


# Policies and Procedures Manual for the Conduct of Human Subjects Research

Saginaw Valley State University

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# I. PREAMBLE

**A.** Ethical Principles. Within the U.S., basic ethical principles underlying the conduct of research with human beings were formally identified in 1979 by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in what has become known as "The Belmont Report."

1. *Original Structure and Purpose*
    - **a. Purpose:** To create a comprehensive set of rules to protect human subjects in research conducted or supported by federal agencies.
    - **b. Foundation:** The regulations are based on the three core ethical principles outlined in the Belmont Report.
    - **c. Key components:** The original regulations included Subpart A (basic policy), and later additions provided extra protections for specific populations such as pregnant women and fetuses (Subpart B), prisoners (Subpart C), and children (Subpart D).
2. *Evolution of the Regulations*
    - **a. 1991:** The Common Rule was adopted, codifying the principles in Subpart A of 45 C.F.R. 46, which applies to most federal departments and agencies.
    - **b. 2018:** A major revision to the Common Rule (Subpart A) was published, strengthening the protection for human subjects and streamlining administrative processes.
    - **c. 2024:** Non-substantive amendments were made to Subparts B, C, and D to align them with the 2018 revisions to the Common Rule.

**B.** The Belmont Report**.** The Belmont Report is a foundational document outlining ethical principles for research involving human subjects, based on three core principles: **respect for persons, beneficence, and justice**. It was created in response to unethical human research practices, such as the Tuskegee Syphilis Study, to establish guidelines for ethical conduct, like informed consent and fair risk-benefit assessment. The report was published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978 and is considered the ethical basis for human subjects research regulations.

1. *Informed Consent*: Characterized by the provision of complete and accurate information to potential research subjects, facilitating full and genuine comprehension of this information by potential research subjects, and assuring the voluntary nature of any

consent obtained.

2. *Risk/Benefit Assessment*: A determination of whether the research study is designed correctly as well as a determination of whether potential risks for subjects are justified by potential benefits resulting from the research.
3. *Research Subject Selection*: Mandating both fair procedures and equitable outcomes (i.e., "justice") in the conduct of human-subjects research.
4. *Core Principles and Guidelines*
   a. ***Respect for Persons*:** This principle emphasizes the autonomy of individuals and the need to protect those with diminished autonomy. This is put into practice through **informed consent**, which ensures participants have sufficient information about the risks and benefits, can comprehend it, and have given their agreement voluntarily.
   b. ***Beneficence*:** This principle involves maximizing potential benefits while minimizing potential harms. This is achieved through careful risk-benefit assessment, ensuring that participants are not exposed to undue risk.
   c. ***Justice*:** This principle addresses the fair distribution of the burdens and benefits of research. It requires that participants be selected equitably and that the risks and benefits of research are not disproportionately borne by a single group in society.
5. *Regulations and Policies Regarding Ethical Research*.
   a. Federal regulations controlling the conduct of human subjects research are found in numerous documents (e.g., 21 CFR 50, 21 CFR 54, 21 CFR 56, HIPAA) but are most centrally codified at Title 45 Part 46 of the Code of Federal Regulations (hereafter simply referred to as "45 CFR 46"). Among other things, 45 CFR 46 mandates that an "Institutional Review Board" (IRB) be established at institutions involved in research with human subjects.
   b. The "original" 45 C.F.R. 46 refers to the initial set of regulations from the Department of Health, Education and Welfare (HEW), now the Department of Health and Human Services (HHS), for the protection of human subjects in research. It was established to implement ethical guidelines, notably the principles from the 1979 Belmont Report (respect for persons, beneficence, and justice), and has since been revised, most recently with the 2018 updates to the "Common Rule" (Subpart A).
   c. The code is available here at (45 CFR 46)

**C.** Glossary of Terms**.**

1. *Adverse Event (AE)*. Any untoward occurrence in a research participant. The occurrence need not have a clear causal relationship with the individual's participation in the research; an AE can be any unfavorable and unintended sign, symptom, event, or occurrence affecting a participant's physical, mental, social, financial, legal, or psychological well-being. An unanticipated AE should be reported to the committee as soon as possible after it is identified.
2. *Assent*. Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent is typically paired with permission from a parent or guardian, and together they comprise the informed consent to participate.
3. *Authorized Institutional Official*. An officer of an institution with the authority to speak for and legally commits the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.
4. *Belmont Report*. A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979. View a summary of the Belmont Report. The Belmont Report principles permeate human subjects research to this day.
5. *Beneficence*. An ethical principle discussed in the Belmont Report requires protecting people from harm. The principle of beneficence can be expressed in two general rules: 1) do not harm; and 2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
6. *Benefit*. A valued or desired outcome associated with a research project. Anticipated benefits may express the probability that subjects and society may benefit from the research procedures. Research may benefit the individual or society. If research will not benefit individuals, it must provide a reasonable likelihood of benefiting society. SVSU's human research application requests information about the direct benefits accruing to the research participants and to society. Compensation and incentives given to participants are not considered benefits.

7. *Certificate of Confidentiality*. This is a certificate issued by the National Institutes of Health that protects identifiable, sensitive research information from forced disclosure. It is typically requested when the researcher believes his/her research objectives could not be met without this form of protection.
8. *Children*. People who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46 46.401(a)]. In Nevada, individuals younger than 18 years of age are considered children for most research situations, and informed consent then consists of the child's assent and the parent's permission.(See "Assent.")
9. *Coercion*. The act of forcing or compelling one to act against one's will. Coercion can be overt or perceived, and it can occur when the researcher holds authority or power over the subject (for example, teachers over students or physicians over patients). It can also occur when incentives become so great that the participant participates only to attain them.
10. *Cognitively Impaired*. Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that the capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
11. *Collaborative Research*. Human subjects research projects conducted by more than one institution. Each institution is responsible for safeguarding the rights and welfare of human subjects. Arrangements for joint review, reliance on a single qualified IRB, or similar arrangements are acceptable. (Please contact the ORI-HS staff if this situation occurs; they can assist with the arrangements.)
12. *Compensation*. Payment for participation in research. Compensation should be appropriate to the effort involved and not excessive or coercive. Compensation is NOT considered a benefit.

13. *Competence*. A legal term used to denote the capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity)
14. *Confidentiality*. Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
15. *Conflict of Interest*. Defined as a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain). See information regarding SVSU's Conflict of Interest/Compensated Outside Services Policy.
16. *Consent.* See "Informed Consent."
17. *Control (Subjects) or Controls*. Subject(s) used for comparison who are not given the treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring at approximately the same time as the condition under study) or historical (occurring before the condition under study). When the present condition of subjects is compared with their condition under a prior regimen or treatment, the study is considered historical control.
18. *Co-Principal Investigator (Co-PI).* The other primary scholar or researcher is involved in conducting the research. Co-PIs must also meet the SVSU PI eligibility requirements.
19. *Debriefing.* Giving subjects previously undisclosed information about the research project following completion of their participation in the research.
20. *Declaration of Helsinki*. A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was last revised in 2008.
21. *Descriptive Study*. Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).
22. *Emancipated Minor*. A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult

responsibilities such as marriage, procreation, or being self-supporting and not living at home. (See also “Mature Minor.”)

**23.** *Equitable*. Fair or just; used in the context of the selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**24.** *Exempt Review*. The Code of Federal Regulations (45 CFR 46.101(b)) identifies several categories of minimal risk research as exempt from the Federal Policy for the Protection of Research Subjects. This determination must not be made by the PI, but by the IRB or someone appointed by the IRB. For more information, see the U.S. Health and Human Services website, “Exempt Research and Research That May Undergo Expedited Review.”

**25.** *Expedited Review*. The Code of Federal Regulations (45 CFR 46.110 and 21 CFR 56.110) identifies several categories of minimal risk research that may be reviewed through an expedited review process. For more information, see the U.S. Health and Human Services website on “Guidance on Expedited Review Procedures.”

**26.** *Family Educational Rights and Privacy Act (FERPA).* This act defines the rights of students and parents to review, amend, and disclose educational records and requires written permission to disclose personally identifiable information from a student’s education record, except under certain circumstances, such as a court order or subpoena.1

**27.** *Federal Policy for the Protection of Human Subjects*. The federal policy that provides regulations for the involvement of human subjects in research. The policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the policy applicable to such research. Currently, 16 federal agencies have adopted this policy, commonly referred to as “The Federal Policy,” but also known as the “Common Rule.”

**28.** *Federal-wide Assurance (FWA).* A formal written, binding commitment that is submitted to the Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) in which an institution agrees to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved. SVSU’s assurance number is FWA00002305.

**29.** *Full Board Review*. Review of proposed research at a convened meeting at which a majority

of the membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting. Generally, studies that undergo full board review involve greater-than-minimal risk, risky, or novel procedures, or vulnerable populations.

**30.** *Guardian*. An individual who is authorized under applicable state or local law to give permission on behalf of a child for general medical care. In Nevada, under NRS 159.0805, guardians may not give permission for a child to enter a research study unless a court order has been obtained.

**31.** *Health Insurance Portability and Accountability Act (HIPAA)*. The rule that protects the privacy of individually identifiable health information. The privacy rule provides federal protection for personal health information held by covered entities and gives patients specific rights with respect to that information.

**32.** *Human Subjects.* Individuals whose physiological or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**33.** *Identifiable*. Federal regulations define identifiable to mean that the identity of the individual subject is, or may readily be, ascertained by the investigator, or is associated with the information.

**34.** *Incapacity*. This refers to a person's mental status and means the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. The term is often used as a synonym for incompetence.

**35.** *Incompetence*. A legal term meaning inability to manage one's own affairs and often used as a synonym for incapacity.

**36.** *Informed Consent*. A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the

investigator, the sponsor, the institution, or agents thereof from liability for negligence.

**37.** *Institutional Research*. Institutional research (also called internal research) is the gathering of data from or about SVSU students, faculty, and staff by university offices or organizations, with the sole intent of using the data for internal informational purposes or for required data-collection purposes. This data would not be made generalizable. Examples include surveys to improve university services or procedures; ascertain the opinions, experiences, or preferences of the university community; or to provide necessary information to characterize the university community. This type of data collection does not require IRB review unless respondents are asked about sensitive aspects of their own behavior. For debatable projects, investigators should submit an exclusion review form to the Chair of IRB.

**38.** *Institutional Review Board (IRB).* A specially constituted, federally mandated review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. SVSU has two IRBs – Social/Behavioral and Biomedical.

**39.** *Interaction.* The federal regulations define interaction as "communication or interpersonal contact between investigator and subject."

**40.** *Intervention*. The federal regulations define intervention as both physical procedures used to gather data (for example, venipuncture) and manipulations of the subject or the subject's environment performed for research purposes.

**41.** *Investigator.* This refers to a researcher conducting the project. Investigators can be principal investigators or co-principal investigators. Students are always listed as student investigators.

**42.** *IRB Authorization Agreement*. A formal agreement between SVSU and another FWA-holding institution that allows the one IRB to serve as the "IRB of Record" for protocols involving collaborative research between SVSU and the other institution.

**43.** *IRB of Record.* A term utilized when an institution assumes the IRB responsibilities for a human subject research protocol conducted at another institution. An IRB authorization agreement signed by institutional officials at both institutions is required.

**44.** *Justice.* An ethical principle discussed in the Belmont Report requires fairness in the

distribution of burdens and benefits; those who bear the burdens of research should also receive the benefits. There must be a fair and equitable selection of subjects.

**45.** *Legally Authorized Representative*. A person is authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, 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.

**46.** *Mature Minor.* Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (See also "Emancipated Minor.")

**47.** *Minimal Risk.* A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed 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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination. Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

**48.** *Modification.* Any change to an IRB-approved study protocol, regardless of the level of review it receives initially.

**49.** *Nonaffiliated Member.* A federally mandated member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community (e.g., businessperson, attorney, or teacher).

**50.** *Nuremberg Code.* A code of research ethics was developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

**51.** *Office of Human Research Protection, DHHS.* The office within the Department of Health and Human Services that is responsible for implementing DHHS regulations (45CFR46) governing research involving human subjects.

**52.** *Office of Institutional Research (OIR).* The SVSU office, formerly known as the Office for the

Protection of Research Subjects (OPRS), that serves as an administrative hub for the SVSU IRB's oversight of human subjects research.

**53.** *Permission.* The agreement of the parent(s) to the participation of their child in research.

**54.** *Principal Investigator (PI).* The scientist or scholar with primary responsibility for the design and conduct of a research project. See SVSU's PI Eligibility Policy for those who are eligible for automatic PI status and how to apply for PI status.

**55.** *Prisoner.* An individual involuntarily confined in a penal institution, including persons: 1) sentenced under a criminal or civil statute; 2) detained pending arraignment, trial, or sentencing; and 3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution. Note that this includes adjudicated youth.

**56.** *Privacy.* Control over the extent, timing, and circumstances of disclosing personal information (physical, behavioral, or intellectual) with others.

**57.** *Private Information.* Defined by the federal regulations to include information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also includes information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for the acquisition of the information to constitute research involving human subjects.

**58.** *Prospective Studies.* Studies are designed to observe outcomes or events that occur after subjects are identified. Prospective studies need not involve manipulation or intervention; they may be purely observational or involve only data collection.

**59.** *Protection of Pupil Rights Amendment.* This applies to survey research conducted in schools and states that parents have the right to inspect surveys and questionnaires distributed within schools. This amendment also requires parental permission for minors to participate in surveys that disclose certain sensitive information.1

**60.** *Protocol.* The formal design or plan of an experiment or research study; specifically, the

plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis for the collected data.

**61.** *Research.* A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

**62.** *Respect for Persons.* An ethical principle discussed in the Belmont Report requires that individual autonomy be respected and people with diminished autonomy be protected.

**63.** *Retrospective Studies.* Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case-control studies are an example of this type of research. This requires IRB review if it involves private information about humans.

**64.** *Risk.* The probability of harm or injury (physical, psychological, social, or economic) occurs because of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks include immediate risks of study participation as well as risks of long-term effects.

**65.** *Secondary Data*. This involves two types of data: 1) data collected by someone other than the principal investigator for a research or non-research purpose, or 2) data that was collected by the principal investigator, but when collected, it was not intended to be used for human subjects research. For data to be considered secondary data, the data must exist prior to the initiation of the current research study or be "on the shelf" at the time of study initiation. Principal investigators must submit and receive approval for use of secondary human subjects data prior to initiation of the project.

**66.** *Site Visit.* A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

**67.** *Subject (Human).* "Participant" is the preferred term because it better reflects the participatory aspects of research. Sometimes "subject" more accurately describes the role.

**68.** *Voluntary*. Free of coercion, duress, or undue inducement or influence. Used in the

research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

## II. POLICY INTENT AND RESPONSIBILITIES OF

**A.** Intent. It is the intent of Saginaw Valley State University (SVSU) to protect research subjects from unnecessary and/or unjustified harm stemming from participation in research. With this goal in mind, SVSU establishes these policies and procedures, intended to be consonant with 45 CFR 46, in order to:

**1.** Govern the conduct of individuals acting on behalf of SVSU when conducting human-subjects research as well as individuals conducting research at or through SVSU, and

**2.** Provide clarity regarding the obligations incumbent upon individuals conducting such research.

**B.** Responsibilities of Researchers.

1. All research involving human subjects conducted, in whole or in part, by any individual acting on behalf of SVSU (e.g., full- or part-time employees, students, and volunteers) regardless of the physical location of the data collection, shall be submitted to the SVSU IRB for purposes of oversight and compliance with this policy. This requirement is binding whether the research is externally funded or not and regardless of the source of any such funding.
2. The IRB alone maintains authority to determine its jurisdiction over all such activities and to determine whether activities are exempt from IRB oversight or the type of review applied to the research.
3. Every person acting on behalf of SVSU who is engaged in human-subjects research is individually responsible for ensuring that research in which he or she is involved follows these policies and procedures.
4. Any individual conducting human-subjects research at SVSU will have successfully completed an approved training program prior to engaging in any such research.

## III. INSTITUTIONAL AUTHORITY AND REPORTING RESPONSIBILITIES

**A.** President (or designee).

1. The President (or designee) holds primary institutional authority for the oversight of human-subjects research at SVSU. The President (or designee), in turn, is responsible to the Board of Control as outlined in other SVSU governance documents.
2. The President (or designee) is responsible for addressing noncompliance with federal regulations and/or SVSU IRB policies and procedures governing research.
3. The President (or designee) will appoint the Chairperson of the IRB and other members of the IRB.
4. Neither the President (or designee) nor any other SVSU community member has the authority to approve any human-subjects research project that has not been approved through the normal functioning of the SVSU IRB. However, the President (or designee) does maintain authority to deny permission to conduct human- subjects research despite prior approval of such research by the IRB.
5. The President (or designee) will ensure sufficient resources for the operation of the IRB as defined in 45 CFR 46.

**B.** IRB Chairperson. The IRB Chairperson is responsible for overseeing the development of all application and investigator reporting forms, with approval from the IRB Committee. The Chairperson also manages official communication with investigators and ensures proper documentation of IRB activities, including meeting agendas and minutes. In addition, the Chairperson determines the appropriate review category for submitted research proposals and reports those decisions to the IRB. The IRB Chairperson reports to the President (or designee) on the routine operations of the IRB and the status of human subjects research at SVSU. The format and schedule of these reports are determined collaboratively between the President (or designee) and the IRB Chairperson. Copies of these reports are shared with all IRB members.

1. *Training and Qualifications*

   The IRB Chair should possess the knowledge, experience, and training necessary to oversee the IRB and the conduct of human subjects research at the institution. Required training and qualifications include:

   a. IRB Chair-Specific Training – Formal instruction on the responsibilities of an IRB Chair,

including leadership of meetings, facilitation of protocol review, and ethical oversight of human subjects research.

b. Human Subjects Research Regulations – Training on federal and state regulations governing human subjects research (e.g., Common Rule, FDA regulations, HIPAA).
c. Responsible Conduct of Research (RCR) – Instruction on principles and expectations for ethical research practice.
d. Administrative and Program Oversight Training – Skills for managing IRB administrative functions, including recordkeeping, reporting, workflow management, and coordination with Academic Affairs and other institutional units.
e. IRB Management Systems – Training in electronic protocol management systems (e.g., IRBNet) and other tools used to support IRB operations.
f. Ongoing Professional Development – Participation in workshops, webinars, or conferences to maintain up-to-date knowledge of evolving regulations, policies, and best practices in human subjects research.
g. These training requirements ensure that the IRB Chair is fully equipped to lead the IRB, support investigators, and maintain compliance with all applicable regulations while overseeing the institution's human subjects research program.

2. *Regulatory Compliance & Recordkeeping*. The IRB Chairperson must ensure all IRB actions and determinations comply with:
   a. Health and Human Services (HHS)/Office of Human Research Protection (OHRP) regulations (45 CFR 46)
   b. FDA human subjects' regulations, if applicable
   c. Institutional policies
3. *Maintain Files*. Maintain complete electronic regulatory files in IRBNet for all approved, closed, or withdrawn studies.
4. *OHRP or FDA Audits*. Assist in preparation for Office of Research Protections (OHRP) or Federal Drug Administration (FDA) audits, internal audits, or accreditation processes (if applicable).
5. *Training, Outreach, and User Support*. Provide training for faculty, students, and staff on:
   a. Requirements for human subjects research.

b. Responsible Conduct of Research (RCR) expectations.
c. Development and maintenance of guidance materials (e.g., documents, videos, FAQs) to improve submission quality.
d. Preparation of compliant research protocols through consultations with investigators (faculty and students).
e. Effective communication and coordination across relevant units.
f. Use of IRBNet and CITI training tools for IRB Committee members.
g. Oversee and maintain all content on the IRB website to ensure materials are accurate, relevant, and up to date.

6. *Collaborate with*:
   b. Academic Affairs, which oversees its operations.
   c. Department Chairs and Deans – to ensure departmental awareness and support for human subjects research.
   d. Legal Counsel – when policies, agreements, or sensitive research issues require review.
   e. Compliance and Risk Management Offices – to align IRB reviews with institutional policies and federal regulations.
   f. Office of Research & Sponsored Programs for grant compliance, reporting, and proposal coordination.
   g. Faculty, Staff, and Student Investigators – for protocol preparation, training, and guidance.
   h. Information Technology/IRBNet Support – for system access, training, and troubleshooting.
   i. Other Institutional Committees (e.g., Biosafety, Animal Care, Data Security) – to coordinate multi-level compliance requirements.

6. *IRB Contact Person for SVSU*. Serve as the main point of contact for outside organizations or partners also using IRBNet for collaborative IRB agreements. This includes working with institutions that utilize SVSU as their IRB provider.

   a. *IRB Meetings and Committee Oversight*. Prepare meeting agendas, distribute reviewer assignments, track quorum, and upload updated materials in IRBNet *(Appendix A, B, & C)*.

7. *Reporting & Continuous Improvement*
    a. Tracks metrics such as submission volume, turnaround times, types of reviews, common issues, and compliance problems.
    b. Recommends process improvements to streamline the IRB workflow and enhance compliance across the university.
8. *IRBNet System Management*.
    1. Serve as the primary administrator for IRBNet, managing user accounts, permissions, roles, and workflows.
    2. Work with IRBNet Facilitator to build and update project templates, submission forms, checklists, and reviewer tools within the system.
    3. Work with IRBNet Facilitator to troubleshoot user access, technical issues, and system errors, liaising with IRBNet support as needed.
    4. Work with IRBNet Facilitator to maintain protocol submission workflows, routing logic, and notification systems.
9. *Oversee Project Initiation, Implementation, to Sunsetting*. The IRB Chair will oversee the IRB process from Phase 1 (Initiation), Phase II (Project Implementation), to Phase III (Expiration).

**C.** IRBNet Facilitator. The IRBNet facilitator serves as the central administrative support for the university's Institutional Review Board (IRB), managing the full lifecycle of research protocol submissions through IRBNet (the electronic research compliance management system). The IRB Facilitator ensures efficiency, regulatory compliance, and high-quality service to investigators, faculty, and students.. Responsibilities include:

1. *IRBNet System Management*.
    a. Serve as recording secretary for the IRB: draft and maintain minutes that meet federal regulations (45 CFR 46). This includes:
        i. Manage continuing review, amendment, and reportable event workflows.
        ii. Ensure timely distribution of IRB determinations to investigators through IRBNet.
    b. Build and update project templates, submission forms, checklists, and reviewer tools within the system.

c. Troubleshoot user access, technical issues, and system errors, liaising with IRBNet support as needed.

d. Maintain protocol submission workflows, routing logic, and notification systems.

2. *Submission Intake & Pre-Review*.

a. Review all new submissions using the intake checklist in IRBNet for completeness**,** ensuring required documents (protocols, consent forms, recruitment materials, data use forms, etc.) are included.

b. Conduct administrative pre-reviews to catch missing elements before sending them to IRBChair.

c. Communicate with investigators regarding revisions or clarifications needed to move a study forward.

3. *IRB Committee Support*.

a. Prepare meeting agendas**,** distribute reviewer assignments, track quorum, and upload updated materials in IRBNet.

b. Serve as recording secretary for the IRB: draft and maintain minutes that meet federal regulations (45 CFR 46).

c. Manage continuing review**,** amendment**,** and reportable event workflows.

d. Ensure timely distribution of IRB determinations to investigators through IRBNet.

4. *Reporting*.

a. Generate reports for the IRB Chairperson.

**D.** IRB Committee Members.

1. Be familiar with all IRB policies and procedures, as well as applicable federal, state, and institutional regulations governing human subjects research.
2. Review submitted materials assigned, serving as primary, secondary, expedited, or limited reviewers, and actively participate in IRB meetings.
3. Notify the IRB Chair of any suspected noncompliance with applicable policies or regulations.
4. Sign and adhere to a confidentiality agreement acknowledging the protection of sensitive IRB materials and discussions.
5. Provide at least one month's written notice to the IRB Chair and the President (or

designee) if they intend to resign from their appointment.

**E.** IRB Composition and Rules of Order.

1. *Composition*. IRB membership must comply with federal regulations (45 CFR 46.107–108) and is structured to ensure a thorough and balanced review of research activities:
   a. IRB members are appointed by the President (or designee).
   b. The IRB must collectively represent a range of disciplinary backgrounds appropriate to the research conducted at the institution.
   c. Because children are frequently included as research participants at SVSU, at least one member must have expertise in working with children.
   d. At least one member must have a scientific background.
   e. At least one member must have a primary background in a non-scientific area.
   f. At least one member must be unaffiliated with the institution and not part of the immediate family of an affiliated individual.
   g. Membership must reflect diversity, including efforts to avoid representation consisting entirely of one gender.
   h. When reviewing research involving vulnerable populations, the IRB may consult with individuals who have relevant expertise. These consultants may participate in discussions but do not have voting privileges.
   i. For research involving FDA-regulated articles, at least one physician must be present and eligible to vote on the review.
2. *Alternate Members*. Alternate members are appointed by the President (or designee) in consultation with the IRB Chair and the member for whom the alternate will serve.
   a. Alternate members must be qualified to fulfill all responsibilities of the IRB member they represent.
   b. The primary member is responsible for notifying the alternate when attendance is required and for providing all necessary materials in advance of meetings.
   c. Alternate members may attend and participate in IRB meetings at any time but may vote only when the primary member is absent or recused.
   d. Alternate members must sign and adhere to a confidentiality agreement acknowledging the protection of sensitive IRB materials and discussions.

3. *Quorum*. A quorum is defined as a simple majority of IRB members and must include at least one member whose primary concerns are in non-scientific areas.
    a. Members may participate virtually when unable to attend in person, and such participation counts toward the quorum.
    b. An alternate member may be counted toward the quorum only when the primary member they represent is not counted.
    c. When a quorum is present, a simple majority vote of members in attendance is sufficient for approval.
        i. Alternate members may vote only when the primary member they represent is not voting.
        ii. No item may be brought to a vote unless it has been included on the meeting agenda, except under special circumstances approved by a three-fourths majority of members present.
4. *Meeting Minutes*. IRB meeting minutes will document actions taken, a summary of key discussion points, and information necessary to demonstrate and maintain quorum. Detailed transcripts of discussions will not be recorded. IRB Facilitator will assist in creating the agenda and attend to take meeting minutes. (Appendices A, B, C)
5. *Confidentiality*. All materials submitted to the IRB are considered confidential and may not be shared outside the IRB, except as permitted by this policy or required by law. All IRB members, alternate members, and consultants are required to sign and adhere to a confidentiality agreement acknowledging their responsibility to protect sensitive information related to IRB submissions, discussions, and decisions.

## IV. DEVELOPMENT AND REVISION OF POLICIES AND PROCEDURES

**A.** Authority**.** Ultimate authority for approval of all SVSU IRB Policies and Procedures resides with the President (or designee).

**B.** IRB Review of Policy and Procedures**.**

1. Anyone subject to this policy is welcome to recommend policy changes to any member of the IRB.
2. Proposed changes to existing policy must be reviewed and approved by the IRB prior to being forwarded for eventual approval by the President (or designee).
3. Receipt of revisions of 45 CFR 46 by the IRB will also trigger immediate review of SVSU IRB Policies and Procedures.
4. Automatic review of existing SVSU IRB Policies and Procedures will occur no less frequently than five years from the date of the last review or revision of such Policies and Procedures. Such reviews will be initiated by the IRB Chairperson and may involve the appointment of a subcommittee to perform the review.

## V. REVIEW CATEGORIES

**A.** Eligible Activities. Every research activity involving human subjects must be submitted to the IRB for a determination of its review category. Approval of any project must be renewed at least annually unless further review is no longer needed, as decided by the IRB.

**B.** Preliminary Review**.** Proposed activities submitted to the IRB will undergo preliminary review by the Chairperson and/or other designated IRB member and an initial decision will be made as to whether the activities:

1. are determined to be outside the purview of the IRB;
2. qualify as exempt from full IRB review;
3. require expedited review; or
4. require full IRB review as defined by 45 CFR 46.

The results of all preliminary reviews will be made available to all IRB members for their consideration no later than the next scheduled IRB meeting. Projects are considered outside IRB purview if the activities do not meet either the definition of human subject or the Common Rule definition of research.

**1.** *Human Subjects*. The term "human subject" is defined in 45 CFR 46 at paragraph 46.102(f). Consistent with this definition, human subject activity involves any interaction with humans, access to identified samples obtained from humans, or existing archives that contain identifiable information about or obtained from humans.

**2.** *Research*. The term "research" is defined in 45 CFR 46 at paragraph 46.102(d). Consistent with this definition, research involves systematic investigation designed to develop or contribute to generalized knowledge, regardless of other purposes or designs that may attend the investigation.

## VI. IRB REVIEW PROCEDURES

**A.** Conflict of Interest**.** To ensure integrity and transparency in the review process, IRB members and alternate members recuse themselves from the review of any project in which they have a present or potential conflict of interest, while remaining available to provide information to the IRB if requested.

1. A member with a conflict of interest should be absent from the meeting room during the voting phases of the review and approval process.
2. IRB meeting minutes should reflect all declared conflicts of interest.

**B.** Review Process**.**

1. *Initiation of Review*. The IRB review process is initiated upon receipt of a Request for Project Approval (RPA).
2. *Responsibilities of the Principal Investigator (PI).* The Principal Investigator (PI) is responsible for ensuring that the submission package is complete prior to submission. This includes:
   a. Completion of the most current version of the RPA in full
   b. Verification that all study personnel have current CITI training
   c. Confirmation that all required signatures are obtained
   d. Inclusion of all supporting documentation (e.g., consent forms, recruitment materials, instruments)

   Incomplete submissions will delay review.
3. *Administrative Review for Completeness*. Upon receipt of the RPA.
   a. *IRB Facilitator*
      i. IRB facilitator will conduct an administrative review to determine completeness.
      ii. If complete, written acknowledgment of receipt will be provided to the PI, including the preliminary category of review.
   b. *Incomplete Applications*
      i. If the submission is incomplete, it will be forwarded to the IRB Chair.
      ii. The IRB Chair will notify the PI of deficiencies and unlock the application for revision.
      iii. The review process will not proceed until a complete package is resubmitted.
   c. *Determination and Implementation of Review Category*. The IRB Chair will determine

whether:

i. The project involves human subjects research; and

ii. The research includes at-risk populations as defined under Subparts B, C, and D of 45 CFR 46.

d. *Projects Outside IRB Purview*. If the Chair determines the activity does not constitute human subjects research or is otherwise outside IRB purview:

i. The project will be placed on the agenda of the next regularly scheduled IRB meeting for notification of members.

ii. The PI will receive written confirmation of this determination.

e. *Expedited Review.* If the Chairperson determines that the project qualifies for expedited review under federal regulations:

i. The Chairperson will either:

1) Serve as the expedited reviewer, or

2) Assign one IRB member to serve as expedited reviewer.

ii. The expedited reviewer may:

1) Approve the research as submitted

2) Require modifications to secure approval

3) Determine that the project requires full board review

iii. An expedited reviewer may not disapprove a project.

iv. If the project cannot be approved through the expedited process, it will be forwarded for full board review at the next regularly scheduled meeting.

v. Projects approved through expedited review will be placed on the agenda of the next IRB meeting for notification of members.

f. *Full Board Review*. Projects requiring full board review will be scheduled for discussion at a convened IRB meeting.

i. **Reviewer Assignments.** The IRB Chairperson will assign:

1) One IRB member to serve as Primary Reviewer.

2) One IRB member to serve as Secondary Reviewer.

**ii. Duties of the Primary Reviewer.** The Primary Reviewer will:

1) Conduct a thorough review of the submission.

2) Present the project to the IRB at the convened meeting.

3) Serve as liaison between the IRB and the investigator.

**iii. Duties of the Secondary Reviewer.** The Secondary Reviewer will:

1) Serve as consultant to the Primary Reviewer

2) Assume the duties of the Primary Reviewer if necessary

g. *Chair Acknowledgment and Final Notification*. Following determination of review category and action:

i. The IRB Chair will formally acknowledge the type of review and the outcome in writing to the PI.

ii. Official approval letters will include the review category and any required conditions.

**C.** Reviewer Qualifications. All projects submitted to the IRB will be reviewed by one or more IRB members who are sufficiently qualified through training and/or experience to evaluate the proposed research topic, the research design and analytical approach, and the characteristics and vulnerabilities of the proposed participant population.

1. *Consideration of Participant Characteristics***.** When assigning expedited, primary, or secondary reviewers, consideration will be given to:

   a. Participant ethnicity

   b. Sex and gender

   c. Cultural background

   d. Other relevant demographic or contextual factors

   Reviewer assignments will reflect, when feasible, expertise relevant to the population under study.

2. *Research Involving At-Risk Populations.* If the proposed research involves at-risk or vulnerable populations (as defined under applicable federal regulations), the IRB will include at least one reviewer who is knowledgeable about and experienced in working with such individuals.

**D.** Project Liaison (Full Board Reviews)**.** For each project undergoing Full Board review, the IRB Chairperson will assign one IRB member to serve as Project Liaison.

1. *Responsibilities of the Project Liaison***.** The assigned liaison will:

   a. Serve as the primary point of contact between investigators and the IRB.

b. Facilitate communication regarding required revisions or clarifications.

c. Assist in ensuring that requested modifications are addressed.

2. *Authority of the Liaison***.** The liaison may communicate interim determinations; however, approval is not final until formally affirmed by the IRB Chairperson.

**E.** Review Parameters**.** Each IRB review will include, at a minimum, explicit consideration of the following:

1. Potential risks to participants
2. Anticipated benefits of the research
3. Scientific and methodological soundness of the study design
4. Adequacy of informed consent procedures
5. Appropriateness of written and verbal communications to participants, taking into account:
   a. Age
   b. Experience
   c. Maturational level
   d. Cognitive and emotional condition
6. Qualifications and expertise of the investigators

**F.** Expedited Review Determinations**.** Expedited reviewers may determine that a project is:

1. *Approved*.
2. *Approved with Conditions — Expedited Review*. If a project is deemed "Approved with Conditions":
   a. Investigators may not begin research activities.
   b. Required modifications must be submitted to the expedited reviewer.
   c. The reviewer must determine that all conditions have been satisfied.
   d. The reviewer will notify the IRB Chairperson of final approval.
   e. Written confirmation of approval and permission to proceed must be issued to the investigator before research begins.
3. *Full Board Review.* If criteria for expedited approval are not met.

**G.** Full Board Review Determinations. Full Board review may result in one of the following determinations:

1. *Approved*.

2. *Approved with Conditions-Full Board Review***.** If a project is deemed "Approved with Conditions":
    a. Investigators may not begin research activities.
    b. Required modifications must be submitted as directed.
    c. The full IRB or a designated IRB member must determine that all conditions have been satisfied.
    d. Written confirmation of final approval must be issued by the IRB Chairperson (or designee) before research begins.
    e. The IRB may designate one member to monitor fulfillment of conditions
3. *Not Approved*. If a project is deemed "Not Approved":
    a. Research may not proceed under any circumstances.
    b. Investigators may submit a new RPA after consultation with the IRB Chairperson.

**H.** Post-Approval Oversight and Continuing Review.

1. *Communication of Decisions***.** The IRB Chairperson will communicate all determinations to the designated research team member in writing.
2. *Ongoing Investigator Responsibility***.** IRB approval does not relieve investigators of their responsibility to protect participants from harm.
3. *Reporting Requirements***.** For all approved research:
    a. Investigators must report any changes in protocol or risk assessment prior to implementation.
    b. Proposed changes will be assigned a review category based on:
        i. The nature of the modification
        ii. The project's original review category
    c. Review of modifications will follow established IRB procedures.
4. *Adverse Events and Unanticipated Problems***.**
    a. All adverse events or unforeseen harms must be reported immediately.
    b. The IRB Chairperson may issue an immediate suspension of research activities, except that clinical care of participants may not be suspended.
    c. The Chair will determine the appropriate review category and next steps.
5. *Continuing Review***.** All approved research will undergo annual review until completion,

unless continuing review is no longer required under applicable regulations.

## I. Research Conducted in Cooperation with Other Institutions

1. *Institutional Responsibility***.** Each institution involved in multi-site research is individually responsible for protecting research participants and complying with federal regulations. All human subjects research conducted by members of the SVSU community must be submitted to the SVSU IRB, regardless of approval status at another institution.
2. *Cooperative or Joint Review Agreements***.** The use of cooperative IRB review arrangements may be considered upon request of:
    a. The submitting investigator(s), or
    b. The SVSU IRB Chairperson
    c. Such arrangements must:
        i. Be approved by vote of the full SVSU IRB.
        ii. Receive approval from the SVSU President (or designee).
        iii. Be documented in writing and distributed to all parties.
3. *IRB Review of Research Involving External (Non-SVSU) Entities.* This policy establishes procedures for the IRB at SVSU when reviewing or relying upon IRB oversight for research involving external organizations or investigators not employed by SVSU. The policy ensures compliance with federal regulations (45 CFR 46, 21 CFR 50/56, as applicable), institutional policies, and ethical principles for the protection of human subjects.
    a. This policy applies to:
        i. Research conducted by external investigators seeking SVSU IRB review.
        ii. Collaborative research between SVSU investigators and non-SVSU institutions.
        iii. Research conducted at SVSU facilities by unaffiliated investigators.
        iv. Situations where SVSU IRB agrees to serve as the **IRB of Record** for an external entity.
        v. Situations where SVSU relies on another institution's IRB via a formal agreement.
    b. *External Entity***.** Any organization, institution, or individual not employed by or formally affiliated with SVSU.
    c. *IRB of Record***.** The IRB designated to provide regulatory oversight for a specific research

study.

d. *Memorandum of Understanding (MOU)*. A formal written agreement between SVSU and an external entity outlining roles, responsibilities, compliance expectations, and liability considerations related to human subjects research.

e. *Policy Statement*. SVSU IRB will review research involving external entities only when:

i. The research aligns with SVSU's mission and ethical standards.

ii. A formal MOU Agreement is executed prior to approval.

iii. Regulatory responsibilities and institutional oversight roles are clearly defined.

iv. External investigators agree to comply with all applicable federal regulations and SVSU IRB policies.

f. *Initiation of Research*. No research involving human subjects may begin until:

i. IRB approval is granted, and

ii. The MOU (or reliance agreement) is fully executed.

g. *Requirements for External Investigators*. External investigators seeking SVSU IRB review must:

i. Submit a complete IRB application.

ii. Provide proof of human subjects research training (e.g., CITI certification).

iii. Demonstrate institutional support from their home organization.

iv. Agree in writing to comply with SVSU IRB policies and reporting requirements.

v. Execute a Memorandum of Understanding prior to approval.

**J.** Research Conducted Outside the United States. Research conducted outside the United States must:

1. Respect local culture, customs, and traditions.
2. Consider whether standard IRB requirements should be supplemented or modified.
3. The IRB may consult individuals with expertise in the local cultural context. Such consultants need not be IRB members.

**K.** Student Research.

1. Student research, whether conducted for course credit or not, is subject to all IRB policies and procedures and must meet the same standards as faculty or staff research.
2. All student research must be conducted under the supervision of a qualified faculty or staff

member designated as the Research Supervisor (RS), who assumes full responsibility for oversight of the project.

**L.** Research Supervisor (RS) Qualifications**.** The Research Supervisor (RS) must meet the following requirements and responsibilities:

1. Qualifications and Expertise**.** Possess appropriate academic credentials and subject-matter expertise relevant to the proposed research.
2. Training Compliance**.** Maintain current training in human subjects research protections (e.g., CITI) and any other required institutional training prior to overseeing student research.
3. Active Oversight**.** Provide active, ongoing supervision of the research project, including review and approval of all IRB submissions, revisions, and communications prior to submission.
4. Accountability**.** Assume responsibility for ensuring that the research is conducted in compliance with all federal, state, and institutional regulations and IRB determinations.
5. Protocol Integrity**.** Ensure that the study is conducted as approved by the IRB and that any modifications are submitted for IRB review and approval prior to implementation.
6. Student Training and Conduct**.** Verify that all student researchers are appropriately trained and understand their responsibilities for the ethical conduct of research.
7. Monitoring and Reporting**.** Monitor the progress of the research and promptly report any adverse events, protocol deviations, or noncompliance to the IRB.
8. Availability and Capacity**.** Maintain sufficient availability to provide meaningful supervision and respond to IRB or student needs in a timely manner.

**M.** Co-Investigators**.**

1. *Definition***.** For IRB purposes, co-investigators include any individual who:
    a. Interacts with research participants or has access to identifiable human subjects data.
    b. Authorship status is not determinative.
2. *Qualifications***.** Co-investigators must have qualifications and expertise appropriate to their role in the research.
3. *Reviewer Qualifications***.** All projects will be reviewed by an IRB member sufficiently qualified through training and/or experience to understand the proposed research topic,

proposed research design and analysis, and research participants.

a. Research subject ethnicity, sex, and gender, and cultural background will be considered when determining assignment of IRB member(s) to serve as expedited, primary, or secondary reviewers.
b. If the proposed research involves at-risk subjects, consideration should be given to the inclusion of one or more reviewers who are knowledgeable about and experienced in working with such individuals.

4. *Project Liaison***.** For each project to be reviewed by Full Board, the Chairperson will assign an IRB committee member to serve as liaison to the investigators of a proposed research project.
   a. The assigned liaison will have primary responsibility for facilitating communication between the investigators and the IRB.
   b. The liaison may communicate interim decisions concerning the project, but approval is not final until affirmed by the IRB Chair.

## VII. RECORD KEEPING AND RETENTION POLICIES

**A.** Minutes**.** Minutes of IRB meetings will reflect attendance of IRB members, alternate members, guests, consultants, and other individuals.

**B.** Quorum. A running indicator of quorum and presence of at least one member whose specialty is not in a scientific area will be maintained in the minutes.

**C.** Action Minutes**.** Action minutes, including a summary of discussion, will be maintained for all IRB meetings and will be stored in a central repository.

**D.** File Retention**.** All materials submitted to, correspondence generated from, and all other work products of the IRB pursuant to a specific research project will be maintained for a period of at least three years after the completion of the research project.

## VIII. PROCEDURES FOR SUBMISSION OF IRB PACKAGE

**A.** IRBNet Submission. (Portal).

1. *Creating an Account*. The user creates an account. Once created, the individual will be able to utilize the submission portal.
2. *Adding/Deleting Members to IRBNet*.
    a. IRB Chair will contact IRBNet to add additional individuals with administration responsibilities.
    b. IRB Chair will add/delete committee members.

**B.** Collaborative Institutional Training Initiative **(CITI Program)**.

1. Individuals connected to any project must complete the CITI training.
2. Individuals will create an individual account using their SVSU email address. (NOTE. Individuals who have an account from a previous institution may connect their SVSU account. There is no need to create a new account).
3. Once the account is created, individuals will complete the training appropriate to their project.
    a. Social-Behavioral Research
    b. Biomedical Research
4. Once training is complete, individual will receive a certificate of completion that must be attached to any submission.

**C.** Reviewer Assignment Spreadsheet. Reviewer Assignment Excel spreadsheet, maintained by IRB Facilitator and IRB Chair, will be located in an IRB Teams Folder. This document is used to track committee member assignments.

**D.** Reviewer Form. Form, located in the IRB Teams Folder, is used by the IRB Chair and committee member for each package reviewed. Completed forms will be maintained in the IRB Teams Folder. Once completed, the reviewer uploads the form to IRBNet. The IRB Chair will review periodically for modifications if appropriate.

**E.** Committee Member List. A list of current committee members (and their term expiration dates) will be maintained in the IRB Teams Folder. It is the responsibility of the IRB Chair to ensure that the committee members' terms are up to date. When a new term begins or a new member is appointed to the committee, the IRB Chair will send a memo to the President (or

President's designee) for final approval. Appointment letters are maintained with the IRB Teams Folder. For committee members whose terms end, a memo of appreciation for their service is drafted for the President (or President's designee) to sign.

**F.** Institutional Review Board Website (IRB Website). The IRB Chair and the IRB Facilitator will maintain the content of the website. If the IRB Facilitator and IRB Chair cannot complete the changes, SVSU Communication will be notified to make the changes.

**G.** Policies and Procedures for the Conduct of Human Subjects Research. The IRB Chair is responsible for updating P&P for the Conduct of Human Subjects Research Manual. The manual will be reviewed annually for any changes, if warranted. Last update April, 2026.

**H.** Forms and Templates. Forms and templates will be reviewed annually to ensure they are current and relevant. The forms and templates will be located on the IRB website for use by individuals participating in research. All forms will be revised by the IRB Chair. Forms will be updated prior to Fall 2026.

**I.** Timeline.

The following are typical target timelines for IRB review, assuming submissions are complete and include all required elements:

1. *Full Board Review Protocol***.** Approximately six to eight weeks.
2. *Expedited Review Protocol***.** Approximately four weeks.
3. *Exempt Review Protocol***.** Approximately two weeks.
4. *Determination of "Not Human Participant Research***."** Approximately one week.

*Stipulations*: These timelines represent standard goals, and the IRB will make every effort to adhere to them. However, circumstances such as incomplete submissions, required clarifications, high volume of protocols, or other institutional constraints may result in delays. The IRB and Research Supervisors commit to prompt communication and best efforts to minimize any such delays.

## IX. LIFE CYCLE OF THE IRB PROCEDURE

### A. Phase I. Initiation.

**1.** Determination Checklist **(Appendix A)**

**2.** *Receipt of Initial Submission*.

a. *IRBNet Facilitator Responsibility.* Receives initial submission via IRBNet and reviews for completeness.

i. **If package is complete**. The IRB Chair receives a message through IRBNet.

ii. **If package is not complete**. Package marked incomplete and IRB Chair receives a message from IRBNet Facilitator through IRBNet indicating follow-up is needed with submitter.

b. *IRB Chair Responsibility.* IRB Chair reviews project to determine if package is ready for review and what type of review it will receive.

i. If a package is not complete, it is unlocked, and the researcher is notified of what needs to be corrected or added.

ii. To resubmit the package, the PI clicks "lock - revisions complete" near the top of the page in IRBNet.

c. *PI Responsibility***.** Resubmission of an Incomplete Package.

i. The PI is responsible for resubmitting the package once all required elements are completed.

ii. The PI will click on "lock - revisions complete" near the top of the page in IRBNet.

iii. IRBNet will automatically notify the IRBNet Facilitator and IRB Chair that the package has been resubmitted.

iv. Once application has been assigned by the IRB Chair, the IRB Chair will submit the appropriate "Publish Acknowledged" letter. NOTE: IRBNet provides a template that can be modified.

**3.** *Determination of Reviews*. The IRB Chair reviews all projects to determine if the package is ready for review and what type of review it will receive.

a. *Exempt or 'Not Human Participant' Review Packages*. Unless there is a conflict of interest, the IRB Chair will complete the review and all communication/administrative duties related to notification and process.

b. *Expedited Review Packages*.

i. If the research is deemed 'expedited' or 'full board review', the IRB Chair will assign a reviewer, and possibly a co-reviewer.

ii. The IRB Assignment Excel spreadsheet will be updated with the assignment.

1) Choose a reviewer and update the Excel spreadsheet.
2) Assign a Ref# on IRBNet to include the name of the reviewer.
3) Share the package with the reviewer on IRBNet. In the message box, paste the appropriate review message (Reference A).
4) Click on set all to have single bell appear. This will send a message to the IRB chair when the committee member completes the review.
5) Remove previous tags from the package and assign the agenda.
6) The IRB Facilitator will then click 'Publish Acknowledged' letter as a Board Document to choose the type of letter publishing. NOTE: IRBNet provides a template that can be modified.
7) Once completed, this letter informs the PI which committee member is reviewing their package and confirms to the PI that their package has been received and is being reviewed.

iii. *Committee Member Review*.

1) **Missing Elements**. If the Reviewer determines elements are missing, they may 'Unlock' the package. The reviewer can send a message to the PI with information. Once the requested information is submitted, the PI will be asked to click 'mark revisions complete,' and a message will be sent to the IRB Chair, who can notify the reviewer.

2) **Projects Tagged**.

a) 'w/PI for Modifications.'
b) 'w/Reviewer after Modifications.'

iv. *Timeliness*. If an expedited project has been with a reviewer for more than 10 days, the IRB Chair emails the reviewer requesting the status of the review.

v. *Completion of Review*. The reviewer alerts the IRB Chair when the initial review is complete.

vi. *Published Review Form*.

1) The IRB Chair publishes the reviewer form completed by the reviewer.
2) The IRB Chair sends either a 'Modifications Required' letter or an 'Approval' letter to the PI using the templates in IRBNet.
3) The IRB Chair will include comments in the 'Modifications' letter.

vii. *Communication Channel*. The IRBNet Facilitator monitors the "back and forth" between the reviewer and the PI by using the status tags to indicate review status. This is done until the project is approved or withdrawn. The IRB Facilitator will notify the reviewer and request that they update the project's status. If the status of a project has not been updated in two weeks, the IRB Facilitator will contact the reviewer.

**4.** *Full Board Review Package***.**

a. IRB Chair records the package on the spreadsheet, listing it as a full-board review.
b. IRB Chair identifies the date/time/location of the meeting. The IRB Chair will review with the committee the best day and time of the month for the meeting.
c. Package is assigned to a primary and a secondary reviewer who is responsible for completing the reviewer form before the meeting. They will lead the discussion at the full board meeting.
d. Package is shared with all committee members.
e. The IRB Chair updates the agenda before each full board meeting. The agenda and previous board minutes are shared with the committee before the scheduled meeting for review.
f. The IRB Chair keeps the meeting minutes and is responsible for transcribing them.
g. The PI is invited to attend (Reference B.)
h. After the full-board meeting, the IRB Chair completes a combined review form. Comments from all members of the board are included in the review form.
i. IRB Chairperson publishes the Reviewer form in IRBNet, and, where necessary, the PI will complete the required modifications.

j. Once the required modifications, if necessary, are submitted, the primary reviewer will review for final approval. If necessary, another full board meeting may be called to review the modifications.

k. *Final Approval*. Once a project is approved IRB Chair will:

i. Publish a letter of approval, choosing which of the three consent options is applicable to that project.

ii. Stamp and publish the consent form.

iii. Send project email to investigator.

iv. The IRB Chair will send applicable information to the IRB Facilitator who will update the IRBNet Data for the Packages Excel spreadsheet.

## B. Phase II. PI Performs Project

1. PI may need to submit modifications during the one-year approval period. This may happen if survey tools are updated or a research team member and added or removed.
2. PI will submit a subsequent package for review which includes the updated document(s).
3. The IRB chair or committee member will review and either publish a Modifications Required letter or an Approval letter to the PI.

## C. Phase III. Expiration of Project

1. IRBNet automatically sends out an email notification 60 days, 30 days, and on the day a project expires.
   a. Following the first notification, IRB Chair sends out an email requesting a close-out report if project is not being renewed.
   b. The project is put on the next agenda, the date of the sent email is noted for the minutes, and the project is tagged “sent close-out form.”
   c. When the close-out form is completed, it is saved as a board document. The project is tagged “Rec’d close-out form.” It is put on the agenda and marked as closed.
   d. If a close-out form or renewal form is not received by the expiration date, the project is terminated.
   e. If project renewal form is completed, review all documents submitted to see if any modified document changes the review type.
   f. If updated consent form is submitted, stamp with new project end date.

g. Active-Data analysis: Choose this option if PI is finished with collection of data and does not need consent form updated.
h. Publish approval letter.

## X. COMMUNICATION REFERENCES

**A.** Message RE: Package Expedited Review**.** From IRB Chair to IRB Committee Member to paste into text box when sharing a package for expedited reviews:

"Thank you for reviewing this expedited package. If you are unable to complete this review in 10 business days, please contact IRB Chair by name, email, or phone, so that it may be promptly assigned to another reviewer. Upon completion of your review, please check the box next to the phrase "Mark my personal review as complete."

**B.** Message RE: Full Board Review**.** Message from IRB Chair to IRB Member to paste into text box when sharing a package for full board reviews:

"Thank you for preparing this package for full board review. If you are unable to review this package, please contact IRB Chair name, email, phone, so that it may be promptly assigned to another reviewer."

**C.** Message RE: Invitation for Full Board Review**.** Invitation from IRB Chair to PI to Attend Full IRB Board Review meeting:

Dear [PI's Name],

Your protocol is scheduled for review at the upcoming Full IRB Board meeting on [Date] at [Time]. While your attendance is not required, you are welcome to be available nearby in case the Board has questions or requires clarification during the review.

If you choose to attend, please arrive shortly before the meeting begins and inform me that you will be waiting nearby. Your project is first on the agenda, and if the Board wishes to speak with you, you will be invited into the meeting. Otherwise, I will notify you once the review has concluded so you may depart.

Please let me know if you have any questions or if you plan to be available.

## *APPENDIX A. IRB Determination Checklist*

**Step 1: Not Human Subjects Research (Start Here)***

No interaction/intervention with individuals
No identifiable private information
Fully de-identified data (no codes or links)
Internal program evaluation/quality improvement only
Literature review or meta-analysis

**If ALL checked → Not Human Subjects Research**

**NOTE: Submit for administrative review.**
***May require additional review as determined by advisor/sponsor**
**Examples of Generalizable knowledge:** ER dental visit study → informs national trends, Simulation training study → improves education practices; Student perception study → informs targeted interventions beyond your own classroom.

**Step 2: Exempt Review (Lowest Risk)****

Anonymous surveys/interviews
No identifiers collected or linked
Public behavior observation
Publicly available data
De-identified existing data
Normal educational practices in standard settings

**If applicable and no higher-risk elements → Exempt Review**

**NOTE: Submit for Review by the IRB Chair**
****What is Exempt?** Research that meets specific federal exemption categories and is considered minimal risk; it still requires IRB review and determination, includes informed consent where appropriate, but is exempt from ongoing/continuing IRB review after initial approval.

**Step 3: Expedited Review (Minimal Risk)*****

Minimal risk only (daily life level)
Noninvasive procedures (adults)
Audio/voice recordings
Moderate exercise (healthy adults)
Existing data, records, or specimens (may be identifiable)
Behavioral research without stress/manipulation

**If ANY checked and no Full Board triggers → Expedited Review**

***Expedited Review:** Minimal risk research; may include some vulnerable populations (excluding

prisoners) when additional safeguards are in place.

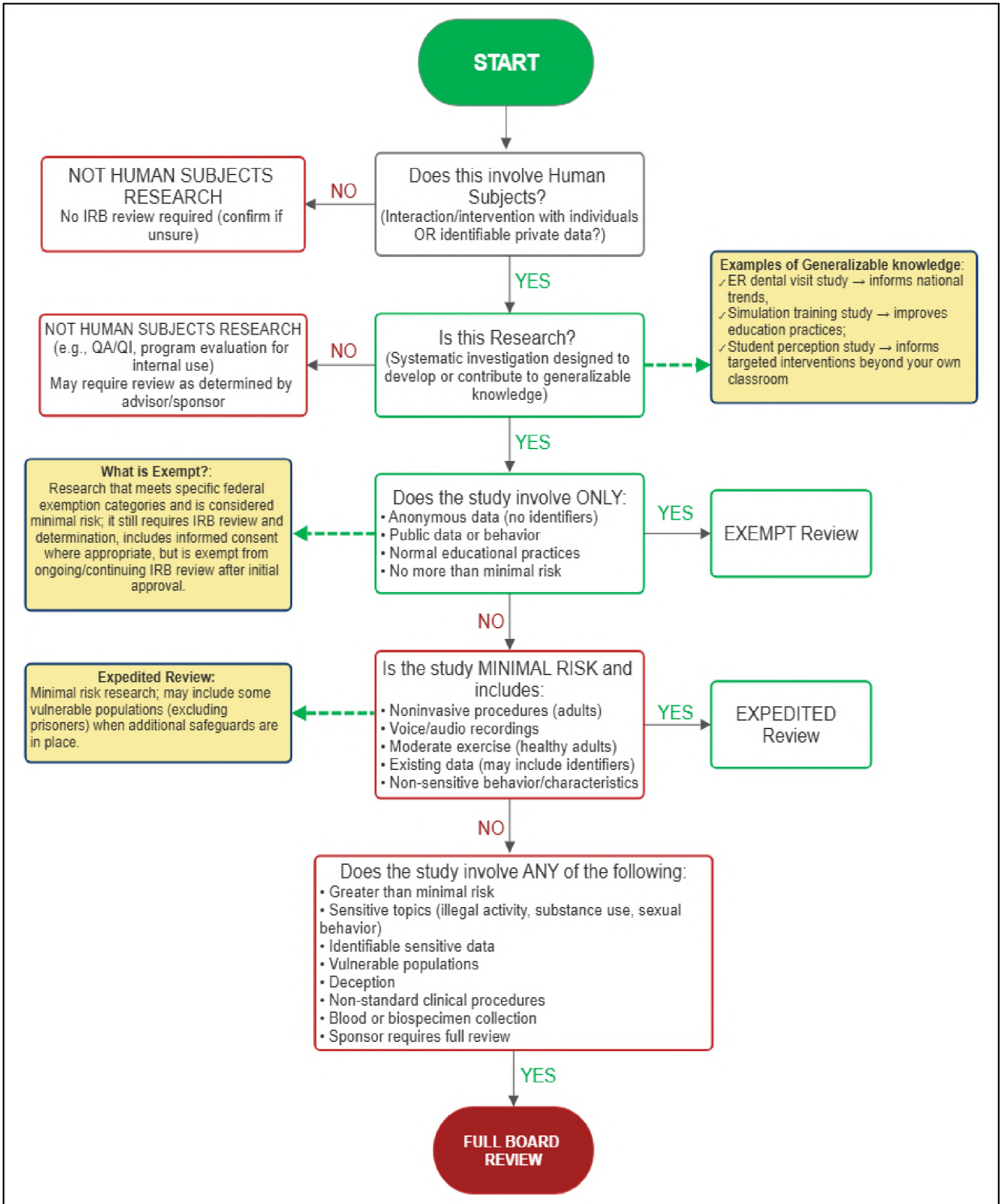
**Step 4: Full Board Review (Highest Risk)**

Greater than minimal risk
Psychological stress, discomfort, or harm possible
Sensitive topics (illegal activity, drug/alcohol use, sexual behavior)
Identifiable sensitive data
Risk to employability, reputation, or legal standing
Vulnerable populations (children, prisoners, pregnant individuals, impaired)
Deception or incomplete informed consent
Non-standard clinical procedures/interventions
Collection of blood or biological specimens not part of routine clinical care
External sponsor requires full IRB review

**If ANY checked → Full Board Review**

**Quick Logic**

- Not human subjects? → Will receive administrative review
- Anonymous/no identifiers? → Exempt – Will received review by IRB Chair
- Minimal risk? → Expedited – Will received review by IRB Chair or an IRB Committee member
- Anything higher risk or sensitive? → Full Board – Will be reviewed by entire IRB Committee


START
Does this involve Human Subjects?
(Interaction/intervention with individuals OR identifiable private data?)
NO
NOT HUMAN SUBJECTS RESEARCH
No IRB review required (confirm if unsure)
YES
Is this Research?
(Systematic investigation designed to develop or contribute to generalizable knowledge)
NO
NOT HUMAN SUBJECTS RESEARCH
(e.g., QA/QI, program evaluation for internal use)
May require review as determined by advisor/sponsor
Examples of Generalizable knowledge:
✓ER dental visit study → informs national trends,
✓Simulation training study → improves education practices;
✓Student perception study → informs targeted interventions beyond your own classroom
YES
Does the study involve ONLY:
• Anonymous data (no identifiers)
• Public data or behavior
• Normal educational practices
• No more than minimal risk
YES
EXEMPT Review
What is Exempt?:
Research that meets specific federal exemption categories and is considered minimal risk; it still requires IRB review and determination, includes informed consent where appropriate, but is exempt from ongoing/continuing IRB review after initial approval.
NO
Is the study MINIMAL RISK and includes:
• Noninvasive procedures (adults)
• Voice/audio recordings
• Moderate exercise (healthy adults)
• Existing data (may include identifiers)
• Non-sensitive behavior/characteristics
YES
EXPEDITED Review
Expedited Review:
Minimal risk research; may include some vulnerable populations (excluding prisoners) when additional safeguards are in place.
NO
Does the study involve ANY of the following:
• Greater than minimal risk
• Sensitive topics (illegal activity, substance use, sexual behavior)
• Identifiable sensitive data
• Vulnerable populations
• Deception
• Non-standard clinical procedures
• Blood or biospecimen collection
• Sponsor requires full review
YES
FULL BOARD REVIEW

## *APPENDIX B. Required Elements for IRB Meeting Minutes*

1. Basic Meeting Information

- Date and time of the meeting
- Whether the meeting was convened (full board)
- Name of the IRB
- Attendance:
    - Members present (including designation: scientist, non-scientist, unaffiliated)
    - Members absent
    - Alternates
    - present and who they replaced
    - Consultants or guests (if applicable)

2. Quorum Documentation

- Confirmation that a quorum was present
- Documentation that:
    - At least one non-scientist was present
    - Any changes in quorum during the meeting (e.g., members leaving/entering)
- Actions taken when quorum was lost (if applicable)

3. Conflicts of Interest

- Identification of members with a conflict of interest
- Documentation that conflicted members:
    - Left the room or were recused
    - Did not participate in discussion or voting

4. Actions Taken on Research Protocols

For each study reviewed:

- Title or identifier of the protocol
- Type of review (initial, continuing review, modification)
- Actions taken:
    - Approved
    - Required modifications to secure approval
    - Deferred

- Disapproved

5. Voting Outcomes

- Number of members voting:
  - For
  - Against
  - Abstaining

6. Basis for IRB Decisions

- A summary of the discussion of controverted issues
- Their resolution
- Documentation that approval criteria under 45 CFR 46.111 were considered, including:
  - Risks minimized
  - Risks reasonable in relation to benefits
  - Equitable subject selection
  - Informed consent requirements
  - Data monitoring (if applicable)
  - Privacy and confidentiality protections
  - Additional safeguards for vulnerable populations

7. Risk Determinations

- Level of risk (e.g., minimal risk, greater than minimal risk)
- Justification if applicable

8. Informed Consent

- Whether consent was:
  - Approved
  - Waived or altered (include regulatory justification)
- Documentation of:
  - Required elements of consent
  - Waivers under applicable criteria

9. Special Determinations (if applicable)

- Waivers of documentation of consent
- Research involving:

    - Children (Subpart D findings)
    - Pregnant women, prisoners, or other vulnerable populations
- HIPAA/privacy considerations (if applicable)

10. Additional Actions

- Required changes or stipulations
- Requests for additional information
- Suspension or termination of research (if applicable)

## *APPENDIX C. Template for MEETING AGENDA TEMPLATE*

Saginaw Valley State University Human Subjects Institutional Review Board

AGENDA

[DATE]

[Virtual/In-Person]

## ITEMS

1 Welcome and Opening Remarks

2 Attendee Roll Call

3 Review of Previous Minutes

4 Action Items: Studies for Full Board Review

5 Action Items: Adverse Events

6 Action Items: Other Business

7 Information Only: Completed Exempt Reviews

8 Information Only: Completed Expedited Reviews

9 Information Only: Completed Excluded Reviews

10 Information Only: Completed Not Considered Research Reviews

11 Next Meeting Date and General Announcements

## *APPENDIX D. Template for MEETING MINUTES TEMPLATE*

Saginaw Valley State University Institutional Review Board

HUMAN SUBJECTS FULL-BOARD REVIEW COMMITTEE MEETING

MEETING MINUTES

[DATE/TIME]

[Virtual/In-Person]

## ATTENDANCE:

Members Present (Including designation):

Alternates Present (who they replaced or in addition):

Consultants/Guests (if applicable):

Members Absent:

## ITEMS

1 Welcome and Opening Remarks

2 Attendee Roll Call/Quorum

2.1 At least one non-scientist

3 Conflicts of Interest

3.1 Identification of Conflict of Interest

- Members who left room or were recused
- Did not participate in discussion or voting

4 Review of Previous Minutes

5 Action Items

5.1 Studies for Full Board Review

- Title or identifier of protocol
- Type of review
- Actions taken (approved, required modifications, deferred, disapproved)
- Voting outcomes (For, against, abstaining, recused)
- Summary for IRB Decisions, their resolution, documentation that approval criteria under 45 CFR 46.111 were considered.

6 Any Reported Adverse Events

7 Information Only

7.1 Completed Exempt Reviews

7.2 Completed Expedited Reviews

7.3 Completed Excluded Reviews

7.4 Completed Not Considered Research Reviews

8 Other Business

9 Next Meeting Date and General Announcements

## *APPENDIX E. CONFIDENTIALITY AGREEMENT*

Confidentiality Agreement

**Name: _____**

**Role:** Member Alternate Consultant/Guest

**Academic Year: _____**

As a member of, or consultant to, the Saginaw Valley State University Human Subjects Institutional Review Board (IRB), I acknowledge that I may have access to confidential, privileged, and proprietary information. This may include, but is not limited to, research protocols involving human subjects, participant data, intellectual property, personnel matters, and commercially sensitive information.

**By signing this agreement, I agree to the following:**

1. **Confidentiality.** I will maintain strict confidentiality of all IRB documents, discussions, and proceedings. I will not disclose such information to any third party (including colleagues, friends, or family) without prior written authorization from the IRB Chair.
2. **Authorized Use.** I will use confidential information solely for the purpose of conducting IRB reviews and fulfilling my responsibilities to the IRB.
3. **Non-Reproduction.** I will not copy, reproduce, or remove IRB materials (in physical or electronic form) without proper authorization.
4. **Handling of Materials.** Upon request, I will return or securely destroy all IRB-related materials, including paper and electronic files, in accordance with IRB procedures.
5. **Conflict of Interest.** I will promptly disclose any actual or potential conflict of interest (financial or personal) related to a protocol under review and will recuse myself from participation **in the review and decision-making process for that protocol.**
6. **Duration of Obligation.** I understand that these confidentiality obligations continue indefinitely, even after my service with the IRB has ended.
7. **Breach of Agreement.** I acknowledge that violation of this agreement may result in removal from the IRB and may lead to institutional disciplinary action or legal consequences.

**Exceptions**

These obligations do not apply to information that is publicly available, lawfully obtained from a third party, or required to be disclosed by law.

**Signature: _____Date: _____**