POLICIES AND PROCEDURES FOR THE CONDUCT OF HUMAN SUBJECTS RESEARCH

Saginaw Valley State University

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I. PREAMBLE

A. Ethical Principles

1. Within the United States, 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." Fundamental principles identified therein include:

a. "respect for persons," manifest through respect for the autonomy of the individual and protection of those with diminished autonomy;

b. "beneficence," an obligation to both minimize harm as well as to maximize possible benefits for research subjects; and

c. "justice," referring to the questions of fairness in the selection of human subjects for study, such as whether or not subjects are selected for study merely because they are conveniently available or unable to protect themselves from potential exploitation, and the relative distribution of benefits of research to subjects and society in general.

2. The Belmont Report includes an elaboration of basic requirements for the conduct of human-subjects research, requirements thought to reflect the natural and logical implications of these basic principles.

a. The first of these requirements is "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.

b. The second requirement involves "risk/benefit assessment," including a determination of whether the research study is properly designed as well as a determination of whether potential risks for subjects are justified by potential benefits resulting from the research.

c. The third requirement involves issues of research subject selection, mandating both fair procedures and equitable outcomes (i.e., "justice") in the conduct of human-subjects research.

B. Regulations and Policies Regarding Ethical Research

1. 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.

II. Policy Intent and Responsibilities of Researchers

A. Intent

1. 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:

a. 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

b. 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 is in compliance with these policies and procedures.

4. Any individual conducting human-subjects research at SVSU will have successfully completed an approved training program in the responsible conduct of human research prior to engaging in any such research.

III. Institutional Authority and Reporting Responsibilities

A. President (or designee)

1. The President holds primary institutional authority for the oversight of human-subjects research at SVSU. The President, in turn, is responsible to the Board of Control as outlined in other SVSU governance documents.

2. The President is responsible for addressing noncompliance with federal regulations and/or SVSU IRB policies and procedures governing research.

3. The President will appoint the Chairperson of the IRB and other members of the IRB.

4. Neither the President 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 does maintain authority to deny permission to conduct human-subjects research despite prior approval of such research by the IRB.

5. The President will ensure sufficient resources for the operation of the IRB as defined in 45 CFR 46.

B. IRB Chairperson

1. The Chairperson of the IRB is responsible for reporting to the President and other members of the IRB regarding individual and institutional compliance with federal regulations and institutional policy, including significant problems involving risk to research subjects, any issues of noncompliance, and any suspension or unanticipated termination of IRB approval of a research project.

2. The IRB Chairperson is responsible for the development of all application and investigator reporting forms (subject to approval of the IRB Members), promulgation of official correspondence with investigators, maintenance of records pertaining to IRB activities, including meeting agendas and action minutes, and determination of review category for submitted proposals, including reporting results of such determinations to the IRB.

3. The IRB Chairperson will report to the President regarding the routine functioning of the IRB and the conduct of human-subjects research at SVSU. This reporting will be done in a manner and on a schedule to be determined by the President in consultation with the IRB Chairperson. Members of the IRB will receive copies of these reports.

C. IRB Members

1. IRB members are to be familiar with all IRB policies and procedures and all applicable laws and regulations regarding human-subjects research.

2. IRB members are expected to examine all materials submitted to the IRB, to serve in the capacity of primary, secondary, or expedited reviewer as assigned, and to attend and participate in all IRB meetings.

3. IRB members are expected to alert the IRB Chairperson to any suspected instances of noncompliance with policies and regulations.

4. An IRB member who wishes to resign from an appointment should provide at least one month written notice of this decision to the IRB committee and the President.

D. IRB Composition and Rules of Order

1. The following requirements for the composition of an IRB are based on federal regulations (see 45 CFR 46.107–108):

a. IRB members are appointed by the President.

b. To ensure complete and adequate review of research projects, IRB members will collectively represent disciplinary specialties consistent with commonly conducted research activities.

c. Because children are regularly accessed as research subjects at SVSU, at least one member must be knowledgeable about and experienced in working with children.

d. At least one member must have a background in a scientific area.

e. At least one member must have a background exclusive of primary interest in scientific areas.

f. At least one member must be an individual who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

g. Every nondiscriminatory effort must be made to ensure that the IRB does not consist entirely of men or of women.

h. When a project includes a vulnerable category of subjects, members may consult with one or more individuals who are knowledgeable about and experienced in working with these subjects. These individuals may not vote with the IRB, but may attend IRB meetings as appropriate to their consultation.

i. When reviewing cases involving Food and Drug Administration (FDA)-regulated articles, at least one physician must be present and eligible to vote on the case.

2. Alternate members are to be appointed by the President, after consultation with the IRB Chairperson and the member for whom the alternate member is to be appointed.

a. Any individual to be considered for an appointment as an alternate member must be able to fulfill all responsibilities attendant to the member of the IRB for whom the individual is to serve as an alternate member.

b. The member for whom an alternate member is appointed is responsible for informing the alternate member as to when meeting attendance is required and for providing copies of necessary materials in preparation of meetings.

c. An alternate member may attend and participate in any meetings of the IRB at any time, but may vote only when the member for whom the alternate member is appointed is unable to vote due to absence or recusement.

3. A simple majority of the membership, but including at least one member whose primary concerns are in non-scientific areas, will be considered a quorum for all business conducted by the IRB.

a. When a member is unable to attend in person, he or she may participate by conference telephone call and such participation will count toward the quorum.

b. An alternate member may be included in the quorum count only when the individual he or she represents is not included in the quorum count.

4. When a quorum exists, a simple majority of present members is sufficient for a decisive vote.

a. An alternate member may vote only when the individual he or she represents does not vote.

b. Unless special circumstances are declared and approved by a three-fourths majority of members present, no issue may come to a vote without prior inclusion on the distributed agenda for that meeting.

5. Minutes of IRB meetings will contain only the actions of the IRB, a brief summary of discussion points, and information relevant to the determination and maintenance of a quorum. The specific content of discussions will not be recorded.

6. All materials submitted to the IRB are to be considered confidential and may not be distributed outside the IRB except as allowed elsewhere in this policy.

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.

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.

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

The IRB may announce that specific types or classes of research activities need not be submitted to the IRB. In the absence of such explicit announcements, 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 exempted from further review.

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: (a) are determined to be outside the purview of the IRB; (b) qualify for an expedited review; or (c) will require review by the full IRB. The results of all preliminary reviews will be made available to all IRB members for their consideration no later than the next scheduled meeting of the IRB.

1. Outside IRB Purview: This category includes activities that are not subject to IRB oversight. This category will be applied by the IRB to activities that do not meet either the definition of human subject or the Common Rule definition of research.

a. 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.

b. “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.

2. Expedited Review: This category of research is described in 45 CFR 46 at paragraph 46.110. Generally, expedited review may be employed for research that involves no more than minimal risk for participants and does not include any special classes of participants, or for minor changes to approved projects.

3. Full Board Review: This category applies to all research that does not fall into other categories. In general, full board review will be required for all projects involving:

a. more than minimal risk to participants,

b. the deception of subjects,

c. sensitive behavioral research (such as research relating to illegal or sexual activity),

d. at-risk populations (e.g., pregnant women, human fetuses, neonates, prisoners, children, individuals with cognitive or emotional impairments).

VI. IRB Review Procedures

A. Conflicts of Interest

No IRB member or alternate member may participate in the review of any project in which the member has a present or potential conflict of interest, except to provide information as requested by the IRB.

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

The review process for all projects submitted to the IRB will include the following considerations.

1. The IRB review process is initiated with the receipt of a Request for Project Approval (RPA), but consultation with one or more members of the IRB may occur at any time.

a. The RPA must be completed in full prior to submission for IRB review.

b. Investigators must use the most current version of the RPA.

2. Upon receipt of a completed RPA, the IRB will provide a written acknowledgment of receipt, which will include the category for review.

3. Determination and Implementation of Review Category

a. Upon receipt of an RPA, the Chairperson will determine whether or not the research involves at-risk groups of human subjects, as defined in Subparts B, C, and D of 45 CFR 46.

b. Submitted activities determined to be "outside IRB purview" will be placed on the agenda of the next regularly scheduled IRB meeting for notification of the members.

c. If the Chairperson determines that the proposed research project meets requirements for expedited review, then the Chairperson will serve as expedited reviewer or assign one member of the IRB to serve as expedited reviewer.

(1) The expedited reviewer will make a determination regarding approval of the proposed research and inform the Chairperson of such.

(2) If the expedited reviewer makes a determination that the project cannot be approved as submitted or as revised following discussion with the investigator(s), the project will be forwarded to the full IRB for final determination at the next regularly scheduled meeting.

(3) An expedited reviewer may either approve the project or decide the project requires full review; an expedited reviewer may not reject (disapprove) a project.

(4) If the expedited reviewer approves the research project, the Chairperson will include the project on the agenda for the next regularly scheduled IRB meeting for notification of members.

d. If the project receives a full board review, the IRB Chairperson will assign one IRB member to serve as primary reviewer and another IRB member to serve as secondary reviewer.

(1) The primary reviewer will present the project to the IRB during the meeting at which the project is to be discussed.

(2) The primary reviewer will act as project liaison.

(3) The secondary reviewer will serve as consultant to the primary reviewer and will perform the duties of the primary reviewer if the primary reviewer is unable to perform them.

C. Reviewer Qualifications

1. 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 shall be given to the inclusion of one or more reviewers who are knowledgeable about and experienced in working with such individuals.

D. Investigator Liaison

1. For each project to be reviewed, 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.

E. Review Parameters

1. Each review of proposed research will include, at a minimum, explicit consideration of

a. potential risks to subjects,

b. potential benefits of the proposed research, including the soundness of the design and methods used to obtain data,

c. adequacy of procedures for obtaining voluntary informed consent,

d. appropriateness of all written and spoken communications to the potential subjects in light of the subjects' age, experience, maturational level, and cognitive/emotional condition, and

e. the credentials and expertise of the investigators proposing the research.

F. Expedited Reviews

1. Expedited reviewer(s) may reach a determination of "Approved as Submitted," "Approved with Conditions," or may determine that the project does not yet meet criteria for approval.

2. If the project is initially deemed "Approved with Conditions," the investigators may not proceed until

a. they have submitted a revised RPA to the reviewer(s),

b. the reviewer(s) have determined that all conditions have been met,

c. the reviewer(s) have notified the IRB Chairperson of their final approval, and

d. the investigator(s) have received written confirmation from the expedited reviewer or the IRB Chairperson of final approval and permission to proceed.

G. Full Board Reviews

1. Full board reviews may result in a determination of "Approved as Submitted," "Approved with Conditions," or "Not Approved."

2. The IRB may appoint one member to monitor whether or not conditions are eventually met for a project determined to be "Approved with Conditions."

a. If the project is initially deemed "Approved with Conditions" the investigators may not proceed until

(1) they have submitted a revised RPA to the IRB,

(2) the full IRB (or the designated member of the IRB) has determined that all conditions have been met, and

(3) the investigators have received written confirmation from the IRB Chairperson (or the designated member of the IRB) of final approval and permission to proceed.

3. If the project is deemed "Not Approved," the investigators may not proceed with the research under any circumstances. However, a new RPA may be submitted for projects deemed "Not Approved" after consultation with the IRB Chairperson.

H. Post Approval Mechanisms

1. The IRB Chairperson will communicate to the designated member of the research team the decision(s) reached by the IRB.

2. Approval of research by the IRB does not absolve any investigator of the responsibility to protect participants from harm.

3. For research involving more than minimal risk to participants, the IRB may impose reporting mechanisms.

4. For all research, the investigator(s) must inform the IRB of any changes in protocol or risk assessment.

a. Proposed changes will be assigned a review category based on the character of the proposed change and the initial review category of the project.

b. Review of proposed changes will otherwise follow the same procedures for any project review.

5. Adverse events or other unforeseen harm to participants must also be reported to the IRB immediately.

a. Depending upon the severity of the event, the IRB Chairperson may issue an immediate "suspension" order regarding further research efforts, except that clinical care of participants may not be suspended.

b. The IRB Chairperson will determine the review category appropriate to the event and the project, whether suspended or ongoing, will be reviewed as specified in procedures above.

6. All approved research must be reviewed annually until the project is completed.

7. A project is completed when the data will no longer be accessed or the data set is de-identified such that it no longer conforms to the definition of Common-Rule research. Upon completion of a project, the investigator(s) will so inform the IRB.

I. Research Conducted in Cooperation with Other Institutions and Approved by Outside IRBs

1. In the conduct of research projects involving more than one institution, each institution is individually responsible for safeguarding the rights and welfare of the research subjects and for complying with federal regulations involving human-subjects research. Consequently, all human-subjects

research conducted by members of the SVSU community must be submitted to the SVSU IRB for review, regardless of the status of the proposed research at institutions other than SVSU.

a. If requested by either the submitting investigator(s) or the SVSU IRB Chairperson, the appropriateness of utilizing joint or cooperative IRB reviews for research conducted by members of the SVSU community will be determined by vote of the full SVSU IRB and approval of the SVSU President.

b. Such cooperative agreements may involve the delegation of responsibility for initial and continuing review of the research activity to an outside cooperating institution and its IRB, and acceptance of responsibility for such review by that outside institution and its IRB. Any such cooperative agreements shall be documented in writing with copies distributed to all parties of the agreement.

J. Research Conducted Outside the United States of America (USA)

1. Research conducted outside the USA must take into account the local culture, traditions, and customs of the proposed subjects of such research. As a consequence, the usual IRB requirements may be either waived in part or supplemented by additional requirements, depending upon the specific nature of the environment within which the research will take place.

2. In reviewing research to take place outside the USA, the IRB may consult individuals with expertise and experience in the local cultural environment of the proposed research. Such individuals need not be members of the SVSU IRB to provide such consultation.

K. Student Research

1. Research conducted by students, whether for course credit or not, is subject to the same policies and procedures as any other research conducted by members of the SVSU community.

2. Research conducted by students must have a faculty or staff member identified as a Research Supervisor.

L. Research Supervisor (RS) Qualifications

The research supervisor (RS) of a proposed research submitted for IRB review must have qualifications and expertise sufficient to conducting the research and must have adequate supervisory capacity for ensuring that all individuals involved in the research will conform to all federal and institutional requirements for protecting human subjects.

M. Co-investigators

1. For the purposes of IRB review, co-investigators include any individuals who will interact with subjects or have access to identifiable human-subject data, regardless of the intended authorship status of such individuals.

2. Co-investigators must have qualifications and expertise sufficient to their described role in the research.

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.