Nevada State University Research and Grants Policy

Division of Academic Affairs

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Introduction

This document contains policies and procedures related to the conduct of research and grant activities at Nevada State University. The Division of Academic Affairs maintains and approves items in this document. Throughout this document, “NS,” “NSU,” “Nevada State,” and “the University” refer to Nevada State University.

Chapter 1: IRB and Protection of Human Subjects

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.

In the event that issues related to human subjects research are not covered by this policy, the IRB relies on the Common Rule.

The NS IRB adheres to the following principles:

Respect for persons: Individuals must be treated as autonomous agents who enter into 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 the research should be maximized for individual subjects; possible harms should be minimized for the individual subjects.

Justice: Risks and benefits of research should be distributed equally across various human groups. The burden of serving as research subjects 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 subjects that meets the definition of generalizable knowledge when 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 subjects do not require a protocol application.

Interacting with a person does not necessarily make them a human subject. People providing factual information about organizations or other groups are not subjects. However, if they provide information about how they *perceive or feel about* an organization or group, they are human subjects. Online surveys generally constitute interaction or intervention with people.

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

1.3 Responsibilities for Protecting Human Subjects

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 within NS so the institution can meet its obligations in the most uniform, effective, and efficient way possible;
6. Providing a communication link between agencies issuing compliance requirements and NS personnel; and
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 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 human subjects protection.

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.

1.5 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.

1.6 Categories of Research

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

Human subjects in Expedited or Full Board review projects must be covered by an approved informed consent process. The PI must provide the IRB Administrator with a legally effective informed consent form annually.

1.6.1 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.

1.6.2 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.

1.6.3 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.

1.7 Applications

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

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 do require IRB review before they will fund a project.

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

1.8 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 subjects complies with 45 CFR 46.116. The IRB may require that additional information be given to subjects when, in the IRB's judgment, the information would meaningfully add to the protection of subjects' 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 at least a quorum is present. The IRB Administrator will provide 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 disapprove 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.

1.9 Expiration, Renewal, Modification, and Continuing Review of Approved Proposals

The IRB determine 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.

1.9.1 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.

1.9.2 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.

1.9.3 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.

1.10 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 subject population;
2. Related or possibly related to participation in the research;
3. Suggests that the research places subjects 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 timeframe specified in the award document.

1.10.1 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 timeframe, 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.

1.11 Noncompliance

Acts and/or allegations of noncompliance 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 noncompliance. 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 be asked to 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 to the Provost initiation of 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 subjects, the IRB will report to the appropriate agency on behalf of the PI, if the PI fails to report.

1.12 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 subjects 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.

1.13 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)

Chapter 2: Use of Students' Education Records in Research

[Revisions in review under GP2. Existing policy in policy library.]

Chapter 3: Research Misconduct

3.1 Ethical Standards for Research and Other Scholarly Activities

Federal regulations require institutions of higher education receiving federal grants and contracts to have a policy for handling allegations of Research Misconduct. The NSHE Code Chapter 6 prohibits faculty from engaging in "acts of academic dishonesty, including but not limited to cheating, plagiarism, falsifying research data or results, or assisting others to do the same." This policy applies to all research, whether funded or not.

NS employees must uphold these ethical standards when performing their activities:

1. Project Directors (PDs) and Principal Investigators (PIs) must comply with all internal and external requirements for protecting human subjects, project personnel, and the public, and for ensuring the welfare of laboratory animals;
2. Scholars and researchers must not fall below accepted professional standards in proposing their activities, carrying them out, and reporting their results. Primary data must be scrupulously collected and retained;
3. All participants in scholarly/research activity must avoid both intentional and negligent behavior which may result in violation of the law, dishonesty or fraud, fabrication, falsification, plagiarism, or artificial intelligence misconduct;
4. Cooperative efforts require mutual attention to the integrity of the scholarly processes involved. Joint authorship entails joint responsibility. Each author claiming shared credit must be aware of the risk of shared discredit;
5. Senior scholars and researchers must avoid exploiting junior colleagues and students. Claims of credit, co-authorship, and intellectual property should reflect actual involvement, responsibility, and effort;
6. PDs and PIs performing sponsored scholarly/research activity (supported through a grant, contract, or gift) must be knowledgeable of and responsive to internal and external requirements of financial responsibility and accountability to avoid misallocation, misappropriation, or misuse of sponsor/donor funds;
7. Some funding agencies require training on responsible conduct of research. PIs and grant-funded personnel must complete all such trainings required by the agency funding their project;
8. Present or proposed activities or financial or professional relationships that present a conflict of interest (such as those that affect the objectivity of research or scholarship, give the appearance of being motivated by private financial gain, or involve unacceptable commitments for a scholar/researcher) must be disclosed and approved by the employee's supervisor and the Provost prior to committing to such activities or relationships.

3.2 Procedures for Addressing Allegations of Research Misconduct

Allegations of misconduct will be dealt with according to the provisions of the NSHE Handbook Title 2, Chapter 6.

1. Allegations of misconduct should be reported in writing to the Executive Vice Provost (EVP) or designee. Allegations must be signed by the submitter. Wherever possible, the allegation must specify details including the date, time, place, people involved, witnesses, and circumstances of the alleged misconduct.
2. The EVP will conduct an inquiry according to NSHE Code Chapter 6, Section 6.8.2, and, based on this inquiry, will determine whether a valid allegation of misconduct exists. The EVP will make a recommendation to the Provost to dismiss the allegation, accept an informal resolution (as described in NSHE Code Section 6.8.2(c)), or conduct a hearing (NSHE Code, Section 6.8.2(d)). If the Provost determines that a hearing is warranted, a hearing will be conducted in accordance with NSHE Code, Sections 6.8.2, 6.8.3, and 6.9. The Provost may instead dismiss the complaint, accept an informal resolution, or determine that a reprimand or warning is appropriate, as set forth in NSHE Code Chapter 6, Section 6.6.
3. Appeals of the Provost's decision must be filed in writing to the EVP by the respondent within 7 calendar days of receiving the decision. Appeals will be conducted according to the requirements and processes described in NSHE Code Chapter 6, Section 6.13.
4. Maintaining confidentiality is the guiding principle for this process, to protect both those making allegations and those against whom allegations are made. As few people as necessary shall be involved in the process, and all records dealing with an allegation, its review, and its disposition shall be treated in accordance with NSHE Code Chapter 6, Sections 6.14 and 6.15. As required by federal law, the EVP shall (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair proceeding and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The EVP should use written confidentiality agreements or other mechanisms to ensure that the recipient of any documentation does not make any further disclosure of identifying information.
5. As required, the EVP will issue a final report to the federal Office of Research Integrity (ORI) and/or any external funding agency. Federal ORI jurisdiction only extends to projects for which Public Health Service funds are requested or provided. If reporting to the ORI is required, documentation to substantiate the investigation's findings will be made available to the federal ORI Director, along with a description of any pending or completed administrative actions against the respondent. The EVP will also determine whether law enforcement agencies, professional licensing boards, editors of journals in which falsified reports/data may have been published, or collaborators on the work in question should be notified.
6. Records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceedings.

7. If an allegation of research misconduct is made regarding a project involving human subjects, the EVP must inform the IRB administrator, which may conduct an audit or other oversight activities according to IRB policy.

3.3 Related Information

- NSHE Handbook Title 2, Chapter 6
- NS Institutional Review Board Policy for the Protection of Human Subjects (RE 1.1)
- NS Conflict of Interest and Compensated Outside Services Policy (HR 1)
- U.S. Office of Research Integrity (ORI), https://ori.hhs.gov/handling-misconduct

Chapter 4: Grants/Sponsored Projects

[In review under GP2. No existing policy.]

Chapter 5: Financial Conflicts of Interest (FCOI)

[In review under GP2. No existing policy.]

Appendix A: Glossary

Adverse event: An untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with participation in the research, whether or not considered related to participation in the research.

Artificial intelligence (AI) misconduct: Using artificial intelligence (e.g., ChatGPT, Bard) for scholarly works or publications without giving proper credit, or using it (even with credit) in situations in which its use has been banned.

Common Rule (45 CFR 46): Federal Department of Health and Human Services regulations regarding research with human subjects in the U.S.; all government-funded research is held to this standard.

Deidentification: Removal of personally identifying information from a dataset. This is not a single technique, but rather a collection of approaches and tools that may be used with different types of data, with different levels of effectiveness.

Directory Information: Includes a student's name; address; telephone listing; email address; photograph; declared major; enrollment status (undergraduate or graduate, full-time or part-time); dates of attendance; participation in officially recognized activities and sports; degrees, honors, and awards received; and most recent educational institution attended.

Fabrication: Making up data or results and recording or reporting them as authentic.

Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Federalwide Assurance (FWA): An institution’s agreement to comply with all federal regulations governing human subjects.

Generalizable knowledge: Exists when a study meets one or more of the following conditions:

1. Data are geared for scholars, practitioners, and/or researchers within a specified field of study;
2. Results are shared by presentation and/or publication to illuminate some topic or issue within a field of study;
3. Results are applied to some population in addition to the sample;
4. Results can be replicated by others;
5. Provides input into some field of study.

Human subject: Living human being *about* whom (not necessarily *from* whom) a researcher obtains information. Data may be obtained through interaction or intervention or may be

existing information that can be linked to an identifiable individual.

Institutional Official: Legally obligated person or entity maintaining compliance with 45 CFR 46 and other relevant regulations and statutes.

Institutional Review Board (IRB): Committee that reviews proposed research protocols to ensure the protection of human subjects.

IRB Administrator: Employee who coordinates IRB activities, reviews applications, maintains IRB files, and assists the Office of Academic Affairs in complying with federal and state laws regarding human subjects. Authorized to act on behalf of NS for Exempt projects and Expedited review.

IRB Chair: Voting IRB member appointed by the Vice Provost of Faculty Affairs and Research to preside at meetings and act on behalf of NS for Exempt projects and Expedited review.

Limited submission: Funding opportunities in which the sponsor limits the number of nominations or proposals that an institution may submit.

Plagiarism: Appropriation of another person's or entity's ideas, processes, results, or words without giving appropriate credit.

Principal Investigator (PI): Investigator responsible for ensuring that work on a project complies with applicable laws, regulations, guidelines, and policies. Sometimes referred to as Program Director.

Quorum: One more than one-half of the total IRB membership.

Research: Systematic, intentional, formalized plan of investigation designed to develop or contribute to generalizable knowledge.

Research misconduct: Dishonesty in proposing, performing, or reviewing research or in reporting results. Includes fabrication, falsification, plagiarism, AI misconduct, or other practices which seriously deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. Does not include honest error.

Student Education Records: Under the Family Educational Rights and Privacy Act of 1974 (FERPA), those records that are directly related to a student and maintained by an educational institution or by a party acting for the institution. Does not include:

1. Records that are kept in the sole possession of the maker, used only as a personal memory aid, and are not accessible or revealed to any other person except a temporary substitute for the maker of the record;
2. Records of the law enforcement unit of the University, subject to CFR §99.8;
3. Records relating to employees of the University that:

   i. Are made and maintained in the normal course of business;
   ii. Relate exclusively to the individual in their capacity as an employee, and;
   iii. Are not available for use for any other purpose;
4. Records relating to an individual attending the University who is employed as a result of their status as a student are student education records and are not excepted under this definition;
5. Records on a student who is 18 years of age or older, or is attending the University, that are:
   i. Made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in their professional capacity or assisting in a paraprofessional capacity;
   ii. Made, maintained, or used only in connection with treatment of the student, and;
   iii. Disclosed only to individuals providing the treatment. “Treatment” does not include remedial educational activities or activities that are part of the program of instruction at the University;
6. Records created or received by the University after an individual is no longer a student and that are not directly related to the individual’s attendance as a student;
7. Grades on peer-graded papers before they are collected and recorded by an instructor.

Appendix B: Approvals

- Chapter 1: IRB & Human Protections revised and approved by Dr. Vickie Shields on 7/14/2022 and President DeRionne Pollard on 3/06/2023.
- Chapter 2: Use of Students' Education Records in Research revised and approved by Dr. Sarah Frey on 5/19/2024 and President DeRionne Pollard on 5/29/2024.
- Chapter 3: Research Misconduct revised and approved by Dr. Molly Appel on 3/19/2024; Dr. Sarah Frey on 4/16/2024; and President DeRionne Pollard on 8/20/2024.