North Idaho College Institutional Research Board Guide for Researchers

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 designate (including Facilitator) 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 (45.46.102, 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. IRB Proposal Submission and Review Procedures

An application for IRB review includes a completed IRB Application for Human Subjects Research and all supporting materials. Supporting materials typically include all recruitment materials, consent forms, survey instruments, debriefing statements, and data use agreements. IRB review submissions should be sent to irb@nic.edu, and should include one electronic copy of the application and all supporting materials.

IRB review requests will be acknowledged by e-mail within three business days of receipt. The IRB Chair or designate (including Facilitator) will evaluate the protocol and determine the required level of review and inform the Principal Investigator of this decision within 30 days of initial review request. Based upon

the Code of Federal Regulations, Title 45 Part 46, NIC will utilize the following categories of review:

(a) Exempt from Review
Projects that are traditionally exempt from an expedited or full IRB review include normal educational practices, educational tests, surveys, instruments, or observation of public behavior when subjects cannot be identified and the information gathered will not put the subjects at risk, research using existing data, documents, and records if publicly available and the subjects cannot be identified, and the evaluation of public benefit service programs.

Protocols that are developed for either instructional purposes or teaching research methodology and are not designed to contribute to generalized knowledge may be exempt from review. Under these circumstances the instructor assumes ethical and professional responsibility to monitor the progress of all research in the classroom.

Applications that are exempt from review will be notified by e-mail as soon as that decision is made. For projects that are approved as exempt, annual resubmission to the IRB is encouraged.

Studies that fit any of the categories below do not need IRB review.

1. **Data collection** for internal departmental, school, or other NIC administrative purposes. Examples: teaching evaluations, customer service surveys.
2. **Service surveys** issued or completed by NIC personnel for the intent and purposes of improving services and programs of the college of for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary.
3. **Information-gathering interviews** where questions focus on things, products, or policies rather than people or their thought regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.
4. **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom. Example: instruction on research methods and techniques.
5. **Biography or oral history** research involving a living individual that is not generalizable beyond that individual. *Epistemologies*, such as, *Narrative* and *Oratology* must be considered by the IRB.
6. **Independent contract for procedures** carried out for an external agency. Examples: personnel studies, cost-benefit analysis, customer satisfaction studies, public park usage, IT usage, and software development.

7. **Research involving cadavers,** autopsy material or bio specimens from now deceased individuals.
8. **Innovative therapies** except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the wellbeing of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals.) *Note: When innovative therapies differ significantly from routine practice it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.*
9. **Quality improvement** projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge **and** use the data derived from the project to improve or alter the quality of care of the efficiency of an institutional practice. Any individual who is unsure whether or not a proposed quality improvement project should be classified as research should contact the IRB for guidance. If the data is re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.
10. **Case histories** which are published and/or presented at national or regional meetings are **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.
11. **Publicly available data** do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB it they are uncertain as to whether the data qualifies as "publicly available."*
12. **Coded private information or biological specimens** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data / specimens back to individual subjects. If the data / specimen provider has access to the identity of the subjects (e.g. subjects' names, addresses, etc.), the investigator must enter into an agreement with the data / specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These projects require verification from the IRB.*

13. Some examples of **Non-Engagement in Research** include: when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research. *Note: the examples above are not an all-inclusive listing.*

(b) Expedited Review

Expedited review covers research that poses no more than minimal risk to human subjects. "Minimal risk" is the risk encountered in everyday life. Expedited review may be employed for minor changes in previously approved research,

collection of small blood samples, collection of data through noninvasive procedures routinely employed in clinical practice, collection of data from voice, video, digital or image recordings, the use of materials that have been collected solely for non-research purposes, research on individual or group characteristics or behavior, or research employing survey or interview methodologies. Expedited review may be used for these types of research regardless of the age of the subjects.

Expedited reviews are completed by the IRB Chair or designate (including Facilitator) and at least two additional IRB members. Expedited reviews are generally completed within two weeks. Minor modifications to the protocol may be requested by IRB members participating in the review during this review process. The applicant will be notified by e-mail as soon as a decision is made.

Protocols that are approved through an expedited review are valid for one year. Researchers may request an extension beyond one year if necessary by contacting the IRB Chair or designate (including Facilitator) and submitting an updated application.

(c) Full Review

Full IRB review includes research where the subjects can be identified and the data collected poses risks to the subjects, in terms of their financial or social standing, employment or criminal or civil liability. It also includes research that involves more than moderate exercise, research on individual or group characteristics or behavior that employs deception of the subjects or where they are placed under psychological or emotional stress, and research that poses potential physical, psychological, social, legal or other risks to the subjects.

Research targeting vulnerable populations, including minors (unless an expedited review is allowed), pregnant women and fetuses, institutionalized populations, individuals with mental disabilities, and economically and educationally disadvantaged persons will receive a full review to ensure that adequate protections are in place.

A protocol that will be reviewed by the full board will be assigned to the next available board meeting on the schedule, but less than 30 days from submission in order to insure adequate time for the board members to conduct their review. The research protocol will be distributed electronically to all board members two weeks prior to the meeting. A majority of board members must be present at the review meeting. The Principal Investigator will be invited to present the research protocol and answer questions at this meeting. The protocol must be approved by a majority of the members present. Members of the IRB who vote to disapprove a protocol shall submit their reasons in writing to the IRB Chair or designate (including Facilitator).

Protocols that are approved through a full review are valid for one year. Researchers may request an extension beyond one year if necessary by

contacting the IRB Chair or designate (including Facilitator) and submitting an updated Protocol Application.

III. Changes to Existing Protocols, Adverse Events, and Renewal Procedures

Regardless of the level of review or existing approval, any changes made to the research protocol must be submitted to the IRB for review in writing prior to their implementation, as they may affect the status of a review. Additionally, the Principal Investigator is responsible for reporting any adverse or unanticipated events that may occur during their research to the IRB immediately, and no later than one week from their occurrence.

In order to submit changes to an existing protocol, Principal Investigators should complete the Project Revision/Amendment Form with proposed changes to their IRB Protocol Application and submit it electronically to the IRB Chair or designate (including Facilitator).

In order to apply for a renewal of an existing protocol, the Principal Investigator should notify the IRB no later than 30 days prior to the expiration of their approval. Renewal requests should include the submission of an electronic copy of the approved IRB Protocol Application with changes added to the file. In addition, any new recruitment materials, consent forms, or other supplementary materials should be submitted with the renewal application.

It is the Principal Investigator's responsibility to keep an electronic copy of their approved IRB Protocol Application in order to facilitate the submission of changes and renewal requests.

IV. Human Subjects Research Training

Faculty members, staff, students, and Principal Investigators contemplating research proposals involving human subjects are encouraged to participate in approved human research protections training. Recommended sources for this training will be made available by the IRB Chair or designate (including Facilitator).

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*.

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