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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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Mailing Address:
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Albuquerque, NM 87131

Tel: 505-277-2644
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Visit UNM IRB website for:
• Submission Forms (see IRB Submission Checklist for comprehensive list of required documents based on submission type) located in the IRB Library
• Templates (consent forms, protocol, HIPAA Authorization, recruitment) located in the IRB Library
• Policies and Guidance documents
• Consultation Request Form
• 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 studies. 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 FDA, DOE, DOD and DOJ 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 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 of Minimal Risk Research Not Covered by Federalwide Assurance.”

UNM Main Campus 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. Main Campus 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 subjects or others.

UNM Institutional Official
Gabriel Lopez, Ph.D.
Vice President for Research
Email: vpr@unm.edu
Tel: 505-277-6128

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, 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(f)).
- 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. UNM IRB maintains a modest full board roster responsible for reviewing human research studies requiring full board review. UNM IRB also has a roster of alternates who conduct minimal risk reviews. The UNM IRB membership list is on the [OIRB website](http://www.oirb.unm.edu).

**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 project staff, and participants. Staff members conduct intake on all submissions, including verification of training and annual conflict of interest disclosure, assign the submission an IRB number if it is a new project, 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 risk level. If any issues are noted, the Analyst will send a clarification message to the researcher 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 studies 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.

What is Human Subjects Research?

IRB policies define the activities that the institution considers to be HSR. A decision tree and guidance document are available in the IRB Library 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 IRBNet as described in the IRB Submission Checklist (p.8).

What are the researcher’s responsibilities?

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.

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 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, project team members 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 a project team member, individuals must:

• Complete required human research protections training (renewed every three (3) years). This requirement is satisfied by completing the CITI Program’s Human Subjects Research course (affiliation “UNM Main Campus Researchers”) ([https://www.citiprogram.org/](https://www.citiprogram.org/)) or NIH Protecting Human Research Participants training ([https://phrp.nihtraining.com/users/login.php](https://phrp.nihtraining.com/users/login.php)). Note that community based researchers may consult OIRB staff regarding alternative training possibilities for community researchers.
• Complete an online UNM **Financial Conflicts of Interest Disclosure** and, if applicable, provide a copy of your COI Management Plan or decision memo.

**How do I submit a research project to the IRB?**

**IRB Library**
The most current versions of IRB submission forms, templates, and research tools are located in the IRB Library: [http://irb.unm.edu/library](http://irb.unm.edu/library).

We recommend that all researchers become familiar with the IRB Submission Checklist and IRBNet Submission Instructions. The IRB Submission Checklist specifies documents required for submitting new projects, amendments, continuing reviews, closures, modifications, HSR determinations, and IRB deferrals. The IRBNet Submission Instructions provide 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. The **blue text** within the
template(s) are prompts of items to be addressed (when applicable) to your project. We ask that you delete all blue text from the document(s) as you fill in your specific project information.

**Consultations**
We strongly encourage researchers to schedule a consultation 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 a consult request form on the OIRB website.

**IRBNet**
IRBNet is an online submission platform used by the UNM IRB to conduct reviews. Researchers submitting projects to the UNM IRB must use IRBNet. IRBNet houses all determinations, communications, and documents reviewed by the UNM IRB over the life of a project and archives documents after a project has closed. Each researcher needing access to the project in IRBNet must create their own account, setting up an individual user name and password (which is not linked to their UNM NetID). For assistance with using IRBNet, see the IRBNet Submission Instructions or attend an IRBNet workshop offered by the OIRB.

**IRB Protocol**
The IRB Protocol is the most important document submitted to the IRB. It provides detailed information about the research, which allows the IRB to review and evaluate it according to the federal criteria for approval (see Criteria for IRB Approval of Research).

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

- The blue help text provides guidance to researchers when developing the protocol for submission to the IRB. Delete all blue text prior to submission.
- Always keep a version-dated electronic copy. This is also available in your project within IRBNet. 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.
- Note that, depending on the nature of your research, certain sections of the template may not be applicable to your project. Indicate this in the section as appropriate by inserting “not applicable”. Do not leave any section blank.
- Inclusion Criteria should be specific for any of the following populations that may be included in the research. These populations have regulatory implications. They may be vulnerable because of participation in the research, and so may require additional protections. Provide justification if your project includes any of the following populations:
  - Children (<18 years of age, depending on state or territory)
  - Pregnant women
  - Prisoners
- Individuals with intellectual disabilities
- Adults unable to provide legally effective consent
- Students
- Non-English speaking individuals

**What is informed consent? Discussion and documentation**

**Informed consent is a process, not 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 overcomes 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 have that understanding and willingness. 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. All consent forms should also include a version date. Use only the approved consent form to enroll participants.

**Informed Consent and Documentation Waivers**
An IRB may waive the requirement to obtain informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of 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) provided the researcher justifies and the IRB finds and documents that:

1) The research involves no more than minimal risk to the participants;
2) The waiver or alteration will not adversely affect the rights and welfare of the participants;
3) The research could not practicably be carried out without the waiver or alteration;
4) Whenever appropriate, the participants are provided with additional pertinent information after participation.

In most cases, informed consent must be documented (obtain signature and date from participant). However, in some cases, waiver of documentation of consent (no 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) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking them with the research, and the participant’s wishes will govern; or
2) 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 (such as surveys or interviews).

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.

**How does the IRB decide whether to approve a project?**

**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 should take into account 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.

What are the 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, oral history, etc.) do not require IRB review. Tools are available in the IRB Library 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 IRBNet as described in 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 meet prescribed ethical criteria including the requirement for informed consent, minimal risk procedures and considerations for participant privacy and data confidentiality. An exempt determination means that the project does not require continuing review. However, 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” 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](https://www.federalregister.gov/notice/cfr/21-cfr-part-50-exempt) 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. These projects are subject to continuing review by the IRB. Some full board projects may eventually qualify for expedited review once the projects 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 on 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 and 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 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 such as grammar corrections, recruitment phone number or format changes, project closures and HSR determinations are reviewed administratively by OIRB staff. Submissions that qualify for administrative review are done on a daily, first come first serve basis.

**What are 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 (modifications, 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/Information Required**
If the IRB was unable to approve a project because one or more approval criteria were not met, the PI will be asked for additional information or modification. In this case, a
**Modification Letter** is sent indicating what additional information needs to be provided or changes that need to be made. If originally reviewed by the full board, the full board must subsequently review the project at a monthly meeting.

**Disapproved**
A fully convened board determines that it is unable to approve the research and cannot describe modifications that might make the research approvable. 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.

**Acknowledgement**
OIRB staff are able to acknowledge certain types of submissions, including but not limited to minor administrative corrections to approved recruitment materials and certified translations of approved documents. These submissions do not require formal review by the IRB.

Do not start human research activities until you have the final IRB approval letter.

**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 IRBNet. Edited documents should be uploaded creating a version trail.

**What are my 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 training is current for all team members. 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. 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;
4. 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
5. Submit all necessary submission 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.

**Amendments**
Prior to implementing a change to a project, an amendment must be submitted to and approved by the IRB. Examples include adding or revising questionnaires or other procedures, 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 (contact the OIRB for guidance).

An **Amendment Application** must be completed and submitted with any new or revised documents using track changes or a similar method to highlight the changes made. Amendments are submitted as a new package within the existing IRBNet project and a version trail is created for each revised document. For further guidance, please see the [IRBNet submission instructions](#) for creating a new package.

**Continuing Review**
Federally funded research must be reviewed by the IRB no less than once per year. Some minimal risk, non-federally funded research may also require continuing review (this requirement will be noted in the approval letter). A **Continuing Review Application** and 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, current project team, etc.) must be submitted **no later than 30 days prior to the expiration date** to allow adequate time for IRB review. IRBNet sends automated email reminders of continuing review at 60- and 30-days prior to expiration of IRB approval.

Please note continuing review and amendments may not be submitted at the same time. Continuing reviews are submitted as new packages within the existing IRBNet project.

**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 study, 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 authorities or other entities may also be required. Event reports are submitted as new packages in the existing project in IRBNet.

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;
- 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**

The PI and/or the IRB may close approved projects under certain circumstances. The PI is responsible for promptly closing out an IRB approved project when:

- all research activities including analysis of identifiable data and reporting are complete;
- 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;
• a student researcher leaves the University without notifying the IRB.

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

To submit a closure request, the PI or student researcher will submit a Closure Application and other documents as outlined in the IRB Submission Checklist as a new package within the existing IRBNet project. Note that closure requests are not required for studies granted exemption.

Expiration of IRB Approval

The PI must submit an application for continuing review at least 30 days in advance of the project 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 project, 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 his or her mentor/PI.

How long do I keep records?

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**

New Mexico state law requires that if an individual is under eighteen years of age, parental permission be obtained for that child to participate in research, unless married or emancipated by court order. Parental permission must be documented in writing unless waived by the IRB. Parental permission may be waived by the IRB if it is not a reasonable requirement to protect the participants (for example, neglected or abused children). 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.

**Assent** means that a child has given affirmative agreement to participate in research. In determining whether children are capable of assenting, the IRB takes into account 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 all instances where children 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 age seven and older are considered capable of providing assent. An assent template can be found in the [OIRB Library](#).

**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 subjects 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 “External and Multi-Site Research” 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 population 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 project information form and 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 legally authorized representatives.

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, or to 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, 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 located in the IRB Library.

Compensation of Participants
The IRB will review the amount and schedule of incentives and 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.

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 studies 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 that are part of the UNM hybrid covered entity 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, a complete list of campus facilities that are considered covered entities, authorization requirements and waiver of authorization requests, please see SOP 505 “HIPAA in Research”. A HIPAA Authorization template for research can be found in the OIRB Library.

**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 on the project information form as some funding sources require additional scrutiny and application of additional regulations and policies. Additionally, if a funding proposal has been submitted for consideration, a copy of the proposal must be included with the IRB submission in order for the IRB to conduct a “congruency review” to ensure that the protocol and the proposal are consistent.

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.
Additional Requirements for Federally Funded or 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.

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.

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.

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 or at Central New Mexico College (CNM) must also be reviewed the APS Research and Evaluation 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 “External and Multi-Site Research”. 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 IRBNet. In most cases, this request is made for multi-site studies in which another institution is the lead site or for studies 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 201 “Reliance on External IRBs”. 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 reference 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.

**What other resources are available to me with regard to the IRB?**

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.