Standard Operating Procedures

Institutional Review Board

Saint Mary's University of Minnesota

Minneapolis & Winona, MN

Section 1. IRB Overview

1.1 Mission - (The Institution and the Institutional Review Board)

Saint Mary's University of Minnesota, in support of its mission to empower learners to ethical lives of service and leadership, encourages and reviews research involving students, faculty, or staff as PI/Researchers or research participants so that the projects are designed in an ethical and technically competent manner.

1.2 Institutional Commitment

Saint Mary's University of Minnesota is committed to protecting human subjects who are involved in research. Through the Common Rule, Federal regulation 45 CFR § 46, the federal government mandates that all research involving human subjects be reviewed by an Institutional Review Board (IRB). Saint Mary's University of Minnesota's IRB is registered with the Office of Human Research Protection which supports the work of the IRB to ensure that research at the institution involving human subjects follows the criteria set forth by the Belmont Report, Catholic Social Teaching (Human Dignity, Community and the Common Good, Rights and Responsibilities, Option for the Poor and Vulnerable, Participation in Society, Dignity of Work, Stewardship of Creation, Global Solidarity, Role of Government, and Promotion of Peace), and Saint Mary's University of Minnesota's Lasallian Catholic heritage (Concern for the Poor and Social Justice; Quality Education, Inclusive Community, Respect for All Persons, and Faith in the Presence of God).

Catholic Social Teaching, according to a hermeneutic of continuity that emphasizes attention to the person with a focus on freedom, equality and participation, as well as a shift to a responsibly ethical model. Of the five Lasallian principles, the principles of "concern for the poor and social justice" and "respect for all persons" are in alignment with the Belmont report's three core principles: respect for person, beneficence, and justice, which provide the basis for Saint Mary's University of Minnesota's IRB. The Saint Mary's University of Minnesota IRB also ensures the dignity of human participants in research.

The IRB is charged with ensuring the protection of the rights and welfare of human research subjects. Principles codified in the Nuremberg Code, the Declaration of Helsinki, Belmont Report, and existing federal regulations (Protection of Human Subjects, 45 CFR § 46 - the Common Rule and Institutional Review Boards, 21 CFR § 56) are employed to provide a framework for ethical considerations and assessment of risk and benefit in individual studies. The Belmont Report's three Basic Ethical Principles of 1) Respect for Persons, 2) Beneficence, and 3) Justice serve as the basis for review and decision making on protocols submitted to the IRB.

1.3 Human Subject Research Oversight (Organizational Structure)

Administratively, the IRB is a part of Academic Affairs with the Provost serving as the Institutional Official. The Institutional Official reports to the President who provides direct supervisory authority over the Institutional Official. The Institutional Official (IO) is legally

authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the Assurance. The Institutional Official is responsible for ensuring that the IRB functions effectively and that the institution provides the necessary resources and support to the IRB to comply with all requirements applicable to research involving human subjects. The Institutional Official represents the institution in all interactions with the Office of Human Research Protection and other federal agencies.

The Institutional Official delegates the administration of the IRB to the Vice Provost for Faculties and Academic Affairs. The Vice Provost for Faculties and Academic Affairs serves as the IRB Administrator. The IRB Administrator is responsible for ensuring that the institution's IRB meets local, national, and international codes and regulations for the conduct of human subject research. The IRB Administrator is responsible for the maintenance of policies and standard operating procedures (SOPs) for the IRB, the IRB support staff, and the functioning of the IRB. The IRB Administrator and IRB Chair advise and make recommendations to the Institutional Official, to faculty policy and administrative bodies, and to any member of the university community on all matters related to the recruitment of human subjects in research. Revisions of policies and procedures are recommended by the IRB Chair and the IRB Administrator and approved by the Institutional Official.

The organizational structure of the IRB includes the IRB Administrator, who has administrative oversight through the authority of the President and Provost, an IRB Chairperson, an IRB Vice Chairperson, and IRB Administrative Assistant (the SGPP Coordinator of Academic Administration). Institutional Review Board membership is made up of volunteers from the university and community. See section 3.4 for overview of the IRB composition, appointment process, IRB membership requirements, and IRB member duties.

1.4 Purpose and Scope of the SOP Document

This SOP document contains Saint Mary's University of Minnesota's rules, regulations, policies and procedures applicable to the protection of human research subjects. It establishes mechanisms for their implementation and is regularly updated to reflect new standards, regulations and University policy.

1.5 Applicability

The rules, regulations, policies and procedures laid out in this SOP document apply to all faculty, staff, and students at the University who intend to recruit human subjects in subsequent research. It also applies to any external entities who seek to recruit or collaborate with faculty, staff, or students of the University for human subjects research.

Saint Mary's University of Minnesota uses the federal definition of research as defined in the Common Rule (45 CFR 46.102): "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include

research activities. For purposes of this part, the following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

The IRB has jurisdiction and oversight responsibilities over human subject research in which the University is engaged. Specific examples include but are not limited to:

1. Research that is sponsored by Saint Mary's University of Minnesota;
2. Research that is conducted by or under the direction of any employee or agent of Saint Mary's University of Minnesota; or
3. Research that involves the use of Saint Mary's University of Minnesota non-public information to identify, recruit, contact, or otherwise engage constituents for human research purposes.

Saint Mary’s University of Minnesota requires Principal Investigators (PIs)/Researchers who propose to complete research at the University and who are not its employees or agents:

1. To obtain the collaboration of a Saint Mary's University of Minnesota faculty member; and
2. To comply with all relevant
    a. IRB determinations,
    b. Federal and state regulatory requirements,
    c. Human subject protection standards,
    d. CITI trainings, and
    e. Cooperating Institutions.

1.6 Revision and Maintenance of the SOP Document

The IRB Administrator is responsible for maintaining and updating this SOP document and will conduct and document this review every three years. The IRB Standard Operating Procedures may be amended as needed by a vote of the IRB members after documented consultation with

the IRB Chair, the IRB Administrator, and the Institutional Review Board members. Strong preference should be given to making any, and only those changes on which consensus is reached in these consultations.

1.7 Revision and Maintenance of Application Forms, Worksheets, and Templates

Proposed changes to IRB application forms, worksheets, and templates will be sent out to the entire IRB and the IRB Administrator. Ten days will be given for any objections or additional changes to the proposals. If no concerns are raised, the proposed changes will be automatically approved. The IRB Administrative Assistant will be responsible for implementing these changes and archiving the new dates of revision and approval.

Section 2: Definitions

Definitions are applicable to all sections of this SOP document.

Adverse Event / Unanticipated Problem

An adverse event may be defined as a death, life-threatening adverse drug or device experience, inpatient hospitalization or prolongation of existing hospitalization, persistent disability/incapacity, or congenital anomaly/birth defect.

An unanticipated problem may be defined as any unexpected event that affects the rights, safety, or welfare of subjects. The event could be physical (such as a therapy dog bites a participant), emotional (a subject has a stronger than anticipated emotional reaction to the questions), or involve some harm (such as, breach in confidentiality or harm to a subject's reputation).

Both must be reported to the IRB no longer than 48 hours after the event or problem occurs.

Amendment

Any changes or modifications made to a protocol after already being approved by the IRB. All amendments must go through the amendment process (see 4.5.4 Amendments or Modifications). Proposed changes are submitted to the IRB for review and must be approved before these changes can be implemented in the research itself.

Anonymous

The identities of the subjects are unknown to the PI/Researcher, and not requested, and not given. To maintain anonymity, consent should be attained using implied consent.

Archival Data

Archival data are any data originally collected for a purpose other than completion of the applicant's research project. Archival does not necessarily mean in the past. Archival data are always collected under the responsibility of an individual or institution other than the applicant.

The individual or institution which owns the data must provide written permission for the applicant to use the data for his or her research project (see Research Cooperation Agreement).

Assent

Affirmative agreement by a participant who is a child or determined to be cognitively impaired to participate in research.

Basic Ethical Principles of the *Belmont Report*

The *Belmont Report* identifies three Basic Ethical Principles 1) Respect for Persons, 2) Beneficence, and 3) Justice.

Belmont Report

"The *Belmont Report* was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles. Informed by monthly discussions that spanned nearly four years and an intensive four days of deliberation in 1976, the Commission published the *Belmont Report*, which identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects." (*The Belmont Report*)

Benefit

A valued or desired outcome to the study that will be an advantage to the subjects participating. Compensation or contribution to the field or society is not considered a benefit.

Broad Consent

Seeking prospective consent to unspecified future research. Broad consent may be obtained only for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Certificate of Confidentiality

A Certificate of Confidentiality (Certificate) protects the privacy of human research subjects enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, research may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.

Certification

The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB.

Children

The legal definition of a child is any individual under the age of 18. If children serve as subjects, consent to participate in the applicant's research study must be given by the parent or guardian, and assent must be obtained from the child except in settings that meet Protection of Human Subjects, 45 CFR § 46.101 (b) (1) (educational settings).

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Coded

The replacement of identifying information (name or SSN) that would allow the PI/Researcher to readily ascertain the identity of the individual to whom the private information or biological specimens pertain with a number, letter, symbol, or combination thereof to protect the confidentiality of the participant. A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Coded Private Information or Biological Specimens

The U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP) guidance considers private information or specimens to be individually identifiable when they can be linked to specific individuals directly or indirectly through coding systems. OHRP (2008) guidance recommends that only a knowledgeable person or entity be authorized to determine if coded specimen or data constitute research. OHRP recommends that researchers not be given authority to make an independent determination that research involving coded private information or specimens does not involve human subjects.

Common Rule

Another name for the Federal Protection of Human Subjects, 45 CFR § 46.

Conditional Approval

When a project meets the criteria for approval but has to fulfill certain conditions before approval can be granted. This normally occurs if, for example, a school administrator requires IRB approval before they agree to sign the Research Cooperation Agreement. The IRB would then grant conditional approval contingent on receiving the signed Research Cooperation Agreement.

Confidential

Pertains to the confidential treatment of information, in which an individual has disclosed information assuming a relationship of trust and with the expectation that the information will not be shared in such a way that identifies the participant. Confidential is not the same as anonymous.

Conflict of Interest

Potential conflicts of interest arise whenever the researcher has a relationship with a research participant outside of the research setting. A conflict of interest may be of particular concern if the research participant has a personal relationship with the researcher (e.g., family member, close friend), a professional relationship with the researcher (e.g., student, client, supervisor) or a financial relationship with the researcher (e.g., customer, in a position to benefit from the results of the research). All potential conflicts of interest must be disclosed in the IRB application.

Conflict of Interest Management Plan

A written plan that identifies ways to reduce or eliminate actual or perceived conflicts of interest.

Consent Form

Individuals must give consent before data may be collected from them for research purposes. (Assent is the term used for consent by subjects under the age of 18 or cognitively impaired.) Consent forms must be developed carefully and conform to a variety of ethical standards. A template for developing a consent form is provided on the IRB website. Anonymously collected data requires implied consent. A template for implied consent can be found on the IRB website.

Continuing Review

Approved research will undergo review until the completion or termination of the research, to ensure continued compliance with the approved protocol and Basic Ethical Principles. Continual reviews of research that will occur at least annually for full reviews.

Cooperative Research

Cooperative research projects are projects conducted by entities external to Saint Mary's University of Minnesota who also have their own IRB. When cooperative research occurs, each institution is responsible for safeguarding the rights and welfare of human subjects through the creation of an IRB Authorization Agreement.

Cover Letter

A cover letter introduces a research study to a potential participant and specifies the terms of participation. Cover letters are almost always used with surveys. A sample cover letter for a survey is provided on the IRB web page.

Data

Refers to information (qualitative or quantitative) that is collected for analysis or used to make decisions.

Debriefing

Debriefing occurs after the participant has completed study procedures. The researcher provides orally and in writing accurate and complete information about the purpose and nature of the study. Debriefing protocols must be designed to mitigate the effects of deception or

incomplete disclosure and provide information about resources to report and/or obtain support related to any adverse effects of study participation.

Deception or Incomplete Disclosure

Deception occurs when researchers purposely mislead research subjects by providing them with false information about some aspect of the research procedure and/or purpose of the research. Examples:

- Subjects are told they are working with a group of other subjects on a task; however, the other "subjects" are confederates acting as research subjects
- Subjects are told they performed poorly on a task regardless of how they actually performed

Incomplete disclosure occurs when the researchers withhold information about some aspect of the research from the subjects. In some instances, researchers may tell subjects the general purpose of the study but do not give them enough details to reveal the entire purpose. Example:

- Researchers inform subjects that the study is exploring people's ability to read quickly, but they do not tell subjects that a task they will complete during the research is intended to also examine their emotional responses to certain words they read.

Deception or incomplete disclosure will only be permitted when the researcher documents that an alteration of the usual informed consent requirements is justified under the criteria presented in the federal regulations (45 CFR § 46.116(d)), and the IRB has documented the necessary related findings.

Educational Setting

Research conducted in established or commonly accepted educational settings, involving 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, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Protection of Human Subjects, 45 CFR § 46.101 (b)(1)).

Emotional or Physical Risk

Physical risk includes physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. Emotional risk includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, or loss of self-esteem experienced during the research situation and/or later, as a result of participating in the research. Emotional risk also includes alterations in relationships with others that are to the disadvantage of the participant, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the participant's opportunities and powers in relation to others.

Exempt IRB Review

Exempt research is research with human subjects that is "exempt" from the provisions stated in 45 CFR § 46, Subpart A (Common Rule). Please refer to the IRB Standard Operations Procedures 4.4.1 for a full list of categories which fit the criteria for exempt level review.

Note: Exempt does not mean that IRB submission is not required. All research projects involving human subjects need to be submitted to the IRB to assure adherence to the ethical standards and may still require modification before meeting the criteria for approval.

Expedited IRB Review

If the research presents no more than minimal risk, the IRB may determine it qualifies for an expedited review. The expedited review covers the same elements as a full/convened committee review but can be conducted by the IRB Chair or one or two designates rather than the full convened committee. There are nine expedited categories in the federal regulations. Examples of expedited research include:

- Research involving minimal risk (see definition) for non-vulnerable participants; or
- Minor changes in previously approved research during the period (of one year or less) for which approval is authorized

Please refer to the IRB Standard Operations Procedures 4.4.1 for a full list of categories which fit the criteria for expedited review.

External Funding

External funding includes financial support of any kind received by the applicant (e.g., an external grant) to support the research project. It does not include contributions from the applicant's own resources.

Faculty Advisor

The Faculty Advisor provides oversight and supervision to the Student PI/Researcher. The Faculty Advisor must be aware of and up to date on the general principles of research ethics so as to guide the PI/Researcher responsibly through any project involving human subjects and the IRB process. Advisors must provide documented approval with every submission, modification, amendment, and resubmission of their advisees' research protocols.

Federalwide Assurances

"The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

FWAs also are approved by OHRP for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support." (HHS.gov)

FERPA Regulations

The Family Educational Rights and Privacy Act (FERPA) is a Federal law that protects the privacy of student education records. All research involving the use of student records must conform to the provisions of FERPA.

Full IRB Review

Research which does not meet the requirements for exempt or expedited review requires approval of the full IRB committee. Generally, any study involving more than minimal risk, utilizing vulnerable populations, or which involves the collection of sensitive information will require full IRB review. Please refer to the IRB Standard Operations Procedures 4.4.1 for a full list of categories which fit the criteria for full review.

Generalizable Knowledge

Projects designed to develop or contribute to generalizable knowledge are those that seek to draw general conclusions, inform policy, create theories, or generalize findings that may be disseminated beyond Saint Mary's University of Minnesota.

Health Care Data

Health care data simply refers to medical records held by a hospital, clinic, or individual health or mental health professional.

HIPAA Regulation

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects the privacy of individually identifiable health information, sets national standards for the security of electronic protected health information, and protects identifiable information being used to analyze patient safety events and improve patient safety. All research utilizing medical records must conform to HIPAA regulations.

Human Subjects

A living individual about whom a PI/Researcher (whether faculty or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable Biospecimen

A biospecimen for which the identity of the subject is or may readily be ascertained by the PI/Researcher or associated with the biospecimen.

Identifiable Private Information

Private information for which the identity of the subject is or may readily be ascertained by the PI/Researcher or associated with the information.

Implied Consent

Implied Consent is the tacit indication that a person has knowingly agreed to participate in research by performing a research activity or task. By completing the research task, the participant has provided consent to participate in the research. Implied consent is a type of a waiver of documentation of informed consent.

Informed Consent

The knowing, voluntary, and legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not they will participate and that minimize the possibility of coercion or undue influence. Only those individuals who are aged 18 or older may give informed consent; individuals under the age of 18 must give assent in addition to the informed consent of their guardian or legally authorized representative.

Instructional strategies

Instructional strategies include demonstrations, curricula, projects, and other teaching methods or techniques implemented in a classroom setting.

Interaction

Interaction includes communication or interpersonal contact between PI/Researcher and subject. (Protection of Human Subjects, 45 CFR § 46.102 f)

Intervention

Includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (Protection of Human Subjects, 45 CFR § 46.102 f)

IRB Approval

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. (Protection of Human Subjects, 45 CFR § 46.102 f) Only an official letter from the IRB Chair provides evidence of IRB approval.

IRB Authorization Agreements

IRB Authorization Agreements require one of the cooperating institutions to be identified as having IRB jurisdiction over the study, the IRB of Record.

IRB of Record

The IRB of Record is the IRB accountable for review and approval of the human subjects review on behalf of the parties to a Cooperation Agreement/IRB Authorization Agreement.

IRB Protocol Identification Number

The number assigned to a submitted protocol for review. It will include the year the protocol was submitted and the number in consecutive order it was submitted. The first protocol submitted for the year would be assigned 201901.

Legally Authorized Representative

Abbreviated as LAR. 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, legally authorized representative means an individual recognized by institutional policy 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

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." (Protection of Human Subjects, 45 CFR § 46.102 f)

Original Data

Data collected explicitly for the purpose of the applicant's research project are considered original data. Data collected for another purpose are considered archival data even if the data are being used for the applicant's research project.

Pilot Study

A Pilot Study is a small study based on a larger primary study and is completed prior to the primary study to evaluate all aspects of the study. Research methodology includes but is not limited to feasibility, time, cost, and adverse events. Information collected in a pilot study is used to amend and improve the primary study. Data collected in a pilot study cannot be used in the primary study.

Population

A group of people in society meeting certain criteria to be eligible as subjects in a project's protocol.

Primary Reviewer

The IRB member assigned to a protocol for review. The Primary Reviewer (PR) may make the final decision for exempt review or collaborate with a Secondary Reviewer (SR) for expedited reviews. During full reviews, the Primary Reviewer is assigned to drive the discussion at the convened meeting as the leading resource on that particular protocol.

Principal Investigator

Also called the Researcher or PI, the Principal Investigator is the individual with primary responsibility for the design and conduct of a research study.

Privacy

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

Private Information

Private information includes information about behavior that occurs in a setting 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. (Protection of Human Subjects, 45 CFR §46.102 f)

Program-Related Review

Studies related to the internal improvement of Saint Mary's University programs (e.g., course observations) which are not generalizable and will not be publicly disseminated, do not need to undergo IRB review.

Protocol

The formal design or plan of a study's activity; specifically, the plan submitted to an IRB for review and to a cooperating agency for support. The protocol includes a description of the design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Publicly Available Data

Data that is intentionally made available to the public, meaning, there is no permission needed to view or use.

Publicly Disseminated

Information that is presented, circulated, or communicated in a public manner.

Public Health Authority

An agency or authority that is responsible for public health matters as part of its official mandate.

Recruitment

All communications inviting individuals to participate in the applicant's research project are included. Communications may be in the form of a letter, poster, flyer, e-mail, verbal request, etc. The text of all such invitations must be provided to the IRB.

PIs/Researchers may recruit participants and students from their own program. However, PIs/Researchers must keep in mind the principle of Beneficence as described by the Belmont Report when recruiting in order to lessen research fatigue or the chance of coercion among participants. Additionally, all PIs/Researchers who recruit from their own program must obtain documented approval from the Dean.

Research

Research is 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 policy, whether or not they are conducted or supported under a program that is considered research for other purposes. (Protection of Human Subjects, 45 CFR § 46.102 d)

Research Cooperation Agreement

If the project requires the cooperation of another agency or institution, a signed Research Cooperation Agreement (RCA) must be submitted with the request for IRB review. A form for the RCA can be found on the IRB website.

Request for a Summary of the Results

Participants in a research study are usually offered an opportunity to obtain a summary of the results of the research when it is completed. As appropriate, this must be done in a fashion which maintains the confidentiality or anonymity of the participant. It is the researcher's responsibility to ensure that a promised summary is actually delivered to all participants.

Risk

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

Secondary Research Use

Re-using (for research purposes) identifiable and non-identifiable information and biospecimens that are collected for some other 'primary' or 'initial' activity (such as, from research studies other than the proposed research study).

Secondary Reviewer

The IRB member assigned to a protocol to collaborate with the Primary Reviewer in making a decision. The Secondary Reviewer (SR) reviews the same application/protocol as the PR and provides an independent, secondary response.

Sensitive Information

Any personal information an individual may be uncomfortable sharing or disclosing may be considered sensitive. Examples include financial information, memories of prior trauma, medical information, information about sexual activities, etc.

State Statutes on Medical Data Archives

Minnesota statute 13.384 Subd. 3 states that "medical data are private but are available only to the subject of the data as provided in sections 144.291 to 144.298." However, under section 13.05, "private data may be used by and disseminated to any person or entity if the individual subject or subjects of the data have given their informed consent. Whether a data subject has given informed consent shall be determined by rules of the commissioner."

*The responsible authority may require a person requesting copies of data under this paragraph to pay the actual costs of making and certifying the copies."

Student Records

Student records include all information in individual student files maintained by an educational institution. Access to student records is strictly governed by FERPA policies.

Voluntary

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (and/or to continue to participate) in a research study.

Vulnerable Populations

At risk/vulnerable populations are populations that are "likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons." (Protection of Human Subjects 45 CFR § 46.111b)

Examples of vulnerable populations could also include individuals with special needs, individuals with a therapeutic association or affiliation with the researcher, and/or those who are appointed the legally authorized representative and/or person responsible for making decisions on their behalf.

When an individual is vulnerable to coercion or undue influence, their ability to make an informed decision about participating in research is unreliable and that person is considered vulnerable. The vulnerability of the subjects in research studies should be considered as a function of the possibility of coercion or undue influence; therefore, the assessment of the equitable selection of subjects should include factors like societal marginalization or discrimination.

Written, or In Writing

Refers to writing on a tangible medium (e.g., paper) or in an electronic format.

Written or Verbal Instructions

Instructions include all explanations, instructions, and directions about participating in a research study. All such instructions must be written out in the IRB submission, and presented to participants in a standardized fashion.

Section 3: General Policies and Procedures

3.1 Applicable Regulations and Laws

The purpose and responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects. The IRB reviews and oversees research activities involving human subjects and requires that the research complies, as applicable, with Federal

regulations at 45 CFR § 46, Subparts A, B, C, and D, (or equivalent policies and procedures), the FDA 21 CFR Parts 50, 56, 312, and 812.

3.2 Purpose

The purpose of the Institutional Review Board is to ensure the protection, privacy, autonomy, dignity, and informed consent of all research involving human subjects. Protection of human subjects is a shared responsibility of the PI/Researcher, advisor, the IRB, and the University. In order to provide for the adequate discharge of the institutional responsibility, any research activity involving human subjects that will be publicly disseminated and undertaken by any faculty, staff, employee or student at Saint Mary's University of Minnesota must be reviewed and approved by the IRB prior to commencing the research activity.

3.3 Designation and Authority

Saint Mary's University of Minnesota has designated the IRB as responsible for conducting initial and continuing reviews and providing oversight for all research activities involving the recruitment of human subjects performed by agents or employees of Saint Mary's University of Minnesota. The scope of research reviewed by the IRB is not limited and the IRB reviews all types of human research submitted.

The President through the Provost, the Institutional Official (IO), grants the IRB the following authority relative to the protection of human subjects at Saint Mary's University of Minnesota:

1. To review, require modifications in research protocols which include but are not limited to participant recruitment strategies, data collection, and data storage; approve, or disapprove all research activities overseen and conducted by the agents of the organization and involving human subjects, based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;
2. To determine level of IRB review (exempt, expedited, or full review);
3. To require that information given to subjects and/or their legally authorized representative as part of informed consent is in accordance with Protection of Human Subjects, 45 CFR § 46.116 and may require additional information if it would meaningfully add to the protection of human subjects;
4. To require documentation of informed consent, or waive documentation in accordance with Protection of Human Subjects, 45 CFR § 46.117;
5. To require reports for protocol continuing review;
6. To continuously monitor the conduct of research with human subjects;
7. To suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with adverse events or unexpected serious risk to subjects;
8. To have the authority to observe or have a third party observe the consent process; and
9. To place restrictions on a protocol involving human participant and/or materials of human origin if it determines circumstances warrant such action.

No official within Saint Mary's University of Minnesota may approve a protocol or human subject research activity that has not been approved, or has been disapproved, by the IRB. However, the Institutional Official (Provost) and/or President may disapprove a protocol or research activity that has been approved by the IRB.

3.4 Composition and Appointment of the IRB

The IRB personnel and structure are formally approved by the IRB Administrator through the authority of the President and Provost (IO) of the University. Members are appointed to the IRB by the Provost after recommendation by IRB Administrator, with input and membership nominations (including the member not affiliated) coming from the IRB Chair and IRB members, the Deans, department chairs and program directors, and through self-nominations. The IRB is composed of a sufficient number of members with varying backgrounds to promote, complete, and provide an adequate review of research activities commonly conducted at Saint Mary's University of Minnesota.

The composition of the IRB must meet the minimum regulatory requirements. The members must be sufficiently qualified through their experience, expertise, and their diversity, 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. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

The IRB at Saint Mary's University will:

1. Consist of at least nine members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
2. Include at least two members from the College and two members from the SGPP, each serving as liaisons to their respective constituencies;
3. Make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
4. Not consist entirely of members of one discipline, school, or program;
5. Include at least one member whose primary concerns are in scientific areas (i.e., natural or social sciences) and at least one member whose primary concerns are in nonscientific areas;
6. Include one member with ethics expertise;
7. Include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of any person affiliated with the institution. Criteria for unaffiliated members include:
    a. Expertise in Research,
    b. Previous experience with IRBs;

8. Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB; and
9. May invite individuals with competence in special areas to assist in the review of protocols which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Up to three alternate members may be appointed by the IRB Administrator upon recommendation of the IRB Chair. Alternates are appointed and function in the same manner as the IRB members and have comparable expertise. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

3.5 Term of Appointment

IRB members, including the IRB Chair and Vice Chair are appointed to a three-year term and may serve only two consecutive terms. Upon appointment and again at time of annual reappointment, each IRB member is queried by the CAA to determine roster information such as affiliation status, relationship of the member to the University, indications of experience and other relevant information. An IRB member's performance will be reviewed annually by the IRB Chair and IRB Administrator. IRB members who are not performing in accordance with the

IRB's mission or policies and procedures or who have an undue number of absences will not be reappointed. Feedback will be provided to the Institutional Official and members by the IRB Chair and the IRB Administrator.

3.6 Committee Officers

The IRB will have a Chair and a Vice Chair chosen from IRB members who have already served on the IRB Committee at least two consecutive years. The Chair and Vice Chair positions will typically be a core faculty member of the SGPP and a faculty member of the College who is knowledgeable in human subject research, including the federal and state regulations, University policies, and ethics relevant to such research. The IRB Chair shall preside over and be authorized to speak for the IRB. Whenever the Chair is not available, the Vice Chair will assume the responsibilities of the IRB Chair during the period of their absence.

3.7 Meetings & Voting

A meeting occurs when a quorum of members communicates in a designated forum. In order to conduct IRB business, there must be a quorum of members (50% + 1) at a convened meeting. The Primary and Secondary Reviewer of a protocol may be required to attend the convened meeting through teleconference to provide information on a protocol and establish the quorum.

If quorum is lost, votes are not taken until it is restored. To be approved, a protocol requiring full review must receive a majority of votes of members. IRB meetings may occur by video or phone conference to accommodate our multiple sites.

The IRB shall hold regular meetings at a time and place to be determined by the IRB and posted electronically. PIs/Researchers are welcome to attend to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. Other members of the University community are permitted to attend meetings but, due to limited seating space, must request attendance through the IRB Chair. Guests may be asked to sign a confidentiality agreement. The IRB Administrator and the IRB Administrative Assistant are non-voting members of the committee, but the IRB Administrator may provide input and guidance in the review of protocols.

3.8 IRB Meeting Minutes

The IRB Chair will monitor quorum at each meeting. Meeting minutes will be taken by the IRB Administrative Assistant (CAA). After all comments are reviewed and addressed, a pending version of the minutes will be available for review prior to discussion at the next IRB meeting. A vote for approval of the final version of the minutes will occur at the next convened meeting. Once approved, the minutes are posted in a secure location and the Institutional Official is notified and provided access to the secure location of the approved minutes in order to review all actions taken by the IRB.

Minutes will include:

1. A summary of each protocol under full review;
2. The approval period for each initial review, continuing review, and amendment;
3. A record of attendance for each protocol reviewed including a notation and the names of members who left the meeting due to a conflict of interest;
4. The voting record for each protocol and the previous meeting's minutes reflecting the number of members for, against or abstaining from the vote and when alternate members replaced a primary member;
5. The basis for requiring changes to a protocol, tabling or disapproving research;
6. A written summary of the discussion and resolution of controverted issues;
7. Justification of deletions or substantive modifications of information concerning risks or alternative procedures contained in an HHS approved consent form;
8. If applicable, summaries of deliberations of protocols for inclusion of vulnerable populations;
9. If applicable, the rationale for significant risks/non-significant risk device determinations;
10. If applicable, protocol specific justifications for waivers of consent and research involving vulnerable populations; and
11. A list of all actions for expedited and exempt level protocols, including the modifications for each and the resulting IRB action.

3.9 Confidentiality of the Review Process

During the process of initial, continuing review, or amendment of an activity, material provided to the IRB shall be considered privileged information and the IRB shall assure the confidentiality of the information contained therein.

3.10 Conflict of Interest

3.10.1 IRB Members – Convened Meeting

Prior to discussion of protocols at a convened meeting, the IRB Chair will ask if any member has a conflict of interest (COI) with any protocol being discussed at that meeting. Should an IRB member declare involvement in any way in a research protocol under review by the IRB, or state a COI with the research protocol, the following is required:

1. The IRB member is excluded from discussion and voting except to provide information requested by the IRB;
2. The IRB member leaves the meeting room during discussion and voting; and
3. The IRB member is not counted towards quorum.

3.10.2 IRB Members - Designated Reviewers

IRB members who are the designated reviewers for initial or continuing review of research protocols, reports of noncompliance, protocol deviations, unanticipated problems, and amendment requests that qualify for expedited review will self-identify any COI that they may have with the research or PI/Researcher and their advisor. In such cases, the IRB member will recuse themselves by notifying the IRB Chair and IRB Administrator, and the review responsibility will be reassigned to another experienced IRB member.

3.10.3 Examples of IRB Member COI

IRB members are considered to have a conflict of interest if they:

1. Are involved in the design, conduct, or reporting of the research study;
2. Have a leadership position in or consulting/advisory relationship with an entity related to the research;
3. Have a financial and/or ownership interest of any amount in or related to the research and the value can be readily determined;
4. Have a financial and/or ownership interest in or related to the research but the value cannot be readily determined;
5. Received or will receive compensation and/or have ownership interest of any amount with value that may be affected by the outcome of the study;
6. Have received in the past year, currently are receiving, or will receive from the sponsor of the study, honoraria, payments, or compensation of any amount;
7. Have a proprietary interest in the research, including but not limited to a patent, trademark, copyright, or licensing agreement;
8. Serve as directors, board members, scientific advisors or hold other decision-making positions in the entity sponsoring the research (Walsh University IRB Policy and Procedure Manual 22);
9. Have personal, familial, or intimate relationships with the PI/Researcher;

10. Are non-tenured and identify a potential conflict of interest with the PI/Researcher; or
11. For any reason, believe they cannot be objective concerning a study.

3.10.4 Principal Investigator (PI)/Researcher

All PIs/Researchers and their research staff are required to disclose any COI. Management plans (see definition) will be used to reduce a researcher's opportunity to bias the research and will be either included in the study design or will include additional controls. Management plans will explain the procedures or extra steps to be taken to minimize the risk of bias. Examples of controls that could be used in a management plan may include one or more of the following:

1. Adding an independent monitor to the study team to make sure that the research procedures are transparent;
2. Creating a safe environment for any research team member and/or student to report any perceived conflicts that may occur while the study is being conducted;
3. Disclosing the potential COI to the subjects in the informed consent form;
4. Reducing the researcher's role in the research if they have a COI (less interaction with subjects, less data analysis);
5. Using an independent third-party review of data;
6. Ensuring a careful study design, which may include randomization and blinding; or
7. Disclosure of the COI, including in publications or presentations of the study results.

If the IRB identifies a possible PI/Researcher conflict, that IRB member formally refers cases to the IRB Chair, then the IRB Administrator, who determines if formal COI management strategies are required. If required, the IRB Administrator will request the PI/Researcher prepare a draft COI Management Plan for submission for review. The IRB Administrator will work with the PI/Researcher to develop and finalize a COI Management Plan. When finalized, the COI Management Plan will be submitted to the IRB for review and final approval. Under no circumstances will research be approved until the IRB has reviewed and approved the COI Management Plan.

3.11 Training Requirements for Principal Investigators/ Researchers, Student Researcher, IRB Administrative Assistant & IRB Members

The University requires Collaborative Institutional Training Initiative (CITI) training for all IRB members, IRB Administrative Assistants, PIs/Researchers, student researchers, student researcher/faculty advisors, and researchers from other institutions who wish to conduct human subject research under the auspices of Saint Mary's University of Minnesota. Completion of this training must be accomplished every three years. Webinars and local conferences are made available to the University community for additional training.

3.12 Roles and Responsibilities

3.12.1 Faculty Advisors for Student Research

Faculty members who supervise student research are responsible for the protection of human subjects and are required to:

1. Be familiar with the ethical and regulatory requirements of human subject research;
2. Review the student research protocols and all supporting document prior to submission to the IRB to ensure accuracy and appropriateness of IRB protocol submission components;
3. Determine whether projects require IRB review and assist students with the process, including:
    a. Obtaining all necessary approvals and ensuring ongoing compliance (federal or institutional) with policies and procedures relating to human subject research;
    b. Documenting approval during every stage of the review process (a form for advisor approval can be found on the IRB website); and
    c. Ensuring that any continuing reviews are submitted in a timely manner.
4. Discuss research ethics with the students;
5. Advise students conducting international studies on understanding the local customs and ethics;
6. Monitor student projects, paying special attention to maintaining confidentiality, privacy, level of risk, voluntary participation and withdrawal, and informed consent; and
7. Assure that any unexpected or adverse events are reported to the IRB.

3.12.2 Institutional Official

The Institutional Official is designated by the University President and has the authority to delegate activities as may be necessary to fulfill the following responsibilities:

1. Is legally authorized to represent the institution in matters regarding human subject research and is the signatory authority for all Federal-Wide Assurances to the Office for Human Research Protections;
2. Is responsible for review and evaluation of internal reports;
3. Is responsible for further institutional review and approval or disapproval of research approved by the University IRB (neither the Institutional Official nor any other University official can approve research that was disapproved by the IRB); and
4. Signs all correspondence and reports sent to federal regulatory agencies regarding PI/Researcher or institutional noncompliance.

3.12.3 IRB Administrator

IRB Administrator's responsibilities are as follows and are not all inclusive:

1. Ensuring the IRB meets local, national, and international codes and regulations for the conduct of human research;
2. Ensuring IRB compliance with institutional policies and all applicable regulations for the protection of human research subjects;
3. Reviewing copies of all IRB meeting minutes containing reports of IRB deliberations on human subject protocols and noncompliance findings;
4. Maintaining policies and standard operating procedures of the IRB, the IRB support staff, the Institutional official, and the institution;
5. Ensuring that there is a mechanism in place to provide readily accessible guidance to:

   a. IRB support staff, through the development of operational manuals or standard operating procedures, for conducting the day-to-day business of the IRB;
   b. Researchers, student researchers, and student research advisors on specific IRB topics; and
   c. Institutional Official and upper administration of their IRB-related roles and responsibilities.
6. Maintaining a thorough knowledge of local and national regulations and laws regarding the IRB;
7. Providing consultation and guidance to the IRB and to the institution on how best to apply IRB policies;
8. Ensuring that the institution's policy on training describes the requirement, frequency for training, and type of training and maintains contact with the training provider;
9. Serving as liaison with federal agencies and sponsors, supporting the Institutional Official;
10. Identifying when IRB authorization agreements, operating agreements, or memorandums of understanding are required for cross-institutional research;
11. Advising when Certificates of Confidentiality are required;
12. Maintaining the IRB's registration with the Office of Human Research Protection (OHRP);
13. Obtaining a Federalwide Assurance (FWA) when research is supported by federal funds;
14. Responding to questions and concerns from the public;
15. Working with the IRB Chair to draft annual reports or request allocation of resources; and
16. Remaining a non-voting member of the IRB.

3.12.4 Institutional Review Board

The IRB's main responsibilities in safeguarding the rights and welfare of subjects are as follows and are not all inclusive:

1. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy and submitted by students, faculty, or staff of the University.
2. The IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
3. The IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.
4. The IRB shall notify PIs/Researchers, their advisors, and the institution in writing of its decision to approve, suspend, or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the PI/Researcher an opportunity to respond in person or in writing.

5. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk and shall have authority to observe or have a third party observe the consent process and the research.
6. The IRB will determine which studies need verification from sources other than the PI/Researchers that no material changes have occurred since the previous IRB review.
7. The IRB will ensure prompt reporting, by PIs/Researchers and their advisors, to the IRB and/or federal agencies or departments (where applicable) of:
    a. Any changes or amendments made to the protocol;
    b. Unanticipated problems involving risks to subjects or others;
    c. Serious or continuing noncompliance with regulations; or
    d. Suspension or termination of IRB approval.
8. If applicable, the IRB will act as the Privacy Board for research involving use of Personal Health Information (PHI).

3.12.5 IRB Chair and Vice Chair

The IRB Chair and Vice Chair responsibilities are as follows and are not all inclusive:

1. Convening meetings of the IRB;
2. Ensuring adequate expertise for review and determinations;
3. Reviewing protocols, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB;
4. Reviewing and confirming a protocol's level of review;
5. Delegating review responsibilities as necessary and applicable;
6. Maintaining up-to-date knowledge of human subject regulations and pertinent events;
7. Consulting with PI/Researchers as necessary;
8. Suspending the conduct of research when individuals are placed at an unacceptable level of risk;
9. Collaborating with the IRB Administrator to provide continuing education for IRB members; and
10. Collaborating with the IRB Administrator to resolve IRB-related issues with faculty or subjects.

3.12.6 IRB Members

IRB members' responsibilities are as follows and are not all inclusive:

1. Being familiar with IRB policies and procedures and federal, state, and local regulations policies or guidelines relating to human subject research;
2. Reviewing submitted protocols as assigned by the Chair or Chair's designate;
3. Reviewing meeting packets in advance of IRB meetings and being prepared for discussion of submitted protocols;
4. Acting as a Primary or Secondary Reviewer of protocols when assigned;
5. Maintaining confidentiality of IRB proceedings; and
6. Disclosing conflicts of interest, if applicable.

3.12.7 IRB Administrative Assistant

The IRB Administrative Assistant's (CAA) responsibilities are as follows and are not all inclusive:

1. Retaining adequate expertise for review and determinations;
2. Verifying that IRB members, PIs/Researchers, and student research advisors have completed CITI training;
3. Logging IRB protocols;
4. Recording meeting minutes;
5. Maintaining IRB files to ensure all official IRB records are maintained electronically;
6. Answering IRB email and fielding initial questions;
7. Maintaining confidentiality of IRB proceedings;
8. Assigning reviewers after Chair or designate has confirmed level of protocol review;
9. Being familiar with IRB policies and procedures and federal, state, and local regulations policies or guidelines relating to human subject research;
10. Checking IRB protocols for completeness;
11. Facilitating reporting, trainings, and quality improvement; and
12. Disclosing conflicts of interest, if applicable.

3.13 Cooperative Research: IRB Authorization Agreements

Cooperative research projects are projects that occur with at least one external partner outside of Saint Mary's University of Minnesota who also have their own IRB. When cooperative research occurs, each institution is responsible for safeguarding the rights and welfare of human subjects. Cooperative Research Agreements require one of the cooperating institutions to be identified as having IRB jurisdiction over the study, the IRB of Record. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

When a cooperative research study is proposed, an IRB Authorization Agreement or a Reliance Agreement must be completed between Saint Mary's University of Minnesota and the IRBs of the additional institutions. The IRB Authorization Agreement identifies the IRB of Record. The IRB of Record is accountable for review and approval of the human subjects review on behalf of those in the IRB Authorization Agreement.

The IRB Authorization Agreement can be for a single study or for longer term, covering multiple studies over time. If the IRB Authorization Agreement is longer term, either party can terminate it. The IRB Authorization Agreement can identify Saint Mary's University of Minnesota as the IRB of Record or it can identify the external IRB as the IRB of Record. Considerations for which institution serves as the IRB of Record include:

- The presence of a Federalwide Assurance approved through the Office of Human Research Protections.
- The location(s) in which most research participant contact will occur.
- Specialization in regulatory processes and protections related to specific population(s) being research.
- Institutional affiliation of the lead PI.

Requests for IRB Authorization Agreement can come through the IRB protocol review process or through the identification by the IRB of an institution with which multiple studies have occurred. The IRB chair reviews the request for the IRB Authorization Agreement and works with the partner institution to identify the IRB of Record. Once this is determined the IRB Chair creates an IRB Authorization Agreement and the Institutional Officials from each partnering IRB sign the IRB Authorization Agreement.

Section 4: IRB Review and Approval of Research Activities

4.1 Governing Principles/Regulations

Using the governing principles spelled out in the Belmont Report and in compliance with the governing regulations found in 45 CFR § 46, and thoughtful of the tenets of the Lasallian Catholic Principles and Catholic Social Teaching, the IRB will evaluate all proposed research projects involving human subjects to determine whether subjects' rights and well-being are adequately protected. The Belmont Report clearly defines three basic ethical principles which guide the protection of human research subjects in the work of the IRB.

1. Respect for Persons
    a. Human subjects should be treated as autonomous actors. The protocol must ensure that participants "enter into the research voluntarily and with adequate information" to self-determine their participation (Belmont Report). When the design of the research requires Deception or Incomplete Disclosure (see definitions), the IRB will review and assess the need for Deception or Incomplete Disclosure.
    b. Persons with diminished autonomy (see Vulnerable Populations) are entitled to the protection of a more thorough review (full review) to ensure the ethical criteria of Respect for Persons is met.
2. Beneficence
    a. All research protocols must be reviewed to ensure they do no harm to the participants.
    b. In addition, protocols must be reviewed to determine that the research maximizes possible benefits and minimizes potential harms or risks to the participant.
3. Justice
    a. All research protocols are reviewed to evaluate who benefits from the research and who bears the burden (participants).
    b. All research protocols are reviewed to ensure that selection of subjects is equitable. Subject selection should reflect the purpose of the research and not the ease of availability and manipulation of potential subjects.

4.2 Criteria for IRB Approval

The IRB will apply the criteria established by federal regulations at 45 CFR § 46 (Protection of Human Subjects 2009), also referred to as the Common Rule, and 21 CFR (Institutional Review Boards, 2015) when reviewing research involving human subjects. The criteria are as follows:

1. The risks to subjects are minimized;
2. The risks are reasonable in relation to any anticipated benefits to the subject, and to the advancement of knowledge;
3. The selection of subjects is equitable;
4. The subjects are fully informed of the study and its risks and benefits through the consent process, and consent will be sought from each prospective subject or the subject's legally authorized representative;
5. Informed consent and assent (when appropriate) will be documented. (See Consent Form Template for details);
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
8. When any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

Approval for full review protocols have an approval expiration of one year from the date of approval. If the PI/Researcher is still conducting research at the date of expiration, the PI/Researcher will need to submit an application for continuing review to renew approval before continuing research.

The above criteria will help assess whether risks to subjects are minimized and whether any risks are reasonable in relation to any anticipated benefits and to the advancement of knowledge.

4.3 Overall Procedure for IRB Application

1. Applications for IRB review are submitted to the IRB Administrative Assistant (CAA). Application materials must be submitted electronically.
2. The IRB Administrative Assistant (CAA) examines the protocol to make sure all of the required elements are present. If required elements are missing, the protocol is returned to the researcher for completion and resubmission.
3. The IRB Administrative Assistant (CAA) assigns an IRB protocol identification number to each protocol and determines if the protocol meets the criteria for exemption. If the CAA determines that the protocol meets the criteria for exemption, the CAA will submit the exemption category for review to the IRB chair (or vice chair when the chair is unavailable). The IRB chair or vice chair will confirm the category as exempt or, when appropriate, assign a different category to the protocol.
4. Assignment

a. The IRB Administrative Assistant (CAA) will assign non-exempt protocols to an IRB member as the Primary Reviewer. Assignment will be on a rotating process to ensure an equal division of labor.
b. The Primary Reviewer will determine the level of review and assign a Secondary Reviewer as needed.
    i. Exempt-limited: protocol requires a Primary Reviewer.
    ii. Expedited: protocol requires a Primary and Secondary Reviewer; or
    iii. Full: protocol requires a Primary and Secondary Reviewer to bring forward to the full IRB Committee.

4.4 Classifications for Review

4.4.1 Exempt

1. Exempt research means that a research protocol is exempt from the federal regulations governing human subject protections, as it fits within one of the exemption categories defined in 45 CFR § 46.101. Determination of exempt research will be made by the IRB Administrative Assistant (CAA) with review and confirmation by the IRB Chair (or IRB vice chair if the chair is not available), not by the researchers themselves. The IRB Chair or their designate reviews all protocols and subsequent amendments and modifications to confirm exempt level review.
2. Research projects are determined to be exempt if they meet the following criteria:
    a. The research is conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.
        i. Normal educational practices include:
            1. Research on regular and special education instructional strategies; or
            2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
        ii. Considerations should be made for state and federal laws and regulations such as the Family Educational Rights and Privacy Act (FERPA), and the Protection of Pupil Rights Amendment (PPRA).
        iii. Research subjects can include populations with special needs, though the IRB will require demonstration of the PI/Researcher's qualifications to work with these vulnerable populations as well as clear explanation of any additional procedures to minimize risks specific to working with this population.
        iv. Examples of research in an educational setting that would qualify for exempt level review:
            1. Test development

2. Trying new instructional methods alone or with the use of pre/posttests, surveys, interviews, and/or observations
3. Assessing student attitudes towards learning

v. Examples of research in an educational setting that does not qualify for exempt level review:
1. Data collection that is beyond the scope of the educational activity being studied.
2. Data collection of privileged data (socio-economic status, physical abuse)
3. Research that may be normal educational practice but poses greater than minimal risk (see definition) to the subjects. The methodology of the study could be determined to create greater risk.

b. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedure, interview procedures or observation of public behavior (including visual or auditory recording), if one of the following criteria is met:
i. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; and
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects are risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
iii. The information is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.
iv. The federal regulations specify that the exemption for survey or interview procedures does not apply to research with children. In addition, the federal regulations specify that the observation of public behavior procedure does not apply to research involving children, except when the researcher does not participate in any of the activities being observed.
v. Research involving benign behavioral interventions:
1. 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 is met:
a. 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;

b. 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 the subjects' financial standing, employability, educational advancement, or reputation; or
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

2. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
3. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research

c. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the PI/Researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
    i. This exemption would not apply if the PI/Researcher(s) collect data in a coded manner since the code would enable subjects to be identified via the code. "Existing" means that the data, documents, records, or specimens must exist and be de-identified at the time the research protocol is submitted.
d. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
    i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, 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;
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E- Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

e. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), 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 possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
    i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be

published on this list prior to commencing the research involving human subjects.

f. Taste and food quality evaluation and consumer acceptance studies
    i. If wholesome foods without additives are consumed, or
    ii. 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 containment 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 Services of the U.S. Department of Agriculture.
g. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
h. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
    ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
    iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
i. According to 45 CFR § 46, research involving the following is not appropriate for exemption:
    i. Prisoners,
    ii. Surveying or interviewing children, or
    iii. Observations of public behavior of children when the researcher participates in the activities being held.

3. Length of approval
    a. Research that is exempt does not require continuing review unless determined by the Primary Reviewer or Administrative Assistant.

4.4.2 Expedited

1. The Common Rule identifies two main criteria for a research project to be considered for Expedited Review (less than a full review but more thorough than an exempt review).

a. Some or all of the research appears on the list and is found by the reviewer(s) to involve no more than minimal risk (see definition):
b. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

2. Research categories that qualify for Expedited Review:
    a. Clinical studies on drugs or medical devices for which an investigational new drug (IND) application or investigational device exemption (IDE) is not required. Similarly, a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling.
    b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
    c. Prospective collection of biological specimens for research purposes by noninvasive means.
    d. Collection of data through noninvasive procedures routinely employed in clinical practice provided that:
        i. The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves
        ii. Where medical devices are employed, they must be cleared/approved for marketing (see CITI Basic Institutional Review Board Regulations and Review Process training for more details).
    e. Research involving the use of educational tests, survey procedure, interview procedures or observation of public behavior, when:
        i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
        ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
        iii. The federal regulations specify that the exemption for survey or interview procedures does not apply to research with children. In addition, the federal regulations specify that the observation of public behavior procedure does not apply to research involving children, except when the researcher does not participate in any of the activities being observed. Saint Mary's University of Minnesota's IRB requires that this rule also apply to subjects considered to be vulnerable adults.
    f. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are not publicly available or if the information is recorded by the PI/Researcher in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.
    g. Research involving data, documents, records, or specimens that have been collected or will be collected solely for non-research purposes (such as, for medical treatment or diagnosis) and that is not classified as exempt.

   h. Collection of data from voice, video, digital, or image recordings made for research purposes.
      i. Any recording must be destroyed immediately after they are transcribed unless the research requires longer retention. Where they will be stored, who will have access to them, and when they will be destroyed must be noted in the application.
   i. Research on individual or group characteristics or behavior. (See CITI Basic Institutional Review Board Regulations and Review Process training for additional categories related to medical research.)
3. Length of approval
   a. Research approved through expedited review does not require Continuing Review unless determined by the Primary Reviewer.

4.4.3 Full Review

1. Research which does not meet the requirements for exempt or expedited level review requires approval of the full IRB committee. Generally, any study that poses more than minimal risk (see definition), or which involves the collection of sensitive information will require full IRB review. Categories include:
   a. Studies involving vulnerable populations;
   b. Studies taking place internationally (particularly those with little or no provisions for protection of human subjects);
   c. Studies where information may be disclosed that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.);
   d. Studies involving deception which raises the risk level for subjects; or
   e. Studies that fall under the jurisdiction of the Food and Drug Administration
2. Length of approval
   a. Protocols requiring full review must be reviewed through the Continued Review process by the IRB every year

4.5 Protocol Reviews

4.5.1 Review

1. Once the IRB Member(s) are assigned a protocol, they will review the protocol using the criteria for IRB approval. For protocols requiring full review, the Primary and Secondary Reviewer will review the application to bring forward to the next convened meeting. The protocol will also be shared with the entire IRB before the meeting. Protocols determined to be exempt or expedited are not discussed at IRB meetings. A list of these protocols will be added to a monthly report by the IRB Administrative Assistant which is included with the minutes of each meeting.
2. Upon review, the PI/Researcher and the research advisor (if applicable) will be notified of the decision made about the protocol. Decisions include:
   a. Approved as Submitted. The IRB Chair will send a letter to the PI/Researcher and their advisor (if a student) confirming approval and allowing study activation.

b. Modifications Required. There are two levels to the "modifications required" category:
    i. The IRB requires minor, administrative, or change(s) requiring simple concurrence from the PI/Researcher prior to final IRB approval and study activation. The PI/Researcher's response to these changes may be reviewed only by the IRB Chair or their designate(s); and
    ii. The requested modifications or clarifications are more substantive, or require explanation by the PI/Researcher, including request for additional information that would affect the IRB's determinations with regards to the criteria for approval (e.g., risk/benefit determination, confidentiality/privacy, appropriate informed consent process, etc.). Responses from the PI/Researcher for these modifications must be brought back to the full committee for final approval.
c. Disapproval. Disapproval may occur because the IRB determines that the study is not scientifically sound, the risks are not reasonable given potential benefit, or any of the factors that would make it impossible for a required approval criterion to be met. The PI/Researcher is permitted a chance to respond to the committee's action and concerns either in person or in writing.

3. The turnaround time for complete protocols from assignment to review on average will take two to three weeks for exempt and expedited. Protocols requiring modification may take longer to process. Protocols requiring a full review must be submitted at least three weeks prior to the IRB meeting in which they will be reviewed. The IRB website will provide yearly IRB meeting dates and the deadlines to be considered for full review.
    a. The IRB does not guarantee any specific time frame for the application and review process. Several factors, including the review level, need for modification, number of protocols, and workload of each IRB member will affect the turnaround time. PIs/Researchers should submit applications with this in mind and apply early enough to account for extemporaneous circumstances.

4.5.2 Resubmission

Should a protocol require modification before it meets the criteria for approval by the IRB, the PI/Researcher has two weeks to make the required changes and send the revised protocol back to the CAA for IRB review. It is the responsibility of the student PIs/Researchers to work with their advisor to resubmit the updated application on time. The time period may be adjusted depending on the length of time before the next convened IRB meeting, if applicable.

4.5.3 Notifications

All notifications will go through the CAA, who will inform the PI/Researcher, along with their research advisor, of the IRB's decision with the IRB Chair's letter attached. The IRB is required to notify the PI/Researcher of every decision and justification for the decision, if applicable, in writing.

1. Exempt or expedited level review: Classification of protocols for exempt or expedited reviews is included in the letter informing the decision.

2. Full review: Because a full convened IRB meeting occurs only once per month, PIs/Researchers will receive a separate notification letter informing them that their protocol fits the criteria for full review and will include the date of the meeting in which the application will be discussed. PIs/Researchers and their research advisors may be asked to attend these meetings to provide useful information to the IRB about the protocol.
    a. Any modifications or changes to protocols with full level review must be submitted to the IRB at least two weeks before the convened meeting, or as soon as possible. Dates are set and maintained on the IRB website.
    b. PIs/Researchers will receive a notification concerning the decision of the full review board approximately one week after the convened meeting.

4.5.4 Amendments or Modifications

1. All amendments and modifications to a study, whether exempt, expedited, or full, need IRB approval before they are implemented. If the researcher wants to change anything in the research that would affect the subjects (such as recruitment procedures - including recruiting from new subject pools, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document/process, or data elements collected), the researcher must obtain IRB review and approval prior to implementation of the changes. The only exceptions are changes necessary to immediately protect subjects' safety, in which case the IRB must be notified no longer than 48 hours after such change occurs.
2. Amendment process
    a. Complete the amendment and/or modification form and submit to the CAA.
    b. The CAA will forward the form to the IRB Chair who will assess if amendments or modifications:
        i. Meet the criteria for IRB approval at the level of the original protocol; or
        ii. Require the research to be reviewed at a higher level due to the nature of the amendments or modifications.
    c. The IRB Chair can approve exempt and expedited amendments for modifications but must seek full IRB input for full review amendments or modifications.
    d. The CAA will notify the PI/Researcher and advisor (if a student) of the IRB Chair's decision to allow the study to continue with the amendments or to require further modifications before it can be approved.
        i. The turnaround time for the amendment process takes an average of two weeks. However, other factors concerning the proposed changes, or the IRB members could prolong the process and should be taken into consideration.
        ii. Should the amendments require full review, the PI/Researcher and their advisor will be notified approximately one week after the convened meeting.
3. Length of approval

a. Approval will follow the original application's timeline for continuing review unless the amendments or modifications moved the study from exempt to expedited or full. If no longer exempt, the protocol must be reviewed in one year.

4.5.5 Application for Continuing Review

1. Exempt reviews must be re-reviewed at a minimum of once every three years. The IRB re-reviews Expedited and Full reviews at least once every year. The IRB may require more frequent reviews based on its assessment of the study's risk/benefit ratio. The IRB will determine whether each continual review will follow expedited or full review procedures.
2. Continuing Review Process
    a. The IRB must do substantive continuing review and consider the same issues as during initial review. During this process:
        i. The IRB uses a full convened committee review procedure unless the research meets the expedited review criteria;
        ii. The IRB must determine that all the level requirements and criteria for IRB approval are met;
        iii. The PI/Researcher and, if a student researcher, their advisor should submit a status report to the CAA. The status report should include:
            1. The number of subjects accrued;
            2. A description of adverse events, unanticipated problems, withdrawal of subjects, complaints, and summary of relevant new information; and
            3. A copy of the current informed consent document.
        iv. The CAA confirms all necessary data is included and forwards the report and the original approved protocol to the IRB Chair for pre-review;
        v. The CAA then distributes the status report and the original approved protocol.
            1. If full: to the full IRB committee for review at the next full IRB meeting; or
            2. If expedited: to a PR and SR identified by the IRB Chair for review.
        vi. Once the review is complete, the IRB Chair informs the researcher and their advisor (if a student):
            1. They may continue with the research;
            2. Modifications are required before the study meets criteria for IRB approval; or
            3. They must stop research.
    b. If a research plan's approval period expires before the IRB completes its review, the researcher must stop all research procedures. If stopping the research could place subjects at risk, the researchers should contact the IRB immediately to obtain approval to continue treating subjects in that study.
3. Length of approval

a. The turnaround time for continuing review takes an average of two to three weeks. However, other factors concerning the protocol itself or the IRB members could prolong the process and should be taken into consideration.

4.6 Closure/Completion of Study

The IRB may request a final report on the completion of a study. All protocols requiring full review, as well as select expedited level protocols, will be notified about submitting a final report when they receive approval. A study is considered closed/completed when:

1. The study is no longer accepting new participants.
2. All interventions by participants have been completed and data is no longer being collected.
3. Data analysis is completed or only continuing on de-identified data.
4. Research was not conducted or was cancelled.
5. The expiration date for approval has been reached with no continuing review.

The report should include:

1. The IRB Protocol Identification Number;
2. Number of participants;
3. Any anticipated problems or adverse events;
4. Understanding that the closure means that no further data collection, follow-up with participants, data analysis and manuscript preparation that requires personal identifiable information may be conducted; and
5. Agreement to maintain research materials for five years after closure of research project.

4.7 Reports of Unanticipated Problems/Adverse Events/Noncompliance to the IRB/Complaints to the Study

1. Unanticipated Problems/Adverse Events/Noncompliance occurs when research involving human subjects violates federal regulations and/or the policies and procedures of the IRB. They can occur within studies that have been approved and within research that is conducted at the Saint Mary's University of Minnesota without IRB approval. Such noncompliance violates the Saint Mary's University of Minnesota Federalwide Assurance Registration. Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.
2. Examples of reportable events include but are not limited to:
    a. An unanticipated problem, which may be defined as any unexpected event that affects the rights, safety, or welfare of subjects. The event could be physical (such as a therapy dog bites a participant), emotional (a subject has a stronger than anticipated emotional reaction to the questions), or involve some harm (such as, breach in confidentiality or harm to a subject’s reputation).

   b. A serious adverse event, which may be defined as a death, life-threatening adverse drug or device experience, inpatient hospitalization or prolongation of existing hospitalization, persistent disability/incapacity, or congenital anomaly/birth defect.
   c. Research plan exception, which may be defined as enrollment of a research subject that fails to meet research plan inclusion/exclusion criteria.
   d. Research plan deviation, which may be defined as a departure from the research plan as approved by the IRB for a single subject.
   e. Data and safety monitoring plan or board summary reports.
   f. Complaints concerning subject rights submitted by subjects or concerned parties, family members, or study personnel. (CITI Basic IRB Regulations and Review Process)
3. If unanticipated problems, adverse events, noncompliance, or complaints against the study occur, the researcher, their advisor, their supervisor, participants, cooperating agencies, or other will report the incident to the IRB Chair, which must be reported no more than 48 hours after the event occurs. The Reporting Process is:
   a. The IRB Chair works with the IRB Administrative Assistant to compile needed information on the incident.
   b. The IRB Chair connects with the PI to discuss the alleged noncompliance.
   c. The IRB Chair collects needed information to determine if noncompliance occurred.
   d. The IRB Chair determines whether noncompliance occurred.
   e. If not serious, the IRB Chair sends a letter to the PI to modify the study to address the noncompliance issue.
   f. If serious, the IRB Chair brings the issue to the full IRB committee for review. The IRB Chair will then inform the PI of this decision in writing and determine if the PI may attend the IRB meeting.
   g. At the full IRB meeting, the committee may ask the PI questions (if present), discuss the concerns, and make a final vote to determine if noncompliance occurred.
   h. The full IRB committee also determines the sanctions for noncompliance with include but are not limited to:
      i. Take no action,
      ii. Inform all previous participants and/or currently enrolled participants of changes to the protocol or consent process,
      iii. Require observation of consent procedures,
      iv. Letters of reprimand,
      v. Restrictions on serving as a PI/Researcher on human subject research,
      vi. Modification of research protocols,
      vii. More frequent continuing review or monitoring,
      viii. Changes in consent process or documents,
      ix. Require observation of consent procedures,
      x. Require additional training for the research team,

xi. Require that currently enrolled subjects re-consent to participate,
xii. Suspension or termination of research and IRB approval,
xiii. Refer issues to other institutional entities (Institutional Official, Dean, Legal Counsel),
xiv. Unable to use previously collected data, or
xv. Any other action deemed appropriate by the IRB to protect the rights and welfare of research participants.

i. The rationale for the decision and subsequent sanctions will be recorded in the IRB committee meeting minutes.
j. The IRB Chair summarizes the investigation, the findings, and the sanctions to report as needed to the OHRP.

4.8 IRB Guidelines and Procedures for Course-Based Research Projects

1. All student activities involving collection of data from human subjects must be supervised by a faculty member.
2. A course-based research project refers to any course requirement that involves the collection of information from or about human subjects. This includes collecting private archival data about living persons.
3. Course-based research projects are projects in which the intent of the research is educational rather than intended for generalizable knowledge.
4. Course-based research projects are considered outside of the purview of the IRB when:
    a. The project is a normal part of the students' coursework;
    b. The primary purpose of the research is the development of the students' skills;
    c. The research is not pursued in order to publish the results or share at professional and academic conferences, presentations, and gatherings;
    d. The research is supervised by a faculty member;
    e. The research does not involve greater than minimal risk (see definition);
    f. The research does not involve any subjects under the age of 18 or protected as vulnerable populations;
    g. The research methods or questions do not involve any sensitive, personal or incriminating topics. Examples include discussing and/or collecting information about traumatic events, sexual history, grief and loss, etc.
5. Course-based research projects that meet these criteria must only complete the Notification of a Course-Based Research Project form. This informs the IRB of the project. This should be completed every three years or if the assignment changes.
6. Course-based research projects fall under the purview of the IRB, and faculty must file an application, when the Course-based research project:
    a. Involves more than minimal risk. Minimal risk is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals or during the performance of routine physical or psychological examinations or tests (Protection of Human Subjects, 45 CFR § 46.102 f). The following specific situations are deemed to involve more than minimal risk:
        i. The project seeks information about illegal activities.

ii. The project exposes participants to potential criminal or civil liability if the data from the project ever became public.
iii. The project exposes participants to potential financial damage, a reduction in employability, or potential damage to their reputation if the data from the project ever became public.
iv. The project involves topics that could lead to significant emotional distress in participants or which address psychologically sensitive subject matter. Examples include discussing and/or collecting information about traumatic events, sexual history, grief and loss, etc.

b. Involves data collection from a vulnerable population. Projects involving children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., persons on probation) need full IRB review. (Exception: Projects conducted in established or commonly accepted educational settings, involving normal educational practices, such as: work on regular and special education instructional strategies, or work on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.)
c. The Course-Based Research Project involves video recording of participants: Projects which will be video recorded must be submitted for IRB approval. Audio recording is allowed in exempt projects; however, the recording must be erased upon transcription or no later than the end of the semester.

7. If the Course-Based Research Project meets the above criteria the faculty must submit an application to the IRB.
    a. The faculty submits the application for IRB review following the process outlined in section 4.9 below. The application must be approved before the class can begin work on the project. The request should be submitted at least six weeks before the start of the semester.
    b. Approved exemption requests are valid for repeated offerings of the course for three years. If there is a significant change (see the Amendment or Modification section) to the requirements for the course-based project, the Program Director must resubmit the Notification of a Course-Based Research Project form.
8. The following activities are NOT considered course-based research projects:
    a. If the intent of the research is generalizable knowledge and the intent is to publish the findings. This includes major research projects like dissertations, capstone projects, or integrative papers. These major projects must be submitted individually for IRB review.
    b. Assignments which only require library research and/or internet research do not collect information from human subjects and as such are not considered a course-based research project and do not require IRB review.
    c. Observation of students for evaluative purposes is not considered a course-based research project.

   d. The project cannot include any deception. Participants must be fully informed and given the opportunity to voluntarily consent to participation.
9. Instructor responsibility for oversight over all student projects and course-based research projects. Those responsibilities include but are not limited to:
   a. Faculty who assign course work which requires the collection of information from human subjects are expected to be knowledgeable about the ethical requirements for such research and are responsible for monitoring student work to ensure compliance with ethical standards.
   b. Course instructors have primary responsibility for ensuring that the rights and welfare of human subjects are not violated in the course of conducting course-based research projects. This responsibility includes communicating to students the ethical principles for the protection of human subjects, reviewing student course project applications, and monitoring research activities and consent procedures.
   c. Instructors are responsible for training students on the IRB, research ethics, and the relevant institutional policies and procedures, and for ensuring student compliance with these standards.
   d. Instructors are responsible for reviewing and approving individual student research projects. This includes review and approval of informed consent procedures, instruments, methods, and procedures prior to use by students. A sample informed consent form for course-based projects is available on the IRB website.
   e. If the instructor is a course contracted faculty, the program director must review the protocol application.
   f. The instructor must notify the IRB within 48 hours if any adverse events occur related to a course-based research project.
10. If the project(s) meets the criteria for exemption from IRB review, the course instructor is responsible for completing and submitting a Notification of a Course-Based Research Project to the IRB.

4.9 Submission Requirements/Materials Reviewed for all Levels

The following documents are required of the PI/Researcher and student research advisor:

1. Submit protocols of proposed research activities for IRB review and approval prior to commencing the research activities. These must Include:
   a. Certificate of Completion of CITI training;
   b. Complete IRB application form with needed signatures (PI/Researcher, all co-investigators, applicant's supervisor and/or faculty advisor); and
   c. The proposed research project which should include:
      i. General information, including study title, investigator names, contact information and positions at the institution, funding sources, types of populations to be studied (for example, men, women, minors, adults, etc.);

ii. Discussion/description of:
    1. The scientific significance and goal of the study;
    2. The number of subjects that would be required to meet the study goals (if secondary data: description of data and its source);
    3. The inclusion/exclusion criteria for subject entry or for use of data/tissues;
    4. The recruitment and consenting processes, providing a detailed description of what subjects will be asked to do;
    5. The potential risks and direct/indirect benefits to subjects, as well as procedures for minimizing the risks;
    6. The procedures to maintain confidentiality and privacy;
    7. The plans for secure and confidential maintenance of records. The Common Rule requires the retention of data for at least 3 years after the completion of the study while the APA requires the retention of data for at least 5 years after publication;
    8. The vulnerable groups that may be encountered in the subject population, with emphasis on additional protections that will be put into place to ensure that the rights and welfare of such groups are protected;
    9. How the capacity to consent will be assessed for all subjects; and
    10. Justification for the use of deception, if applicable, and the steps taken to minimize risk.
iii. Research methods used (e.g., survey, qualitative, quantitative, observation, secondary data analysis, longitudinal, cross-sectional, etc.);
iv. A copy of all data collection tools; and
v. Data analysis plan: Overview of intended statistical analysis or qualitative analysis.

2. Determine whether your research project utilizes or involves any of the following. If an item is part of the study, the specified documentation must be submitted with the IRB application. Templates for certain forms can be found on the IRB website.
    a. All materials to be used for recruitment of subjects. Attach as Appendix A. Items include:
        i. Dean approval if recruiting from your own program;
        ii. Recruiting posters;
        iii. Advertisements;
        iv. Emails;
        v. Written or verbal announcements; or
        vi. Other communication used to recruit participants for the research study.
    b. All informed consent documents (consent form, assent form with subsequent notification form, implied consent language). Attach as Appendix B.
    c. Cover letter, written or verbal instructions, request for a summary of the results, or other document(s) given to research participants. Include research protocol

and procedure (what participants will be asked to do, step-by-step). Attach as Appendix C.

d. All original data collection tools, including survey, questionnaire, test, demographic information sheet, or other instrument designed by the researchers for this research project. The instrument must be in its final form, ready to distribute to participants. Attach instrument(s) as Appendix D.
e. All external data collection tools, including tests, measurement scales, or other instruments developed by another individual or agency. Attach a copy of each instrument and a link to the website from which the instrument is available. For each instrument used by the study, provide documentation for one of the following:
    i. The instrument is in the public domain;
    ii. You have the written permission of the author of the instrument to use it for your research; or
    iii. A receipt for purchase of the instrument. Attach the instrument and these documents as Appendix E.
f. Research Cooperation Agreement. This letter of support must be included if the research involves the cooperation of any agency or institution (including Saint Mary's University of Minnesota) for any of the following activities
    i. Recruitment or solicitation of participants/subjects;
    ii. Collection of original data for your research project;
    iii. Use of archival data owned by the agency or institution; or
    iv. IRB review or its equivalent by the cooperating institution. Attach this documentation as Appendix F.
g. Any conflicts of interest with the individuals or agencies/institutions involved in the research study must be disclosed and accounted for in the COI Management Plan. Attach as Appendix G.
h. Archival data subject to regulations governing the use of health care data or student records. Provide documentation explaining how the use of the data is consistent with relevant HIPAA regulations, FERPA regulations, or state statutes. Attach this documentation as Appendix H.
i. If external funding or other grant funding supports the research, include a description of the external funding or a copy of the grant application/protocol. External funding can involve conflict of interest. In addition to the description of the external funding and the grant application, include a description of any past, present, or future relationships with any of the research subjects outside of the context of the research project. Attach as Appendix I.
j. If the PI/Researcher is working with a cooperating institution that utilizes its own IRB/Human Research Protection Program, the Researcher must include the cooperating institution's IRB approval. See Section 3.13 for the process for cooperating institutions. Include a description of any past, present, or future relationships with the cooperation institution. Attach documentation as Appendix J.

3. After the protocol is approved, a number of forms may need to be utilized to ensure the protection of the rights and welfare of human research subjects. These forms include:
    a. Amendment/Modification application
    b. Report of Unanticipated Problems/Adverse Events/Noncompliance/Complaints against the study
    c. Incident Report
    d. Application for Continuing Review
    e. Closing Research Form

Based on the CITI training and the Institutional Review Board Written Procedures: Guidance for Institutions and IRBs
(https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm512761.pdf)