ADMINISTRATIVE POLICY

Institutional Review Board Policy for the Protection of Human Subjects (RE 1.1)

POLICY STATEMENT

Federal regulations mandate that Research that involves gathering information about living human beings must be evaluated by an Institutional Review Board (IRB) to assure that appropriate measures are followed to protect the safety and well-being of Human Subjects. NSC must also provide a Federalwide Assurance that all Research conducted by faculty, staff, and students will be reviewed for compliance with federal regulations, whether the Research is funded by federal dollars or not.

In the event that issues related to the use of Human Subjects in Research at NSC are not covered by this policy, the IRB will rely on the 45 CFR 46 as revised.

DEFINITIONS

Adverse Event: Any 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 the Human Subject's participation in the Research, whether or not considered related to participation in the Research.

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

Federalwide Assurance (FWA): An institution's official agreement to comply with all federal regulations governing Human Subjects. Also known as Institutional Assurance.

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 disseminated by presentation and/or publication in order 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 with the person, or may be existing information that can be linked specifically to an identifiable individual.

Institutional Official: Legally-obligated entity maintaining compliance with 45 CFR 46 and other relevant regulations and statues for Human Subjects Research.

Institutional Review Board (IRB): Campus committee established to review proposed Research protocols to ensure the protection of Human Subjects.

IRB Administrator: NSC employee appointed by the Provost to coordinate IRB activities, review applications, maintain IRB files, and assist the Provost in complying with federal and state laws regarding Human Subjects protection. Authorized to act on behalf of NSC for Exempt projects and Expedited review.

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

Principal Investigator (PI): Investigator responsible for ensuring that work on a project is conducted in full compliance with all applicable laws, regulations, guidelines, and policies.

Quorum: One more than one-half of the total official membership of the IRB in any given year.

Research: Systematic, intentional, formalized plan of investigation designed to develop or contribute to Generalizable Knowledge.

Working Day: Monday through Friday when College classes are scheduled and in session during fall and spring semesters.

PROCEDURES

I. Fundamental Principles

The NSC Institutional Review Board (IRB) adheres to the following principles:

A. *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 (children, prisoners, individuals who are in some way incapacitated) have a right to be protected.

B. *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; at the same time, possible harms from participating in the research should be minimized for the individual subjects.

C. *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 in certain groups such as the poor or imprisoned while other groups primarily benefit from the results of the research.

II. Projects Requiring IRB Review

Any proposed systematic plan of investigation involving Human Subjects that meets the definition of Generalizable Knowledge, the results of which will (or may) be disseminated to audiences outside NSC, must be submitted to the IRB for review. Activities that meet these conditions constitute Research even if they are supported or funded under a program that serves other purposes.

Interacting with a person does not necessarily make them a Human Subject. Humans 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 detailed information on which types of investigations qualify as Research.

III. Human Subjects Protection and IRB Responsibilities

Nevada State College meets its responsibilities with respect to complying with applicable laws, regulations, guidelines, and policies. Among these responsibilities are:

A. Developing and maintaining a coordinated system of compliance that includes activity review and approval, monitoring, reporting, and enforcement;
B. Developing and maintaining a system of auditable files and information for the benefit of NSC and external oversight;
C. Providing administrative and consultation services for offices, departments, review bodies, and individuals to assist in establishing compliance;
D. Providing educational services to faculty, staff, and students so they can better meet compliance requirements;
E. Coordinating activities with other units within NSC so the institution can meet its obligations in the most uniform, effective, and efficient way possible;
F. Providing a communication link between agencies issuing compliance requirements and NSC personnel; and
G. Submitting assurances, reports, and/or 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:

- Conducting training programs and distributing materials for investigators, such as annual briefings to faculty and deans and preparation guidance published on the IRB website;
- Including specific directions in approval letters to Principal Investigators (e.g., cautioning that significant changes in protocol must be reviewed by the IRB);
- Random audits of research records.

IV. IRB Membership and Meeting Schedule

The IRB is a committee serving at the discretion of the Provost, not an independent unit of the Faculty Senate or any other body.

Federal regulations (see 21 CFR 56.107) require IRBs to contain no fewer than five (5) members of varying backgrounds. At least one member must have a scientific background, while at least one must have a non-scientific background. In addition, the IRB must contain one member from outside the institution.

At its discretion, the IRB may invite non-members with relevant expertise to assist in the review of individual proposals.

A. *Membership*: There is no fixed number of members for the NSC IRB. However, the membership will meet the following criteria:

1. No fewer than five (5) members;
    i. One (1) of whom has a background in a scientific discipline;
    ii. One (1) of whom has a background in a non-scientific area;
    iii. And one (1) of whom is not employed at NSC.
2. The IRB Administrator is a non-voting member;
3. The Provost, or designee, shall serve as a non-voting member, and may also serve as the IRB Administrator;
4. Every effort will be made to ensure sufficient diversity to represent a wide array of perspectives and expertise on Human Subjects protection.

B. *Selection of Members*: The IRB Administrator will request annual faculty nominations from the Deans of each academic unit. The IRB Administrator will identify an appropriate non-NSC member to serve on the IRB.

C. *Term Length*: Members will be appointed for one-year terms.

D. *Meeting Frequency*: The IRB will meet face-to-face or via video-conference as needed to review proposals and complete trainings. IRB members serve without compensation.

V. IRB Administration

NSC's IRB includes three administrative positions:

A. *IRB Chair*: The Provost (or designee) shall designate an IRB Chair to preside over meetings; the Chair may be one of the members of the IRB described in IV.A, or may be an additional member. The Chair serves a one-year term, with up to two (2) year-long extensions (for a maximum of three [3] consecutive years).

B. *IRB Administrator*: The IRB Administrator documents receipt of all IRB protocol submissions. The Administrator also archives all IRB correspondence, records notes at in-person meetings, and schedules meetings.

C. *Institutional Official*: The Provost serves in this role and signs NSC's Federalwide Assurance (FWA).

VI. Categories of Research

Three categories of Research are recognized by federal regulations. The NSC IRB determines which category applies to proposed Research; therefore, all proposed Human Subjects Research must be submitted for IRB approval. The three possible categories are:

A. *Exempt* (Revised Common Rule, 45 CFR 46.104). Contact the IRB for a complete description of eligibility for exemption.
    1. The IRB Administrator has the authority to determine Exempt status. If a proposal is determined to be Exempt, the PI will be notified within ten (10) Working Days of receiving the complete protocol.
    2. Once a project is determined to be Exempt, no additional interaction with the IRB is needed unless changes are made to the protocol.

B. *Expedited Approval* (45 CFR 46.110a): For Research in which participants will experience no more than minimal risk. Contact the IRB for details on projects that qualify for Expedited review.
    1. 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. Allow twenty (20) Working Days after submission for a response from the NSC IRB.

C. *Full Board Approval*: For Research that presents greater than minimal risk to participants. Contact the IRB for details.
    1. Proposals requiring Full Board action will be considered at an IRB meeting. The PI may be invited to discuss the proposal with the IRB. Allow up to thirty (30) Working Days after submission for approval during the nine-month academic year; review may be delayed during summer and winter off-contract periods.

Human Subjects may participate in an Expedited or Full Board review project only after they are covered by an approved process of informed consent. The PI must prepare and provide the IRB Chair with a legally-effective informed consent form on an annual basis.

VII. Application Procedures

At the point that a researcher formulates a systematic, intentional plan of investigation that meets the definition of Research and involves Human Subjects, the IRB must be involved. Projects that are not Research and/or do not involve Human Subjects do not require a protocol application. Refer to the NSC IRB Handbook for detailed information on which projects require an IRB application. If you have questions at any point, contact the IRB Administrator (irb@nsc.edu) for clarification.

Proposed Research involving Human Subjects must receive IRB approval **before** recruitment of subjects, data collection, or analysis may commence. Information gathered for other purposes may be used for Research purposes, but only after IRB review. If the proposed Research requires external funding, IRB review is **not** needed before a proposal for funding or Research is submitted to a target agency. However, it must be made clear in any proposal that the NSC IRB will review the project (if funded), and recommend changes if needed, before any Research involving Human Subjects may begin.

A. *Required Materials*: IRB proposals should be submitted online and must include the materials listed in the IRB Handbook. All forms are available on the IRB website.

B. *Application Deadlines*: New proposals are due by the last day of each month for potential review at the mid-month IRB meeting.

C. *Application Review*: The IRB Administrator will check regularly for new proposals. If the IRB Administrator is out of the office or otherwise unavailable, the IRB Chair will be notified and respond in a timely fashion to questions sent to irb@nsc.edu.

The IRB Administrator maintains and edits the IRB Handbook and required forms as needed. The Handbook and all forms are published on the NSC IRB website.

VIII. Protocol Approval

The IRB shall review and have authority to approve, require modifications in, or disapprove all Research activities covered by this policy. The IRB shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. The IRB may require that information in addition to that specifically mentioned in 45 CFR.46.116 be given to subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects. The IRB may require documentation of informed consent or may waive documentation in accordance with 45 CFR.46.117.

A. *Full Board Review*: In cases requiring Full IRB review, actions will be made by majority vote when at least a Quorum is present.

B. *Notification*: The IRB Administrator or Chair shall notify PIs in a letter, sent via NSC email, of the IRB decision to approve or disapprove the proposed Research activity or of modifications required to secure IRB approval.

C. *Disapproval*: If the IRB disapproves a Research protocol, it shall include in its written notification the reasons for its decision and give the PI an opportunity to respond in person or in writing.

IX. Expiration, Renewal, and Modification of Approved Protocols

The IRB will determine the term of approval and notify the researcher of the date of expiration of approval.It is the responsibility of the Principal Investigator to submit a renewal application if Research will continue beyond the expiration date. *Research activity must cease at the expiration date if renewal has not been obtained.*

A. *Renewal of Protocols*: Renewal of Full Board and some Expedited protocols is required annually.

B. *PI Changes*: If the Principal Investigator ceases to be responsible for the study, approval automatically ceases. Should a new Principal Investigator desire to continue the study, renewal is required.
    1. If the project is funded by a federal agency, most federal agencies require prior approval before replacing the designated Principal Investigator.

C. *Protocol Modifications*: If during the course of any Research (including Exempt research), a change in plans is made so that Human Subjects are now to be used, the Research methods or techniques are significantly different, or new hazards are evident, a statement of such change in plans must be submitted to the IRB, and an approval of modifications must be obtained. In general, any change which alters the risk/benefit balance or which modifies informed consent in some way requires approval.
    1. Minor modifications to a protocol that do not alter the risk to participants do not require IRB approval.

The IRB Handbook provides details on submitting a Renewal or Modification application.

X. Continuing Review and Audits

Federal policy requires that the IRB conduct at least an annual review of certain categories of non-Exempt approved Research activities (45 CFR 46.109.(e)). The IRB shall have authority to observe or have a third party observe the consent process and the Research.

Continuing review is not required for the following:

- Projects with Expedited approval that present no more than minimal risk;
- Projects in which data collection has ceased and only data analysis continues.

The researcher is responsible for initiating any and all needed renewals. Renewal applications should be submitted **at least twenty (20) Working Days before the expiration of IRB approval**, bearing in mind the time needed for review.

XI. Unanticipated Problems

The phrase "unanticipated problems involving risks to subjects or others" is found but not defined in the Common Rule at 45 CFR part 46. The Office of Human Research Protections considers Unanticipated Problems to include any incident, experience, or outcome that meets **all** of the following criteria:

A. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol and the characteristics of the subject population;
B. Related or possibly related to participation in the Research;
C. 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 Principal Investigator is responsible for reporting any serious Unanticipated Problem or Adverse Event to the IRB Administrator and IRB Chair within **five (5) Working Days** of the occurrence. After seeking emergency assistance, any life-threatening Adverse Events must be reported to the IRB **within twenty-four** (**24) hours.** If applicable, the Principal Investigator may also be required to report any serious Unanticipated Problem to the sponsoring federal funding agency within the timeframe specified by the award document.

The IRB may respond in any of the following ways:

- terminate the Research immediately;
- require a temporary cessation of Research activity while an investigation is conducted;
- allow the Research to continue while an investigation is conducted;
- 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 Office of Human Research Protections (OHRP).

XII. IRB Internal Reporting Requirements

The IRB Administrator will provide an annual report to the IRB committee listing all protocols submitted during that period and their level of review (Exempt, Expedited, or Full Board). For proposals that require Full Board review, the IRB Administrator will provide the minutes of the

meeting(s) at which the proposal was discussed, the outcome of the vote, and a summary of the Research. This will be completed **within ten (10) working days** after Board approval.

XIII. Noncompliance

All acts and/or allegations of noncompliance with applicable rules, procedures, policies, and/or regulations are initially reviewed by the IRB. Following an investigative process, 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 during a noncompliance resolution process.

In any instance where IRB requirements are not being followed, the IRB shall inform the Principal Investigator and the Provost, who will be asked to enforce the requirements. If the Principal Investigator does not comply, the Provost will terminate the research. Such action will be accompanied by a letter to the PI stating the reason for the action. In the case of noncompliance, the IRB can recommend to the Provost initiation of disciplinary action under Chapter 6 of the NSHE Code.

If any research which is federally funded 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 shall report to the appropriate agency on behalf of the researcher, if the researcher fails to report.

XIV. Records Retention

Investigators are required to make and keep written records of IRB reviews and decisions and to obtain and keep documentary evidence of informed consent of subjects or their legally authorized representatives. Such forms must be retained on file by the responsible individual for a **minimum of 3 years** after termination of the project.

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

The NSC 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 three (3) years after the termination of the project.

FORMS/INSTRUCTIONS

The following items are available on the NSC IRB website (https://nsc.instructure.com/courses/2079313/pages/forms) :

- IRB Handbook
- IRB Submission Checklist
- Protocol Application
- Modification Request Form
- Continuing Review Form
- Closure Form

- Adverse Event Form
- Required Elements of Informed Consent

CONTACTS

OFFICE/UNIT	CONTACT	PHONE	EMAIL
Office of the Provost	Gwen Sharp	X2645	Gwen.sharp@nsc.edu
Office of the Provost	IRB Administrator		irb@nsc.edu

RELATED INFORMATION

- 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/
- Nevada State Laws for Human Research: http://www.unr.edu/research-integrity/human-research/human-research-protection-policy-manual/170-nevada-state-laws-for-human-research
- NSC IRB Handbook
- NSHE Code, Chapter 6
- Office of Human Research Protections page on Unanticipated Problems & Adverse Events (http://www.hhs.gov/ohrp/policy/advevntguid.html)

HISTORY

- NSC IRB Policy and Handbook, last revised July 2016.
- Updated in 2022 to clarify membership and meeting requirements.

APPROVAL SIGNATURES PAGE

Vicki Shields 7-14-2022

Recommendation (check one):

Office of the Provost (Provost's Signature) Date

	Denial*	X	Approval		Approval w/ condition*

3.06.2023_____

Office of the President (President's Signature) Date

Final decision (check one):

	Denied*	X	Approved

*Attach rationale for denial or conditional approval