# UNM IRB PROTOCOL

|  |  |
| --- | --- |
| Title: |  |
| Version Date: |  |
| Principal Investigator/  Faculty Supervisor: |  |
| Student Investigator: |  |
| Funding/Sponsor: |  |

## *Background Information*

* Provide the background and scientific rationale for conducting the research.
* List research questions or specific aims of the protocol. In experimental designs, objectives should be stated as hypotheses to be tested.
* This section should not be more than 1 paragraph MAX.

## *Anticipated End Date*

* Specify the expected date for final de-identification of research data.

## *Participant Inclusion/Exclusion Criteria*

* Describe the target participant population including age range, gender and other relevant criteria.
* List all inclusion and exclusion criteria including enrollment of vulnerable populations (such as children, prisoners, pregnant women, cognitively impaired individuals).

## *Participant Enrollment*

* Provide the estimated maximum number of participants to be enrolled or records to be accessed.

## *Recruitment and Screening Procedures*

* Describe the plan to identify potential participants (when, where, how) including database/records review if applicable.
* Describe how the population will be identified, and how initial contact will be made.
* Provide information regarding access to the population that will allow recruitment of the necessary number of participants.
* Specify if any advertising/recruitment materials will be used, including verbal/electronic announcements of the research. Upload recruitment material(s) as attachments to this submission.
* Provide letters of support if utilizing external organizations to conduct recruitment activities.
* Describe the screening process (how researchers will confirm that potential participants meet inclusion/exclusion criteria). Explain what happens with screen failures and any data obtained from screen failures, if applicable.

## *Informed Consent Process*

**Are you obtaining informed consent?** *If yes, address the bullets below. If no, indicate that you are requesting a waiver of informed consent, delete the bullets below and skip to next question.*

* Describe the process (when, where, how) for obtaining informed consent including considerations for a private setting. If research involves children, describe assent process and whether/how parent permission will be obtained.
* Describe steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, who might be asked to provide permission or consent on behalf of the participant, and any use of comprehension quizzes, if applicable.
* Indicate if you are obtaining signed consent forms. If not obtaining signatures, request a waiver of consent documentation below.

**Are you requesting a waiver of informed consent (no consent from participants)?** *If yes, address the bullets below. If no, delete section and skip to next question.*

* Describe how the research meets the definition of [minimal risk](http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm):
* Describe how the waiver/alteration will not adversely affect the rights and welfare of the participants:
* Describe how the research could NOT be practicably carried out without the waiver/alteration:
* If requesting access to identifiable private information or biospecimens, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format:
* Describe how the participants will be provided with additional pertinent information after participation, if appropriate:

**Are you requesting an alteration (does not include all required elements) of informed consent?** *If yes, address the bullets below. If no, delete section and skip to next question.*

* Describe how the research meets the definition of [minimal risk](http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm):
* Describe how the waiver/alteration will not adversely affect the rights and welfare of the participants:
* Describe how the research could NOT be practicably carried out without the waiver/alteration:
* If requesting access to identifiable private information or biospecimens, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format:
* Describe how the participants will be provided with additional pertinent information after participation, such a de-briefing.

**Are you requesting a waiver of consent documentation (no signature)?** *If yes, address one or more of the bullets below. If no, delete section and skip to next question.*

* Describe how the research presents no more than minimal risk or harm and involves no procedures for which written consent is normally required outside of the research context; OR
* Describe how a signed consent form would be the only record linking the participant and the project, and breach of confidentiality would be the principal risk; OR
* For participants or legally authorization representatives that are members of distinct cultural group or community in which signing forms is not the norm, describe how the research presents no more than minimal risk of harm and provide an appropriate alternative mechanism for documenting informed consent was obtained (e.g. fingerprint, write an “X”, etc.).

**Are you enrolling cognitively impaired adults that require use of a Legally Authorized Representative (LAR)?** *If yes, address bullets below. If no, delete section and skip to next section.*

NOTE: Definition of LAR in the state of New Mexico includes people 18 years or older that have a legal document or next of kin. There are additional situations that may be included under the LAR classification (ex. custody of the state).

* Describe the process (how, who) to determine whether an individual is capable of consent.
* Describe how the participants’ decisional capacity will be assessed as the project proceeds in order to evaluate any deterioration or improvement in the ability to consent.
* Describe the process for obtaining assent from the research participants and consent from the LAR, and how the authority to provide consent will be confirmed.

**Are you enrolling non-English speaking participants?** *If yes, address the bullets below. If no, delete section and skip to next section.*

* List the language(s) that is/are the primary language(s) of prospective participants and will be used by those obtaining informed consent. The informed consent discussion must be conducted in language in which the participant is proficient.
* Describe the process to ensure that the verbal/written information provided to those participants (including recruitment materials, surveys, etc.) will be in the appropriate language.
* Upload translated consent forms and other study materials as an attachment to this submission.
* Upload a completed Translation Certification form as an attachment to this submission.

## *Data Collection Procedures*

* Provide a detailed, sequential description of all research procedures, interventions, assessments, and participant activities.
* Describe how much time is required to complete each procedure including total time commitment.
* Describe any use or collection of existing data, including educational or medical records; identify the sources of identifiable research material.
* Describe how information will be captured (e.g. hard copy forms, audio and/or video recordings, note taking, computer task, etc.).
* Upload data collection forms, surveys, etc. as attachments to this submission.
* Provide letters of support if utilizing external organizations to conduct research activities.

***Are you conducting a Community-Engaged Project? If yes, address the bullets below; if no, delete this section and move to next section.***

* Describe details regarding community engagement include identification of the community partners, how the partnership was formed and how will the community be involved throughout the project (roles and responsibilities).
* Discuss any literacy issues, language barriers, cultural sensitivities, etc.
* Describe how research processes and outcomes will benefit the community and how they will be disseminated to the community.

***Use of Medical Device or Drugs***

* Provide product details (name, manufacturer, model number).
* Describe route of administration, dosing, dosage regimen and duration.
* State whether device or drug is FDA approved for the purpose being studied.
* Provide a package insert (drugs) or device insert for FDA approved products.
* Complete and submit the Device and/or Drug Information Form(s), if applicable.

***Use or Collection of Protected Health Information (PHI) - HIPAA***

* Will you be collecting [Protected Health Information](http://hsc.unm.edu/admin/privacy/protected-info.html) (PHI) from a covered entity or will the research information being collected be added to a medical record? If yes, include a detailed list of all PHI, including identifiers, to be collected. If no, delete section and skip to next section.
* Will you be obtaining HIPAA authorization for access to and/or collection of PHI? If yes, upload HIPAA Authorization form OR a consent document that includes a HIPAA Authorization section (see “Additional Elements of Informed Consent” document).
* Are you requesting a waiver of HIPAA Authorization or a waiver of HIPAA for recruitment purposes?

If yes, complete the HIPAA Waiver Request Form and submit as an attachment to this submission.

***Use or Collection of Educational Records (FERPA)***

* Are you accessing academic records protected under [FERPA](https://irb.unm.edu/library/documents/guidance/family-educational-rights-and-privacy-act-ferpa.pdf) which includes graded assignments, test scores, etc.? If yes, provide the source of the records and include the specific records being accessed in the consent form document (requires signature). If no, delete section.

## *Project Location(s)*

* Describe the sites or locations where your research team will conduct the research. For more information, see [SOP 508](https://irb.unm.edu/policies-guidance/index.html).
* Upload Letter(s) of Support as supporting documents with your submission.
* Detail the responsibilities of each site with regard to protections of participants, such as reporting of findings or adverse events.
* For research conducted outside of UNM and its affiliates, describe any site-specific regulations or customs affecting the research and any local scientific and/or ethical review requirements.
* For research conducted internationally describe any additional procedures to ensure researcher safety; data/sample safety, storage, and transfer; relationship with the communities; other information as appropriate.

## *Participant Compensation*

* Describe any compensation to participants including amounts and payment schedule (class credit, merchandise cards, transportation expenses, cash, check, raffles, etc.).
* Describe why the proposed amount is reasonable and appropriate. If your project includes multiple visits, include a description of any proration of compensation.
* Note: Consult [SOP 503](https://irb.unm.edu/policies-guidance/index.html) for the specific IRB policy on compensating participants and consent form requirements and [UNM Policy 2480](https://policy.unm.edu/university-policies/2000/2480.html) for institutional reporting requirements.

## *Project Resources*

* Describe what resources/facilities are available to perform the research (i.e. staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and d) resources for participant communication, such as language interpreter services.

## *Potential Risks of Harm*

Identify any possible psychological, physical, social, economic, or legal risk of harm to participants including their likelihood and seriousness. Examples:

* Is there potential for a loss of data confidentiality and how serious would loss of confidentiality be for the participant? Consider breach of confidentiality or invasion of privacy as a risk for all participants.
* If there is a potential for participants to become upset as a result of the research procedures, and thus require psychological or medical attention?
* Is there potential for emotional stress, boredom, or fatigue?
* Is there risk of physical harm from the intervention (such as from blood draws, brain stimulation or maximal exercise)?
* Could the research create potential social stigmatization or legal action by authorities if research data become known outside of the project team?
* Are there potential risks to the participant related to the political, social, or economic context in which they live?
* Are there economic burdens that may result from participating in the research?
* State the plan for preventing or minimizing risk of harm (e.g. screening to assure appropriate selection of participants, sound research design, appropriate project team training, prompt de-identification of data, safety monitoring and reporting).
* If collecting identifiable information about risk of harm to self or others, provide a mental health safety plan. See the guidance on [Mental Health Safety Plans](https://irb.unm.edu/library/documents/guidance/mental-health-safety-plans.pdf).
* Provide details regarding additional protections for vulnerable populations.
* Describe provisions for psychological or medical attention, if required as a result of research procedures or the means for referral for such services (upload as an attachment). See the guidance on [Assessing and Minimizing Risk](https://irb.unm.edu/library/documents/guidance/assessing-and-minimizing-risk-in-human-research.pdf) for assistance completing this section.

## *Potential Benefits*

* Describe any potential direct benefit that individual participants may experience from taking part in the research. Indicate if there is no direct benefit to participating (e.g. completing a survey).
* Describe the anticipated societal benefit of the research.

## *Privacy of Participants*

* Describe procedures to protect participants’ privacy including privacy considerations during recruitment, informed consent, and data collection (such as access to private rooms, closed doors, etc.).
* Describe the setting in which the participant will be interacting with a researcher.

## *Unanticipated Problems/Adverse Events*

* Describe the process for monitoring and reporting any unanticipated problems or adverse events to the IRB and other relevant agencies. Note: these must be reported to OIRB within 7 calendar days. See [SOP 401](https://irb.unm.edu/policies-guidance/index.html) for examples of reportable events. Discuss injury compensation, if applicable.

## *Participant Complaints*

* Describe procedures (other than information provided in consent document) for handling participant complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research participants (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

## 

## *Data Management Procedures and Confidentiality*

* Describe data management procedures (for electronic, paper, recordings, etc.) from the time it is collected until the data are permanently de-identified or destroyed, if applicable.
* Describe who will have access to the data and how data will be handled/maintained securely.
* Provide specific information regarding where identifiable data and consent forms will be stored.
* If portable devices are being used, describe how data are being protected.
* If data will be transferred to collaborators outside of UNM, describe procedures for data transfer.
* Describe plans for destroying all identifiers prior to project completion.
* Describe whether research data may or will be used for future research.
* Describe what will be done with any audio, video, or digital records after the project is completed.
* If more than minimal risk, briefly describe the data and safety monitoring for the project and upload supporting documents. See [SOP 307](https://irb.unm.edu/policies-guidance/index.html) for additional information.

*Considerations for securely storing data include:*

* Paper records are locked in a secure location.
* Electronic records are stored on password protected or encrypted computer as appropriate based on sensitivity of data.
* Identifiers are stored separately from project data.
* For identifiable data and/or specimens, a coding process should be used to store data and/or specimens without identifiers, the list linking participant name to their study ID or pseudonym should be stored separately from all other project records. Please note the document linking identifiers to the study ID or pseudonym must be destroyed prior to study conclusion.
* Reference the [UNM Human Research Data Security Standards](https://irb.unm.edu/library/documents/guidance/unm-human-research-data-security-standards.pdf) for more information.

## *Data Analysis/**Statistical Considerations*

* Provide a brief sample size calculation or description of sample size calculation. Include methods and assumptions such as loss to follow-up, as appropriate.
* Describe procedures for data analysis including how the data will be examined and analyzed to answer research objectives.

## *Participant Withdrawal*

* Describe procedures that will be followed when participants withdraw during data collection.
* Describe the process for participants to withdraw from the project after participation is complete, if applicable.
* Describe conditions under which the researcher might withdraw a participant from the project.
* Describe what will happen to data obtained from withdrawn participants.