NEVADA STATE COLLEGE
INSTITUTIONAL REVIEW BOARD (IRB) POLICY FOR
THE PROTECTION OF HUMAN SUBJECTS

OFFICE OF THE PROVOST

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NEVADA STATE COLLEGE
INSTITUTIONAL REVIEW BOARD (IRB) POLICY

INTRODUCTION

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 being followed to protect the safety and well-being of the human subjects. NSC must also provide an Institutional Assurance to the federal government 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. The National Institutes of Health, a major source of funds for health science research in nursing programs (among others) now require that researchers funded by them must submit proof that they have received training in IRB policies.

This document ('The handbook") describes procedures implemented at NSC to protect human subjects involved in research. It is intended to comply with 45 CFR 46. Faculty should use the following decision tree to determine whether their project needs IRB approval:

https://nevadasc.co1.qualtrics.com/jfe5/form/SV_cTsC7HNVxWQBKgR

This decision-tree form was originally developed by Cornell University and adopted for use at Nevada State College. It should only be used to determine whether or not an IRB application is needed. If you determine that you do need to submit an IRB protocol, please use NSC forms (http://nsc.edu/provost/irb-review-board/forms.aspx). If you have questions at any point in the decision tree, you should contact the IRB for clarification.

PROTOCOL DEADLINES

New IRB protocols are due by **the last day of each month.** Full board review occurs during the second week of each month during the academic year.

HANDBOOK INFORMATION

The document below describes some fundamentals about human subjects research, and describes standard operating procedures that NSC follows in protecting human subjects involved in research.

NSC affiliated investigators are afforded the normal legal protection by the College, provided that their activities have IRB approval and they are working within the scope of their employment or College association. It is important to recognize that unless these conditions have been met, the College will not be in a position to protect NSC affiliated investigators performing research with human subjects.

AUTHORITY

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

The Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research."

The 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

FUNDAMENTAL 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 (children, prisoners, individuals 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, at the same time possible harms from participating in the research 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 in certain groups such as the poor or imprisoned while other groups primarily benefit from the results of the research.

All NSC researchers must:

- Adhere to the principles of Respect for Persons, Beneficence, and Justice embodied in the *Belmont Report*.

- Adhere to the policies and procedures set forth in this Handbook.

- Make sure that the decision to participate in human subjects research governed by this policy meets the **standards of informed consent**. The decision must be: (a) voluntary - it must occur as the result of free choice, without compulsion or obligation; (b) based on full disclosure of the information needed to make an informed decision about whether or

not to participate; c) based on the subject's comprehension of the information provided. (d) If children are involved as subjects and are capable of assent, normally their assent to participate must be solicited in addition to the permission of their parents.

- Make sure that the selection of research subjects is fair. Subjects should not be selected for potentially beneficial research on the basis of favoritism, nor should risky research be targeted to subjects who are less powerful.

- Make sure that the procedures for recruiting subjects protect their privacy and be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Any payment made to subjects should not be so large as to constitute excessive inducement for participation. When access to subjects is gained through cooperating institutions or individuals, the subject will be afforded the level of protection required by this document.

- Make sure that risks to subjects are minimized and that they are justified by the anticipated benefits to the subject or society.

- Make sure that adequate provision is made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.

- Assure that approval for conducting research with human subjects is obtained prior to any involvement of subjects. All such research must either be reviewed or designated as exempt from this policy by the IRB. All approved projects must be periodically reevaluated.

Members of the research team will be required to:

Demonstrate knowledge of the principles and processes of ethical research involving human subjects by submitting a certificate of completion of the human subjects tutorial (https://phrp.nihtraining.com/users/login.php) or equivalent tutorial approved by the IRB when submitting a proposal to NSC/IRB. The certificate is valid for 3 years.

DEFINITIONS:

To help faculty, staff, and students know when their activities need to be submitted for IRB review at NSC, we provide the following definitions and our local interpretation of them.

1 **Research**. A systematic, intentional, formalized plan of investigation that is **designed to develop or contribute to generalizable knowledge.** Nevada State College, following Humboldt State University (the source of much of this draft document) defines *research* as:

> "… any systematic gathering and analysis of information, usually made under conditions determined by the investigator, that aims to test a hypothesis, to

discover some unknown principle, or effect, or to re-examine some known or suggested principle. The term research includes: (a) studies in which any substance or stimulus is administered to a [human] subject by any means; (b) studies that involve changes in physical or psychological state or environment or major changes in diet; (c) interviews, surveys, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups; and (d) studies of existing public or privately held records where the identity of individuals is known." (HUMBOLDT STATE UNIVERSITY OFFICE OF THE PRESIDENT POLICY FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH SEPTEMBER 2007).

2. **Generalizable Knowledge** includes one or more of the following:
    - The data is geared for scholars, practitioners, and/or researchers within a specified field of study
    - Results of the study are disseminated either by presentation and/or publication in order to illuminate some topic/issue within one's field of study
    - Results from the study are applied to some population in addition to the sample
    - The study's results can be replicated by others
    - The study provides input into some field of study (adapted from the University of Michigan)"

    The NSC IRB has taken the position that any proposed systematic plan of investigation involving human subjects that meets the definition above of generalizable knowledge the results of which **will (or may) be disseminated to audiences outside NSC** should be submitted to the IRB for review.

    Activities that meet this definition constitute research even if they are supported or funded under a program that serves other purposes.

3. **Human subject**. A 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 information that can be linked specifically to an identifiable individual. Interacting with a human being does not necessarily make them a "human subject." Humans providing factual information about organizations or other groups are not "subjects" but if they are providing information about how they perceive or feel about an organization or group they are "subjects." On-line surveys generally constitute interaction or intervention with people.

Examples of research that may be subject to review by NSC's IRB (not exhaustive):

- Research that faculty, staff, or students might submit for possible conference presentations or publication must be cleared by the IRB.
- Undergraduate student research in courses (like senior capstones) and independent projects must be cleared because these projects might become available in the library and/or submitted for consideration of awards offered by professional associations or other

organizations.
- If a faculty member is conducting research using data collected by his/her students, and if these data were gathered from or about human subjects, then this research must be submitted to the IRB for review.

The term "research" is not intended to apply to:

- Routine course, workshop, or curriculum development using accepted educational practices sponsored by NSC, including evaluation to determine participant satisfaction, attitude change, and/or knowledge gain during the educational experience; or to

- Aid or services provided by professionals to their clients that are consistent with accepted and established practice, and intended only to meet the clients' own personal needs.

- Administrative surveys, questionnaires, and interviews not supported by federal funds and designed for use in the internal management and operation of NSC do not constitute research within the meaning of this policy if the information or conclusions of the surveys are not intended for scholarly publication or for dissemination to persons outside the administrative organization of the College. A survey which is not research need not be submitted to the IRB.

- The NSC IRB does not require that data gathering activities conducted by students as part of courses in research methods or data analysis **using students in their own classes** be brought before the IRB. We expect instructors of these classes to include principles of human subject protection in these courses. **BUT** the NSC IRB **does require** that instructors of courses where students conduct research with students outside such classes submit such plans to the NSC IRB. We also strongly recommend that departments offering such courses have one or more faculty trained in IRB policies review the data generating activities, as a protection for the instructor offering the course. The IRB also strongly recommends that faculty members encourage their students who may seek to present their findings to outside agencies and/or conferences in the future submit an IRB application.

SCOPE OF THE REVIEW

The **Principal Investigator (PI)** is an employee of NSC and is responsible for ensuring that his/her work is conducted in full compliance with all applicable laws, regulations, guidelines, and policies. It is his/her responsibility to refer to the Compliance sections of the Human Subjects Policy on any questions related to compliance or to seek clarification from the IRB. The Principal Investigator will be the Principal Investigator (PI) on all applications by students to conduct research, and will be responsible for ensuring the studies follow this handbook.

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

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 NSC, units, and external oversight;
3. Providing administrative and consultation services for offices, departments, review bodies and individuals to assist the process of establishing compliance;
4. Providing educational services to faculty, staff, and students so that they can better meet compliance requirements;
5. Coordinating activities with other units of NSC so that the institution can meet its obligations in the most uniform, effective, and efficient way possible;
6. Providing a communications link between agencies issuing compliance requirements and NSC personnel; and
7. Submitting assurances, reports and/or other required communications to the appropriate federal and state agencies.

The IRB administrator is appointed by the Provost to coordinate and help review the applications with the IRB Chair, and to assist the Provost in complying with federal and state laws regarding human subjects protection.

IRB PROCEDURES

Initial Review of Research

Submitting an Application

It is at the point that a researcher formulates a systematic, intentional plan of investigation that meets the definition of research and involves human subjects that the IRB must be involved. Researchers should use the on-line interactive decision tree (https://nevadasc.co1.qualtrics.com/jfe5/form/SV_cTsC7HNVxWQBKgR) to help them determine if an application should be submitted. Even if they believe their research could fall into the "exempt" category, an application is needed. Those projects that the decision tree indicates are not "research" and do not involve "human subjects" will not need to submit a protocol application. **If you have questions at any point during the decision tree you should contact the IRB for clarification.**

Proposed research involving human subjects must receive IRB approval **before** recruitment of subjects, data collection, or analysis may commence. This means that 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 proposal for 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) for compliance with NSC IRB policies, and recommend changes if needed, before any research involving human subjects may be started.

All IRB proposals should be submitted to irb@nsc.edu and must include:

a. IRB Application Checklist
b. Completed HSR Protocol Application
c. Copy of Informed Consent or Research Information Sheet
d. Copies of all research instruments, interview questions, questionnaires, or survey tools (with instructions that will be given to participants)
e. Copies of any recruitment materials (brochures, flyers, design for internet materials, etc.)
f. Optional: Copy of Human Subjects Certificates for research team
g. Optional: Letter of authorization to conduct research off-site
h. Optional: Award letter from granting agency

Go to http://nsc.edu/provost/irb-review-board/index.aspx for guidance and forms.

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

Working with Outside Institutions

Principal Investigators who are not faculty or staff at NSC may request to use participants some or all of whom may be faculty, staff or students at NSC. In these cases, those faculty must have IRB approval from their home institutions prior to applying to NSC. The NSC IRB will generally accept IRB approval from our sister institutions in the NSHE. PI's from other institutions should expect that the NSC IRB will draft an IRB authorization agreement with the outside FWA holding institution. For collaborating institutions who are not FWA holding institutions, a Memo of Understanding (MOU) or other agreement with the PI home institution will be required prior to accepting their IRB approval. Additionally, the Dean or other Administrator of the study participants at NSC must give their written consent to allow the study to go forward.

If a staff member collaborates with an outside agency/institution and received IRB approval from the outside agency/institution, the IRB will review the protocol that was approved by the outside agency/institution. If the protocol is consistent with IRB policies, the IRB will approve the study. The IRB retains the right to request a new IRB application for the project.

Application Review

The IRB administrator will check regularly and often for new proposals or requests at irb@nsc.edu. In certain cases the IRB administrator may be out of town or otherwise unavailable due to other teaching and/or research obligations; in these cases the Chair of the IRB will be notified and respond in a timely fashion to requests and queries sent to irb@nsc.edu.

In normal circumstances, the IRB administrator will review the proposal and is authorized to make a determination of "exempt" without further consultation with the IRB Chair or the IRB; if it is determined to be exempt, the PI will be notified within 10 business days of the initial

submission (assuming the protocol is complete as required).

Categories of Research

There are **three categories of research** recognized by the federal regulations:

- "**EXEMPT**" (§45 CFR 46.101b) -- for research that is conducted in educational settings, survey/observation procedures, and/or existing data, where participants have not responded to sensitive information or cannot be identified. Research involving video recording of participants, minors, or deception may not be exempt.
- "**EXPEDITED**" Approval (§45 CFR 46.110a)-- in cases where participants will experience no more than **minimal risk** when participating in the research; but identifiable information was collected, sensitive questions were asked, or deception was involved.
- "**FULL BOARD**" Approval -- in cases where the research presents a **greater than minimal risk** to research participants.

Ultimately, **it is the responsibility of the NSC IRB to determine what category applies to proposed research.** Therefore, all proposed human subjects research including "exempt" research must be submitted for IRB clearance; the process for exempt research will be streamlined to ensure minimal faculty time and effort. Once a determination of "exempt" is made by the IRB on a given research project, no additional interaction with the IRB will be needed unless changes are made to the exempt protocol.

Those projects not determined "exempt" may be processed through either expedited review or full board review. The IRB administrator, in consultation with the Chair and one or more IRB members with relevant experience, may review and respond without full committee action for "expedited" proposals. Proposers must allow 10 additional working days after submission for response from the NSC IRB (i.e., up to 20 working days from initial submission, assuming the protocol is complete with all required attachments).

In those cases where subjects are "at risk," (e.g., situations that do not qualify as exempt or expedited) full membership review by the IRB is required for approval. The full IRB meets at regular intervals, optimally once a month generally at the middle of the month, to consider any proposals submitted by the last day of the previous month. 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. Proposals requiring "full board" action will be considered at the monthly full board meeting after the proposal has been submitted by the last day of the previous month.

To expedite the process of a full board review, the PI may be invited to discuss their proposal with the IRB. Proposers must allow up to 30 working days for approval after initial submission.

Membership and Governance

Committee Composition
This Committee has no fixed number of persons; however, there will not be less than **seven** (7) members, at least one of which shall not be affiliated with NSC. The membership shall be of varying backgrounds to promote complete and adequate review of projects.

- Each School (Liberal Arts and Sciences, Nursing, Education) shall nominate **two** members to serve, and at least one Alternate Member to ensure a quorum at scheduled meetings of the IRB.
- There will be at least **one** member of the IRB whose primary concerns are in scientific areas and one member whose primary concerns are in nonscientific areas.
- Other membership may be of formal or ad hoc nature to ensure compliance with pertinent regulations when dealing with special types of research situations.
- The Provost, or her/his designee, shall serve as an ex-officio, non-voting member of the committee.
- The IRB Administrator attends meetings but is not a voting member of the committee

Nomination for membership on the committee must be submitted to the Provost by the Dean of each school. Members will be appointed by the Provost for one, two, or three year terms. The Provost has sole discretion to decide not to re-invite members to continue to serve any multiple year appointment.

The IRB will meet face to face (or over video conferencing or similar if need be) as needed, but not less than once a quarter and possibly each month if needed. IRB members are expected to serve without compensation, and may be asked to attend meetings even when they are off contract.

Administrative Roles and Responsibilities

IRB Chair
The Chair of IRB shall be elected by the committee's membership and shall serve for **one** year with up to two additional year-long extensions. A majority vote of a quorum is sufficient to elect the IRB Chair.

The Chair (a voting member) will call the committee together and preside at meetings. The IRB Chair or delegated member are authorized by the Provost to act on behalf of NSC for exempted projects and expedited review. The Provost is the Institutional Official, the person who signed the FWA. In cases requiring full IRB review, actions will be made by majority vote of the members when at least a quorum (one more than one-half of the membership) is present.

IRB Administrator
The IRB Administrator receives and documents receipt of all incoming IRB protocols. The IRB Administrator has the authority to determine "Exempt" status for submitted protocols. The Administrator is also responsible for archiving all correspondence of the IRB, record notes of the

in-person meetings, and arrange meetings of the IRB. All records shall be maintained and available in the IRB administrator's office; minutes of meetings shall be available at the IRB administrators office within 10 working days of any meeting.

The IRB Administrator will also maintain and edit the IRB Handbook and required forms as needed. The Handbook and all Forms will be published on the NSC IRB website.

The IRB Administrator is available in person, via telephone or e-mail for consultation before protocols are submited. Such consultation is encouraged if a faculty member has not completed a prior application.

The IRB Administrator will send a courtesy reminder e-mail to faculty (using the e-mail shown on the original application) about the renewal date of the proposal for all expedited and full board reviewed proposals. However, it is the responsibility of Principal Investigator to comply with all the terms of the approval letter.

IRB Obligations for Researcher Compliance

The IRB has the obligation to inform researchers of procedures related to being compliance with federal regulations. The IRB will be responsible for:

- conducting training programs and distributing materials for investigators, such as the annual briefing to faculty and Deans and preparation guidance published on NSC website

- including specific directions in approval letters to investigators (e.g., cautioning faculty that significant changes in protocol must be reviewed first by the IRB);

- random audits of research records.

Further information:

- Federal IRB guidelines - http://www.hhs.gov/ohrp/
- 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
- Nevada Revised Statues -- https://www.leg.state.nv.us/nrs/
    - NRS 159.0805 State law regarding research with wards of the State.

Renewal of Approved Protocols

The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

a. Federal policy requires that the IRB conduct at least an annual review of non-exempt approved research activities, (CFR 46.109.(e)). Researchers should indicate the expected overall duration of the research when submitting an initial protocol. Renewal applications should be made **at least 30 days before the date of expiration of IRB approval**, bearing in mind the time needed for review and that research activity must cease at expiration date if renewal has not been obtained. The researcher is responsible for initiating any and all needed renewals.

b. The IRB will determine the term of approval and will notify the researcher of the date of expiration of approval at the date of approval. As a courtesy, the IRB Administrator will send a notice of expiration of approval to the principal investigator approximately six weeks before the expiration date of any currently approved protocol. However, it is ultimately the responsibility of the principal investigator to submit an IRB protocol if the researcher plans to continue the approved research beyond the expiration of approval. If the principal investigator ceases to be responsible for the study, approval automatically ceases. Should a new principal investigator desire to continue the study, reapplication (as for a renewal see below) to the IRB is required

Federal law requires that research involving human subjects that is determined "expedited" or full board review must be reviewed once a year at a minimum. Approval for these projects is granted for one year only; Principal Investigators of projects that last more than one year must file each year for renewal of a project, and also upon completion of a project. It is the responsibility of each PI for applying for renewal not less than 30 days before the expiration of their protocol. The IRB shall review and have authority to approve, require modifications in (to secure approval), 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 CFR 46.116. The IRB may require that information, in addition to that specifically mentioned in CFR.46.116., be given to the subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects. The IRB shall require documentation of informed consent or may waive documentation in accordance with CFR.46.117. The IRB Administrator, Chair, or other delegated person shall notify investigators and the institution (NSC) in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. This written notification may take the form of an e-mail addressed to the PI's e-mail address. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Continuing Review of Research

Modifications to Approved Protocols

a. Renewal of approved expedited and full-board protocols are required annually and are also required if the principal investigator changes (NOTE: If the IRB application is the

result of an award from a federal agency, most federal agencies require prior approval before replacing the designated Principal Investigator with someone else) .

b. If during the course of any research (including exempt research), training, or demonstration, a change in plans is made so that human subjects are now to be used, or that 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 modification of the existing protocol must be obtained. In general, any change which alters the risk/benefit balance or which modifies the informed consent in some way, requires approval.

Submitting a Renewal or Modification Application

a. **Renewal applications** require a copy of the current or new consent form and completion of Continuing Review Form, which addresses the following:
(1) a **summary** of the previous (approved) protocol, or copy of the previous protocol;
(2) a **status report**, which includes the following:
    - The **number of subjects** studied and the number approached who refused permission;
    - A **discussion of the experience of the subjects** undergoing study, with particular reference to any adverse events occurring to them during the conduct of the study (if no adverse event has occurred, it should be stated, rather than omitting this item altogether); and
    - A **brief description of the scientific or research results**, if any, to date.

    Status reports should not be photocopies of papers either published or submitted for publication. The papers primarily inform their readership of scientific advances. It is necessary to inform the IRB, in as concise a manner as possible, of the results only as they influence the balance of benefit to risk to human subject. Published papers may be appended as evidence of benefits of the research.

    Renewal applications will be accepted any time of year. Proposals previously approved as expedited may be reviewed by the IRB Administrator, or jointly with the IRB administrator and Chair and may require consultation with other member(s) of the IRB. PI's should **allow up to 20 working days** for review. If the initial approval was approved with full board review, renewal applications may need to go before the full board for review; PI's should **allow 30 working days** for such review to be completed.

b. **Modification applications** require a copy of the current or new consent form and completion of the Modification Request Form, which addresses the following:
(1) a **summary** of the previously approved protocol, or copy of the previous protocol itself and
(2) a **description** of any modifications to the current or previous protocol, such as:
    - background or reason for modification
    - change in compensation

- discussion of updated benefits, risks, etc.
- if change in principal investigator, describe research background of new principal investigator

The time frame for Modification Forms are the same as for Continuing Renewal (see above).

IRB Reporting Requirements

Notifying Investgators
The IRB administrator has the authority to review and approve exempt research and will notify the Principal Investigator in writing of his/her decision **within 10 working days** of receipt of a full and complete application with all supporting materials. An expedited review may require consultation with the IRB Chair and other member(s) of the IRB before approval is given; this may take an **additional 10 working days** for approval to be sent by the IRB administrator to the PI. Proposals of a higher risk may require full board review; the Chair of the IRB will forward the recommendations to the IRB Administrator who will respond to the PI with approval, disapproval, or other action.

Notifying the Institution
All members of the IRB will be notified of all approvals (including exempt and expedited) made by the IRB Administrator or IRB Chair.

The IRB administrator will provide a **quarterly report** to the Vice Provost of Scholarship and Experiential Curriculum and to the IRB committee. The report will list all of the protocols submitted during that period, and identified as exempt, expedited, or requiring full board review. Furthermore, for those that go to 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 provided to the Vice Provost of Scholarship and Experiential Curriculum **within 10 working days** after Board approval.

Additional Review Requirements
Federal regulations require that all projects approved as either expedited or full board review be reviewed at least annually. In some cases, projects approved as expedited and full board may require review more than once per year.

In order to determine which projects require review more frequently than every year, the IRB will consider:

- Projects that are unusually complex or seem to have higher potential for risk may be reviewed as needed but not less than twice a year;

- The history of the Principal Investigator in maintaining compliance or a large number of amendments may indicate that these proposals may need to be reviewed more than once a

year;

- Even if no obvious problems are known, to maintain quality control a sample of the expedited and full board proposals may be reviewed more than once a year for compliance purposes.

To ensure compliance and quality control, protocol audits may require seeking information from sources beyond the Principal Investigator (e.g., the research team, subjects; colleagues).

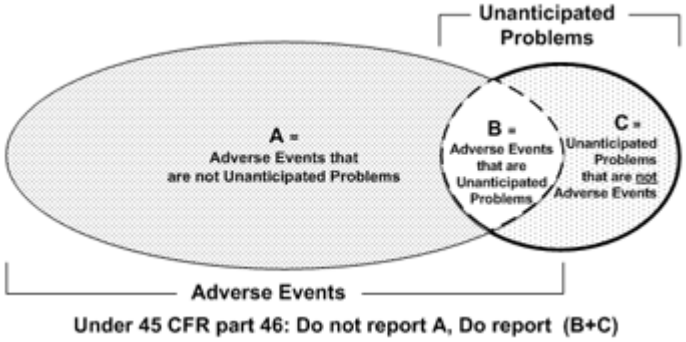
To confirm that no material changes have occurred, the IRB has the authority to audit protocols that involve:

- complex projects that have unusual levels or types of risk to subjects;

- investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB may be audited;

- projects where concern about possible material changes without IRB approval have occurred based upon information provided in continuing review reports or from other sources (i.e., subjects or other faculty).

Types of Incidents that May Need to be Reported to IRB and/or OHRP



Category #1: Unanticipated Problems Involving Risks to Subjects or Others

"What are *unanticipated problems*?" The phrase "unanticipated problems involving risks to subjects or others" is found but not defined in the HHS regulations at 45 CFR part 46. OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

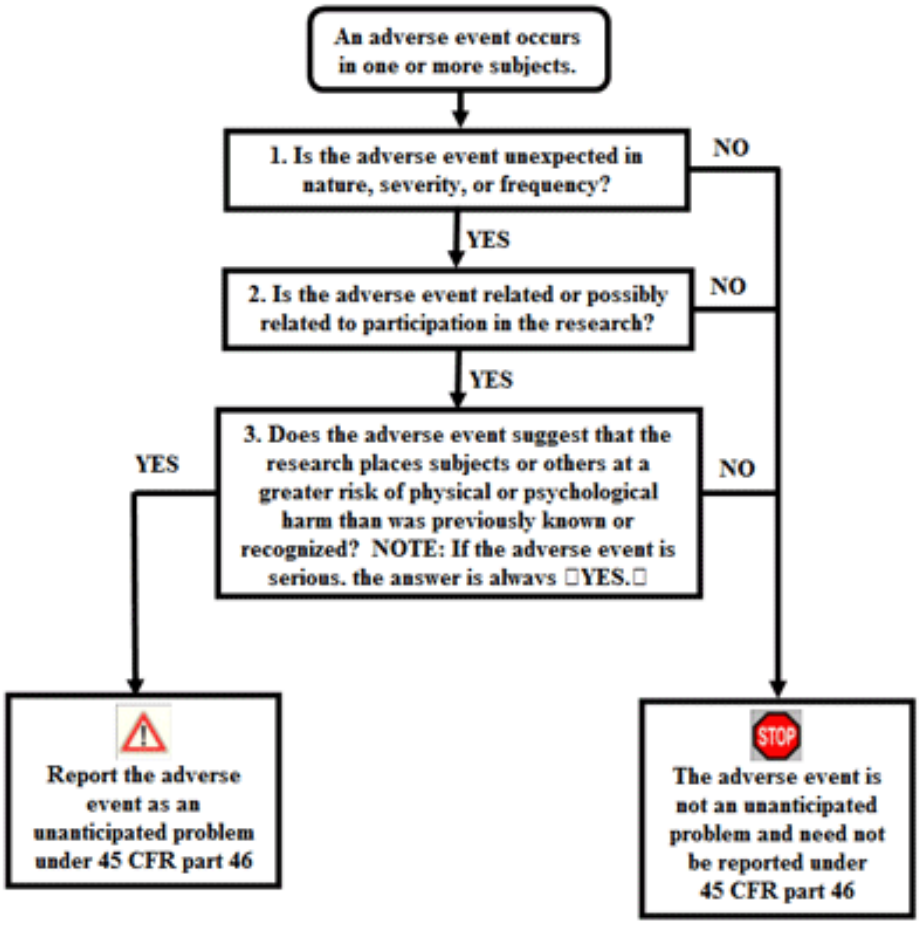
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

"OHRP recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others"

Category #2: Adverse Events

"What are *adverse events*?" The HHS regulations at 45 CFR part 46 do not define or use the term adverse event, nor is there a common definition of this term across government and non-government entities. In this guidance document, the term *adverse event* is used very broadly and includes any event meeting the following definition:

1. 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 subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).
2. Adverse events encompass both *physical* and *psychological* harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.



Category #3: Non-Compliance

In the event of...

- Any serious or continuing non compliance
- And suspension or termination of IRB approval.

a. All acts and/or allegations of noncompliance with applicable rules, procedures, policies, and/or regulations are intiially 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.

b. The IRB can recommend to the Provost to initiate disciplinary action under Title 2 Chapter 6 of the NSHE Code: http://system.nevada.edu/tasks/sites/Nshe/assets/File/BoardOfRegents/Handbook/T2CH06RulesandDisciplinaryProceduresforMembersoftheUniversityCommunityExceptDRI(2).pdf

c. 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.

d. In any instance where IRB requirements are not being followed, the IRB shall inform the principal investigator and also the Provost who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the Provost will terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action.

Procedures for Reporting Serious, Unanticipated Adverse Events or Problems

The Principal Investigator is responsible for reporting any serious, unanticipated adverse event or problem within **five business days** of the occurence to the IRB Administrator, the Chair of the IRB, and the Vice Provost of Scholarship and Experiential Curriculum. After seeking emergency assistance, any life-threatening adverse events or problems must be reported to the IRB **within 24 hours.**

If an adverse effect was anticipated by the protocol (and disclosed to a subject), but has otherwise changed in nature, severity, or frequency, this must be report to the IRB in a timely manner. Required reporting also includes, but is not limited to, any procedural errors durin g the research, a breach in confidentiality or privacy, emotional disturbances, noncompliance with the regulations or IRB requirements, or any other problems occuring during the research. Researchers should contact the IRB for consulatation if unsure whether an event is reportable.

Within **five business days** of the serious, unanticipated adverse event or problem, the Principal Investigator should complete the **Adverse Event form**, which address the following:

1. appropriate identifying information for the research protocol, including the title, investigator's name, and the IRB project number;
2. a detailed description of the adverse event, incident, experience, or outcome;
3. an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem; and

4. a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Possible Outcomes

Determiniation of Reporting to Office for Human Research Protections (OHRP)

Within a reasonable timeframe, the Provost (as the Institutional Official) will consult with the IRB Chair, IRB Administrator, and Vice Provost of Scholarship and Experiential Curriculum and then decide how, when, and whether to report to the OHRP. In cases where the research is

federally-funded, the Provost and IRB will use the following OHRP flowchart in making determinations of what needs to be reported to the OHRP and funding agencies: **http://www.hhs.gov/ohrp/compliance/reports/#**

In addition to the above requirements, the Principal Investigator may be required to report any serious, unanticipated adverse event or problem to the sponsoring federal funding agency within the timeframe specified by the award document.

See the Federal OHRP's page on Unanticipated Problems & Adverse Events (http://www.hhs.gov/ohrp/policy/advevntguid.html).

IRB Actions

The IRB may respond in any of the following ways:

- terminate the research immediately;
- ask for 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.

STEPPING THROUGH NSC's IRB COMPLIANCE PROCESS

The IRB Administrator (who reports to the Vice Provost of Scholarship and Experiential Curriculum) is the main point of contact for all IRB correspondence. The IRB office is responsible for guidance, instruction, policy, and approval. The Provost, who is legally the Institutional Official (IO) and is signatory to the Federal-Wide Assurance, is responsible for oversight.

The IRB is a faculty committee serving at the discretion of the Provost, not an independent unit of the faculty senate or any other body. The Provost's office will provide staff support (for example, an IRB Administrator and necessary staff), and other resources needed to ensure the IRB is in compliance with federal regulations and to support on-going training of the IRB Administrator, Chair, and IRB members as necessary. The Provost is the legally obligated entity within NSC and will maintain compliance with 45 CFR title 46 and other relevant regulations and statues for human subjects research. The IRB Administrator is responsible for recording for all files generated by the IRB. The IRB Administrator is charged with the responsibility of seeing that the official record is complete at all times during research projects, and at their termination.

DOCUMENTATION

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

In compliance with Uniform Federal Policy on the Protection of Human Subjects, researchers will maintain records of research data for at least three years after the research is concluded. The researchers must periodically review research results to assure (1) that harm has not occurred and (2) that the ongoing research protocol is producing adequate results such that benefits of the research continue to balance risks to human subjects. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefit, the researcher must report immediately to the IRB.

The IRB. The IRB is required to keep copies of all documents presented or required for initial and continuing review by the Board. The records of the IRB pertaining to individual research activities are not accessible to persons outside the Board 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.

The IRB Administrator shall prepare and maintain adequate documentation of IRB activities, including the following:

1 Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, reports submitted by investigators, and reports of injuries to subjects.

2 Minutes of any full board IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

3 Records of continuing review activities.

4 Copies of all correspondence between the IRB and the investigators.

5 A list of IRB members in the same detail as described in CFR 46.103.(b)(3).

6 Written procedures for the IRB in the same detail as described in CFR.46.103.(b)(4) and CFR 46.103.(b)(5).

7 Statements of significant new findings provided to subjects, as required by CFR 46.116.(b)(5). The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

The Institution. It is the responsibility of NSC through the appropriate administrator or

administrative office, as appointed by the President, to assure compliance with and provide documentation of compliance with the Uniform Federal Policy for the Protection of Human Subjects.

Research that is covered by the Uniform Federal Policy ("The Common Rule") and that is conducted or supported by a federal department or agency must provide written assurance satisfactory to the federal department or agency head that it will comply with the requirements set forth in the policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, DHHS, and approved for federal wide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, DHHS.

Federal departments and agencies will conduct or support research covered by this policy only if NSC has an approved assurance and only if NSC has certified to the federal department or agency head that the research has been reviewed and approved by the IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

1 A statement of principles governing NSC in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by NSC, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by NSC itself. This requirement need not be applicable to any research exempted or waived under CFR 46.101. (b) or (I).

2 Designation of one or more IRBs established in accordance with the requirements of the Uniform Federal Policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and record keeping duties.

3 A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB membership shall be reported to the department or agency head, unless in accord with CFR.46.103 (b) (3) of this policy the existence of an DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, DHHS.

4 Written procedures which the IRB will follow for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and for ensuring prompt reporting to

the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5 Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and any suspension or termination of IRB approval.

The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of NSC the obligations imposed by the Uniform Federal Policy and shall be filed in such form and manner as the federal department or agency head prescribes. This individual is the Provost of NSC.

Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under CFR 46.101.(b) or (I). NSC shall certify that each application or proposal for research covered by the assurance and by CFR 46.103. of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the federal department or agency to which the application or proposal is submitted. Under no condition shall research covered by CFR 46.103. of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. If NSC is without an approved assurance covering the research, NSC shall certify within 30 days after receipt of a request for such a certification from the federal department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to NSC.

ADVICE AND CONSULTATION

Researchers and departments may call upon the IRB for informational consultation. Any consultation extended is informational in nature. It is neither interpretative nor decisional, as these are solely the prerogatives of the IRB in its review function.

OMISSIONS

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, i.e., as followed by Common Rule agencies.

AMENDMENTS

Minor amendments (as determined by the IRB Chair and IRB Administrator) to this policy require the approval of 51% of members where a quorum has been established at an IRB meeting.

Major revisions of this policy require the approval of two-thirds of the full membership of the IRB and the endorsement of the Provost.

New NSC or NSHE requirements, or changes in state or federal laws shall be incorporated in this document by the appropriate administrator without further review. The final authority for amendment of these policies and procedures, and for the adoption of a new revision rests with the President.

For current information on the Policy for Protection of Human Subjects, refer to the federal web site: http://www.hhs.gov/ohrp

The regulations referred to in this document are available at the United States Department of Health and Human Services (regulations),
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html