes determinations that are consistent with federal criteria for IRB approval of research, whether or not the research has federal funding.

Approved

The IRB approves a project when all criteria for approval are met. No further action is required from the researcher and research may begin. Researchers must not begin research (new proposals) or continue research (amendments or continuing review) until the researcher has received a letter documenting IRB approval.

Modifications Required

The protocol and/or supporting documents require specific changes in order to meet the criteria for approval. The **modification letter** will list the changes and/or modifications required by the IRB. The researcher must revise and submit the changes within 30 days and receive an approval letter from the IRB before the project may begin or continue.

Tabled

If the fully convened board was unable to approve a project because one or more criteria for approval were not met or there was insufficient detail in the submission to make a determination, the PI will be asked for additional information or modifications. In this case, a **tabled letter** is sent indicating what additional information needs to be provided or changes that need to be made. When a response addressing what has been requested is submitted to the IRB, the OIRB staff will schedule the PI's response to the requested revisions for review by the full board, at the next IRB committee meeting.

Disapproved

A fully convened board determines that it is unable to approve the research. Disapproval of a project or amendment usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB approval. When making this determination, the IRB will describe its reasons for this decision and give the researcher an opportunity to respond to the IRB's concerns. If disapproved, the research cannot be conducted.

Acknowledged

OIRB staff are able to acknowledge minor changes to already approved documents, including but not limited to, project team changes, grammar corrections, recruitment phone number or format changes and certified translations of approved documents. These submissions do not require formal review by the IRB.

Appeals Process

If a researcher is not satisfied with the IRB determination, they may submit an appeal within 30 days of receiving the determination by submitting a written defense to the IRB. The IRB will review the appeal at the next available full board meeting. The following should be included in the appeal:

- A letter elaborating a defense that includes why the IRB should reconsider the determination and a point-by-point response to the listed reasons for the determination including any information not previously provided or considered.
- Any changes to documents should be highlighted using track changes or a similar method to indicate what changes were made.
- Submit the response and any revised documents via Streamlyne. Revisions to documents should be made using track changes.

Researcher Obligations after IRB Approval

1. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient time, oversight, equipment, and space;
2. Ensure that project team members are qualified and trained to perform procedures and duties assigned to them during the project and retain documentation showing human subjects research training (CITI) has been completed within the last 3 years for all study personnel. The PI should also have confirmation of COI disclosures on file for the current year for all team members prior to having them perform research duties;

3. Use monitoring and compliance tools, if needed, available on the OIRB website on the Researchers, study tools tab;
4. Personally conduct or supervise the human research in accordance with the IRB approved protocol including ensuring informed consent or permission is appropriately obtained from participants;
5. Faculty serving as PI of Record on student projects are responsible for maintaining appropriate oversight of the conduct of student research;
6. Not change the project protocol without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to participants. The IRB will need to be notified of any changes implemented related to immediate hazards within 7 days; and
7. Submit all necessary submissions to the OIRB, including amendments, continuing review (if required), closures, deviations, and events.

Note that researchers may not start human research activities or implement proposed changes until the IRB has granted approval.

Type of Submissions

New Projects

Researchers should submit a new project for IRB approval before they begin any human research. These submissions should include the protocol, consent form, and any documents that are used with participants in the course of the research. In addition to research specific documents, a signed **Scientific Validity Review** form is also required. Scientific validity review is to be completed prior to submitting to the IRB and is typically completed by the Department Chair from the PI's department (note potential exception for thesis/dissertation projects).

Amendments

Prior to implementing a change to any project, an amendment must be submitted to and approved by the IRB. Examples include adding or revising questionnaires or other procedures, adding project team members, increasing enrollment, changes in project location or population, changes in recruitment, compensation, etc. Amendments to federally funded exempt projects should only be submitted if the proposed change disqualifies the project from exemption status or changes the category of exemption to one that requires limited IRB review. (Contact the OIRB for guidance).

Renewal

Research that is greater than minimal risk must be reviewed by the IRB at least once per year. Some minimal risk research may also require continuing review (this requirement will be noted in the approval letter). Applicable paperwork as outlined in the IRB Submission Checklist (e.g. abstracts and publications that occurred within the last approval period, protocol deviations if appropriate, etc.) must be submitted ***no later than 30 days prior to the expiration date*** to allow adequate time for IRB review.

Protocol Deviations Report

A protocol deviations report is completed over the course of the approval period when protocol deviations occur, as well as at the time of continuing review or closure if any deviations occurred. This report documents minor deviations that caused no harm to participants, such as lack of researcher signature on the consent, over enrollment in a minimal risk project, etc. For more information, please see SOP 405 "Reporting of Protocol Deviations."

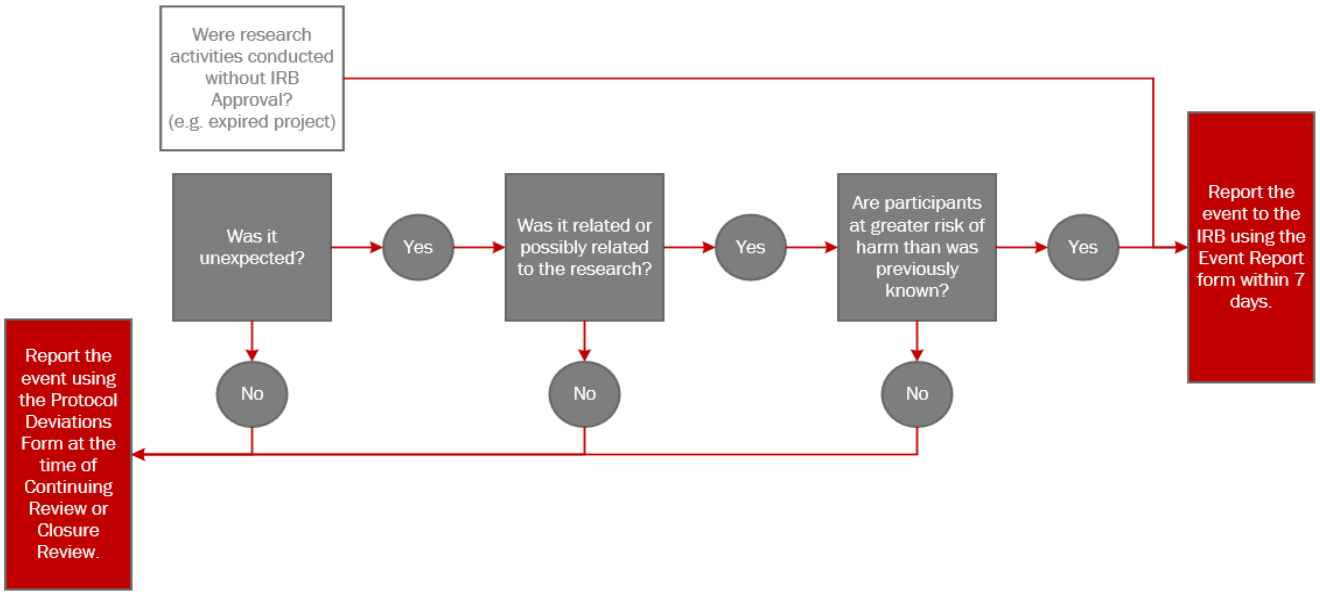
Event Reports

An **unanticipated problem** is a significant complication or other unfavorable occurrence that is related or possibly related to research participation, is not anticipated at the time of protocol review and arises in or following the conduct of a project. Unanticipated problems may occur with the **participants or others**. **Adverse events** are harms that occur to research participants or others. They range from minor to severe and may be anticipated or unanticipated.

An event report must be submitted to the IRB within **7 days** of discovery of an unanticipated problem or adverse event occurring during the project. Additional reporting requirements to federal agencies, sponsors, risk management, legal counsel, police or other entities may also be required. Event reports are submitted as notifications to the IRB in Streamlyne.

Examples of reportable events include:

- injury, disability, hospitalization, life-threatening experience, death, unexpected side-effects, aggressive or unusual behavior;
- harm or damage to the safety, rights, or welfare of research participants, research staff, or others;
- any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
- breach of privacy, confidentiality or data security that caused harm or increased the risk of harm; and/or
- loss or destruction of project data not in accordance with IRB approved procedures.



For more information, please see SOP 401 "Reporting and Review of Events Involving Risks to Participants or Others."

Project Closure

Researchers should understand when to close a project in order to remove it from IRB oversight. Closures do not need to wait until the expiration date and may be submitted even if data analysis is on-going, as long as identifiers are destroyed. The PI is responsible for promptly closing out an IRB approved project when:

- the PI never initiated the project;

- participant enrollment is closed, all data collection is complete and the only remaining activity is analysis of de-identified data with no identifying links or codes;
- the PI plans to leave the University; or
- a student researcher leaves the University without notifying the IRB.

The study cannot be closed if the research team is analyzing identifiable data (including data with codes or links to identifiers).

To submit a closure request, see the relevant Tip Sheet on the IRB website. Note that closure requests are not required for federally funded projects granted exemption.

Expiration of IRB Approval

The PI must submit a renewal request ***at least 30 days in advance*** of the IRB expiration date. The expiration date is the last date that the protocol is approved (i.e. IRB approval expires at midnight on the expiration date). If the PI fails to do so, and IRB approval expires, all human research activities, including data analysis, must stop. Failure to have a project approved or closed prior to the IRB approval expiration date is noncompliance. When IRB approval expires on a project, a formal noncompliance determination is issued. If a PI has a pattern of IRB approval expiring for projects under their oversight, compliance training will be required and a fully convened IRB may review the noncompliance. Even if IRB approval has expired, the PI is still responsible for closing the project. The project may be reactivated up to 6 months after IRB approval has expired; after 6 months, it must be closed. For more information, see SOP 408 "Expiration of IRB Approval."

NOTE: The IRB may withdraw or administratively close a project if the PI fails to respond to the IRBs requested modifications within 30 days, the OIRB has not received a response to clarifications within 30 days, or the PI fails to submit a complete continuing review or closure submission. PIs/responsible faculty also have the authority to file a continuing review, amendment or closure of a student research project if said student has failed to file required paperwork and/or failed to remain in close contact with their mentor/PI.

Post Approval Monitoring (PAM)

Researcher interactions with the IRB are not limited to submitting paperwork for review. Once a project is approved, it is under IRB oversight as long as participant interactions continue, identifiers exist, and the project is not closed. The PAM program has two goals: 1) ensure ongoing monitoring and compliance of active projects and 2) serve as a training opportunity for researchers as they conduct their research. To assist researchers with establishing their projects and monitor them over time, study tools are available on the OIRB website. Additionally, the IRB may contact the researcher in order to assess the project in real time through a full assessment, self-assessment, consent document review, consent process review, or other activity.

Records Retention

Researchers are advised to retain all project records according to NM statute, currently 3 years after closure of the project, and take measures to prevent accidental or premature destruction of these documents, unless specified in the IRB protocol and approved by the IRB. This includes approved IRB documents, signed consent documents, as well as de-identified recordings, tapes or transcripts (unless destroyed earlier according to approved protocol), and all other de-identified data collection instruments and source documents. Confidential data must be stored in such a way to prevent breach or loss and may be stored in hard copy or electronically.

Data may also need to be retained for copyright and intellectual property applications. Researchers must store the records consistent with the plan approved by the IRB to prevent breach of confidentiality.

For research that falls under the authority of FDA, HIPAA, or other regulatory agencies, the PI must retain documents and IRB records for the period specified in the applicable regulations if the requirements are longer than three years after the project closure. For multi-site studies, the PI should consult the sponsor regarding retention requirements, but must maintain the records for at least five years after closure. There are longer retention periods for certain research records:

- Records involving the generation, disclosure, and/or use of Protected Health Information (PHI) must be retained for six years.
- Record retention for funded research must comply with Sponsor requirements.
- The National Institutes of Health and National Science Foundation require that grant recipients keep all data three years beyond grant final expenditure report.
- American Psychological Association expects its members to retain data for a minimum of five years.

The PI must ensure that retained records are accessible for confidential inspection and/or copying by authorized representatives of institutional or regulatory agencies.

Special Considerations

Assessing Risk of Harm

Assessing risk of harm to individuals who participate in research is one of the IRB's primary responsibilities. Risk is the probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a project. Both the probability and magnitude (severity) of a possible harm may vary from minimal to significant. The magnitude of potential harm is the summative measure of its severity, duration, and reversibility. A research protocol with a low probability of harm occurring, but a high magnitude of harm if it occurs, may be determined to be greater than a minimal risk (e.g. a severe allergic reaction to a new medication, or stigmatization from unintentionally releasing HIV status of participants). Alternatively, a protocol with a high probability of harm occurring, but a low magnitude of harm may be minimal risk for participants (e.g. itchiness after electrode tape removal, or distress related to answering sensitive, personal questions).

Federal regulations define ***minimal risk*** as the "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CRF46.102(j) and 21 CFR56.102(i)).

The IRB will consider a wide range of categories or types of risks including physical, psychological, social, economic, legal, or unknown risks. In most cases, these risks apply to individuals; however, risks can also apply to groups of individuals (e.g. research on alcoholism among Native Americans may be perceived as reinforcing a negative stereotype). The *overall project risk* is determined by the risk to the *most vulnerable known members of the group*. IRB reviewers identify any anticipated risks involved with participation in the project and classify those risks as minimal or greater than minimal risk. Reviewers then determine whether the anticipated risks to participants are reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge that may reasonably be expected to result.

Researchers should provide detailed information in the IRB protocol about potential risks and benefits associated with the research and provide information about the probability, magnitude, and potential harms

associated with each risk. For more information, please see our guidance on Assessing and Minimizing Risk in Human Research.

Child Assent and Parent Permission

Age of majority is determined by the locality in which the participant is physically located. In New Mexico, state law requires that if an individual is under eighteen years of age, parent permission be obtained for that child to participate in research, unless married or emancipated by court order. Parent permission must be documented in writing unless waived by the IRB. Parent permission may be waived by the IRB if it is not a reasonable requirement to protect the participants (for example, neglected or abused children) in accord with 45 CFR 46 Subpart D and 46.408(c) and Subpart A 46.116. However, the PI requesting the waiver must provide a justification for this waiver and propose an alternative mechanism for protecting the children who will be participating in the project. In most cases, when a project involves minimal risk or involves greater than minimal risk but presents the possibility of direct benefit to the child, one parent or guardian's permission is sufficient. The research must not be FDA-regulated.

Assent means that a child has given affirmative agreement to participate in research. In determining whether children are capable of assenting, the IRB considers the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. In instances where children ages 7-11 are capable of providing assent, the researcher should develop a separate assent form written in the language appropriate to the educational level of the child. As a general guideline, children ages 12 and older are considered capable of providing assent and can sign the standard consent form. An assent template can be found on the website.

International Research

UNM researchers who conduct HSR activities at or collaborate with non-U.S. institutions must meet the requirements of U.S. federal laws pertaining to human research as specified in the UNM policies and procedures, as well as any laws that govern research that is conducted in the foreign locality. All researchers must know and comply with relevant laws in the localities where they conduct research, including U.S. tribal, territorial, and foreign localities. In the case of variances between federal laws and state or local laws, or between U.S. and foreign laws and regulations, the more protective standard typically takes precedence.

If the proposed research will be conducted in whole or part at a site in a foreign country or territory and requires any type of access to non-public facilities (e.g. local organizations, schools, Universities) then authorization to conduct the project must be provided to the IRB. This is a letter or attestation issued by an appropriate official in the local (foreign) jurisdiction (as determined by that site) that the project complies with local regulations and laws. In many cases, this will involve additional approval of the project by a local IRB or ethics board. If the proposed research will be conducted on tribal land, appropriate authorizations must be obtained such as Navajo Nation Human Research Review Board (NNHRRB) and/or tribal council approval. If there are no relevant regulations or laws in the foreign country pertaining to the proposed research, or no local IRB or ethics board, then a letter of support (translated into English) by an academic administrator or government official from the local jurisdiction may be requested by the IRB (we recommend consulting with the OIRB to determine what is appropriate). In most cases, it will be sufficient to have the equivalent of a department head or dean from a local academic institution provide the letter. For more information, see SOP 508 "Research at External Sites" and SOP 511 "Compliance with Applicable Laws and Regulations."

Non-English Speaking Participants

In order to ensure that prospective participants have sufficient information to provide informed consent to participate in research, it is necessary for the researchers to effectively convey information to participants in a language that they are comfortable reading, understanding and speaking. If the project targets a particular group that does not speak and/or read English, the recruitment material(s) (e.g. approach letters, flyers) and informed consent document(s) must be translated into the language understood by the targeted group (45CFR46.116-117 and 21CFR50.20). See SOP 506 "Translation for Non-English Speaking Participants" for information regarding the creation, submission, and use of translated documents.

Vulnerable Populations

The UNM IRB gives special consideration to protecting the welfare of research participants who may be particularly vulnerable to the risks of participation, such as children, prisoners, fetuses/neonates, pregnant women, and individuals with impaired capacity to provide informed consent. The IRB also recognizes that additional populations such as students, disenfranchised groups, and others may qualify as vulnerable populations and may need safeguards in place for their protection during project participation.

It is the researcher's responsibility to identify the categories of vulnerable participants involved in the research and note the nature of participant vulnerability in the protocol. The protocol should include details regarding the procedures in place to protect vulnerable populations. The IRB submission must include consent/assent forms appropriate to the reading level, language, and cultural sensitivity of the vulnerable population. Additionally, it is the researcher's responsibility to identify and abide by state or country (if outside the U.S) laws applicable to the use of vulnerable populations.

Recruitment of Participants

The UNM IRB is charged with evaluating and approving all planned recruitment methods including appropriateness of materials, inclusion and exclusion criteria, and incentive and compensation components. Researchers and the IRB must ensure that recruitment activities are free of bias, do not exert undue influence on or coerce a potential participant to volunteer, and do not imply a guarantee of benefits beyond what is outlined in the IRB approved protocol and consent form. Researchers should make reasonable efforts to assure open access to research opportunities. However, efforts to be broadly inclusive are only required if there is potential direct benefit to those participating in the research.

The researcher must carefully consider the targeted research population, research aim(s), participant privacy, and potential for bias and influence when designing recruitment activities for specific protocols. For example, teachers who also serve as researchers and wish to enroll their students into research must ensure that recruitment methods do not cause undue influence, coercion, or inappropriately promise or suggest classroom or personal benefit beyond what is written in the protocol and consent form. In this example, an acceptable way to address issues of undue influence would be to utilize a third party to present the project information to potential participants.

Advertisements planned for the recruitment of research participants must be approved by the IRB prior to use. Any changes made following approval must be re-evaluated by the IRB prior to implementation (including exempt research where the new recruitment procedures may create substantial changes in risk levels or vulnerability to participants). When developing advertisements, be sure materials clearly state that research participation is being solicited, materials do not contain misleading statements, written in plain language that participants can understand, potential risks/benefits from participation are accurate, if included, incentives or

compensation are not inappropriately emphasized and communication materials and processes are culturally sensitive and appropriate. For more details on advertisement and recruitment in human research, please see SOP 510 “Advertisement and Recruitment for Human Research”. Templates are available on the website.

Compensation of Participants

The IRB will review the amount and schedule of incentives/compensation to assess the appearance or fact of undue influence or coercion for participants who may be overly influenced due to their economic insecurity or vulnerability. All information concerning participant compensation should be stated in the IRB protocol and informed consent document(s), including amount, method, and timing of disbursement. If compensation is mentioned in recruitment materials, the recruitment materials must also include a brief description of project procedures. Compensation cannot be made conditional on completion of the study procedures. If researchers choose to prorate compensation for partial participation in the study, the payment schedule must be outlined in the protocol and consent documents.

Payment for purposes of research participation by cash, check, money order, or gift card in the amount of $600 or more per year is taxable income. As such, each participant receiving compensation to participate in a project is required to sign a participant receipt form (for less than $600) as per UNM Policy 2480: Incentives for Program Participants.

For researchers who would like to offer course credit or extra credit to the project population, they must also offer a non-research activity that is equivalent in effort and time/duration to project participation. Research lotteries and raffles can be utilized under certain specific conditions. Please note that projects that receive federal funding may have additional requirements associated with compensation. For more information on participant compensation, see SOP 503 “Compensating Participants.”

Family Educational Rights and Privacy Act (FERPA)

FERPA regulates the disclosure of personally identifiable information from education records in all public elementary and secondary schools, school districts, intermediate education agencies and state education agencies, and any public or private agency or institution (e.g. UNM, APS, etc.) that uses funds from the U.S. Department of Education. The purpose of FERPA is to protect all student and parent information maintained in an Education Record.

Researchers are responsible for complying with FERPA, IRB, and University policy when accessing education records for the purpose of research. For more guidance on FERPA in human research, review our Guidance on FERPA.

For more information about best practices to protect personally identifiable information from education records, contact the PTAC Help Desk - PrivacyTA@ed.gov; 855-249-3072.

Health Insurance Portability and Accountability Act (HIPAA)

The UNM IRB serves as the Main and Branch campus HIPAA Privacy Board with regard to accessing Protected Health Information (PHI) for the purposes of human research. All other HIPAA issues such as PHI access preparatory to research (e.g. prepare research protocol), descendent research, limited data sets, public health activities, business associate agreements, privacy notice, and accounting of disclosures fall under the jurisdiction of UNM’s Privacy Officer (privacy@salud.unm.edu).

In general, researchers must obtain HIPAA Authorization or a waiver of HIPAA Authorization for any use and/or disclosure of PHI for research. On UNM's Main Campus, covered entities include the Speech and Hearing Sciences and the Student Health Center. For further guidance on when HIPAA applies, HIPAA authorization requirements and how to submit waiver of HIPAA authorization requests, please see SOP 505 "HIPAA in Research". A HIPAA Authorization template for research can be found on the website. For a complete list of campus facilities that are considered covered entities, please see the Regents' Policy Manual Section 3.7.

Sponsored Projects

When submitting a new project to the IRB, researchers are required to provide information about acquiring or the intention to acquire external funding for research in the IRB New Questionnaire as some funding sources require additional scrutiny and application of additional regulations and policies.

The OIRB suggests that an IRB application be submitted at the time a proposal is submitted for funding to ensure that IRB review has been completed by the time that the funding agency needs confirmation of IRB approval. If IRB approval has not been obtained when a notification of award is received, the OIRB will work with the Office of Sponsored Projects (OSP) to determine whether the award can be issued and index code set up pending IRB approval.

If IRB approval expires on a funded project, it is the responsibility of the researcher to contact their sponsor and provide appropriate documentation of the occurrence. Additionally, if an adverse event occurs during the conduct of the project that is determined to be serious and reportable by the IRB, it is the responsibility of the researcher to report the event to the funder.

Clinical Trials Requirements and Reporting

NIH policy requires that the Principal Investigator register a clinical trial on ClinicalTrials.gov within 21 days of enrollment of the first participant. A clinical trial is a research project in which one or more research participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information about clinicaltrials.gov requirements, who to contact with questions and who the protocol registration system (PRS) administrators are for clinicaltrials.gov at UNM, that can assist with registering your clinical trial, see the following website: https://hsc.unm.edu/about/finance/sponsored-projects/grants-contracts-clinical-trials/clinical-trials.html

Additional Requirements for Federally Funded or FDA Regulated Research

When a project is federally funded (i.e. NSF, NIH, DOJ, ED, etc.) or falls under FDA regulations, additional human protections requirements may be applicable. For more information regarding this, see the Guidance on Additional Requirements for Federally Funded Research on the IRB website**.**

Some federal agencies require use of a single IRB of record (sIRB) for multi-site projects. In most cases, the IRB at the institution that serves as the prime awardee will function as the sIRB. When participating in a multi-site federally funded project, please contact the OIRB as soon as possible to discuss the required paperwork. In order to be compliant with federal regulations, IRB Authorization Agreements (IAAs) must be put in place prior to the commencement of the research. For more information, see SOP 207 "IRB Reliance Process."

Research Data Security

Researchers are often entrusted with confidential and privileged human data, whether in paper or electronic form, and must, therefore, take measures to protect the information. Given the wide range of diversity in

project locations, methods, and electronic data devices, researchers should carefully consider confidentiality and data security when electronic data are collected and/or stored because electronic data are vulnerable to hacking and other threats.

Each member of the campus community is responsible for the security and protection of information resources over which they control. All researchers must be familiar with information security policies and procedures of their department or unit, UNM, the State of New Mexico and Federal privacy laws (e.g. HIPAA, FERPA, FOIA, New Mexico IPRA, as well as the data confidentiality requirements associated with sponsor funding (e.g. NIH, DOJ, etc.) For guidelines on human research data management and security, see the Human Research Data Security Standards on the IRB website.

In the event that there is a breach or loss of human research data, an event report must be submitted to the IRB within 7 days of the discovery of the occurrence. Additional reporting may be required to the institution and sponsor. To initiate sponsor related reporting, contact UNM Office of Sponsored Projects.

Certificates of Confidentiality

NIH issues Certificates of Confidentiality (CoCs) to protect identifiable, sensitive research information from forced disclosure. They allow the researcher and others who have access to research records to refuse to disclose all copies of the research record and prohibits disclosure of name, information and biospecimens in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. CoCs are granted for projects collecting information that, if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, CoCs help achieve the research objectives and promote participation in research by assuring confidentiality and privacy to participants. All NIH-funded research that collects or uses identifiable, sensitive information is deemed to be issued a Certificate of Confidentiality. Researchers not funded by NIH may also apply for a CoC.

When research is covered by a CoC, researchers:

- May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
- May disclose information only when:
    - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
    - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
    - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

- Made for the purposes of other scientific research that follows applicable Federal regulations governing the protection of participants in human research.

For more information on CoCs, please see the guidance on NIH Certificates of Confidentiality on the IRB website.

Additional Approvals

Some UNM research may require approval by an additional IRB depending on location or organization. For example, research done on the Navajo Nation requires approval by the Navajo Nation Human Research Review Board. Likewise, research conducted in any school in the Albuquerque Public School district, Rio Rancho public schools or at Central New Mexico College (CNM) must also be reviewed the APS Research and Evaluation Committee, Rio Rancho ethics committee and CNM IRB respectively. If a site does not use an IRB, approval from that site to conduct research is still required in the form of a Letter of Support (LOS). For more information on external and multi-site research, see SOP 508 "Research at External Sites". Researchers are encouraged to consult with OIRB staff to determine whether additional approvals may apply to their research.

Request for Deferral to External IRB

Researchers can request permission to use an external IRB by submitting a Request for External IRB Review form along with other documentation as listed on the IRB Submission Checklist via Streamlyne. In most cases, this request is made for multi-site projects in which another institution is the lead site or for projects in which all human research activities are conducted at a collaborating institution and does not preclude dual IRB review as noted in the section above. Additionally, the UNM IRB may defer a project to an external IRB if they believe the other IRB is better suited in expertise to review the project or as part of the requirement by NIH for single IRB review. Per UNM policy, the OIRB must make the decision whether to defer to an external IRB; the researcher cannot make this decision. For more information, see SOP 207 "IRB Reliance Process". If the external IRB requires review fees, the researcher is responsible for payment of those fees.

Researchers may also request that an external site that is engaged in HSR defer oversight to the UNM IRB. To make such a request, email the IRB office (irbmaincampus@unm.edu) and provide the project title and protocol number, external collaborator's name, and a contact name and phone number for the external site's IRB office. The external collaborator should be listed as a project team member and the protocol must include details regarding activities being conducted at the external site.

Additional Resources Available

The OIRB helps researchers understand and navigate the UNM IRB review process by providing guidance and education. Contact us to register for an IRB workshop, schedule a one-on-one consult, or to invite us to your next meeting/class. Please visit the OIRB website for more information about educational opportunities.