INSTITUTIONAL REVIEW BOARD
RESEARCH PROPOSAL APPLICATION

The New Mexico Highlands University (NMHU) Institutional Review Board (IRB) has been charged with the responsibility of screening all studies that employ human participants conducted under the auspices of New Mexico Highlands University. This form is to be used for both expedited and full reviews:

Please complete all items on this application. When complete, the application can be submitted via email to the IRB chair, Dr. Lara Heflin (lheflin@nmhu.edu).

This application can be used for two types of IRB review:

1. *Expedited Review*. If your proposed study involves only minimal risk to human participants, the study may be eligible for Expedited Review. The committee chair reserves the right to require Full Committee Review should s/he deem the risk to human participants more than minimal, or if the study involves research with a protected population or class (see below). The committee chair may take up to two weeks to evaluate your proposal before taking action.
2. *Full Committee Review*. If your study may create more than minimal risk to human participants, it will require Full Committee Review by the IRB at its next scheduled meeting. If the study needs Full Committee Review, it needs to have been submitted two weeks prior to the next scheduled Full Committee meeting in order to be added to the agenda for review. You will be notified and informed of the date and time of the next meeting. You may attend, but attendance is not required. Full IRB meetings generally convene monthly during the Fall and Spring semesters. The IRB committee generally does not have planned meetings during the Summer.
    a. Protected populations and classes - If your application includes any of the following populations or components, it is not eligible for Expedited Review. A Full Committee Review of your application is necessary.
        i. Research activities involving: minor subjects, except in the case of i) Educational Research Conducted in Educational Settings and ii) Survey/ Interview/ Observational Research as defined in Code of Federal Regulations, Title 45, Part 46.101); pregnant women (where pregnancy is the focus of the research); prisoners; fetuses in utero; or persons incompetent to provide informed consent.
        ii. Research involving the use of medical, academic and other personal records (including psychiatric records) without consent.
        iii. Research involving the use of tissue obtained at autopsy.
        iv. Research involving Native American populations.

1. Title of investigation (if deception is involved, provide the actual title of investigation *and* the title provided to participants):

2. Name of Principal Investigator (PI):

3. Email, telephone number, and NMHU Academic Department of PI:

4. If PI is a NMHU student, provide name, email, telephone number, and NMHU Academic Department of Faculty Sponsor:

5. Other persons/agencies involved in project (identify status: graduate, undergraduate, agency, etc.):

6. Description of the Purpose of the Study: (1500 character limit):

7. Description of participant population (750 character limit):

8. Recruitment – describe how you plan to recruit participants, include any recruitment materials you intend on using (500 character limit):

9. Estimated number of participants required:

10. Describe the Procedures to which each participant will be exposed. Attach a copy of any data gathering instrument(s), otherwise provide a detailed description here (1000 character limit):

11. Source of project funds:

12. Provide an assessment on the extent to which participants will be exposed to stress, discomfort, or risk (physical, psychological, or social) in this proposal (750 character limit):

13. For any risks that are anticipated, then
    a. Specify the precautions to be taken (750 character limit):

b. The plans for dealing with emergent problems (750 character limit):

c. The plans for protecting gathered data and/or training of study personnel (750 character limit):

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d. An evaluation of the extent to which the benefits of the study justify the likelihood of risk or discomfort (750 character limit):

14. Deception - Will this research require participants to be uninformed, mislead, or misinformed about any aspect of the research? If so, justify the need for deception (750 character limit).

15. Debriefing and Conclusion - Summarize the information to be given to the participants at the debriefing following completion of the project or activity (750 character limit).

16. Informed Consent - Include a copy of your informed consent form with this application. Your informed consent form must contain each of the following items:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) Additional elements of informed consent. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative

17. Human Subjects Certification – All PIs must submit valid certificates with this application that indicate they have completed training for conducting research with human subjects. Human Subjects training can be completed at www.cititraining.org and complete the online training modules.

Checklist Prior to Submitting Application

1. All IRB Application questions have been answered ☐
2. Informed Consent Form included ☐
3. Human Subjects Certificates included ☐
4. Copies of questionnaires included ☐