NEBRASKA INDIAN COMMUNITY COLLEGE

Institutional Review Board

Standard Operating Procedures

Introduction

Research at, or sponsored by Nebraska Indian Community College (NICC), will be well designed and properly executed. All researchers will abide by ethical principles of respect for persons, beneficence, and justice. All researchers will respect the cultures of the sovereign nations from whom we are chartered (i.e., Santee Sioux Nation and Omaha Tribe of Nebraska and Iowa) and all Indigenous peoples when designing and carrying out proposed research. All researchers will follow the guidelines and procedures for protection of human subjects outlined by NICC and carried out by the Institutional Review Board (IRB). Data collection cannot begin without IRB approval. Research results will be shared with Nebraska Indian Community College.

Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects. An institution involved in biomedical or behavioral research should have in place a set of principles and guidelines that govern the institution, its faculty, and staff, in the discharge of its responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by the institution, regardless of the source of funding [Federal Policy §__.103(b)(1)].

Ethical Principles

a. Respect for Persons

Individuals should be treated as autonomous agents and those persons with diminished autonomy should be entitled to protection. This principle is applied by obtaining informed consent with due consideration of privacy, confidentiality, and additional protections for vulnerable populations

b. Beneficence

Individuals should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. This principle is applied by appropriately weighing risks and benefits

c. Justice

All individuals should equally share the burdens and benefits of research. This principle applied by the equitable selection of research subjects

An important aspect of respect for persons is that individuals should be treated as being autonomous. Potential study participants should be given information about a study without undue influence or coercion, so that they can make a reasoned decision on their own. However, there are certain individuals who are particularly subject to influences that may limit their ability to make decisions freely (e.g., children and prisoners). They are considered to be vulnerable and are entitled to additional protections. Respect for persons is particularly relevant to the consent process. In striving for beneficence, harm should be minimized and benefits maximized. Investigators should attempt to seek alternative ways of investigating. All hypotheses should lead to a more favorable risk-benefit ratio.
Justice involves the equitable treatment of human subjects. Thus, care should be taken to avoid performing studies that might cause excessive risks or benefits for one group over another group. Justice is highly relevant to the selection of research subjects for a study.
In accordance with the above ethical principles, in reviewing grant and research proposals, NICC Institutional Review Board must consider all of the following:

a. The rights and welfare of the individual or group involved
b. The minimization of risks to human subjects by using procedures consistent with sound research design
c. The appropriateness of the procedures and methods employed to the aims, underlying hypotheses and goals of the research
d. The adequacy and appropriateness of the consent form and the process by which consent would be obtained
e. The medical, social or psychological risks to the subject and the reasonableness of these risks in relation to the anticipated medical and/or psychosocial benefits of the investigation, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result
f. The fairness and equitability of the inclusion of individuals according to race, ethnicity, gender, and age

These policies and procedures are based on the shared commitment by the Nebraska Indian Community College and its faculty, students, staff, and stakeholders to the dignity and welfare of individuals who participate in its research.

Summary of Procedures

- The Institutional Review Board at Nebraska Indian Community College convenes quarterly on the calendar year.
- Board meetings to discuss, comment, and review IRB applications will be held:
    - In person on the NICC campuses - Online if further discussions are required on applications, or if a quorum cannot be reached to make binding decisions at a seating meeting.
    - Due to COVID-19, ALL meetings will transition to the online meeting platform.
- Upon receipt of the proposal, the IRB will verify and make sure the packet is complete. Applications should be submitted at least a week prior to the next scheduled meeting.
- Then the chair will forward the application to designated reviewers or the entire board who will examine the documents and determine if the project is eligible for approval or disapproval.

- A decision will be rendered by the committee at the next scheduled meeting based on review comments and after any requests and clarification demands about the project have been addressed by the PI.
- A majority decision will be rendered on an application after review and deliberation.
- Review Procedures are based on the type of application sort: Full, Exempt, and Expedited
- Review timeline:
    - For exempt projects and projects qualifying for expedited review (no foreseeable risk), the researcher(s) and, if applicable, the faculty sponsor, will be notified within five working days after necessary information is received by the IRB Chair.
    - For projects requiring full IRB review, notice of the Board's decision will be mailed within seven working days after the IRB meeting.

Types of IRB Review Applications:

1. Exempt Review: An exempt review procedure consists of a review of research involving human subjects by the Chair or Member of the IRB.
    a. Research conducted in established or commonly accepted education settings, involving normal education practices, such as (a) research on regular and special education strategies; or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
    b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers liked to the subjects.
    c. Research involving survey or interview procedures, except where the following conditions exist: (a) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception when the respondents are elected or appointed public officials or candidates for public office.
    d. Research involving the observation (including observation by participants) of public behavior, except where the conditions named in number three above exist.
    e. 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 subjects cannot be identified, directly or through identifiers linked to the subject.

2. Expedited Review: An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. For full list of categories, see Appendix A.
    a. Clinical studies of drugs and medical devices only when certain conditions are met.
    b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
    c. Prospective collection of biological specimens for research purposes by noninvasive means.
    d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
    e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.
    f. Collection of data from voice, video, digital, or image recordings made for research purposes.
    g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
    h. Continuing review of research previously approved by the convened IRB.
    i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and

documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Regular Review: A regular or full review procedure consists of a review of research involving human subjects by the full IRB.
    a. Any research involving the use of vulnerable subjects. A vulnerable subject is defined as follows: "Vulnerability refers to the risks that researchers request their subjects to undertake in relation to the ability of the subjects to make fully informed consent. Populations routinely considered to be vulnerable include: children; prisoners; pregnant women; non-English speaking people; the mentally handicapped; those subjects engaged in illegal activities; people who are under medical treatment for an illness that is relevant to the risk they are being asked to assume by the researcher; and subjects who may risk retribution by a person with authority over them as a consequence of participation or non-participation in the study.
    b. Any research involving more than minimal risk, either mental or physical to the subject. Examples of protocols of this type may include surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subject's behavior, including sexual practices, studies that solicit information regarding instances of child or sexual abuse suffered by the subject, criminal activities and for studies regarding eating disorders. Examples of studies that involve more than minimal physical risk to the subject include stress testing, drug and alcohol use by the subjects and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject. This should not be considered an exhaustive list of studies that may involve more than minimal risk to the subject. The investigator should include a comprehensive statement of the potential risk/benefit ratio to the subject for consideration by the committee.

IRB Membership and Structure

The NICC Institutional Review Board is a regularly meeting committee that reports to NICC's Institutional Assessment Committee. The board shall consist of an interdisciplinary team of at least five members (e.g., scientific, financial, HR, student environment and academics). A priority shall be placed on diversity of IRB membership, including race, gender, cultural backgrounds, sensitivity to community issues and community attitudes, and multiple professions representing the scope of the research and programs under IRB review.

The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. The qualifications of each alternate member must be comparable to those of the primary member to be replaced. Alternate members are invited to attend IRB meetings and may participate in discussions but may vote only when replacing a voting member of the IRB. When an alternate member replaces the primary member, the alternate member will

receive and review the same material that the primary member received. IRB meeting minutes shall document instances in which an alternate member replaces a primary member.

IRB members should be committed to safeguarding the rights and welfare of human subjects. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair or the College President may be asked to step down from IRB membership.

IRB Meetings and Quorum

A goal to assure the effectiveness of the review process shall be to schedule IRB meetings at least quarterly throughout the calendar year. The IRB chair shall ensure that meetings are scheduled in advance and that an agenda and all pertinent documents are made available to members (and alternates if appropriate) with sufficient time prior to meetings. Individual meetings may be cancelled by the IRB Chair or his/her designee, do to:

1) Insufficient applications or other matters requiring convened board review
2) College holiday
3) Inability to secure a quorum for attendance
4) Other reasons (such as inclement weather) that make a scheduled meeting unnecessary or otherwise inappropriate

Except when an exempt or expedited review procedure is used, the IRB shall review initial or continuing studies at convened meeting at which a quorum is present. A quorum for a convened IRB meeting is 50% of the voting primary membership (including alternate members who may replace voting members) plus one. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the meeting shall end or be suspended and the study shall be tabled.

Additional quorum policies are:

1) The IRB chair or his/her designee count toward the quorum
2) If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum
3) Members absenting themselves due to conflicts of interest may not be counted toward quorum requirements

Although the physical presence of IRB members at meetings is encouraged, a member or alternate member (if appropriate) may be considered present if participating through teleconferencing or videoconferencing. In this case, the member or alternate member must have received all pertinent material prior to the meeting and must be able to participate activity and equally in all discussions and votes. Minutes of such meetings shall clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements.

Conflict of Interest

Objectivity is essential to the conduct of research and the basis for public confidence in the integrity of IRB oversight. Research must not be led by interests that might undermine scientific integrity and ethical values.

The primary duty of the NICC's IRB must be to protect the rights and welfare of human subjects while conducting unbiased research. The College, and the IRB must consider whether specific financial relationships or other considerations create conflicts of interest in research and grant funded program that may bias judgment and affect the rights and welfare of subjects and, if so, to determine what actions must be taken to protect those subjects. It is within the discretion of the IRB to decide whether conflicts of interest are manageable, and if so, to devise a management plan for the protection of human subjects participating in the study.