NEVADA STATE COLLEGE

Office of the Provost

Institutional Review Board Handbook

After Implementation of Revised Common Rule
January 21, 2019

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Chapter

1

Introduction

This handbook describes procedures implemented at Nevada State College to protect human subjects involved in research. It is intended to ensure all research at NSC complies with 45 CFR 46, the federal statute regulating human subjects research.

IRB Administrator

CONTACT THE IRB AT IRB@NSC.EDU

The IRB Administrator is your main point of contact for the IRB. The IRB Administrator saves all relevant files to ensure that the official record regarding research activities is complete at all times.

Your legal protections

If you are a Principal Investigator (PI) affiliated with NSC, you are afforded normal legal protection by the College, provided the NSC IRB approved your research activities, you are following the approved protocol, and you are working within the scope of your employment or College association. If you don't meet these conditions, the College will not be able to protect you in your role as PI performing research with human subjects.

Chapter

2

Do You Need to Submit an IRB Application?

For help determining whether your research project requires IRB approval, follow the IRB's online decision tree. The decision tree was developed by Cornell University and adopted for use at NSC.

If you determine that you need to submit an IRB application before beginning your research, see Chapter 3 for information about applying for IRB approval.

If you still aren't sure if you need to submit an application, or if you have any questions, email the IRB Administrator for clarification.

What is research?

If you're conducting research that involves human subjects, then you have to submit an IRB application. But what counts as research?

> For the purposes of the IRB, **research** is a systematic, intentional, formalized plan of investigation designed to develop or contribute to generalizable knowledge.

Research includes studies in which any substance or stimulus is administered to a human subject; studies that involve changes to a person's physical or psychological state or environment, or major changes to diet; interviews, surveys, tests, observations, or

inquiries designed to elicit or obtain non-public information about individuals or groups; or studies of existing records or biospecimens if people can be individually identified.[1]

Not all studies with human participants qualify as human subjects research. To determine if a project will contribute to **generalizable knowledge**, consider if it falls into one of the following categories:

1. Data are geared for scholars, practitioners, and/or researchers;
2. The results will (or may) be shared through presentations and/or publications in order to help illuminate a topic or issue;
3. The results may be applied to a larger human population beyond the sample in the study;
4. The results can be replicated;
5. The results will provide input into some field of study.

If your project won't meet any of the criteria above, then it may not qualify as research. If you believe your project isn't research, use the online decision-tree tool described above or reach out to the IRB Administrator to discuss your research plan.

WILL YOU SHARE IT? THEN IT'S PROBABLY RESEARCH.

If your research project does meet any of the five criteria above, **and may be shared with audiences outside of NSC**, then you must submit it to the IRB for review. This is the case even if the activities are funded under a program that is not, itself, a research project (e.g., assessments of grant-related activities that you may decide to present or publish).

Generally, students' coursework doesn't require IRB review. However, if students collect data for a course project and that project may be published, kept on file at a library, or submitted to outside evaluators as part of applications for awards offered by professional organizations or other groups, then the project may need IRB approval. Talk to the IRB Administrator before the project gets started.

Things that aren't research

Some activities that involve collecting information about people don't qualify as research. Here are some examples:

- Routine course, workshop, or curriculum development using accepted educational practices, including evaluation of participant or student satisfaction, attitude changes, and/or knowledge gained;

[1] Adapted from Humboldt State University Office of the President, Policy for Protection of Human Subjects in Research, September 2007.

INTERNAL EVALUATIONS OF PROGRAMS OR SERVICES DON'T REQUIRE IRB APPROVAL

- Aid or services provided to clients that are consistent with accepted and established practice and intended only to meet the clients' own personal needs;
- Surveys, questionnaires, and interviews that are not supported by federal funds and are designed only for internal management and operations at NSC, as long as the data and results aren't intended for publication or presentation outside the College;
- Projects completed by students as part of research methods or data analysis courses, as long as the projects will not be published or presented outside the course;
- Journalistic or historic case studies that focus directly on a specific individual and are not intended to provide any knowledge that can be generalized beyond that specific case.

Even if your project is meant only for internal assessment (e.g., determining if a learning technique was effective in class or if a student services program improved retention), think carefully about whether you would ever want to publish or present any of the data you gathered. Sometimes evaluations meant only for internal purposes lead to interesting findings, and you may want to share the results. If there's any chance this might occur, get IRB approval in advance so you'll be free to share the results in conference presentations or academic publications.

Are you using human subjects?

Will you be collecting or obtaining information about a living human being? If so, congratulations, you're doing research on **human subjects**! The information doesn't have to be *from* those participants to qualify as human subjects research; you may get information about them from a third party. But you still have to ensure you aren't putting human subjects at risk.

> A person is a human subject if you obtain information through interaction or intervention with the person or if you access existing information that can be linked to specific, identifiable people.

Interacting with a person doesn't always make them a human subject. For instance, a person providing strictly factual information about organizations or other groups isn't a subject (e.g., if you ask a state employee for basic information about how to apply for a government program or how many people participate per year). But if you ask that person how they feel about or perceive the organization or group (say, if you ask the

state employee if they think the program should continue or be eliminated), then they *are* subjects.

SECONDARY ANALYSIS OF EXISTING DATASETS MAY NOT REQUIRE IRB APPROVAL

Surveys, including online surveys, generally constitute interaction or intervention and are considered human subjects research. If your research plan includes surveys or interviews, you'll most likely need IRB approval. However, if you are conducting secondary data analysis of existing and publicly-available datasets, such as Census data or the Youth Risk Behavior Surveillance System (YRBSS), and the dataset doesn't include any information that allows you to identify specific individuals, your project isn't human subjects research and you don't need IRB approval.

Chapter

3

IRB Approvals

This chapter explains the initial review process, as well as applications for renewal or modifications. The PI is responsible for submitting all application materials in a timely manner. A faculty member must serve as PI on all IRB applications for research projects conducted by students.

If you have any questions, consult with the IRB Administrator before submitting your proposal.

Initial application

Once you've determined that you're doing research and it involves human subjects, it's time to prepare your IRB application. All forms for your proposal are available on the IRB Canvas site. You'll submit the application electronically; the link is on the Canvas site homepage. You need to include the following:

- IRB Submission Checklist;
- Protocol Application;
- Copy of Informed Consent document;
- Copies of all research instruments, interview questions, surveys, or questionnaires, along with any instructions given to participants;
- Copies of any recruitment materials (e.g., brochures, flyers, design for social media announcements);
- Copy of certificate verifying completion of Human Subjects Training for all members of research team (training must be renewed every three years).

FIND ALL FORMS AND OTHER RESOURCES AT THE IRB CANVAS PAGE

Depending on your research project, you may also need to submit a letter of authorization to conduct research off-site or an award letter from a granting agency.

Application deadlines

FULL BOARD REVIEW GENERALLY DOESN'T HAPPEN OVER THE SUMMER

IRB applications are **due by the last day of each month** in order to be reviewed the following month. Applications that are Exempt or eligible for Expedited review are considered year-round. Applications that require Full Board Review are evaluated at the next IRB meeting, which occurs each month during the fall and spring semesters.

The IRB determines which category of review is required for each proposal. Submit your application well in advance of when you wish to begin research in case your proposal requires Full Board Review or additional information or protocol revisions are requested by the IRB.

IRB review

Federal regulations recognize three categories of research. When you submit a proposal, the IRB Administrator reviews it and makes an initial determination about the project.

The NSC IRB determines which category applies to your research proposal. Even if you feel certain that your research is Exempt, you must submit it for IRB review. You cannot begin recruiting participants or collecting data until the IRB approves you to do so.

Exempt (45 CFR 46.101b) Research conducted in educational settings, survey/observation procedures, benign behavioral interventions, and/or existing data. To be Exempt, the research design must ensure that participants will not respond to sensitive information or cannot be identified. NSC recognizes six categories for exemption as described in the Revised Common Rule.

The IRB Administrator is authorized to declare a project Exempt without further consultation with the IRB. If your project is determined to be Exempt, you will be notified within **10 College working days**. If any parts of your application are missing, review will be delayed.

Once a project is declared Exempt, no further IRB review is required. You don't have to renew your proposal unless significant changes are made to the protocol.

Expedited (45 CFR 46.110a) Participants will experience no more than minimal risk, but identifiable information will be collected, sensitive questions asked, or deception used, and none of the exemption categories apply.

The IRB Administrator, in consultation with the IRB Chair and one or more IRB members with relevant experience, may review and approve projects determined to be Exempt without further IRB involvement. It may take **up to 20 College working days**

for you to receive a response; missing materials or incomplete applications may delay review.

Some Expedited proposals must be renewed annually until all data collection is complete; see the section on renewals below for more information.

Full Board Review Research presents a greater than minimal risk to participants, either because of research procedures or because the subjects come from a vulnerable population. Full Board Review occurs at the next regularly-scheduled IRB meeting. You may be invited to attend the meeting to discuss your proposal with the IRB. Allow **up to 30 College working days** for approval of Full Board Reviewed proposals.

Full Board proposals must be renewed annually until all data collection is complete.

Approval period

For non-Exempt projects, the IRB will determine the term of approval and notify you of the expiration date in your approval letter. For most projects, approvals last one full calendar year. Some Expedited projects will have longer approval periods.

As a courtesy, the IRB Administrator will send a reminder several weeks before your approval expires. However, it is ultimately your responsibility to keep track of the expiration date and submit a renewal application if data collection will continue past that date.

IF THE PI ON A PROJECT CHANGES, YOU MUST APPLY FOR RENEWAL

If the PI of an approved study ceases to be responsible for the project, approval automatically expires immediately. If a new PI wishes to continue the study, a renewal application is required. If the project is grant-funded, keep in mind that most federal agencies require you to get their approval before replacing a designated PI.

Renewing approved protocols

Federal policy requires the IRB to conduct at least annual reviews of Full Board and some Expedited research (CFR 46.109(3)). This is referred to as **continuing review**. Continuing review is *not* required for the following:

- Expedited projects that present no more than minimal risk;
- Projects in which data collection is complete and only data analysis continues.

RENEWALS AREN'T REQUIRED ONCE DATA COLLECTION IS DONE

Your approval letter indicates whether your Expedited project requires annual renewals. Once all data collection for a project that requires continuing review is completed, you may contact the IRB Administrator to update your files; at that point, continuing review will no longer be necessary. However, if you decide at a later date to collect more data, you must first renew your IRB approval.

Continuing review may occur more than once per year, or for projects that otherwise would not require continuing review, if the IRB deems greater oversight necessary. Projects that are unusually complex or seem to have a higher-than-usual potential for risk may be reviewed as needed, but not less than twice per year. If the PI on a project has a history of noncompliance with IRB requirements or federal regulations, or if a large number of modifications to the research protocol are submitted, the IRB will develop a review schedule based on its judgment of the need for supervision. Even if no obvious problems are known, the IRB may review a sample of Full Board projects more than once per year for quality control and compliance purposes.

APPLIES TO FULL BOARD AND SOME EXPEDITED PROPOSALS

In your initial application, you will indicate when you believe the research will end. However, data collection and analysis can take longer than anticipated, and multiple renewals may be necessary even if they were not anticipated at the beginning of the project.

If your approval letter indicated that you must renew your application, then you must submit a Continuing Review Form and a copy of your informed consent document at least 30 days before your IRB approval expires. **All research activity must stop if you don't get approval for a renewal before the expiration date**, so be sure you submit a continuing review application with sufficient time for review.

Renewal applications for Expedited projects may be approved by the IRB Administrator alone or the IRB Administrator in consultation with the IRB Chair. In some cases, consultation with other IRB members may be necessary. **Allow up to 20 College working days** for review.

If your project initially went through Full Board Review, then the full IRB must evaluate the renewal application as well. **Allow up to 20 College working days** for the process to be completed during the fall and spring semesters; review may not be possible during the summer or winter terms.

Modifications to approved proposals

Any type of research – including Exempt proposals – may require a modification application in some circumstances.

APPLIES TO ALL PROPOSALS

A request to modify a project is required if:

- a change in plans is made so that human subjects will be used;
- the research methods or techniques are significantly different;
- the informed consent document or process would change; or
- new hazards are evident.

MINOR CHANGES THAT DON'T ALTER RISKS OR INFORMED CONSENT DON'T REQUIRE APPROVAL

Anything that alters the risk/benefit balance of a project or modifies informed consent in any way requires approval. The changes must be approved before you implement them. Minor modifications that don't alter the risks to participants don't require IRB approval.

To make modifications, submit the Modification Request form and a copy of the current or proposed informed consent document. For Exempt or Expedited proposals, allow **up to 20 College working days for review**; for Full Board approved proposals, it may take **30 College working days or more.**

The IRB has the authority to audit projects if there is reason to believe that significant changes may have occurred without IRB approval.

Working with outside institutions

If you are a PI who is not a faculty or staff member at NSC, you may request to recruit participants who may be NSC faculty, staff, or students. To do so, you must have IRB approval from your home institution. The NSC IRB generally accepts IRB approvals from other NSHE institutions without further review. If your home institution is outside NSHE, the NSC IRB will draft an IRB authorization agreement with your institution if it holds a current Federal-Wide Assurance (FWA). If your institution does not have a current FWA, NSC requires a Memorandum of Understanding (MOU) or other agreement with your institution before we accept your IRB approval.

The dean or other relevant administrator responsible for the NSC population you hope to recruit as participants must give consent to allow the study to go forward.

If an NSC staff member collaborates with an outside agency or institution that received IRB approval, the NSC IRB will review the approved protocol. If the IRB protocol is consistent with NSC's policies, the NSC IRB will approve the study. The NSC IRB retains the right to require a full application for the project if it determines that the approved protocol is not consistent with College policies or requirements.

A caution for graduate students

If you're a graduate student at another institution, you will likely have to get IRB approval through that institution, even if you are a full-time faculty or staff member at NSC. Graduate programs generally require graduate students to receive IRB approval through them, with a faculty advisor overseeing the project. Failing to inform your advisor or receive your graduate institution's IRB approval can be a serious breach of their research procedures.

Even if you work full-time at NSC, if you're enrolled in a graduate program elsewhere, we strongly encourage you to speak to your advisor to determine the proper avenue for seeking IRB approval for any projects.

Chapter

4

Principal Investigator Responsibilities

As a Principal Investigator (PI), you have a number of responsibilities:

- Receive IRB approval before beginning any research on human subjects;
- Complete Human Subjects Protections training with passing scores and renew the training every three years;
- Adhere to the three fundamental principles of Respect for Persons, Beneficence, and Justice;
- Follow all policies and procedures described in this handbook, in the NSC IRB Policy (RE 1), and in the federal Revised Common Rule that was implemented in January 2019;
- Make sure that your subjects' decisions to participate meet the **standards of informed consent**;
- Make sure the selection of research subjects is fair – subjects for potentially beneficial research shouldn't be chosen based on favoritism, and subjects for risky research shouldn't be targeted because they lack social or political power;
- Ensure recruiting procedures are reasonable and that subjects aren't coerced or unduly enticed to participate;
- Minimize all risks and ensure they are justified by the anticipated benefits to the subject or society;

- Protect research subjects' privacy and the confidentiality of identifiable information;

- If you're working with other institutions or researchers outside of NSC, ensure that human subjects receive all protections required by the NSC IRB;

- Complete application renewals, if needed;

- Periodically review results to ensure that no harm has occurred to subjects and that the protocol is producing adequate results to justify any potential risks;

- Report any unanticipated problems or other issues to the IRB in a timely manner;

- Retain all research documents, including signed consent forms, for a minimum of three years after the end of the project.

Belmont Report Fundamental Principles

Your Human Subjects Protections training will give you detailed information about the three fundamental principles listed in the *Belmont Report*. Here's a brief reminder.

Respect for Persons People must be treated as autonomous agents who enter into research voluntarily and with adequate information about the purpose and procedures of the research. Anyone with diminished autonomy (e.g., children, prisoners, those who are incapacitated in some way) has a right to be protected.

Beneficence You're obligated to secure the well-being of your subjects. Possible benefits to participants should be maximized for each subject; potential risks should be minimized.

Justice The risks and benefits of research should be distributed equally across groups. The burden of participating in research should not fall largely on certain groups, such as the poor or prisoners, while other groups primarily benefit from the results.

Standards of informed consent

All participants in your study must give informed consent. This doesn't just mean that they agree to take part; their agreement to participate must meet several criteria.

First, **it must be voluntary**. Subjects can't be compelled to take part. And rewards or inducements to participate can't be so large that they might unduly affect a person's decision; this is particularly important if you're working with groups (e.g., the homeless, low-income individuals) who may be more vulnerable to such persuasion.

Second, **you must fully disclose** all information that a person would reasonably need to make an informed decision about whether or not to participate. This includes any potential risks, the amount of time participation will take, any discomfort they might experience, and so on.

Third, **the person must be able to comprehend** the information provided.

And finally, if your study involves children who are old enough to assent to participate, you generally must get their assent even if their parents have already given permission.

Adverse events and unanticipated problems

As your research progresses, issues regarding human subjects may arise. Some, but not all, must be reported to the IRB and, potentially, to the federal Office of Human Research Protections. To understand what must be reported, it's important to distinguish between adverse events and unanticipated problems.

Adverse Events

The term **adverse event** is used broadly to include any event that meets the following definition:

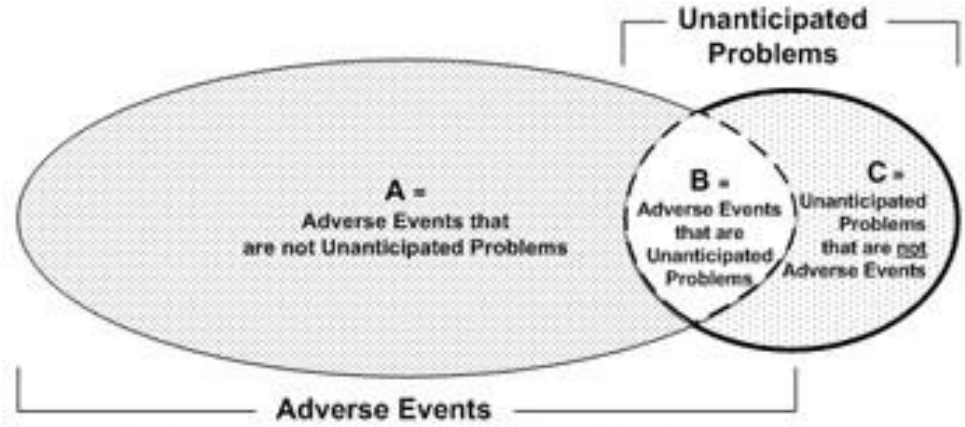
> Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in a research project, whether or not it is considered related to the subject's participation in the research.[2]

Adverse events can be physical or psychological. They're most common in biomedical research, though they can occur in social and behavioral research projects.

Adverse events don't automatically need to be reported. Some adverse events are expected based on the research protocol. If so, they should have been included in the IRB application and addressed in the informed consent document.

However, if an adverse event is surprisingly severe or frequent, or altogether unexpected, then we enter the realm of unanticipated problems.

[2] Modified from the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice.



Under 45 CFR part 46: Do not report A, Do report (B+C)

Unanticipated Problems

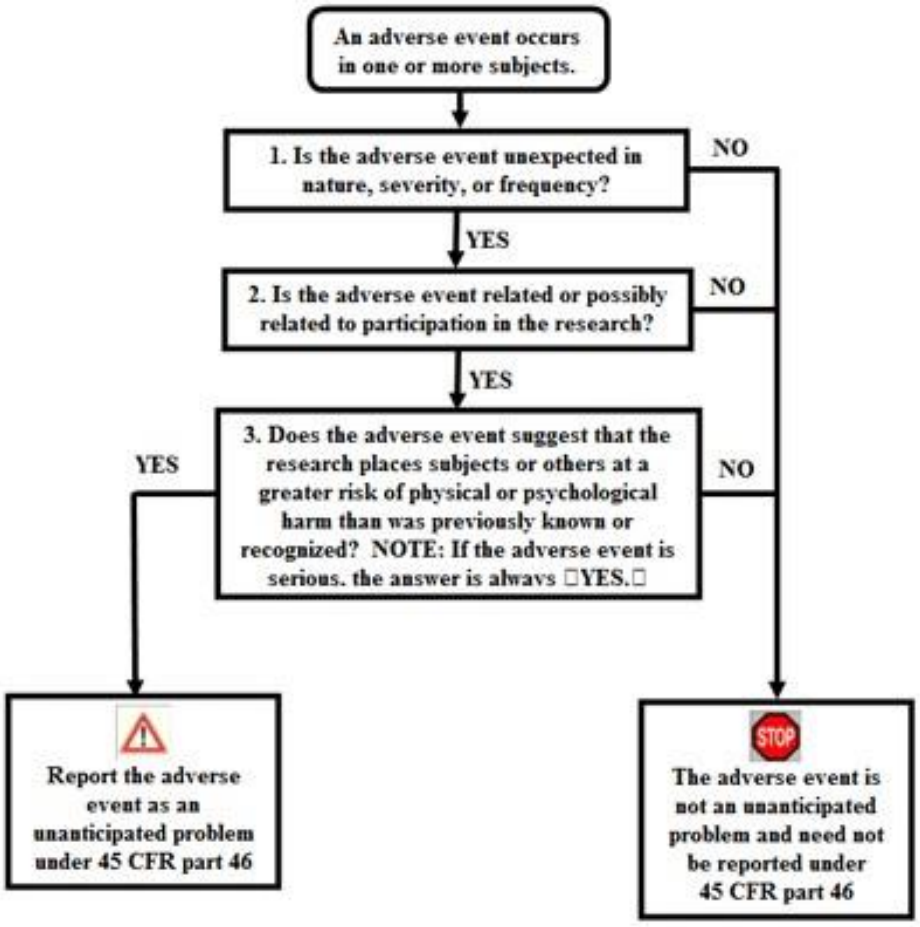
The Office for Human Research Protections (OHRP) defines an **unanticipated problem** as any incident, experience, or outcome that meets *all* of the following:

1. Unexpected (in nature, severity, or frequency) given the research procedures described in the approved protocol and the characteristics of the subject population;

2. Related or possibly related to participation in the research project – that is, there is a reasonable possibility that the problem is caused by research procedures;

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

To decide whether an adverse event qualifies as an unanticipated problem, use the following decision tree:



If any issue arises that meets all three criteria, contact the IRB Administrator (irb@nsc.edu) to discuss the situation. An unexpected problem generally warrants serious consideration of changes to the research protocol or informed consent document, or other possible actions to ensure human subjects are protected. In some cases, the IRB Administrator may determine that the problem must be reported to the OHRP.

When and what you must report to the IRB

Serious unanticipated problems

If any serious unanticipated problem occurs with your research project, you must report it to the IRB Administrator and IRB Chair within **five College working days**. If an event is life-threatening, seek immediate emergency assistance and follow up with an IRB report **within 24 hours**. Within five College working days of any serious unanticipated problem, you must complete the **Adverse Event Form**, available on the IRB Canvas site. If your research project is grant-funded, you may also need to report the problem to your funding agency; see your award document for details.

Changes in expected adverse events If an adverse event was expected but changes in nature, severity, or frequency, report it to the IRB Administrator in a timely manner.

Other issues You must also report the following to the IRB Administrator: any procedural errors during research; breaches in confidentiality or privacy; emotional disturbances among subjects; noncompliance with federal regulations or IRB requirements by anyone working on the research project; any other problems that occur during research.

When a report is received, the IRB may respond in any of the following ways:

- Terminate the research project immediately;
- Temporarily halt the research while an investigation occurs;
- Allow the research to continue while an investigation occurs;
- Ask for a detailed written explanation.

The IRB will choose a course of action based on the nature and severity of the event. Within a reasonable timeframe of receiving your report, the Provost will consult with the IRB Chair and IRB Administrator and decide whether to report to the OHRP, based on OHRP guidelines for reporting.

Non-compliance

As a Principal Investigator, you are required to comply with all federal regulations and IRB requirements and policies. Using human subjects in your research is a serious responsibility and should not be taken lightly. In return for the privilege of asking people to participate in your research project, you are obligated to follow the procedures that have been set up to protect them.

Should the IRB discover, through an audit or other means, that you are not complying with some requirement, the IRB may suspend or terminate IRB approval of your research. If so, your research must cease immediately.

The IRB may also allow your research to continue while an investigation occurs, or ask for a detailed written explanation.

All allegations of serious or continuing noncompliance are investigated by the IRB. Following an investigation, the IRB may issue an official notice of findings and/or an official determination of noncompliance. The IRB may propose or require corrective action at any time during the investigation process.

If the IRB determines that IRB requirements were not followed, the IRB will inform you and the Provost and request that the Provost enforce the requirements. If you do not comply, the Provost will terminate the research project; you will be notified in writing of the reason for the termination. Based on the investigation, the IRB may recommend that the Provost initiate disciplinary action according to NSHE Code Title 2, Chapter 6.

If the project is federally funded and is found to be out of compliance with any federal regulations, or if the project is terminated and IRB approval withdrawn, you are required to report to the funding agency. If you don't do so, the IRB will file a report on your behalf.

Within a reasonable timeframe, the Provost will consult with the IRB Chair and IRB Administrator and decide whether to report to the OHRP, based on OHRP guidelines for reporting.

Chapter

5

IRB Responsibilities

The IRB is responsible for ensuring that all research conducted by faculty, staff, and students associated with NSC complies with federal regulations, state law, and other statutes regarding the protection of human subjects. This includes:

- Developing and distributing materials about IRB requirements and procedures to the campus community;
- Providing training regarding changes to federal regulations;
- Including specific directions in approval letters to PIs (e.g., expiration dates, reminders that significant changes require a Modification Request approval);
- Random audits of research records;
- Maintaining documents related to IRB review activities.

For detailed information about the IRB and relevant federal protections, see NSC's Institutional Review Board Policy for the Protection of Human Subjects (RE 1).

The Provost is the Institutional Official (IO) and signatory to the Federal-Wide Assurance (FWA); as a result, the Provost is legally responsible for research oversight and maintaining compliance with 45 CFR 46 and other relevant regulations and statutes. The IRB serves at the discretion of the Provost and is not an independent body of the Faculty Senate or any other body. The Provost's Office provides staff support and other resources needed to ensure the IRB complies with federal regulations and to provide on-going training for the IRB Administrator, Chair, and members as needed.

IRB records

IRB records pertaining to individual projects are only accessible to IRB members and the project PI, except for the purposes of audit or inspection by federal agencies or appropriate College administrators to assure compliance with federal regulations.

The IRB Administrator prepares and maintains documentation of IRB activities, including:

- Copies of all IRB applications and accompanying materials;
- Minutes of all IRB meetings, including attendance, actions taken, votes on any actions (including a tally of votes), the basis for requested changes to or disapproval of research applications, and a summary of any discussion of controversial issues and their resolution;
- Records of continuing reviews;
- Copies of all approval letters and other significant correspondence between the IRB and PIs;
- A current list of all IRB members, with details required by 46.103(b)(3);
- Maintain current IRB registration with the OHRP;
- Written procedures for the IRB as described in 46.103(b)(4) and (5);
- Statements of significant new findings provided to subjects, as required by 46.116(b)(5).

Records pertaining to a specific research project will be retained for at least three years after the end of the project.

Protocol audits

The IRB has the authority to audit projects when any of the following apply:

- The project is unusually complex;
- There is higher-than-usual potential risk to subjects;
- A researcher on the project has previously failed to comply with IRB requirements or federal regulations;
- There is reason to believe substantial changes may have occurred to the research protocol without IRB approval.

Audits may require information from sources other than the PI, such as the research team, subjects, or colleagues. The IRB also has the authority to observe or have a third party observe the consent process for a project.