Institutional Review Board Procedures Handbook

Protection of Human Research Subjects

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ST. CLOUD STATE UNIVERSITY™

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IRB Procedures Handbook

With this document, St. Cloud State University commits to the assurance that it will comply with the Department of Health and Human Services (HHS) regulations codified at 45 CFR 46, Subparts A – D, for the protection of human subjects involved in research.

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Basic Institutional Procedures

Institutional Responsibility

Consideration for the well-being of living individuals is of the utmost importance whenever conducting research with human subjects. The Institutional Review Board (IRB) is charged with the oversight and responsibility of protecting the welfare and rights of human subjects involved in research under the rules laid out by the code of federal regulations, *Title 45 CFR Part 46 (1979: 45 CFR 46)*, known as the "Final Common Rule," hereafter referred to as "Final Rule." St. Cloud State University (university) requires all human subject research to be in accordance with the Final Rule, both before and during the research being conducted. The IRB reserves the right to defer to legal counsel related to the applicability of policies and procedures.

Scope and Applicability

This assurance applies to all human subject research activities at St. Cloud State University and all collaborations with other institutions which may also fall under that institution's code of conduct within Title 45 CFR Part 46. Ethical principles which govern human subject research include accountability for the following:

- Risks to participants will be minimized and reasonable in relation to anticipated benefits.
- Informed consent will be obtained from all participants to be studied. Each person or their legally authorized parent/guardian/representative will have the consent form fully and carefully explained in language which they can understand. Consent to be obtained without coercion, deception or withholding of information.
- Privacy and safety of all participants during and after the completion of the research will be maintained throughout the entire lifecycle of each project.

Research activity subject to this procedure includes:

- Research that intervenes in the personal lives of living individuals participating in research or where the behavior of the person is being directly or indirectly observed and
- Research designed to develop or contribute to generalizable knowledge.
- Research using the college's non-public records to identify, contact, or recruit potential participants.

Research conducted by any student in a class falls under the faculty member's responsibility if the research is an established item on the syllabus and the faculty member deems the research appropriate.

The university requires ***all individuals*** conducting human subject research to complete IRB training equivalent to or greater than their status on campus at the time the research is conducted (e.g., IRB member, faculty researcher, faculty mentor, undergraduate student, or graduate student).

Cooperative Research

Per Final Rule §46.114, cooperative research projects involve more than one institution, and each institution is responsible for safeguarding human subjects' rights and welfare and complying with 45 CFR 46.

St. Cloud State University will, for cooperative research with other institutions located in the United States, rely upon approval by a single IRB, except when more than a single IRB review is required by law (e.g., tribal law passed by the official governing body of an American Indian or Alaska Native tribe), or when a Federal department or agency supporting the research determines and documents that the use of a single IRB is not appropriate for that particular context.

When SCSU investigators are partnering with investigators from other institutions, it is the SCSU IRB's responsibility to ensure that those investigators are appropriately trained in human subject research. If SCSU is the only IRB reviewing and approving the study, the submission process will involve asking those investigators outside of SCSU for their contact information, university affiliation, and human subject research training records. If SCSU investigators are working on a multi-center study with an external lead investigator (and multiple IRBs are involved), the SCSU IRB will want to see the IRB approval from the lead investigator's institution.

For cooperative research not solely conducted in the United States, St. Cloud State University must rely on a single IRB review for the portion(s) of the research conducted in the United States. For the remainder of the research, St. Cloud State University may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangement to avoid duplication of effort.

Prior Review and Approval Requirement

The President of St. Cloud State University is responsible for all programs and activities conducted through the university and, within this authority, is the assurance that all individuals involved in human subject research have completed the necessary review and approval steps before research implementation.

The Associate Provost for Research serves as the IRB Institutional Official and is responsible for maintaining institutional compliance with federal regulations.

St. Cloud State University requires that all research projects which involve human subjects will only be conducted after a complete research protocol has been submitted and the IRB has reviewed and approved the study.

Guiding Principles of Human Subjects Research

The ethical principles for the conduct of human subject research are defined by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In the Belmont Report, the three principles outlined within the report are central to the ethical treatment of human subjects in assurance of their welfare and protection of rights and include: 1) respect for persons, 2) beneficence and 3) justice.

> **Respect for persons** requires all human subjects participating in the research be given the opportunity to choose what will and will not happen to them during the course of the research to be submitted and approved by the participant during the informed consent process. This includes all information, comprehension, and voluntariness of each participant and all additional protections for those considered vulnerable.
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> **Beneficence** means the principal investigator takes into consideration to "do no harm", maximizes possible benefits, and minimizes potential harms. Therefore, benefits must

outweigh risks, and using human subjects for research is not acceptable unless the research is likely to have some benefit.

Justice requires fair procedures in the selection process of human subjects within the research, and researchers should not take from human subjects without giving back, both individually and collectively. This occurs through an equal selection of human subjects, not targeting a specific population, and enabling sharing of the research risks and benefits.

Researchers are responsible for conducting human subject research legally and ethically. The individual investigator is responsible for establishing and maintaining ethical research practice.

The investigator is responsible for the ethical treatment and prevention of negligent treatment of research participants by collaborators, assistants, students, and employees, all of whom incur parallel obligations.

Ethically acceptable research begins with establishing a clear agreement between the investigator and each participant, which clarifies the responsibilities of each. The investigator must honor all promises and commitments included in this agreement.

The investigator must respect the participant's freedom to decline or discontinue participation at any time. The participant's freedom to deny answers to specific items or questions must be respected. Special vigilance is required to ensure freedom from coercion whenever the investigator is in a position of power over the participant (e.g., coach and athlete, professor and student, caregiver, and client). Any decision to limit freedom from coercion increases the investigator's responsibility to protect the participant's dignity and welfare.

Where research procedures result in undesirable consequences for the participant, the investigator is responsible for detecting and removing or correcting these consequences, including long-term after-effects.

Confidentiality must be respected. If standards of confidentiality are guaranteed to participants, these standards must be met.

Definitions

Terminology

All relevant terminology should meet the definitions laid out by Final Rule, Title *45 CFR Part 46.102*.

Anonymity means that the identity of a participant is not identifiable with their responses by any research team member and cannot be ascertained, directly or indirectly, from any attached information (e.g., IP address, demographic information).

Assent is an agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in human subject research.

Benign behavioral interventions are brief, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples may include having subjects play an online game, solve puzzles under various non-harmful noise conditions, or have them decide how to allocate a nominal amount of received cash between themselves and another person.

Confidentiality means that the identity of a participant is identifiable with their responses by at least one member of the research team or that the identity of a participant could be ascertained from the information collected for the study. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Continuing review refers to reviews of the research protocol by the IRB after the initial review. Continuing review is required annually for expedited and full-review protocols. Federal regulation requires an annual or more frequent review of human subject research projects.

Data collection is any research procedure intended to elicit from or record the actions, reactions, attitudes and/or behavioral manifestations of human subjects participating in a research project.

Debriefing provides participants with previously undisclosed information about the research project following completion of their participation in the research. Debriefing is required whenever deception is used as part of the research.

Deception is deliberately misleading or deceiving participants during the research by withholding information or even providing false information.

Exempt review means a research protocol in which the participants are placed at no more than minimal risk, the participants' confidentiality is maintained, and the protocol meets the criteria for exempt review.

Expedited review is a review by a subcommittee of the IRB for human subject research which involves no more than minimal risk and the protocol meets the criteria for expedited review.

Faculty mentor/advisor is any faculty member who is advising, guiding, or supervising the research of a graduate or undergraduate student. This faculty member is required to maintain up- to-date IRB training and to take full responsibility for the compliance of the student PI with IRB policies and procedures.

Full committee review means reviewing a protocol involving human subject research by a quorum of the IRB.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

> **From or about a living individual** as a participant, including control participant; the focus is on personal opinion or collects private information; collection data about the participant; identifiable private information about business/organization/group members, employees, or staff.

Identifiable means that the participant's identity is or may be readily ascertained by the investigator or will be associated with the information; direct or indirect identifiers which would enable the investigator to readily ascertain the identity of the individual to whom the private information pertains and has been deidentified with a coding system; a key to decipher the code exists, enabling linkage of the identifying information to the private information.

> **Identifiable biospecimen** is a biospecimen for which the subject's identity is or may readily be ascertained by the investigator or associated with the biospecimen.
>
> **Identifiable private information** is private information for which the subject's identity is or may readily be ascertained by the investigator or associated with the information.

Informed consent means participants' willingness to participate after the researcher communicates to them, in a language they can understand, information the participants may reasonably expect in considering whether or not to participate and that minimizes the possibility of coercion or undue influence.

Institution means any public or private entity, or department or agency (including federal, state, and other agencies).

Institutional Official for the IRB is responsible for maintaining institutional compliance with federal regulations.

Interaction includes communication or interpersonal contact between the investigator and the subject.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes (e.g., experimental manipulation; single case; group design; physical procedures or manipulations of individuals or their environment; manipulation of the environment in order to stimulate certain types of behavior.

IRB means an Institutional Review Board established in accord with and for the purposes expressed in this procedure.

IRB Administrator serves as the initial reviewer on behalf of the IRB to follow established policies and procedures in the review of human subject research.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

IRB certification means the official notification by the institution to the supporting federal department or agency component, under the requirements of the Final Rule, that a research project or activity involving human subjects has been reviewed and approved by an IRB following an approved assurance.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, a *legally authorized representative* means an individual recognized by the institutional procedure as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Permission means the agreement of the participant or his or her parent or guardian to participate in the research.

Principal Investigator (PI) is the individual who assumes full responsibility for the research project being conducted and oversight of the entire research process. This may include the supervision of any co-investigators such as a collaborators and student or research assistants. The IRB only recognizes one principal investigator per human subject research study.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., medical record).

Privacy is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally or intellectually) with others.

Protocol is the formal design or plan of a human subject research activity; specifically, the plan submitted to an IRB for review. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for potential participants and research controls, the treatment regimen(s) and the proposed methods of analysis to be performed on the collected data.

Public health authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this procedure, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed ***not*** to be research: (a) scholarly and journalistic activities (e.g., oral history, biography, literary criticism), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; (b) public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority; (c) collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court solely for criminal justice or criminal investigative purposes; and (d) authorized operational activities in support of intelligence, homeland security, defense, or other national security missions.

> **Systematic** is having or involving a system, method or plan; incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.
>
> **Investigation** is a searching inquiry for ascertaining facts; a detailed or careful examination.
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> **Research** is an activity designed to test a hypothesis or answer a research question and permit conclusions to be drawn; sets forth an objective and a set of procedures to reach that objective.
>
> **Designed** is done with purpose and intent; research design/methodology.
>
> **Develop** is to elaborate or expand in detail.
>
> **Contribute** to be an important factor in; help to cause.
>
> **Generalizable** is universally applicable; findings can be applied to populations or situations beyond that studied:
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> - Thesis or dissertation projects involving human subjects conducted to meet a graduate degree requirement are usually generalizable.

- Some publishers or professional organizations may require IRB approval, but the IRB cannot approve human subject research after the fact. The recommendation is to seek IRB approval for research that may be published.

Knowledge is truth, facts, or information.

Research assistant means any person who participates in the gathering or analyzing of identifiable personal information or identifiable biospecimens whose sole access to those data is through their involvement in the research. Clinicians who gather data, including identifiable data, during their regular job duties and produce those data for research purposes are not considered research assistants.

Risk means the extent to which a human participating in research procedures may be exposed to physical, psychological, or other harm.

University, for the purposes of this procedure, refers to St. Cloud State University.

Voluntary refers to a participant's decision to participate, or continue to participate, in a human subject research activity.

Vulnerable population refers to participants such as children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged individuals, or any other population that may be relatively or incapable of protecting their interests through the informed consent process.

Activities Which are Not Human Subjects Research

Activities that do not meet the Final Rule definition of human subject research are not covered by this procedure and do not present more than minimal risk to participants are not human subjects research. It is strongly recommended to seek clarification from the IRB for any human subject's research activities.

Human subject research requires a researcher to obtain IRB approval before conducting research involving human subjects unless it involves class activities or classes designed to teach research methods, where the purpose is research training, and the results will not be disseminated outside the classroom. Even though the student research/training is excluded from IRB review, faculty are responsible for overseeing their student research activities including:

- Informing students of their role in protecting the rights of participants involved in research activities.
- Designing, reviewing and monitoring student research projects to ensure projects are conducted in accordance with all applicable university IRB policies and procedures.
- Assessing the level of risk to research participants and identifying adequate safeguards for the protection of all participants.
- Ensuring all elements of the informed consent process are met.
- Faculty to consult with the IRB Administrator or Chair if any research may be considered greater than minimal risk; involve a vulnerable population; or involve possible physical effects, undesired and/or unexpected psychological changes, invasion of privacy/absence of informed consent or sensitive information.

Examples of activities that do not meet the definition of research may include:

- Class activities/classes designed to teach research methods, where the purpose is research training, and no results dissemination will occur outside the classroom. Faculty are responsible for overseeing their student research activities. Such activities will follow professional ethics and have the permission of any external organization which is being studied.
- Activities designed for educational purposes that teach research methods or demonstrate course concepts only; instructors ensure students meet professional and ethical standards.
- Activity is solely pedagogical, and results are intended for classroom use only.
- Student volunteers or other participants are clearly informed that the activities are an instructional exercise and not actual research and/or will not be used as research data.
- Internal management purposes only such as program evaluation, quality assurance, quality improvement, fiscal or program audits or marketing studies.
- University assessment and strategic planning initiatives (i.e. university collection and assessment of data on student retention; focus groups on mandatory on-campus housing; external organization assessment and strategic planning initiatives about university operations, budgets, etc. from university spokespersons or data sources).
- Initiatives whereby the university collects and submits or permits collection and submission of identifiable data to an outside entity to aggregate the data with information from other institutions and report benchmarking standards to the participating institutions, unless the sharing of data is for research purposes.
- Activities designed solely to ensure university programs or services meet regulations or standards established by outside entities and applicable to postsecondary or professional education institutions (i.e., reports to and evaluations by accrediting bodies).
- Internal customer service or academic program evaluation surveys (i.e., dining services satisfaction surveys, department surveys to assess interest in proposed courses).
- Reports to federal or state agencies for quality measurement of public health monitoring which are required by law.
- Collection of external organizational policies, practices and/or procedures which do not include personal or demographic information. Professional ethics is expected. Permission from the external organization(s) may be required.
- Program evaluation of an organization such as a business, school, programs within schools, government programs, or after-school programs which do not include personal identifiers or demographic information. Professional ethics is expected. Permission from the external organization(s) may be required.

IRB Committee

Member Qualifications

St. Cloud State University's Institutional Official is responsible for appointing qualified IRB members and maintaining membership per §46.107 requiring a minimum of five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB will be sufficiently qualified through the experience and expertise of its members and the diversity of the members, including consideration of race, gender and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Membership will consist of persons knowledgeable in areas of research in which the IRB regularly reviews. The IRB may not consist entirely of members from one discipline. The IRB shall include the IRB administrator and at least one member each: 1) whose primary concerns are in scientific areas, 2) whose primary concerns are in nonscientific areas, and 3) who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The committee shall choose a member to serve as chair for the year and in the absence of the chair, designate another member to preside over a meeting on the chair's behalf.

The Institutional Official has oversight that all members are trained and knowledgeable in the issues typically encountered by the IRB. The Institutional Official will ensure sufficient resources, space, and staff are available to support the activities of the IRB and its recordkeeping responsibilities.

IRB members will not have voting privileges or rights until they have completed the CITI IRB member training. IRB members must complete the CITI IRB member training within sixty days of appointment to the committee or at least before providing guidance/voting on IRB protocols or other official IRB business. To retain membership with voting rights, members must complete and remain current with the IRB member training and meet participation requirements which include the review of up to two protocols per month outside of meetings (if needed) and attendance at more than 50% of the meetings held during the academic year. Protocol review and meeting attendance are required to retain membership, regardless of voting status. If any member does not meet these requirements, they lose the ability to serve as a member for one year. Membership is determined on an annual basis.

Quorum Requirements

The IRB shall review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this procedure. To conduct official business, the IRB meeting must meet the quorum which is defined as 50% of the total voting members plus one additional voting member. At least one nonscientific voting member is needed as part of a quorum. On an occasional basis, members may attend meetings via phone or teleconferencing. IRB approval is obtained through a majority vote when a quorum is present. IRB business that occurs outside of a scheduled IRB meeting will require a majority vote of the total voting members.

Per the Final Rule, IRB members who are directly or indirectly engaged with the research (researcher, co-investigator, faculty advisor on protocol) or who have a direct financial interest in the protocol under consideration may not be counted towards quorum or be involved in the review or approval of the project, except to provide any information requested by the IRB.

Alternate Membership

Two members may share one IRB member position when the timeframe for primary membership is clearly defined for each. The alternate member may substitute for the primary member who cannot attend a meeting and may vote in the primary member's absence if their voting status is maintained.

Specific Expertise

At its discretion, the IRB may invite individuals with competence in special areas to assist in reviewing issues that require expertise beyond or in addition to that available on the IRB; however, these individuals may not vote with the IRB.

Recordkeeping

The IRB Chairperson shall maintain appropriate records for three years following the completion of a research project, in accordance with 45 CFR 46.115(b) including, in particular, the following:

- File on each research proposal received that contains a copy of the original proposal and a separate copy that documents any modifications to it
- A record of the review procedure used, and copies of the written evaluations of the reviewer(s)
- Copies of correspondence and memoranda of discussions relevant to the consideration of the proposal;
- Copies of all notifications relating to the proposal;
- Records of continuing IRB oversight activities;
- Reports from researchers on the progress of the project
- Copies of statements of significant new findings provided to participants, as required by 45 CFR 46.116(b) (5).
- Provide an updated list of all IRB members and a written description of IRB procedures, as required by 45 CFR 46.103.
- Annual reports summarizing activities covered by this assurance.

IRB Review Types

St. Cloud State University uses several methods to review and approve research protocols, changes to protocols and annual renewal of approved protocols which involve human subjects. This section will outline the review methods used for various types of research.

Exempt Review Research Categories

Exempt reviews are conducted by at least one experienced IRB member, typically the IRB Chair. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The IRB reviewer(s) must determine if the research qualifies for the exempt review process; investigators cannot make this determination for themselves. The IRB reviewer(s) may also elevate the research to expedited or full board review.

The significance of an exempt review is that the IRB does not monitor the research activity is after the exempt status designation. However, all ethical requirements for conducting human subject research still apply. To qualify for the exempt review process, the research must be no more than minimal risk and the only involvement of human subjects would be in one or more of the exempt categories as defined by federal regulation §46.104(3):

1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on
   - Regular and special education instructional strategies,
   - The effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) ***if*** at least one of the following criteria is met:
   - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation;
   - Neither of the above conditions are met, but a limited IRB review determines that adequate provisions have been made to protect the privacy of subjects and to maintain the confidentiality of the data.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording ***if*** the subject prospectively agrees to the intervention and information collection ***and*** at least one of the following criteria are met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation;
- Neither of the above conditions are met, but a limited IRB review determines that adequate provisions have been made to protect the privacy of subjects and to maintain the confidentiality of the data.

Research involving deception does not qualify for exempt review unless the subject authorized the deception through a prospective agreement to participate in research in circumstances in which they will be unaware of or misled regarding the nature or purpose of the research.

4. Secondary research for which consent is not required, which uses existing data, documents, records, pathological specimens or diagnostic specimens if at least one of the following criteria is met:
   - The identifiable private information or identifiable biospecimens are publicly available,
   - Information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects,
   - The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

   Some examples of existing data from publicly available sources may include:
   - Data set used for public sources such as newspapers, reports, books or journals;
   - Data set from federal or state government program/agency available to the general public (i.e. census data);
   - Information shared without conditions on its use;
   - Data sets which require payment of a fee to gain access to the data;
   - Data set used for published documents such as thesis or dissertations; or
   - Information available to members of the general public

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or are otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or passible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies:
   - If wholesome foods without additives are consumed; or
   - If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for potential secondary research use for which broad consent is required. This exemption does not provide IRB approval for any subsequent secondary research; additional protocol review may be required for any subsequent use of the data beyond storage and maintenance.

8. Secondary research for which broad consent is required, using identifiable private information or identifiable biospecimens, if all of the following criteria are met:
   - Broad consent for the storage, maintenance, and secondary use of the identifiable private information or identifiable biospecimens was obtained in accordance with informed consent policies;
   - Documentation of informed consent is presented, or waiver of documentation was obtained in accordance with §46.117; ***and***
   - An IRB conducts a limited review and makes the determination that (a) the research to be conducted is within the score of the original broad consent, and (b) the investigator does not include returning individual research results to subjects as part of the study plan. This provision may be waived if there are legal requirements for the investigator to return individual research results.

Expedited Review Research Categories

Expedited reviews of initial protocols are conducted by at least two qualified IRB members. Typically, the IRB Chair conducts the initial protocol review and IRB members rotate responsibility for second review, excluding any protocols that represent a conflict of interest for the designated reviewer(s). The significance of an expedited review is that the review of the research does not need to wait for the full IRB to convene. All IRB members will receive an electronic copy of any expedited review protocol, and members will have one week in which to review the protocol, provide review comments or request full board review. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research.

The IRB reviewers must determine the research project qualifies for the expedited review process; investigators cannot make this determination for themselves. In order to qualify for the expedited review process, the research must be no more than minimal risk and meet one of the categories listed below:

1. Clinical studies of drugs and medical devices only when one of these conditions is met:
   - Research on drugs for which an investigational new drug (IND) application (21 CFR 312) is not required. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
   - Research on medical devices for which (i) an investigational device exemption (IDE) application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, as follows:

- From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
   - Hair and nail clippings in a nondisfiguring manner
   - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
   - Permanent teeth if routine patient care indicates a need for extraction
   - Excreta and external secretions (including sweat)
   - Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
   - Placenta removed at delivery
   - Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
   - Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
   - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings,
   - Sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples include:
   - Physical sensors that are applied either to the surface of the body or used at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
   - Weighing or testing sensory acuity
   - Magnetic resonance imaging
   - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). Some research in this category may be exempt from the HHS regulations for the protections of human subjects.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies that are not eligible for exempt review because they
   - Involve children as subjects,
   - Involve individuals with impaired decision-making capacity,
   - Are conducted without the prospective agreement of the subject, including interventions involving deception,
   - Are not brief in duration,
   - Are not limited to verbal or written responses by the subject, data entry by the subject, or observations of the subject.

8. Continuing review of research previously approved by the convened IRB as follows:
   - Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   - Where no subjects have been enrolled no additional risks have been identified; or
   - Where the remaining research activities are limited to data analysis.

9. Minor changes to, including continuing review of, research previously approved by the convened IRB. Minor changes are changes to the research protocol that do not impact the level of risk imposed on human subjects, involve no additional risks, do not change the subjects' experience of participation, and do not disqualify the research from the exempt or expedited review category under which it was initially approved. Examples include:
   - Adding or removing sites for participant recruitment, such as including additional public listservs or recruiting teachers from an additional school district.
   - Approval of recruitment fliers or scripts, provided that the method of recruitment (i.e., the use of fliers or the use of scripts) was included in the initial protocol reviewed and approved by the IRB,
   - Changing the total number of subjects to be enrolled in the study, provided that the risk to confidentiality is not impacted.

Full Board Review Research Categories

The full board may approve, require modifications before approval, or disapprove any research as it deems appropriate. In order for the research to be approved, it must receive approval of a majority of a quorum of IRB voting members at a convened meeting. Research subject to full board review is any research not meeting the standards for exempt or expedited review and includes:

- Research which presents more than minimal risk to participants;
- Research requested for full board review by any IRB member;

- Research where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation or be stigmatizing;
- Classified research involving human subjects
- Umbrella protocol which outlines the standard processes a department/center will use when proposing research with participants; once approved, a shortened version of the IRB protocol may be submitted for each individual research project covered under the umbrella protocol

IRB Approvals

Criteria for IRB Approval of Research

Per Final Rule §46.111, minimally the criteria used to review and approve research shall determine that all of the following requirements are satisfied:

Risks to subjects are minimized

- By using procedures which are consistent with sound research design and which do not necessarily expose subjects to risk and
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (i.e. possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable, considering the research purpose, research setting and research involving subjects who are vulnerable to coercion or undue influence.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116 General Requirements for Informed Consent.

Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 Documentation of Informed Consent.

Data Monitoring - When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

Privacy and Confidentiality - When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, people with cognitive impairments, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

Researcher(s) are adequately trained and qualified for their respective role(s).

Informed Consent

Informed consent must be obtained and documented from each prospective human subject or the subject's legally authorized representative before involving them in any research covered by this procedure, except when a waiver of informed consent procedures has been approved and documented by the IRB. The information that is given to the subject or the legally authorized

representative must be in language that is understandable to the subject or the legally authorized representative. Informed consent must include a concise and focused description of key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons one might or might not want to participate in the research. The information must be organized and presented in a manner that facilitates comprehension.

The IRB may approve implied informed consent for some survey-based research. Implied informed consent does not require a signature but is not exempt from the required elements of informed consent. An implied consent on a survey asks the participant to acknowledge that by continuing with the survey, they are indicating that they are consenting to participate in the study. Therefore, completing the survey serves as documentation of the participant's consent.

No informed consent may include any exculpatory language through which the subject or legally authorized representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, sponsor, institution, or its agents from liability for negligence.

Informed consent must, at minimum, include

- A statement that the study is research,
- An explanation of the purposes of the research,
- The expected duration of the subject's participation,
- A description of the procedures to be followed,
- Identification of any procedures that are experimental,
- A description of any reasonably foreseeable risks or discomforts to the subject,
- A description of any benefits to the subject or to others that may reasonably be expected from the research,
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject,
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained,
- An explanation of whom to contact for answers to pertinent questions about the research, research subjects' rights, or research results,
- An explanation of whom to contact in the event of a research-related injury to the subject,
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

For research that involves more than minimal risk:

- An explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained

For research that involves the collection of identifiable private information or identifiable biospecimens, one of the following must be included:

- A statement that identifiers will be removed from the data and, after such removal, the information or biospecimens could be used for future research studies or distributed to

another investigator for future research without additional informed consent from the subject or legally authorized representative, or

- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research.

As appropriate, additional elements of informed consent may include:

- A statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus, should the subject be or become pregnant) that are currently unforeseeable,
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or legally authorized representative's consent,
- Any additional costs to the subject that may result from participation in the research,
- The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject,
- A statement that significant new findings developed during the course of the research may relate to the subject's willingness to continue participation, and a statement that any such findings will be provided to the subject,
- The approximate number of subjects involved in the study,
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit, and whether or not the subject may share in this commercial profit,
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subject and, if so, under what conditions,
- Whether research involving biospecimens will or might include whole genome sequencing,
- The period of time for which identifiable personal information or identifiable biospecimens will be stored, maintained, and/or used for research purposes

Researchers must ensure that participants are not coerced into participating in the research. If the researcher is conducting the research with their own students (or is in a position of power relative to the participants), the SCSU IRB recommends that someone other than the researcher conduct the consent process. Otherwise, the researcher will need to explain to the IRB the process that they will follow to ensure the participants will be free from experiencing any real or perceived coercion.

Waiver of Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain informed consent provided the IRB finds and documents that:

> The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate or otherwise examine:
>
> - Public benefit or service programs;
> - Procedures for obtaining benefits or services under those programs;

- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs

And the research could not practicably be carried out without the waiver or alteration.

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

The informed consent requirements in this procedure are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed for informed consent to be legally effective. Nothing in this procedure is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable federal, state, or local law.

Deception

Sometimes, to accomplish research objectives, researchers must deliberately mislead/deceive participants during the research by withholding information or even providing false information. As a result, participants are not fully informed about the research when they consent to participate. After an investigation utilizing deception, the investigator is required to explain to participants all reasons for the deception to provide full clarification of the nature of the study and remove any misconceptions which may have arisen. Where scientific or humane values justify delaying or withholding information, the investigator is responsible for ensuring that no damaging consequences to participants may occur.

Letters of Cooperation

Letters of cooperation for any external research site or cooperating organization or agency will be required. A letter of cooperation serves as documentation from the external entity that it understands the nature of the researcher's work, outlines its commitment to the project, and states approval of the study as it relates to its involvement. The letter is generally signed by someone in authority at the external entity. When working with other colleges and universities, it is strongly suggested that researchers check with central administration as these institutions may have specific processes for oversight of research occurring on or with their campuses.

Recruitment

Recruitment materials used in human subject research must be reviewed by the IRB. Content should be limited to the information the prospective participants need to determine their eligibility and interest. It is generally acceptable to include basic study information in recruitment materials, including:

- The title of the research study
- The purpose of the research
- A brief summary of the protocol
- Basic eligibility criteria
- Study location
- Name and contact information of the primary investigator
- Time or other commitment required of participants

Recruitment materials should not:

- Promise or imply a benefit beyond what is explained in the informed consent
- Use language that is unduly coercive
- Advertise compensation using bigger or bolder font than the rest of the messaging

IRB Approval

Exempt reviews are conducted by at least one experienced IRB member, typically the IRB Chair or a designated member if the Chair has a conflict of interest. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research.

Expedited reviews of initial protocols are conducted by at least two qualified IRB members. Typically, the IRB Chair conducts the initial protocol review, and IRB members rotate responsibility for the second review, excluding any protocols that represent a conflict of interest for the designated reviewer(s).

The full board may approve, require modifications before approval or disapprove any research deemed appropriate. For the research to be approved, it must receive approval of a majority of a quorum of IRB voting members at a convened meeting.

Conditional Approval

The IRB reviewer(s) for exempt, expedited, or full board review may grant conditional approval of a protocol subject to modifications outlined. As designated by the IRB Chair, the IRB Administrator would work with the principal investigator to update the protocol in accordance with the requirements of this procedure, and the IRB approval would be effective once the outlined modifications have been satisfied.

Minor Changes to Study Approval

Minor change requests for research previously approved by exempt, expedited, or full board review shall be conducted by at least one qualified IRB member, typically the IRB Administrator, as designated by the IRB Chair. In reviewing a minor change request, the reviewer(s) may exercise all of the authorities of the IRB, except the reviewer(s) may not disapprove the research.

Continuing Review Approval

Continuing review requests for research previously approved shall be conducted by at least one qualified IRB member, typically the IRB Administrator, as designated by the IRB Chair. In reviewing the continuing research request, the reviewer(s) may exercise all of the authorities of

the IRB, except the reviewer(s) may not disapprove the research. Examples of continuing review requests may include:

- Participant recruitment/enrollment continues; current consent/assent form(s) to be attached
- Data collection continues with enrolled participants; no additional participants will be recruited
- Research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants
- No participants have been enrolled, and no additional risks have been identified
- Protocols reviewed by the full board have documented research involves no greater than minimal risk, and no additional risks have been identified

Final Report Approval

The principal investigator on expedited or full board review protocols should complete and file a final report with the IRB when:

- The project is complete;
- Data collection has been completed, but data analysis continues; or
- The research project will not be conducted.

Final reports will be reviewed by at least one qualified IRB member, typically the IRB Administrator, as designed by the IRB Chair. If any significant reactions or problems are reported, the IRB reviewer will bring the matter to the attention of the Institutional Official in a timely manner. The Institutional Official will review the final report and the related IRB protocol according to the Policies and Procedures for the Handling of Allegations of Academic or Research Fraud and Serious Misconduct at St. Cloud State University.

Federally Funded Proposals Lacking Definite Plans

Certain types of applications for grants, cooperative agreements or contracts are submitted to federal departments or agencies with the knowledge that participants may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving participants remain to be selected; and projects in which participants' involvement will depend upon completion of instruments, prior animal studies or purification of compounds. These applications need not be reviewed by the IRB before a federal award may be made. However, no participants may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in the Final Rule §46.118 Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects, and certification submitted by the university to the federal department or agency.

Federally Funded Research Later Proposed to Involve Human Subjects

In the event federally funded research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by the IRB, as provided in Final Rule §46.119 Research Undertaken

Without the Intention of Involving Human Subjects, a certification submitted by the university to the federal department or agency and final approval given to the proposed change by the federal department or agency.

Review Timeframe and Approval Period

The IRB members strive to review all research protocols in a timely manner. The length of time needed for the review process depends greatly upon the completeness of the protocol and required IRB training. Questions need to be answered in their entirety, and all supporting documents need to be attached. Incomplete protocols increase the total amount of time needed for the review and approval process.

Review Timeframe

Initial IRB review should occur within two weeks of receiving the protocol. When this review occurs, the researcher may receive an email requesting additional information or clarification. Once a researcher responds, the review process continues with communication to and from the researcher until the first IRB reviewer believes the protocol is complete.

If the protocol qualifies for the exempt review process, approval can be granted after the protocol is complete and the first reviewer assures the study is in alignment with IRB procedures.

If the protocol qualifies for the expedited review process, the first reviewer will continue the initial review process until the protocol is complete. Then the protocol is sent to a second IRB member for their review and feedback; one week is a standard timeframe for the second review process. When the protocol is sent to the second IRB member, it is also sent to all IRB members who then have one week to review, comment and/or request full board review of the research.

Any changes requested by IRB members are submitted to the first reviewer who then reviews and/or addresses these concerns with the researcher. Once any requested changes have been made to the protocol and the research is in alignment with IRB procedures, IRB approval can be granted.

If the protocol is to be reviewed by the full board, members are sent the protocol one week prior to the regularly scheduled IRB meeting. Often times the IRB administrator will request the researcher and, if this is a student, their faculty advisor, to attend the IRB meeting to address any questions the board may have. The full board may grant approval, grant conditional approval pending modifications, request the protocol to be reviewed at the next IRB meeting or may withhold approval. Timeframe for IRB review and approval depends upon the review time needed for this process.

Length of Approval Period

When the research is approved, the IRB administrator's office will send email notification of the IRB approval letter and stamped consent form(s) to the researcher, co-investigators and faculty advisor, as applicable. The approval letter will indicate the type of IRB approval and the approval period.

The approval period is dependent upon the type of IRB review conducted. For protocols reviewed through the exempt review process, approval can be given for up to three years without the need for continuing review. Research continuing beyond three years from initial approval may be resubmitted.

Approvals granted through the expedited or full board review process may be granted for up to one year in length, with the option to renew for up to two one-year extensions through review and approval of a submitted Continuing Review Report. There are times when risks associated with a particular protocol are such that continuing review should occur more frequently than annually, thus the approval period may have a shorter time interval.

Protocol Closure

The researcher may close an expedited or full board approved protocol at any time by completing, signing and submitting to the IRB the Final Report form.

The IRB administrator's office will send email notification to the researcher about 30 days in advance of an IRB approval end date requesting either the Final Report or a Continuing Review form. A second attempt will be made to receive either form and if no request is received, the IRB file will be administratively closed. If the researcher subsequently decides to pursue the study at a later date, a new IRB protocol will need to be completed and submitted for review.

Approval Overturned, Denied or Suspended

After IRB approval has been granted at any review level, the approval may be overturned or denied through a majority vote of a quorum of IRB voting members at a convened meeting, if the approval is later deemed inappropriate and further revisions to the research are needed in order to meet the standards of ethical research.

Per Final Rule §46.112 Review by Institution, research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the university. However, those officials may not approve the research if it has not been approved by the IRB.

Per Final Rule §46.113 suspension or Termination of IRB Approval of Research, an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the principal investigator, appropriate university officials and the federal department or agency head, if applicable.

Appealing an IRB Decision

If a researcher believes an IRB decision is unfair, unsubstantiated or too restrictive, the researcher may discuss their viewpoint with the IRB chair, IRB administrator or Institutional Official. The researcher should be prepared to present how their proposed study aligns with the Final Rule and the university's IRB Procedure.

If the differences cannot be resolved, the researcher must present to the full IRB at a convened meeting with a quorum of members. At least one week prior to the meeting, the researcher needs to provide the IRB administrator with a written appeal and any supportive documents which can be disseminated to board members for their review prior to the meeting. Based upon this appeal, the IRB will issue a determination on the proposed research within 30 days of the meeting.

Research Conducted Without IRB Approval

In such cases where they may fall within the realm of human subject research and this research is being conducted without having obtained the prior approval of the IRB board or chairperson, the IRB Chairperson will initially send a memorandum to the researchers requesting that they suspend the research project immediately. Until such time as the research and researcher in question has gone through the appropriate measures of obtaining IRB approval.

Failure to respond and act upon this request within a reasonable time of 14 days, a second request memorandum will be sent and copies will be sent to the Dean of graduate studies, Vice President of Academic affairs, and the acting President of the University. Again, the research should cease to continue until such time as they have received an official IRB approval notification from the IRB board or measures have been taken from the appropriate authorities.

Training and Research Responsibilities

IRB Training

All investigators and research personnel involved with human subject research are required to complete IRB training, regardless of funding source. The training provides a base knowledge for the ethical and responsible treatment of human subjects and is required per our Federal wide Assurance. Training must be completed prior to the submission of an IRB protocol.

The university uses the Collaborative Institutional Training Initiative (CITI) to provide online training for various learner groups served on campus. In coordination with Academic Affairs and Graduate Studies, the IRB has determined the following levels of training:

- IRB Training for Undergraduate Students
  - Complete 2 required modules and 1 elective module
  - Note: if you plan to attend graduate school, recommend completing the training at the graduate student level since training is good for five years and fairly standardized across institutions
- IRB Training for Graduate Students
  - Complete 3 required modules and 1 elective module
- IRB Training for SCSU Faculty and Staff
  - Complete 4 required modules and 2 elective modules
- IRB Training for IRB Members
  - Complete 6 required modules and 2 elective modules

Research Responsibilities

All research involving human subjects conducted by or under the direction of any faculty member, student, or other employee of St. Cloud State University is subject to the policies and procedures set forth within this document. It is the responsibility of the individual researcher to determine whether a project will involve human participant involvement. Furthermore, it is the responsibility of each principal investigator (whether faculty or student) to contact the IRB chairperson for advice unless the research proposed clearly defines that the data collection method does not involve human participation.

The institutional responsibility of St. Cloud State University and its researchers shall determine the full scope of applicability concerning appropriate assurance measures are taken with each research project held on the grounds of St. Cloud State University (i.e., all research sponsored by St. Cloud State University and all research being conducted using any facility or property of St. Cloud State University). If any doubt exists, the researcher should contact the Chairperson of the IRB for advice unless the research proposed clearly defines that the data collection method does not involve human participation. The policies and procedures described in this assurance apply to all activities, regardless of funding.

Scholarship of Teaching and Learning (SoTL) Research

SoTL research occurs when faculty treat their own teaching as an area of scholarly inquiry. The St. Cloud State University IRB acknowledges that SoTL research might have unique considerations in design, reporting, and oversight, and therefore we provide some guidance and considerations for researchers conducting this category of research.

Definition of SoTL Research

Federal guidelines define **research** as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

The difference between research and instructor or course assessment activities is based on the goal of the study. With SoTL research, the researcher is adding to a body of knowledge about teaching and learning and intends to share their findings with the broader scholarly community. SoTL researchers typically make changes in their course design or practice and provide an account of the results that draw on evidence of student learning. The SCSU IRB interprets SoTL research as the collection and evaluation of teaching and learning data intended to be generalized and shared outside of the SCSU learning community.

Definition of SoTL Research Using Human Subjects

The federal definition for **human subjects** is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information". If either of these conditions are true, the federal definition for use of human subjects has been met.

Most SoTL investigations meet the federal definition for human subjects because they involve interactions with students where the classroom environment is changed for research purposes or where identifiable private information is being collected.

Consent to Participate in SoTL Research

All research involving human subjects, including SoTL research, requires an informed consent process. Human participants must voluntarily agree to participate in the research after they are made aware of everything involved in the research study, including all potential benefits and risks. Researchers must ensure that participants are not coerced into participating in the research. In SoTL research, if the researcher is conducting the research with their own students (or is in a position of power relative to the participants), the SCSU IRB recommends that someone other than the researcher conduct the consent process. Alternatively, the researcher will need to explain to the IRB the process that they will follow to ensure participants won't experience any real or perceived coercion.

SoTL Research Not Requiring Consent

Some SoTL research may require IRB review but may not require consent from the participants. This research would fall under "Exempt Category 4: Secondary research".

Secondary SoTL research uses **preexisting** identifiable private information if at least one of the following criteria is met: (i) the identifiable private information is publicly available, or (ii) information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Example: An instructor has developed a new method for teaching a particular unit of Biology. They plan to compare the students' final exam scores after learning the material with the new methodology with the final exam scores from students from the previous academic year. Because the SoTL researcher designed this research study during the current semester, they must obtain informed consent from the group of students they are teaching with the new methodology. However, they do not need to obtain informed consent from the students from the previous academic year, provided that the final exam scores are not attached to the students' identities and the researcher does not have any need to contact any of those students.

SoTL Research Involving Minors

In research involving human subjects, minors (under the age of 18 in Minnesota) cannot give informed consent. The parent or guardian must give consent for their minor to participate, and the minor must give assent to their involvement. However, in the university setting, there are some 17-year-olds in classrooms performing the same academic work as their peers who are legal adults. Since SoTL research is an evaluation of teaching and learning, and the risk in this type of research is minimal, the SCSU IRB does not require SoTL investigators to ask the age of their research participants.