AR 1: IRB and Protection of Human Research Participants

1.1 Fundamental Principles

Research that involves gathering information about living human beings must be evaluated by our Institutional Review Board (IRB) to assure that appropriate measures are followed to protect the safety and well-being of human subjects. NS provides a Federalwide Assurance that all research conducted by faculty, staff, and students is reviewed for compliance with federal regulations, whether the research is funded by federal dollars or not.

If issues related to human participant research are not covered by this policy, the IRB relies on the federal Common Rule.

The NS IRB adheres to the following principles:

Respect for persons: Individuals must be treated as autonomous agents who take part in research voluntarily and with adequate information about the purpose and procedures of the research. Individuals with diminished autonomy (including children, prisoners, and those who are in some way incapacitated) have a right to be protected.

Beneficence: Researchers are obliged to secure the well-being of their subjects. Possible benefits from participating in research should be maximized for individual participants; possible harms should be minimized for the individual participants.

Justice: Risks and benefits of research should be distributed equally across various groups. The burden of serving as research participants should not largely fall on groups such as the poor or imprisoned while other groups primarily benefit from the results.

1.2 Projects Requiring IRB Review

Research involves any proposed systematic plan of investigation involving human participants that a) meets the definition of generalizable knowledge when b) the results will (or may) be shared with audiences outside of the University. These activities must be submitted to the IRB for review. Projects that are not research or do not involve human participants do not require an IRB application.

Interacting with a person does not necessarily make them a research participant. People providing factual information about organizations or other groups are not themselves participants. However, if they provide information about how they *perceive or feel about* an organization or group, they are human participants. Online surveys generally count as interaction or intervention with people and thus require IRB review.

The IRB Handbook provides more information on what qualifies as research.

1.3 Responsibilities for Protecting Human Participants

The University's responsibilities for compliance with applicable laws, regulations, guidelines, and policies include:

1. Developing and maintaining a coordinated system of compliance that includes activity review and approval, monitoring, reporting, and enforcement.
2. Developing and maintaining a system of auditable files and information for the benefit of NS and external oversight.
3. Providing administrative and consultation services for offices, departments, and individuals to assist in establishing compliance.
4. Providing educational services to faculty, staff, and students so they can better meet requirements.
5. Coordinating activities with other units so NSU can meet its obligations in the most uniform, effective, and efficient way possible.
6. Providing a communication link between agencies that issue compliance requirements and NS personnel.
7. Submitting assurances, reports, and other required communications to appropriate federal and state agencies.

The IRB is obligated to inform researchers of procedures related to compliance with federal regulations, including the following:

1. Conducting training programs and distributing materials for investigators, such as annual briefings to faculty and deans and guidance on preparing protocols.
2. Including specific directions in approval letters (such as cautioning that significant changes in the protocol must be reviewed by the IRB).
3. Random audits of research records.

The IRB serves at the discretion of the Provost. It is not an independent unit of the Academic Faculty Senate or any other body.

1.4 IRB Membership and Meetings

The IRB must contain no fewer than 5 members of varying backgrounds. At least one member must have a scientific background and at least one must have a non-scientific background. In addition, the IRB must contain one member from outside the University. At its discretion, the IRB may invite non-members with relevant expertise to review individual proposals. Every effort will be made to ensure sufficient diversity to represent a wide array of perspectives and expertise on protecting human participants.

The Vice Provost of Faculty Affairs and Research serves as the IRB Administrator, a non-voting member.

IRB members are not compensated but may count active contributions, review, and attendance toward University service requirements.

1.4.1 Membership Selection

The IRB Administrator consults with the academic deans annually regarding appropriate faculty nominations. The IRB Administrator identifies an appropriate external IRB member.

1.4.2 Terms

Members, including the IRB Chair, are appointed for one-year terms, which may be renewed.

1.4.3 Meetings

The IRB meets in person or remotely as needed to review proposals and complete trainings.

1.4.4 IRB Administration

The IRB includes three administrative positions.

1. *IRB Chair*: The Vice Provost for Faculty Affairs and Research appoints a chair to preside over meetings.
2. *IRB Administrator*: The IRB Administrator documents all IRB protocol submissions, archives correspondence, schedules meetings as needed, and records notes at meetings. They also maintain IRB forms, the IRB Handbook, and the IRB Canvas page and provide an annual summary of proposal submissions and IRB activities to IRB members.
3. *Institutional Official*: The Provost serves in this role and signs NS's Federalwide Assurance.

1.5 Categories of Research

Federal regulations recognize three categories of research. The NS IRB determines which category applies to proposed research projects. All proposed human participants research must be submitted for IRB approval.

Human participants in Expedited or Full Board review projects must be covered by an approved informed consent process.

1.5.1 Exempt (Revised Common Rule, 45 CFR 46.104)

The IRB Administrator has the authority to determine that a project is Exempt. No additional IRB review is needed for Exempt projects unless changes are made to the protocol. Review and approval generally occurs within 10 days of submission.

1.5.2 Expedited Approval (45 CFR 46.110a)

This category is for research in which participants will experience no more than minimal risk. The IRB Administrator, in consultation with the IRB Chair and one or more IRB

members with relevant experience, may review and respond to Expedited proposals without full committee action. PIs should allow 20 days for a response.

1.5.3 Full Board Approval

This category is for research that presents greater than minimal risk to participants. Proposals requiring Full Board action are considered at an IRB meeting. The PI may be invited to discuss the proposal with the IRB. Allow up to 30 days after submission for approval; review may be delayed during off-contract periods for 9-month academic faculty.

1.6 Applications and Review

Proposals must receive IRB approval before any aspect of the project begins, including recruiting or collecting data. Information gathered for other purposes may be used for research purposes after IRB review.

IRB proposals are submitted online and must include the materials listed in the IRB Handbook. The handbook, all forms, and a submission link are available on the IRB Canvas page: https://nsc.instructure.com/courses/2079313

Proposals are accepted on an ongoing basis. The IRB Administrator tracks new proposals. If the IRB Administrator is out of the office or otherwise unavailable for a significant time period, the IRB Chair is notified and will respond to emails sent to irb@nevadastate.edu

1.6.1 Grant-Funded Projects

NS does not require IRB review before a proposal for grant funding is submitted. However, it should be made clear in the proposal that the NS IRB will review the project and recommend changes, if needed, before the project may begin. Some external granting agencies require IRB approval before they fund a project.

1.6.2 Review and Approval

The IRB reviews and has authority to approve, require modifications to, or deny research activities covered by this policy. The IRB requires that informed consent information given to participants complies with 45 CFR 46.116. The IRB may require that additional information be given when, in the IRB's judgment, it would meaningfully add to the protection of participants' rights and welfare. The IRB may require documentation of informed consent or may waive documentation.

In cases requiring Full Board review, decisions are made by majority vote when a quorum is present. The IRB Administrator provides the minutes of the meeting, the outcome of the vote, and a summary of the proposal to the IRB members within 10 days of a Full Board decision.

The IRB Administrator or Chair notifies PIs in a letter, sent via NS email, of the IRB decision to approve or deny the proposal or of modifications required to secure IRB approval.

If the IRB denies a proposal, the letter will include the reasons for its decision and will give the PI an opportunity to respond in person or in writing. The IRB attempts to work with PIs to modify research activities so they may be approved.

1.6.3 Expiration and Renewal

The IRB determines the period of approval and notifies the PI of the expiration date, if any. The PI is responsible for submitting a renewal application if research will continue beyond the expiration date. Research activity must stop at the expiration date if renewal has not been approved.

Full Board and some Expedited protocols must be renewed annually. This will be stated in the approval letter.

1.6.4 PI Changes

If the PI ceases to be responsible for the study, the approval automatically expires. If a new PI wants to continue the study, renewal is required. If the project is externally funded, most federal agencies require prior approval before replacing the designated PI; the Office of Grants Award Services can assist with the agency notification process.

1.6.5 Modifications

If a change is made such that the research methods or techniques are significantly different or new risks are evident, the modification form must be submitted for review and approval. In general, any change that alters the risk/benefit balance or modifies informed consent in some way requires approval.

Minor modifications to a protocol that do not alter the risk to participants do not require IRB approval. PIs may email irb@nevadastate.edu to clarify whether a proposed change requires review.

1.6.6 Continuing Review and Audits

Federal law requires the IRB to conduct at least an annual review of certain categories of non-Exempt research (45 CFR 46.109.(e)). The IRB has authority to observe or have a third party observe the consent process and the research.

Continuing review is not required for the following:

- Exempt projects.
- Expedited projects that present no more than minimal risk.
- Projects in which data collection has ended and only data analysis continues.

The PI is responsible for initiating required annual renewals. Renewal applications should be submitted at least 20 days before the IRB approval expires.

1.7 Unanticipated Problems

The Common Rule refers to but does not define “unanticipated problems involving risks to subjects or others.” The federal Office of Human Research Protections (OHRP) considers unanticipated problems to include any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given the research procedures and the characteristics of the participant population.
2. Related or possibly related to participation in the research.
3. Suggests that the research places participants or others at a greater risk of harm (physical, psychological, economic, or social) than was previously known or recognized.

The PI is responsible for reporting any serious unanticipated problem or adverse event to the IRB Administrator and IRB Chair within 5 days. After seeking emergency assistance, any life-threatening adverse events must be reported to the IRB within 24 hours. If applicable, the PI may be required to report a serious unanticipated problem to the sponsoring federal funding agency within the time frame specified in the award document.

1.7.1 IRB Responses

The IRB may respond to unanticipated problems in any of the following ways:

1. Terminate the research immediately.
2. Require the research to temporarily stop while an investigation is conducted.
3. Allow the research to continue while an investigation is conducted.
4. Ask for a detailed written explanation at any time.

Within a reasonable time, the Provost (as the Institutional Official) will consult with the IRB Chair and IRB Administrator and decide how, when, and whether to report to the federal OHRP.

1.8 Noncompliance

Acts and/or allegations of non-compliance with applicable rules, procedures, policies, and/or regulations are initially reviewed by the IRB. Following an investigation, there may be an official notice of findings and/or an official determination of non-compliance. Corrective action(s) may be proposed and/or required at any time.

In any instance where IRB requirements are not being followed, the IRB Administrator will inform the PI and the Provost, who will enforce the requirements. If the PI does not comply, the Provost will terminate the research project. This will be accompanied by a letter to the PI stating the reason for the action. The IRB can recommend that the Provost initiate disciplinary action under Chapter 6 of the NSHE Code.

If any federally funded research is found to be in violation of any of the federally mandated portions of this policy, or of appropriate federal regulations regarding the

protection of human participants, the IRB will report to the appropriate agency on behalf of the PI, if the PI fails to report.

1.9 Records Retention

PIs must make and keep written records of IRB reviews and decisions and must obtain and keep documentary evidence of informed consent by participants or their legally authorized representatives. These forms must be retained on file by the responsible individual for at least 3 years after the end of the project.

IRB records pertaining to individual research activities are not accessible to people other than IRB members and the PI, except for purposes of audit or inspection by federal agencies and appropriate University administrators to assure compliance with the Uniform Federal Policy. All records are accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

The NS IRB follows a "FY + 3 years" retention period as set forth in the NSHE Procedures and Guidelines Manual, Chapter 16. Copies of protocol applications, decision letters, and other materials are kept for 3 years after the end of a project.

1.10 Related Information

Forms, the IRB Handbook, a link to the submission portal, and other materials are available on the IRB Canvas site: https://nsc.instructure.com/courses/2079313

Contact the IRB at irb@nevadastate.edu

- Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"
- Code of Federal Regulations, Title 45 (45 CFR 46) Protection of Human Subjects, Revised June 18, 1991, and Title 34 (34 CFR 97) Protection of Human Subjects
- Federal IRB guidelines: http://www.hhs.gov/ohrp/ and http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979
- National Research Act, Public Law 93-348, July 12, 1997
- Nevada Revised Statues, NRS 159.0805 – State law regarding research with wards of the State: https://www.leg.state.nv.us/nrs/
- Office of Human Research Protections page on Unanticipated Problems & Adverse Events (http://www.hhs.gov/ohrp/policy/advevntguid.html)

1.10.1 Revision History

- Revisions approved by Dr. Vickie Shields on 7/14/2022 and President DeRionne Pollard on 3/06/2023.