NORTHWEST INDIAN COLLEGE
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INSTITUTIONAL REVIEW BOARD MANUAL:

PURPOSE and POLICIES.

This manual complies with the Office of Human Resource Protection's (OHRP's) regulatory guidance on written procedures in "Guidance on Written IRB Procedures" at http://www/hhs.gov/ohrp/policy/irbgd107.pdf .

I. PURPOSE of the NWIC IRB

Researchers seeking to conduct research in American Indian/Alaska Native communities must respect and understand the unique concerns and approval procedures specific to each individual Tribe or Nation where the proposed research is to be conducted, in order to proceed in an ethical and culturally sensitive manner. They must recognize that they are working on sovereign lands and that cultural and legal issues differ from those in their own community or academic setting. They must become informed about the requirements in place at the specific Tribe or Nation of interest. They must also insure that the appropriate Tribal representative or group has issued approval, in writing, before proceeding with any research activities.

Institutional Review Boards (IRBs) review research protocols to assess the harms (risks) and benefits for the people to be studied. Each proposal is reviewed using criteria listed in the Code of Federal Regulations (CFR) Title 45 Part 46, "Protection of Human Subjects" (1991, with minor updates since). Research proposals are reviewed for safety, subject confidentiality, degree of benefit, and the need for and quality of informed consent. Title 45 CFR Part 46 considers primarily the effects of research on individuals, including the three basic principles of: respect for individual persons; potential harms and benefits to individuals; and justice for individuals.

The Northwest Indian College (NWIC) IRB, similar to most American Indian/Alaska Native-based IRBs, goes further and considers the effects of research on *Tribes / communities* as well, including respect for communities, potential harms and benefits to communities, and justice in and for communities. The NWIC IRB recognizes and respects the sovereignty of the American Indian and Alaska Native people to make decisions about research on their lands. The IRB expects the research to maximize the benefits to the community as a whole and to individual volunteers, to contribute to community's own powers and abilities, to support community goals of health and wellness, to promote healthy lifestyles and improve self-esteem, and to fulfill traditional responsibility of caring for future generations.

The NWIC IRB thus encourages research that honors, respects, and incorporates what several tribal Elders have expressed to the NWIC IRB, that the research:

1. **Protects** and **benefits** their Tribe;
2. **Respects** elders and their Tribe's traditional knowledge;
3. **Respects** and **promotes** their Tribe's sovereignty, power, strengths and survival;
4. **Promotes** resiliency and **assists** their Tribe to identify, address and solve problems;
5. **Incorporates** traditional spiritual beliefs and practices;
6. **Promotes** Tribal/community pride and ownership of the project and its results;
7. **Expresses** pride in their Tribe's role in the project; and
8. **Expresses** hope for their Tribe's future.

II. POLICIES OF THE NWIC IRB

Structure of the IRB

A. IRB Membership

The NWIC President will appoint all members and officers of the IRB. The IRB will have nine (9) Members, and include at least one member whose primary expertise is in a non-scientific area ***and also*** is enrolled in a federally-recognized tribe. Highest recruitment priority will be interested Elders from the Lummi Nation and other Tribes with whom the IRB has formal agreements to review research.

B. Meetings

The IRB will review proposed research at convened meetings in which:

- a quorum of at least five (5) members is present; and
- at least one (1) member is present whose primary background, interest, and expertise is in a non-scientific area ***and also*** is enrolled in a federally-recognized tribe.

C. IRB Agreements with Other IRBs and Outside Researchers

The IRB may sign formal agreements:

- with tribal and other IRBs by an IRB Authorization Agreement, and
- with outside researchers to review their research by an Individual Investigator Agreement.

Research proposed by outside researchers to study NWIC staff, students, or faculty must first be approved by the NWIC President and IRB.

IRB Review of Research Plans or Protocols

D. Criteria for "Human Subject Research"

The IRB will review research that meets regulations by NWIC, federal government, and funding agency, or is covered by NWIC's Federal Wide Assurance (FWA). The IRB will include as "human subjects" people both who are now living and also who were once living in the past, whether or not they are or were identified to or by a researcher at any time.

E. Criteria for IRB Approval of Research

The IRB will consider each of the following factors of the proposed research when reviewing research protocols:

1. Study design;
2. Potential Harms (or risks) and Benefits both to individuals and also to tribes and communities (hereafter "communities");
3. Equitable Selection of individual and community participants/subjects;
4. Identification, Confidentiality, and Privacy of individuals and communities;

5. Process and content of Informed Consent by potential individual and community participants/subjects;
6. Plans for dissemination of reports, presentations, and publications; and
7. Additional IRB-specific decisions.

F. General Requirements of Voluntary Informed Consent

The IRB will ensure that the research:

- presents information on research goals and activities clearly and understandably to potential individual and community participants/subjects or to their legal parent or guardian; and
- asks potential participants/subjects to voluntarily consent, or (if a legal parent or guardian) to voluntarily give permission and (if the legal minor participant/subject) to voluntarily assent, whether to take part.

The IRB may decide to waive these requirement under limited circumstances, and only when permitted by the federal regulations.

G. Documentation of Voluntary Informed Consent

Voluntary informed consent/permission/assent will be documented by:

- the researcher using written consent/permission/assent documents that had been approved by the NWIC IRB; and
- the participants/subjects, or minor participants/subjects and their legal parent or guardian, signing the appropriate consent/permission/assent documents.

The IRB may decide to waive this requirement under limited circumstances, and only when permitted by the federal regulations.

H. The Application to the IRB for Approval of a Protocol

The IRB will have a formal process for researchers to use when applying to the NWIC IRB for approval of their protocol. The process will include one or more Application Form(s) developed by the IRB. The IRB will provide technical assistance to researchers about the Application process and Form[s].

I. Phases and Types of IRB Review

The IRB will have explicit criteria and procedures that meet regulatory and NWIC IRB requirements for:

- Pre-review and technical assistance;
- “Not human subject research”;
- “Exempt” status;
- Eligible for Expedited Review;
- Full Review of protocols; and
- Review of “phase 1” of protocols planning to develop their human participant/subject involvement in “phase 2.”

J. IRB Review of Changes in Approved Research Activities

The IRB will have procedures to review the potential harms and benefits of researcher-proposed changes to the protocol after the IRB approved the original

protocol, and to review and approve minor modifications separately from major modifications.

K. Confidentiality of IRB Meetings

The content of the IRB *discussions* and of the applications being reviewed will remain confidential. IRB *decisions* will be available to the public, as will the minutes of the IRB meetings (except otherwise confidential or private information will be redacted from the minutes).

L. IRB Review of Reports, Presentations, and Publications

To minimize harms to communities and individuals, the IRB will review and approve proposed reports, presentations, and publications derived from the research projects.

M. Research Close-Out and Transfer

The IRB will have formal procedures to close-out the IRB's oversight of the research. The IRB may decide to transfer oversight to another IRB before close-out, if the other IRB will observe both the federal and NWIC IRB regulations, and if the other IRB will ensure continued minimization of harms and maximization of benefits to individuals and communities.

IRB Reporting

N. IRB Reports

The IRB will periodically report information about NWIC IRB activities to the NWIC President, to interested tribal governments, and to organizations for which it reviews research. The IRB will report changes of IRB membership to Office for Human Research Protection.

O. IRB correspondence

The IRB will maintain up-to-date written and e-mail correspondence to and from researchers, and as needed to and from other IRBs, tribes, and institutions.

P. Retention and Storage of IRB records

The IRB will retain in a secure area:

- records of research by NWIC student researchers, for three (3) years;
- records of research by other researchers, for seven (7) years; and
- records of research involved in litigation and that had a serious violation or problem, for an indefinite period without transfer to another storage facility.

IRB Management of Special Problems

Q. Complaints or Grievances, and Allegations of Non-Compliance

The IRB will respond within five (5) working days to complaints or grievances by participant[s] or others about the research, and to allegations of researcher non-compliance. The IRB will observe legal due process, and will comply with federal and NWIC requirements.

R. Problems, Deviations, Violations and Adverse Events

The IRB will respond within five (5) working days to problems, deviations, or violations of the approved protocol, and to serious adverse events. The IRB will observe legal due process, and will comply with federal and NWIC requirements.

S. Suspension or Termination of Prior IRB Approval

The NWIC IRB has the authority to suspend or terminate "for cause" a prior IRB approval of an active research project. The IRB will:

- first, investigate the alleged cause;
- then, determine if there was/is a problem, and (if any problem) its severity; and
- finally, decide IRB action, if any.

The IRB will observe legal due process, and will comply with federal and NWIC requirements. The decision to **permanently** suspend or terminate prior approval of research activities will be made by only a convened IRB meeting with quorum.

T. Report Suspension or Termination of Prior IRB Approval

The IRB will report within five (5) working days to the researcher, and to specific applicable federal, funding, tribal, and NWIC officials if the IRB suspends or terminates prior IRB approval of an active research project.

U. Lapse of IRB approval of research due to Failure to Renew

The IRB's approval of a research project ends on the date of the next periodic review deadline, and no more than 365 days since last approval, whichever comes first. The IRB will quickly provide technical assistance to the PI to minimize both potential harms and disruption of the research and to maximize potential benefits of the research. The IRB will observe legal due process, and will comply with federal and NWIC requirements

V. Appeal of IRB decisions

A researcher may appeal a NWIC IRB's decision to the NWIC IRB. The NWIC IRB will consult with a Resource Person (*see section C of Appendix 4*) before and while responding the appeal.