A. Purpose of the Institutional Review Board

1. Description of the Charge

The institution affirms its policy to safeguard and respect the rights and welfare of human subjects in scientific research. In order to carry out this obligation, the institution, through its IRB, is responsible for conducting initial and continuing review of all research that involves human subjects. Decisions regarding protection of human subjects in research submitted to the IRB are final as required by 45 CFR 46. No official in the institution may approve research protocols if it has not been approved by the IRB. The IRB reports to the Vice President for Academic Affairs and may consult with the Educational Policies Committee (EPC) as needed to change or implement new policies. The IRB will also educate the university community about the research process and concerns for protection of human subjects. It will also address concerns faculty, students, and staff may have about the IRB process.

2. General Statement of Responsibility

All research involving human subjects must be reviewed at one of three levels or through class protocols, described in more detail below and in the IRB website. According to the Office of Human Research Subjects Protection (OHRP), human subjects research requiring IRB review is defined as “a systematic investigation designed to contribute to generalizable knowledge.” In order to approve research, the IRB shall determine that all of the following requirements are satisfied:
a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
b. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
c. Selection of subjects is equitable.
d. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative.
e. Informed consent will be appropriately documented.
f. Adequate provision is made to monitor data to ensure the safety of the subjects.
g. There are adequate provisions to protect the privacy of subjects and confidentiality of the data, including no attempts to coerce subjects. (45 CFR 46.116)

Investigators cannot begin research involving human subjects until a complete application has been submitted to the IRB, reviewed and approved. The IRB will notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval. If the IRB disapproves a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person and in writing.

The use of human subjects is a privilege granted to the investigator rather than a right. The policies and procedures of this board are designed to meet minimal criteria established by Federal law and Federal regulations. A project approved by the IRB that lasts longer than one year is required to submit a written annual report to verify that no material changes have occurred since previous the IRB review. The IRB may require more frequent reviews at its discretion. Material changes in the study or in the consent form must be reported to and reviewed by the IRB before the changes may be implemented.

B. Definitions

1. Research

Research is defined in 45 CFR 46 as “systematic investigation designed to develop or contribute to generalizable knowledge.” Activities that meet this definition constitute “research” for purposes of the regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some “demonstration” and
“service” programs may include research activities. This may include projects at the undergraduate or graduate level such as thesis, honors, or seminar projects.

2. Human subject

“Human subject” is defined in 45 CFR 46 as “a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. See 45 CFR 46 for the definitions of “interaction”, “intervention”, and “private information.”

3. Risk

“Risk” is the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both probability and magnitude may vary from minimal to significant.

4. Minimal risk

“Minimal risk” is defined in 45 CFR 46 as “the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

5. Informed consent

An investigator may involve a human subject in research only if the investigator has obtained the legally effective and informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The investigator must provide the information to the subject or representative in a written format that uses language understandable to the subject or representative. The investigator cannot include in the consent process, either through written or oral information, any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Please review the format for a consent form provided in Appendix and the checklist in Appendix for essential elements of consent.
C. Scope of Activities

The IRB reviews applications at three levels. These levels are briefly introduced below. In addition, the IRB will receive reports on and review material concerning class protocols. Researchers have the initial responsibility to determine the level of review of their project; however the IRB has the ultimate responsibility to identify this level for committee review. Specific information about the nature of each level is located in the application policies found in the IRB website.

1. Level 1: Review for Exempt Status

Research is reviewed for exempt status by an IRB committee member if it involves minimal or no risk procedures such as surveys/ interviews, observation of non-institutionalized adults, and educational tests. Exempt from Committee review does not mean exempt from consent! Exempt research is exempt only from full Committee review. Any research involving protected classes or vulnerable populations of subjects (such as children, prisoners, pregnant women, mentally disabled persons, research by faculty on university students enrolled in their own courses, or economically or educationally disadvantaged persons) including surveys, is never exempt. See below for details of the Exempt application process.

2. Level 2: Expedited Review.

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Requests that qualify for this level of review require reading by at least two members of the IRB and the chair or one co-chair. The reviewers may exercise all the authorities of the IRB except disapproval. If the application is recommended for disapproval, the full committee must review it. Only the full IRB can disapprove an application.

Research at the Expedited level covers minimal risk procedures such as those involving small amounts of blood, dental plaque, moderate exercise, voice recordings, etc. Also, see the exceptions outlined above in the Exempt section that would move research involving surveys or interviews to the expedited level.

3. Level 3: Full Review.

All research not falling into the other two categories and most research involving children or minors requires full review because it places the subject at more risk than research that qualifies for exempt or expedited
review. Research requiring full review means that it is read, discussed, and voted upon by the full IRB committee.

4. **Class protocols**

Class protocols involve projects done by a SCU student for a SCU class and conform to the following criteria:

a. All projects should be Exempt from risk/benefit review as defined by Federal guidelines (see above, Level 1: Review for Exempt Status).
b. Subjects will not provide and researchers will not keep any identifiers that will link the results back to the participants.
c. Projects will not involve any personal, sensitive, or incriminating topics or questions.
d. Projects will not manipulate behavior of the subjects beyond the range of usual classroom activity or university life.
e. Projects will not involve physically invasive contact with subjects.

Class protocols should be turned into the IRB as early as possible during the semester. Class protocols will be reviewed by the IRB Chair(s) as they are submitted to the IRB. Any student project that is not consistent with the criteria defined above should be submitted to the IRB for review.

5. **Requests for review from researchers sponsored by other institutions.**

All researchers who are not enrolled students, faculty or staff members of St. Catherine University are required to have a university faculty or staff member as a sponsor for any projects using human subjects. All researchers from other institutions who want to conduct human subject research at St. Catherine University must include in their applications the signature of the primary investigator from their own institution, the signature of the St. Catherine's sponsor, and documentation showing approval by the IRB of the researcher's own institution. For purposes of review, the St. Catherine University IRB may accept the approved IRB application from the researcher’s institution in lieu of the SCU IRB application, according to the discretion of the SCU IRB chair or co-chair.

6. **Amended Protocols.**

During the course of a study, subjects may experience unexpected side effects or the researcher may gain knowledge from another research project that impacts research design. The researcher(s) are required to inform subjects of any important new information that might affect a subject’s willingness to continue participating in the research. If
researchers want to change a procedure in a study that has already received approval, they must prepare a written description of the change and the reasons for the change. Such changes include the entry or enrollment criteria of subjects, procedures for data collection, or some activity or procedure that must be changed because of an adverse event. The IRB will then reassess the balance of risks to benefits. In light of the reassessment, the IRB may require that the research be modified or halted altogether. Alternatively, the Committee may relax special precautions or criteria for inclusion.

7. Adverse Events

An adverse event is defined as any undesirable and unintended, although not necessarily unexpected impact on a subject, as a result of therapy or other intervention. Researchers must report in writing to the IRB all adverse events, including isolated incidents of unanticipated adverse reactions. The IRB must then decide whether the research should be modified. In addition, a report from one research activity may sometimes be relevant to the evaluation of another.

D. Review Procedures

Detailed review procedures are described in the IRB website. Information about procedures concerning class protocols and general review procedures are included below. Researchers may not begin recruitment, enrollment of subjects, or data collection until they have received IRB approval.

1. General procedures

a. It may be helpful for the researcher to consult with the IRB office, IRB chair(s), or committee member to determine the level at which to submit an application or procedures concerning the protection of human subjects. Members of the committee will provide assistance when asked. All student initiated research and all research proposed by non-SCU community members must be overseen by a faculty or staff sponsor.

b. Applications are turned into the IRB administrative assistant. Researchers should provide the appropriate number of copies for the assigned level of review.

c. Exempt and Expedited reviews may be turned in at any time. Full reviews need to be turned in a minimum of one week prior to the next scheduled IRB meeting (see schedule on the IRB website).

d. The whole committee will conduct full reviews. The researcher and/or their faculty advisor should plan to attend this meeting if possible. In collaboration with the applicant(s), the IRB Chair(s) and administrative
The assistant will attempt to schedule the project for full committee review at the earliest possible date when the researcher may be available.

e. Researchers and faculty advisors will receive a response from the committee in writing. This may indicate approval as written, approval with stipulations, deferment/tabling the project, or disapproval/removal of ongoing approval. The IRB response will include details of any modifications requested and reasons for the committee’s decision.

2. Continuing review of previously approved research

a. Annual review is required for ongoing research projects. Researchers planning to continue a project beyond one year must submit the IRB renewal form, which may be found at the St. Catherine University IRB website.

b. IRB renewals will be reviewed at the same level as the initial application. For projects initially approved by the full committee, Federal regulations permit continuing review at the expedited level when no additional risks have been identified and the initial IRB review indicated no more than minimal risk or 2) the remaining activities are limited to data analysis.

c. IRB oversight of a research project is considered complete when the data collection is complete and all original identifiable data has been destroyed. At that point, the investigator is expected to submit to the IRB a project completion summary.

d. Research projects that qualify as exempt are not required to undergo annual renewal. If the investigator intends to alter the original protocol in terms of additional subject recruitment, personnel changes, extension of the timeline for data collection, or any change that could affect the risk to subjects, then IRB approval must be obtained prior to implementation.

3. Class protocols

a. The instructor should submit one protocol application to the IRB. The protocol should be submitted each year that the class is offered.

b. The instructor will educate the students on the IRB process and state that they have completed the class protocol on the student’s behalf.

c. Projects should not be initiated until the class protocol is submitted to the IRB.

d. The instructor should refer to the IRB all proposals that do not meet the conditions for Exempt review, or are in dispute.

f. If questions arise, the instructor should consult with the IRB chair or other IRB member, or reference the OHRP IRB Guidebook at [http://www.hhs.gov/ohrp/irb/irb_guidebook.htm](http://www.hhs.gov/ohrp/irb/irb_guidebook.htm).
g. The instructor will be responsible for the oversight of all projects to assure that ethical standards are followed, to deal with any ethical violations, and to report such violations to the IRB immediately.

h. It is also recommended that all projects should use the SCU IRB application form and a checklist, which identifies and confirms that projects meet one of the categories eligible for Exempt review.

E. Roles and responsibilities

1. **Saint Catherine University.** Saint Catherine University has assured the U.S. Department of health and Human Services that it requires prior review and approval for all research involving human participants, including faculty and staff studies, theses and student projects. The university provides for an Institutional Review Board (IRB) to carry out this review and approval process. The university accepts the responsibility to meet the compositional requirements of IRB membership, and to provide both meeting space and sufficient staff to insure the IRB’s timely and appropriate review and record keeping duties. The university’s Federalwide Assurance (FWA) number is 00010937.

The university assumes full responsibility for IRB policy and research concerns. Anyone who brings a complaint against the IRB shall present his/her concerns as follows

- first to the chair or co-chair, and if unresolved shall proceed to the following levels
- full IRB
- Vice President of Academic Affairs
- President of the University

In observance of 45 CFR 46.112, neither the IRB Chair nor any office of the institution, including the President, may approve a research activity that has been disapproved by the IRB. The Institution may however prohibit research approved by the IRB.

2. **IRB.** The main function of the IRB is to ensure that all research with human participants is conducted in accordance with certain ethical principles. All research involving human subjects must be reviewed at one of three levels, described in more detail in C. and D. above. The purpose of these reviews is to determine if subjects will be placed at risk and if the benefits of the research warrant the risk. The review process will determine if:

a. The potential risks to the subjects are clearly identified in the research protocol and in the consent form.

b. The risks to the subjects are outweighed by the benefits to the subjects and the importance of the knowledge to be gained so that approval of the research project is warranted.
c. The rights and welfare of all subjects will be adequately protected.
d. A process is guaranteed to provide an adequate explanation of the
   potential risks and safeguards, as well as the benefits.
e. The process and documentation conform to federal and university
guidelines.

IRB decisions and requirements for modifications will be conveyed promptly to
investigators in writing. Written notification of decisions to disapprove an
application will be accompanied by reasons for the decision with provision of
the opportunity to respond.

In accordance with 45 CFR 46.109, the IRB will have the authority to suspend
or terminate previously approved research when it determines that the
research is not being conducted in accordance with the stipulations made by
the IRB, or if the approved project experiences unexpected serious harm to
subjects.

3. Researcher responsibilities. Students, staff and faculty who propose to
   undertake research involving human subjects acknowledge and accept
   their responsibility for protecting the rights and welfare of human research
   subjects. They also must comply with all applicable provisions outlined in
   this document. Research investigators involving human subjects also
   shall be responsible for complying with all IRB decisions, conditions, and
   requirements. Investigators will promptly report to the IRB anticipated
   changes they may propose or that may be imposed by an external IRB for
   previously approved human subject research activities. Researchers will
   not initiate any changes without IRB review and approval except where
   necessary to eliminate apparent immediate hazard to subjects.
   Researchers will report promptly to the IRB any injuries or unanticipated
   problems involving risk to research subjects or others.

4. Research Advisors. Academic advisors, faculty research advisors, or
   faculty members assigning research projects involving human subjects
   must take an active part in preparing students for the role of researcher,
   instructing them in the ethical conduct of research and assisting in the
   preparation of applications for IRB approval. Advisors shall take an active
   role in ensuring that the conduct of the research meets the highest ethical
   standards. Faculty research advisors shall ensure that their advisees:

   a. understand the elements of the consent process
   b. develop a readable consent form
   c. plan and accomplish appropriate recruitment strategies for identifying
      subjects, and
   d. establish and maintain strict guidelines for protecting anonymity, where
      names are not known or recorded and thus cannot be disclosed, or
confidentiality, where names are known/recorded but will not be disclosed.

The signature of the faculty research advisor is required on the IRB application form, providing documentation that these aspects of research have been addressed, and that the advisor is ultimately responsible for the protection of human subjects in student research.

If any research project also will be subject to review by an outside IRB, the application for that review may not be submitted until the research has been reviewed and approved by the St. Catherine University IRB. Research advisors are responsible for assuring that applications to outside IRB’s contain only the revised documents finally approved by the IRB. If the outside IRB requires further changes in the project and/or the consent form, the amended documents must be filed with the chair or co-chair of the SCU IRB.

F. Structure and process

1. **Membership of the IRB.** The IRB shall be composed of at least five members but not more than 18, including faculty, staff and non-t community representatives. The number and composition shall be in compliance with 45 CFR 46.107.

   a. **Composition.** University representation should include but is not limited to Biology, Education, Nursing, Occupational Therapy, Physical Therapy, Psychology, and Social Work. Others with expertise in human subjects research may be added either as members or as consultants for specific topics. The IRB shall also include at least one member who is not otherwise directly affiliated with SCU and who is not part of the immediate family of a person who is affiliated with SCU.

   b. **Term of office.** Members of the IRB will serve staggered three-year terms, with no limit to the number of terms for any member. No more than one third of the members shall end their terms in any one academic year. Members who wish to discontinue service after their term shall notify the IRB chair or co-chair by the end of winter semester. Members who wish to continue service beyond a three year term will also notify the IRB chair; their names will be forwarded to the Senior Vice President for reappointment.

   c. **Method of appointment.** Each university unit with representation on the IRB shall recommend to the IRB Chair(s) prospective committee members when a vacancy occurs from that unit. The IRB will vote on the candidate, and if approved, forward to the Senior Vice President a written recommendation for appointment. The Vice President shall provide a written letter of appointment to the IRB and the candidate. The letter of appointment shall include the term of office.
d. **Alternates.** Departments may choose to recommend an alternate as well as a representative. Alternates must attend a minimum of three meetings each academic year. When both a representative and an alternate attend the same meeting, only one vote is permitted. Alternates will receive the same orientation and training on IRB issues as other IRB members. Alternates will participate fully in discussion of projects submitted for full review, and in review of applications at the exempt and expedited level.

e. **Quorum.** The IRB will observe the quorum requirements of Section 108(b). A quorum is met by the presence of a majority of the total number of members; the quorum must include at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of the members present at the meeting. Informal discussion may occur in the event that a quorum is not present. No action can be taken without a quorum. The minutes will reflect discussion held when a quorum was not present.

f. **Attendance.** Any member who misses two or more consecutive meetings without an excused absence from the chair or co-chair may be removed from the IRB.

g. **Conflict of interest.** Members who serve as advisers to an application under review or who have any other interest in an application or issue before the committee will declare this to the IRB and refrain from discussion on the topic and refrain from voting.

h. **Chairperson.** The IRB shall elect its own chairperson in the last meeting of the academic year for the appointment to begin in September of the following academic year for a term of one year. The IRB may choose to elect two co-chairpersons. No one may serve as a chair or co-chair who has served on the IRB for less than one academic year.

i. **Agenda.** The chairperson will distribute an agenda in advance of the meeting. Discretionary changes can be made in the agenda by the chair or co-chair and members may bring new issues to the group for addition to the initial agenda.

j. **Amendments to procedures or policy.** The IRB cannot make amendments to written policies and/or procedures at a meeting unless sufficient notice of the proposed change has been provided to all members in advance of the meeting.

2. **Maintenance of Records**

a. **Applications.** The IRB will maintain and arrange access for inspection of IRB records as provided for in Section 46.115. This includes applications, sample consent documents, correspondence between the IRB and the researchers, progress reports, statements of significant new findings provided to subjects, complaints and reports of
injuries to subjects. All records will be retained for at least three years after completion of the research.

b. **Meeting minutes.** The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115 and in conformance with any other requirements the committee may develop for itself. **Meeting minutes will be distributed to IRB members and the Vice President of Academic Affairs.** The minutes will include:

- attendance of members including excused absences, researchers and advisers, and other visitors or observers
- actions taken by the IRB
- the vote on the actions, including the number of members voting for, against and abstaining
- the basis for requiring changes in or disapproving research
- a written summary of the discussion of issues and recommendations for their resolution.

c. **Membership records.** The chair or co-chairs will be responsible for maintaining a list of current IRB members as required by 46.103(b)(3). The membership records shall include the correspondence between the IRB and the President regarding appointments of members. The list will identify members by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc. sufficient to describe each member’s chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution.

d. **Written procedures.** Each member of the IRB will maintain a current manual of operations that includes the current OHRP Institutional Review Board Guidebook (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm) and the Federal Policy (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) and all additional subparts and revisions to the Federal Policy. The Guidebook shall contain OHRP Reports that provide additional guidance on topics of concern to IRB members. In addition, the IRB will maintain and follow written procedures:

- For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution
- For determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review
- For ensuring prompt reporting to the IRB of proposed changes in a research activity,
- For ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be
initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.