Institutional Review Board Membership Manual

I. Introduction and Definitions

Federal law requires that all research protocols involving human subjects must be reviewed and approved by an IRB, even if the proposal is not externally funded. The North Idaho College IRB must review any human subjects research conducted at NIC regardless of outside approval. This includes all research with human subjects conducted at NIC including faculty, staff and/or students as research subjects or by NIC faculty, staff and or students at any location. Research conducted as part of a classroom exercise MAY be exempt from IRB review. However, the IRB Chair or designee must make that decision based upon a protocol review.

According to federal law, an IRB is a requirement for all entities conducting research on human subjects. These terms are defined in the law as follows (46.102, a-j):

> **Research:** *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes."*
>
> **Human Subjects:** *"living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."*

According to the American Association for Public Opinion Research, "most surveys do meet the federal definition of research."

II. Scope of Authority

It should be well understood that NIC is not a four-year research institution; therefore, the focus of the NIC IRB will be necessarily different than at such universities. The IRB will not, as a unit, seek out opportunities for research, but will exist to review NIC research in order to protect human research participants (whether participation is known or not) at NIC. Examples of common community college research efforts that should be reviewed by an IRB include:

- Research projects with or without funding

- Internal student surveys, whether for the entire student population or a special population
- Internal employee surveys, whether for the entire population or a special population
- External surveys for students or employees may qualify for the IRB exemption process
- Data-informed research projects that use student record-level data to inform the institution about patterns of student behavior such as course success and matriculation studies
- Student research project assignments that involve human subjects for courses such as Psychology, Biology, Sociology, Anthropology, Nutrition, Fitness, and others

Under both federal and college policy, the IRB has the authority to approve proposed research, to require revisions in proposed research to ensure it includes safeguards to protect subjects, or to refuse to approve proposed research if the applicant cannot or will not revise the protocol to prevent identified risks to the subjects.

Researchers with protocols that lack protection for human subjects will be offered guidance to make necessary modifications to augment approval. No proposal will be rejected without recommendations for modification and resubmission.

Once the research is approved the IRB has the authority to monitor the research to ensure that research is conducted as approved. Additionally, multi-year research projects are required to be reviewed and re-authorized according to the review process outlined below.

All IRB reviews begin with an application (see application procedures below). Only the IRB Chair, or designee, can determine which type of review is applicable. Regardless of level of review, a record must be kept by the IRB of all research involving human subjects at NIC.

Following an initial review of the application describing the nature of the research, a proposal may be:

- *Exempt* from further IRB review
- Appropriate for an *expedited review* by the chairperson of the IRB or a subcommittee of the IRB
- Subject to *full review* by the *full* IRB

III. Membership

The President's Cabinet appoints full-time IRB members, who must have been employed for at least one academic year, for three-year terms. The IRB must be comprised of "at least five members" from "varying backgrounds" (46.107a). Further, at least one member must have a background with "scientific areas" and at least one member must have experience primarily with "nonscientific areas" (46.107b). Additionally, at least one member must not be otherwise affiliated with the institution, not part of the immediate family of a person who is affiliated with the institution" (46.107c). It may be beneficial for an IRB to include a direct link to the institutional leadership group, as "The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice" (46.107a). No IRB member may participate in the review of a proposal in which he or she has a conflict of interest. Specialists may be invited by the IRB to provide input, if the subject matter is deemed outside the expertise of the sitting IRB members.

The following positions are recommended to fulfill the membership of the NIC IRB:

- AVP for Planning and Effectiveness, Facilitator
- Community member not affiliated with NIC, but with a research background
- Two faculty members from different areas of study
- Two staff members with different research backgrounds
- One recorder for meeting minutes

IV. Procedures

A. Human Subjects Research Training

- IRB members must participate in approved human research protections training at the time of committee appointment, and renew training at least once every three years.
- Recommended sources for this training will be made available by the Associate Vice President for Planning and Effectiveness.

B. Review Process

- IRB review requests will be acknowledged by e-mail within three business days of receipt.
- IRB Chair or designee will evaluate the protocol and determine the required level of review

- IRB Chair or designee will inform the Principal Investigator of the IRB decision via e-mail within 30 days.

C. Meetings

- IRB members shall set their own meeting schedule, but must accommodate review submissions not less than 30 days after a submission has been received.
- For meetings where a full board review of a protocol takes place, the principal investigator (or delegate) may be asked to attend to present a review of the research and answer any relevant questions posed by the committee.

D. Documentation

- IRB will keep adequate records of all protocols and requests for continuing review, including decisions made.
- Minutes of each IRB meeting will include the names of members who attended, actions taken by the board, the outcome of voting on research protocols including numbers of votes for and against, the rationale for requiring modifications to a protocol or informed consent process, and a summary of discussion of controversial issues and their resolution.
- Records of all protocols, requests for continuing review, and records of IRB reviews and meeting minutes will be kept on file for a minimum of three years.

V. Research Misconduct in Human Subjects Research

The IRB will promptly report any potential research misconduct involving human subjects by Principal Investigators affiliated with NIC to the Associate Vice President for Planning and Effectiveness. Additionally, the IRB is required by federal law to promptly report certain incidents to the Office for Human Research Protections (OHRP), a division of the Department of Health and Human Services. These incidents include unanticipated problems in research that involve risk to subjects or others, serious or continuing noncompliance with federal policies or the requirements or determinations of the IRB, and any suspension or termination of IRB approval. The Principal Investigator and the Associate Vice President for Planning and Effectiveness will receive a copy of the report submitted by the IRB to OHRP.

NOTE: All references in this document taken from the requirements set forth by

the *Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects*.