

**NORTHERN NEW MEXICO COLLEGE
INSTITUTIONAL REVIEW BOARD**

**PROCEDURES AND GUIDELINES FOR RESEARCHERS
FOR THE PROTECTION OF HUMAN PARTICIPANTS**

I. Purpose/Policy Statement

Northern New Mexico College is committed to safeguarding the rights and welfare of human participants in all research under its sponsorship and to serve as their protector on behalf of the community of persons of which the College is a part. (See Office of Science and Technology Policy, "Federal Policy for the Protection of Human Participants," *Federal Register*, Vol. 56, No. 117, June 18, 1991).

Therein, the Institutional Review Board for the Protection of Human Participants (hereafter referred to as the "IRB") of Northern New Mexico College is created to provide an independent determination concerning:

- A. how the rights and welfare of individual research participants are safeguarded;
and
- B. whether these participants are placed at risk; and, if risk is involved, whether:
 - 1. the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept such risks;
 - 2. the rights and welfare of any participants are protected;
 - 3. legally effective informed consent will be obtained by adequate and appropriate means;
 - 4. the conduct of the activity will be reviewed at timely intervals.

II. IRB Membership and Qualifications

Federal regulations state that an IRB must have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must possess the professional competence necessary to review specific research activities and must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Any IRB regularly reviewing research involving a vulnerable category of participants must include at least one person primarily concerned with the welfare of these participants.

Further, the IRB must consist of: at least one person with an advanced degree, equivalent professional certifications, or experience in fields in physical science or life science; at least one person with an advanced degree or equivalent professional certification in a non-science field;

and at least one person who is not affiliated with Northern New Mexico College to act as a community representative. This unaffiliated member should be knowledgeable about the local community and willing to discuss issues and research from that perspective.

All members from non-science fields and community representatives to the IRB are required to complete a formal on-line training on protecting human research participants provided by the National Institute of Health Office of Extramural Research prior to serving on the Board.

A. In regard to IRB membership at Northern New Mexico College:

1. The IRB will consist of five (5) members. The Provost/Chief Academic Officer will appoint the members of the IRB according to Code of Federal Regulations (CFR) guidelines. One member of the IRB will be an individual not employed by the College or independent on the College for facilities who will also be appointed by the Provost. In addition to the five members, the Provost will appoint at least one alternate who will serve on the board in cases where regular members must recuse themselves from voting.
2. Members will be identified by name, position and earned degrees as evidence of their qualification to serve on the IRB. This information will be made available to the College community at the start of the academic year.
3. No member of the IRB shall be involved in the review of an activity in which he/she has a professional responsibility or a conflicting interest except to provide information requested by the IRB.
4. A majority of the IRB membership must be present for IRB deliberations to commence. A majority of those present shall be necessary for approval of an application.
5. The Provost will appoint the IRB chairperson.
6. Each member of the committee will be appointed to a term of three years. Initial appointments will be staggered to prevent complete turnover every three years.
7. Individuals with competence in special areas may be invited to assist in reviewing proposed projects requiring expertise beyond that available on the IRB. These individuals may not vote with the IRB and will not be counted in determining the existence of a quorum.

- B. Meetings/Record Keeping - The College is responsible for seeing that adequate documentation of IRB activities is maintained. This will include, at a minimum, copies of all research proposals reviewed, minutes of IRB meetings, actions taken, and the basis for requiring changes in or disapproving research. IRB records must be maintained for at least three years after completion of the research. Such records must be reasonably accessible by authorized representatives of the department or sponsoring agency.

The IRB will meet monthly or as needed, and will consider applications that have been submitted at least 10 days prior to the scheduled meeting. In exceptional cases, the IRB may conduct business via telephone, mail, or e-mail.

III. Research Studies Requiring Review

Research proposals and activities are defined, independent of source of funding, as those that include data collection procedures and testing that involve human participants. The scope of this policy includes, but is not limited to, surveys, case studies, experimentation, testing, and other sources of data collection requiring the involvement of human participants.

All research activity involving students of the College as participants is covered by this policy as is research conducted or supervised by faculty in their professional capacity as members of the faculty.

Further, it is recognized that faculty serving in the role of researchers still enjoy a privileged status with students and, therefore, care must be exercised to ensure that there is no appearance of pressure in securing student consent to participate in research activity.

To this end, any research activity involving human participants, whether conducted at NNMC or under the sponsorship of the NNMC at another location, must be reviewed and approved by the IRB before project approval will be granted.

- A. Principal Investigators (PI) and their responsibilities - The Northern New Mexico College IRB will accept, review, and approve research activities only for studies by, or including members of the faculty, staff, student body, or administration of NNMC. All student applications (e.g. students preparing master's thesis) must be sponsored by a faculty or staff member familiar with the student and the proposed activity. Principal Investigators shall:
1. be responsible for complying with all IRB decisions, conditions, and requirements. PIs are responsible for reporting the progress of the research to the IRB and/or appropriate institutional officials as often as, and in the manner prescribed by the IRB but no less than, once per year.
 2. immediately notify the IRB and the department chairperson of any injury (physical, psychological, or social) suffered by a subject because of his or her participation in a research activity.

3. make provisions to keep records, documents, and informed consent forms for at least three years following the completion of the project or activity, or for a longer period as judged necessary. PIs must retain adequate records relating to IRB approved research for a period of at least three years following completion of the research. No records related to the project or activity may be destroyed without approval of the IRB which shall consult with the State Division of Archives and Records Management concerning record retention schedules.
 4. take proper measures to insure confidentiality and security of all information obtained from the participants. A written explanation of these measures must be included with the application for review.
- B. Student Research - All undergraduate and graduate students intending to perform research using human participants must follow the procedures set forth by the IRB except when the research is a classroom demonstration guided by a faculty member in which the goal is to teach research techniques by acquiring anonymous data. In this instance the faculty member will have the responsibility of overseeing the collection of the data and ensuring that the students comply with all ethical guidelines established by NNMC. All other research (e.g., master's theses, honors projects, independent projects) must be reviewed by the IRB. All student applications must be sponsored by a faculty member who has expertise in the area of research and is willing to serve as an advisor.
- C. Course-Related Research - Research that is conducted solely as an instructional technique in a course does not require IRB approval. It is assumed that all instructors who use this instructional technique are well versed in the ethical treatment of human participants and are knowledgeable of all IRB policies concerning the ethical treatment of human participants. If the purpose of course-related research is to advance knowledge in a particular field or discipline and the possibility exists that the knowledge will be disseminated beyond the classroom, then the faculty member is required to seek the approval IRB.

IV. Definition of Human Participants and Human Research; Minimum Risk; Informed Consent; IRB Approval

- A. *Research* is defined as any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the knowledge base. Activities whose sole purpose is related to course or program development are not considered research.
- B. *Human Participants* - The IRB has been established to protect the welfare of all human participants including fetuses, children, adults, and the deceased. All individuals affiliated with Northern New Mexico College (including faculty, staff, administrators, and students) must obtain IRB approval for any research they conduct with human participants whether or not the participants are affiliated with NNMC.

If an investigator plans to collect data from or about participants outside of NNMC, he/she must receive approval from the IRB and, if applicable, the other institutions' IRBs.

- C. *Minimal Risk* - The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination.
- D. *Informed Consent* - All human participants must give their consent to participate in research. It is the responsibility of the investigator to provide potential participants with information that would allow them to make an informed decision as to whether they are willing to participate. An agreement to participate in research constitutes a valid consent only if it is given voluntarily. This element of informed consent requires conditions free of coercion and undue influence (e.g. there should be no sanctions against individuals who choose not to participate).

No exculpatory language should be used anywhere in the consent form. All potential participants must be told the following:

1. that they will be participating in research;
2. the purpose of the research;
3. the expected duration of the participant's participation;
4. the procedures to be followed;
5. any foreseeable risks or discomforts the participant may suffer;
6. the benefits to the participant and others that may occur as a result of the research if applicable;
7. appropriate alternative procedures or courses of treatment that are open to the participant if applicable;
8. the extent to which confidentiality and anonymity will be maintained;
9. the amount of compensation or medical treatment that is available for research that involves more than minimal risk if applicable;
10. whom to contact (principal investigator) with any questions they may have, e.g., name and telephone number of the principal investigator and faculty sponsor where applicable;
11. that participation is voluntary, and that the participant may withdraw at any time without suffering a penalty; and

12. that participation does not imply that an employer-employee relationship exists between the participant and the state of New Mexico, Northern New Mexico College, the principal investigator or any other project facilitator. If participants are your own students, a statement that class-standing will not be affected in any way based on participation.

Consent is given by signing a written statement that includes the above elements. If participants are minors or unable to give consent (due to a mental disability or other impairments) consent must be obtained from the legal guardian.

There may be instances where the integrity of the research could be compromised by adhering to the above informed consent requirements. In such a case, modifications to the informed consent may be requested by the investigator but all modifications must be approved by the IRB.

A copy of the informed consent form must be included with each application submitted to the IRB.

- E. *IRB Approval* - Approval is given to research that complies with the institutional and federal requirements concerning the ethical treatment of human participants. Approval by the IRB does not indicate the quality of research, only that it is in compliance with the established policies.

V. **Procedures for Submitting an Application for Full Review**

- A. Preparing an Application for Review - PIs shall prepare protocols giving complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective participants and ensure that pertinent laws and regulations are observed. Examples of informed consent forms must be included with the protocols and applications.

Any individual intending to conduct research involving human participants, whether or not the research is supported by a grant, contract, or fellowship from any public or private agency must file an IRB application in order to determine whether the activities proposed require formal IRB review.

If a grant or contract application is involved, an IRB application must be sent directly to the IRB no later than seven (7) business days after the due date of the grant or contract application and allow at least twenty five (25) business days for the review process. After the review process, the application will either be approved, denied, or revisions and a resubmission may be requested. Applications received during the Summer months or Winter months between Fall and Spring academic terms will not be reviewed until the first IRB meeting of the following Fall or Spring academic terms. All research involving more than minimal risk (as defined above) or those involving extramural funding must be reviewed by the IRB.

- B. Application Preparation - All applications must include a completed Application for Review of Research Form. All research protocols (i.e., the purpose of the research, the recruitment of the participants, the procedures the participants will follow, etc.) must be explained in sufficient detail such that the IRB can make an informed decision. A copy of all surveys, questionnaires, and standardized tests must accompany the application.

- C. Consent Form Preparation – All application must include a copy of the Informed Consent Form. Applications that do not contain an Informed Consent Form will be returned to the applicant without consideration by the IRB.

VI. Research Exempt From Full Review

As per the *Federal Policy for the Protection of Human Participants: Notices and Rules* (56 FR 28001), certain types of research are exempted from a full IRB review. Responsibility for granting an exemption rests solely with the IRB. If the PI believes that the research falls into an exemption category, he/she must indicate in the application form the category for which the research is being considered for exemption.

Exemption categories (45 CFR 46. 101b)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless: (i) information is obtained in such a way that the participants can be identified directly or through identifiers linked to the participants; and (ii) the participant's responses, if they became known, could place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing, reputation, or employability. All research involving survey and interview procedures is exempt when the participants are elected or appointed public officials or candidates for public office. Confidentiality must be maintained when required by federal statute.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified.

4. Research and demonstration projects which are funded by a federal agency and determined to be exempt by the agency head and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service

programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment of benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

VII. Expedited Review

The IRB may use an expedited procedure to review

1. research proposed by the reviewer(s) to involve no more than minimal risk, or
2. minor changes in previously approved research.

Under an expedited review procedure, the review may be carried out by the IRB chairperson and by one or more experienced reviewers designated by the chairperson from among the members of the IRB. The IRB will adopt a method to keep all members advised of research proposals which have been approved under the expedited procedure. No research proposal may be disapproved under the expedited review process; those research proposals which are not approved under the expedited process must be forwarded to the IRB for consideration under full review. The IRB will inform the principal investigator if the research is exempt in writing.

VIII. Action by the IRB

Applications submitted no later than 10 days prior to the monthly meeting will be discussed by the IRB members in order to determine if the proposed research complies with the ethical guidelines established by the IRB. The committee may take one of the following actions:

- A. Approve as Submitted - The PI will be sent an approval notice including a statement of his/her responsibility to report any kind of adverse reactions to the research protocol and/or changes to the research protocol to the IRB.
- B. Approve contingent on Specific Revisions - The PI will be sent a memo describing the revisions requested. The revised application will be forwarded to the IRB Chair. If the revisions are satisfactory, the PI will receive written notification of approval. If the PI disagrees with the requested revisions, he/she will present in writing the reasons for non-compliance. The Chair will review the response and, if necessary, will request the PI to appear at the next IRB meeting

to answer specific questions and explain in further detail the reasons for non-compliance. The PI will be notified in writing of the decision of the IRB.

- C. Disapprove - The PI will be sent a disapproval notice describing the reasons for disapproving the application. Disapproval usually occurs when the IRB determines that the risks of the protocol outweigh the benefits to be gained. The PI may respond to the disapproval notice in writing and may submit a revised application for review at a subsequent meeting.

IX. Institutional Endorsement

Many funding agencies require certification that research involving human participants is conducted according to the ethical guidelines outlined in this document and has been approved by an authorized IRB. The Provost, in consultation with the IRB Chair will be responsible for submitting such certification to funding agencies.

X. Reapproval Process/Continuing Review

Federal regulations require that all research involving human participants be reviewed at least every 12 months as long as the project is continued. PIs will be responsible for submitting re-approval applications every 12 months.

XI. Protocol Changes

If the PI plans to make changes to the research protocol, the changes must be communicated to the IRB. If the changes necessitate changes in the Informed Consent Form a revised Informed Consent Form should be forwarded to the IRB. The PI will be notified in writing as to whether the changes have been approved by the IRB.

XII. Adverse Reactions

If any participants have suffered harm as a result of participation in the research, the PI must notify the IRB immediately. The IRB will review the matter and may decide to terminate approval if it appears that participants are at risk of psychological and/or physical harm.



President

Date: _____

10/3/2017

| IRB Membership | | | |
|-----------------------|-------------------------|--------------------------|--------------|
| Member | Anthony Sena (Chair) | asena@nnmc.edu | X5430 |
| Member | Jee Hwang | jee.hwang@nnmc.edu | X2181 |
| Member | Teresa Beaty | teresa.beaty@nnmc.edu | X2212 |
| Member | Ashis Nandy | ashis@nnmc.edu | X2249 |
| External Member | Zachary A Leonard | zleonard@lanl.gov | 505-699-4053 |
| Alternative | Mario Izaguirre-Sierra | Mario.izaguirre@nnmc.edu | X5474 |
| Alternative | Sushmita Nandy | sushmita.nandy@nnmc.edu | X5468 |
| Alternative | Darlene Hess | drhess@nnmc.edu | X2278 |
| Alternative | Rose Cavalcante | rcavalcante@nnmc.edu | X5463 |