UNM IRB PROTOCOL

TITLE:	Text
VERSION DATE:	Text
INVESTIGATOR/RESPONSIBLE FACULTY:	Text
STUDENT INVESTIGATOR:	Text
FUNDING AGENCY:	Text

Note that text in blue are **instructions and points to consider**. Please complete the section with study appropriate information and delete the blue text. Do not delete any headers - if a header does not apply to your research, state N/A.

BACKGROUND/SCIENTIFIC RATIONALE

Describe the research problem and provide rationale for the research.
Briefly summarize prior experience and/or history relevant to the research.
Discuss briefly any literature important to this study. It should be no more than two to three pages and cite appropriately.

OBJECTIVES/AIMS/HYPOTHESES

Specify objectives or specific aims.

STUDY DESIGN AND PROCEDURES

I. *Study Design*

Describe the study design. The description should be capable of meeting the study objectives.

II. *Study Procedures*

Provide a thorough description of all study procedures, assessments and participant activities in a sequential format. Include assessment document(s) as an appendix. If your study has multiple sessions that involve different assessments, consider using a table to describe each session and corresponding assessments.

For particular types of studies, the following information should be considered:

Behavioral Intervention Studies

- Describe how the behavioral intervention will be developed or adapted for use.
- Describe how fidelity of the intervention process will be assured.
- Describe how competence or compliance with fidelity will be demonstrated.
- Describe how fidelity and competence will be maintained and demonstrated throughout the study.
- Describe how compliance with intervention will be ascertained.
- Describe what will be done with any audio or video tapes after the study is completed.

Consent Considerations:

Describe in the informed consent what will be done with any audio, image, video or digital records after the study is completed

Survey studies

Describe interview methodology.
Describe development or selection of questionnaire.
Describe any literacy or foreign language concerns or accommodations.
Indicate whether questionnaire is validated.
Describe how questionnaire will be tested (e.g., piloted).
Describe how missing or incomplete information will be handled in analysis.

Studies that Collect Existing or Prospective Data

Describe the source of the information.
Describe whether data are to be collected prospectively (come into existence after the award).
Describe whether data are collected retrospectively (exist at the time of the award).
Describe the time period of the information under review.
Describe who will have access to collected information.
Describe how long will the information be kept.
Describe plans for destroying the data or other handling once the study is completed.
Describe any plans for de-linking, coding, or de-identifying collected information.

Focus Group Requirements

Describe qualifications of facilitator or individual supervising facilitation. Expectations include:
Prior experience facilitating groups; Knowledge of the topic; Understands the purpose of group
Provide script or discussion questions that will be used in focus group.
Describe any literacy or foreign language concerns or accommodations.
Describe how information will be captured.
Describe how information from focus group will be presented and used.
How will focus group responses be summarized and integrated?
How will contradictory responses be handled?
Will there be thematic or qualitative coding of transcribed discussions?
Will focus group responses be used to guide the development of education materials, measures, interventions or other research procedures, publication, or inform study design?
Describe whether information drawn from focus group will be shared with group participants.
Describe what will be done with any audio, image, video or digital records after the study is completed.

Consent Considerations:

Describe in informed consent what will be done with any audio, image, video or digital records after the study is completed.

Community-engaged studies

Define ‘community’ as it relates to this particular study.
Describe community engagement in this study:
Who are the community partners? How was the partnership formed?
Describe community partners’ involvement in study development, including helping to define research objectives and having input into how the study will be organized and conducted. (*Consider literacy issues, language barriers, cultural sensitivities, Community Advisory Board (CAB), etc.).*
Describe community partners’ involvement in collection, analysis and/or interpretation of data, and input into how the results are distributed. *(This does not imply censorship of data or of publication,*

but rather the opportunity to make clear the community's views about the interpretation. Indicate if they will not be involved in this phase of research)

Describe how research processes and outcomes will benefit the community.

Describe community partner(s) roles and responsibilities:

Will the community partner(s) provide a physical location or facilities for the conduct of this study?

Will community partner(s) and/or community partner site personnel interact with research participants?

Provide a list of responsibilities community partner(s) and/or community partner site personnel will have in the conduct of this study.

How will the Principal Investigator assure that community partner(s) and/or community partner site personnel are implementing study procedures according to the study protocol and application (fidelity to the protocol)?

Will the Principal Investigator or research coordinator be at the community partner site to provide direct supervision?

Explain how supervision by the Principal Investigator will occur during the study.

Will someone from the community partner site be trained to supervise the conduct of the study?

Provide the name and contact information for personnel from the community partner site who will oversee research activities for this study, and explain how supervision will occur

How will the Principal Investigator and the community partner(s) and/or community partner site personnel communicate about the study?

How will study progress be monitored?

How will the Principal Investigator assure that changes in the study protocol or procedures are communicated to the community partner(s) in a timely fashion?

How will the Principal Investigator assure that the current version of all IRB approved documents is available to the community partner(s)?

Specimen Collection Studies

Describe the specimens to be collected.

Describe aliquoting and any plans for retention specimens.

Describe tracking and labeling system.

Describe where the specimens will be stored and who will be responsible for care of specimens during storage.

Describe how long the specimens will be kept.

Describe how specimens will be destroyed at study completion.

If specimens will be banked for future use, describe what the process is for providing investigators with access to the bank.

Describe how such requests and access with be tracked.

Describe how specimens will be analyzed (type and state of development of assay, controls, etc.)

Consent Considerations:

Informed consent must allow participants to determine future use, other use beside specific research and use for genomic projects.

Provisions must be made to allow for withdrawal of a specimen if a participant withdraws consent and link is still maintained.

Studies involving use of Medical Apparatus or Drugs

Name and description of product.

Route of administration, dosing, dosage regimen and duration.

Describe how compliance with product will be ascertained.

Include information on how product will be obtained, stored, and tracked.
Describe how any adverse events or serious adverse events will be handled.
Attach product label as an Appendix to the protocol. The adverse events will describe expected adverse events.

III. *Consent Procedures*

Describe how informed consent will be obtained and who will obtain it.
If research involves minors, describe assent process, as applicable.
Use the Consent form template on the OIRB website and include informed consent document as an appendix. If you will obtain consent verbally, attach a consent script. If you will be obtaining consent via an on-line survey, please include your e-mail script with your submission. If this study is collecting and/or storing tissue samples include a Tissue Banking Consent Form.
Fully describe the consenting process including:

- Where the consent process will take place and provisions for privacy
- Waiting periods between informing the prospective participant and obtaining the consent
- Processes to ensure ongoing consent throughout the study
- Any procedure/ testing for ensuring that the consent is understood by the participants

If you are requesting **alteration or waiver of informed consent,** please address the following items:

- Research does NOT involve non-viable neonates.
- How does the research meet criteria for minimal risk?
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could NOT be practicably carried out without the waiver or alteration.
- If the research is to be conducted by or subject to the approval of state and local government officials, please state.
- If the research is designed to study, evaluate or examine one or more of the following, please state and explain:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Potential changes in or alternatives to those programs/ procedures
  - Potential changes in methods or levels of payment for benefits or services under those programs

If you are requesting a **waiver of consent documentation**, please address the following:

- Attach the written script to be provided orally and assurance that any written information contains all required elements of informed consent.
- How does the research meet criteria for minimal risk?
- State if the consent would be the only record linking the participant and the research data and would therefore represent the principal risk of harm resulting from a breach of confidentiality.

HIPAA Authorization:

- If you are collecting PHI, please include a detailed list of all identifiers that will be a part of the study data. Provide justification for use of the PHI being collected. If you will you be obtaining HIPAA authorization for collection of PHI, provide a current HIPAA form. Specific UNM HIPAA language must be used. Clearly state that you will be using either a HIPAA form OR that the consent document includes a HIPAA section.

If you are requesting a **waiver of HIPAA** or a **waiver of HIPAA for recruitment purposes only**, please address all of the following items:

- Explain how the use of PHI involves no more than minimal risk to the privacy of the research participants based on one of the following:
- Describe an adequate plan to protect the PHI.
- Describe an adequate plan to destroy PHI at the earliest opportunity, unless there is a reason to retain it (please justify).
- Provide assurance that PHI will not be re-used or disclosed inappropriately.
- Justification that waiver will not adversely affect rights of participants.
- Justification that research could not be practicably carried out without waiver.
- Provide a comprehensive list of PHI being collected under the waiver.
- Steps that will be taken to minimize the possibility of coercion or undue influence.
- Steps that will be taken to ensure the participants' understanding.

Non-English Speaking Participants

- Indicate what language(s) other than English is/are the primary language(s) of prospective participants. Indicate the language(s) that will be used by those obtaining consent.
- If participants are expected to be non-English speakers, describe the process to ensure that the oral and written information provided to those participants will be in the appropriate language. All consents and study materials should be translated.
- If there is the potential that very few participants might be non-English speakers (up to 10-15%) then a short form should be used to guide the consent process with interpreters.

Cognitively Impaired Adults/ Use of a Legally Authorized Representative (LAR)

- 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 to determine whether an individual is capable of consent.
- Describe how the participant's decisional capacity will be assessed/documented and by whom.
- Describe how the participant's decisional capacity will be assessed as the study proceeds in order to evaluate any deterioration in the participant's level of capacity to consent.
- Will the participant's decisional capacity be assessed as the study proceeds in order to evaluate any improvement in the participant's level of consent capacity?
- List the individuals from whom permission will be obtained (e.g. close relative, legal guardian, legally authorized representative appointed in a medical durable power of attorney) and describe the process for assent of these research participants.
- Describe how this authority to provide consent will be confirmed.

IV. *Study Timelines*

Include the expected duration of the study and of participation. Consider including a flow diagram for clarity.

V. *Study Location(s)*

Describe the sites or locations where your research team will conduct the research

- Identify where research procedures will be performed, including any laboratory sites conducting analytical procedures.
- For research conducted outside of UNM and its affiliates describe:
  - Site-specific regulations or customs affecting the research outside of UNM

Local scientific and ethical review structure

International research: If your study is conducted outside of the US, please provide appropriate support or permission letters. Describe investigator safety; data/sample safety, storage, and transferring; relationship with the communities; other information as appropriate.

VI. *Participant Compensation*

Describe any reimbursement/compensation to participants including amounts and payment schedule (class credit, merchandise cards, transportation, money, etc.). Describe why the proposed amount is reasonable and appropriate for the participant's time. If your study includes multiple visits, include a description of prorating and equal payment. Note: Consult your department official for reporting requirements associated with cash or merchandise cards distributed to research participants.

VII. *Study Resources*

Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met. Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical/psychological care, and any support services.

Describe other resources available to conduct the research:

Feasibility of your recruitment plan/access to potential recruits

Facilities

Availability of all resources that participants might require as a result of participation in human research. Include contact information, where applicable.

VIII. *Unanticipated Problems*

Describe process for reporting any unanticipated problems to the IRB. See http://www.hhs.gov/ohrp/policy/advevntguid.html. Discuss injury compensation if applicable.

EXPECTED RISKS/BENEFITS

I. *Risks*

State any psychological, physical, social, or legal risks and assess their likelihood and seriousness.

Examples:

Is there potential for emotional stress, boredom, or fatigue?

If there is a potential for participants to become upset, and thus require psychological or medical attention as a result of the research procedures, then a means of supplying this attention must be addressed.

Is there potential for a loss of confidentiality about the information given by the participants and how serious would loss of confidentiality be for the participant? Consider breach of confidentiality or privacy as a risk for all study participants.

Does the research create potential social stigmatization, physical harm to participants such as potential abuse, legal action by authorities if participant information, responses to survey questions, etc., become known outside of research?

Are there potential risks to the participant related to the political, social, or economic context in which they live?

Are there economic burdens that the participant will encounter?

State the plan for preventing or minimizing risks (e.g., screening to assure appropriate selection of participants, identify standard of care procedures, sound research design, safety monitoring and reporting).

Include provision for psychological or medical attestation, if required as a result of research procedures or means for referral for such services.

II. *Benefits*

Describe the potential benefits that individual participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Clearly indicate if there is no direct benefit to participating in the study.

Human Subjects Interactions

I. *Target Population*

Identify the participant population being evaluated by the protocol. If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. Provide rationale and justification for including any of the populations listed below:

Vulnerable populations:

- Developmentally disabled
- Diminished decision-making capacity
- Economically disadvantaged
- Educationally disadvantaged
- Foster system
- Minors/Children under 18 years of age
- Pregnant women
- Prisoners
- School-based population

Special populations:

- Court-ordered treatment
- Elderly/aged
- Illiterate
- Institutionalized
- Patients
- Psychotherapy
- Private psychotherapist
- Self-referral
- Substance abuse treatment
- Terminally ill patients
- Traumatized
- Victims of abuse

Other populations:

- Employees
- Females (excludes males)
- Foreign (non U.S. resident)
- Foreign (U.S. resident)
- Healthy (non-patient)
- Male (excludes females)
- Minorities
- Non-English speaking populations
- Physically handicapped
- Public officials
- Religious cohort
- Students

II. *Inclusion and Exclusion Criteria*

Describe and list inclusion and exclusion criteria.

III. *Participant Enrollment*

Provide the maximum target enrollment number of participants. Give a specific number, do not give a range.

IV. *Recruitment and Screening Procedures*

Describe screening and recruitment plan:

- Describe methods that will be used to identify potential participants, including chart review if applicable
- Describe any advertising or recruitment materials that will be used, including verbal/electronic announcement of the research. Include recruitment document(s) as an appendix.
- Describe when, from where, and how potential participants will be recruited:
  - PI/collaborators will recruit his/her/their own patients/clients/students/employees.
  - PI/collaborators will recruit individuals unknown to them (for example, snowball sampling, social network – personal or electronic, direct approach in public situations, random digit dialing).
  - Recruitment database (individuals have previously given permission to be contacted for research).
  - PI will send an IRB-approved letter to colleagues asking for referrals. If patients, clinical personnel will make initial contact. If the patient is interested, the patient will contact the PI or (with permission of the patient) the treating physician will invite the PI to talk with the patient about enrollment.
  - PI will send an IRB-approved letter to colleagues asking him/her to send out IRB approved general "Dear Friend" letters describing the research study. The PI may draft the letter with the treating physician's signature but may not have access to the patient names or addresses for mailing. If the PI wants the letters to be personalized (Dear Mr. Doe), the personal information would have to be entered by the treating physician.

Describe what happens with screen failures and any data obtained from screen failures.

V. *Privacy of Participants*

Privacy refers to the study participant and provisions for making them feel at ease and in control of with whom they interact (e.g., the prevention of 'eavesdropping' or observation by non-study team members). Describe the steps that will be taken to protect participants' privacy including privacy protections during recruitment, consent, and data collection. Indicate how the research team is permitted to access any sources of information about the participants. If PHI is being collected, HIPAA authorization is required unless a waiver is granted.

STUDY DATA

I. *Data Management Procedures*

Outline the process for data procurement.

Describe source documents and how data will be collected from source documents and incorporated into the database.

Describe who will have access to the data and how data will be handled/maintained in a secure manner.

II. *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 arrangements for data analysis. If a study incorporates qualitative rather than quantitative methods, indicate this and describe qualitative analysis.
Describe how the data will be examined and statistically analyzed to answer the objectives.

III. *Quality Control and Quality Assurance*

Describe how data will be evaluated for adherence with the protocol and for accuracy in relation to source documents.
Describe who is responsible for the evaluation of data quality and how frequently this will be done.

IV. *Participant Confidentiality*

Describe how the participant's confidentiality will be maintained.
Describe who will have access to the data.
Provide justification for use of personally identifiable data or private health information (PHI).
Describe whether a Certificate of Confidentiality will be required. Some research involving human participants could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; or the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. In such cases, the IRB suggests that the investigator apply for a "Certificate of Confidentiality" from the Department of Health and Human Services (DHHS). The certificate protects researchers against being compelled to disclose the identity of their participants in any legal proceeding. See http://grants.nih.gov/grants/policy/coc/appl_extramural.htm.

V. *Participant Withdrawal*

Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection. Describe any conditions in which the investigators would withdraw a participant from the study.
Describe what will happen to any data obtained from withdrawn participants.

PRIOR APPROVALS/REVIEWED AT OTHER IRBS

Indicate if this project is being reviewed by another IRB. Attach a copy of this approval to this application or submit it when you receive it.

REFERENCES

Cite supporting material organized in a standardized bibliographical manner.