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 ᵀMe ou pɹɔɹ$gi! U oµ ˢ

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.

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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*.