

**SAGINAW VALLEY STATE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD,  
PROTECTION OF HUMAN SUBJECTS  
POLICY MANUAL**



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## POLICIES

### General

Saginaw Valley State University will comply with the regulations of the United States Department of Health and Human Services (HHS) for the Protection of Human Research Subjects (Part 46 of Title 45 of the Code of Federal Regulations, as amended). The requirements set forth in 45CFR46 will be met for all applicable federally-funded research, and except for the requirements for reporting information to federal agencies, for all other research without regard to source of funding.

### Applicability

This institution has established and will maintain an Institutional Review Board (IRB) competent to review projects and activities that involve human research subjects. The membership (including titles, affiliations, degrees, and/or relevant experience) will be reported to the HHS Office of Protection from Research Risks and other federal agencies as required. The IRB shall determine for each activity as planned and conducted whether:

- a. The costs and risks to the subjects are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these costs and risks;
- b. The rights and welfare of any such subject will be adequately protected;
- c. Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of the regulations;
- d. The conduct of the activity will be reviewed at timely intervals.

This institution will provide for reviews to be conducted by the IRB with objectivity and in a manner to ensure the exercise of independent judgment by the members. Members will be excluded from review of projects or activities in which they have an active role or a conflict of interest.

### Human Subjects Defined

For all purposes hereunder, the phrase, Human Subjects, shall refer to persons employed as subjects in the conduct of instructional investigation and research and/or other research in which such persons are to take part in activities designated as research/investigation and which are beyond the generally understood scope of usual professional pedagogic and

classroom practice or which, by evident legal requirement, are to be governed by the policies here established.

## Responsibility

Responsibility for the implementation and administration of this Policy, where activities in instruction or research involve humans as subjects, rests with the President. The Board has the responsibility and authority to review, approve, disapprove, or require changes in appropriate research activities involving human subjects. While the President may impose stricter limitations on the conduct of the research or instructional investigation than approved by the Board, he/she may not relax any limitation imposed by a Board nor overrule a disapproval. Individual and collective faculty rights established and/or protected under the contract between the University and the SVSUFA shall not be abridged by reason of the application of this provision save under the specific application of Article A.6 (1981–82) and any successor agreement clause.

## Implementation

The general procedure for implementation of this policy will be the review of the plan of any investigation involving humans as subjects by an Institutional Review Board in accordance with the provisions of this Policy. If the Board, after reviewing a written plan for the investigation and/or interviewing the principal investigator(s), is convinced that all the provisions of this Policy will be met, the President will be so informed in writing, with a copy to the principal investigator and his/her dean or director. The investigator's copy of this communication will be his/her authorization to conduct the proposed investigation when and if all other college requirements are met.

## Implementation Review Board

The IRB is to be composed of five or more members with varying backgrounds and professional competence pertinent to the judgments that are to be made in the implementation of this Policy. In disciplinary and professional areas, the Board should include, when appropriate, persons whose primary concerns lie in the areas of law, standards of professional conduct and practice, and community attitudes.

Each Board must contain, in accordance with Federal regulations: (a) at least one member who is not associated with the University apart from his or her membership on that Board; (b) at least one member whose primary concerns are in non-scientific areas; and (c) both male and female members. Furthermore, when research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, or institutionalized mentally disabled), the

Review Board shall include one or more individuals with a primary concern for the welfare of such subjects. As appropriate for judgements of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, the Board will include persons knowledgeable in those areas. The membership of the Review Board will be reported to Federal agencies as required.

## Judgments

The makeup of the Board need not be restricted to the appointed members but may be supplemented with additional members by the President to ensure that the Board includes professionals appropriate to judgments concerning:

1. the rights and welfare of the individual(s) involved, including the equitable selection of those subjects;
2. the appropriateness of the methods used to secure and document informed consent;
3. the determination of the costs (including time) and risks to the subjects, and the minimization of those costs and risks, and the relationship of the reasonableness of those costs and risks to the anticipated benefits to the subject and the importance of the knowledge expected to be gained; and
4. the confidence that the Board can place in the principal investigator in matters related to the policy objectives.

## Conflict of Interest

A member of the Board having vested interest in an investigation being reviewed must be disqualified from participating in the decision.

## PROCEDURES

### Submission

Before an activity involving humans as subjects may be undertaken, or before a proposal for its support or continuation may be submitted to a prospective internal or external sponsor (but if necessary within 30 days after submission to an external sponsor), the plan of the investigation must be submitted to the Institutional Review Board with due regard to the lead time required by that Board.

### Board Action

The Board will review the plan and procedures to ensure compliance with the “Judgments” paragraph above (rights and welfare of the individual, appropriateness of the methods for informed consent, determination and reasonableness of costs and risks to the benefits and knowledge to be gained, and the confidence in the investigator) and if necessary, the Board will conduct interviews with the project director, principal investigator, or individual(s) directing the investigation, instruction, demonstration, or activity. The Board is required to review the plan as it will be submitted to the sponsor. When the Board is satisfied after this review that the University’s policy and the rights of individuals will not be compromised, the Chairperson of the Board will confirm the approval of the project in a memorandum to the President with copies to the principal investigator and the dean or director of the investigating unit.

### Disapproval

If the Institutional Review Board disapproves the plan for use of human subjects, the Chairperson will notify the principal investigator by written communication of the reasons for the disapproval. The principal investigator will have the opportunity to modify the plan to meet the objections of the Institutional Review Board.

The principal investigator may also communicate in writing or orally with the Chairperson and Board if necessary, to explain the basis for appealing the original decision, seeking reconsideration and approval.

The plan for use of human subjects must be finally approved by the Institutional Review Board. No employee or agent of the University in connection with his/her institutional responsibilities, nor anyone using University property or facilities, is permitted to employ human subjects in research or instructional investigation without the approval of the Institutional Review Board.

## Expedited Review

An expedited review procedure using the one-page rather than the four-page form may be used to review minor changes in previously approved research during the authorized period in which there is no or minimal risk to the subjects. Expedited review is also possible for renewal of previously approved proposals.

Expedited review shall be conducted by the Institutional Review Board Chairperson or his/her designated alternate who may exercise all of the authorities of the Institutional Review Board except that he/she may not disapprove the research. The Chairperson will refer to the full Board research protocols for which the reviewer believes that full review is warranted.

When the expedited review procedure is used, the Chairperson shall inform the Institutional Review Board members. Any other Board member may request that an activity under expedited review procedures be reviewed by the full Board in accordance with non-expedited procedures.

## Approval Conditions

The Institutional Review Board's approval, in addition to indicating favorable review and special conditions if any, includes the following general conditions:

1. that the principal investigator is required to advise the Review Board before making any change in protocol which might bring into question the involvement of human subjects in a manner at variance with the consideration on which the prior Board approval was based;
2. that the principal investigator is required to immediately suspend an inquiry if he/she observes an unanticipated negative change in the health or behavior of a subject that may be attributable to the research, and he/she shall report the circumstances promptly to the Review Board for its further review and decision on continuation/termination of the project, and
3. that every 12 months from the date of the approval (or at shorter intervals if the risks are such that in the opinion of the Board a shorter period would be appropriate), a review by the Board is required through submission of the one-page expedited form. If a continuing proposal is not submitted for annual review, or if it is not approved as a result of such a review, the project will be discontinued, pending later approval.

## Office of Sponsored Programs

When the review is related to a sponsored research or training project, a copy of the memorandum from the Chairperson of the Review Board is to accompany the proposal as it is processed within the Office of Sponsored Programs. The Review Board will likewise notify this office when prior approval of a protocol is withdrawn by the Board, and such projects will be discontinued.

## Quorum

A simple majority of the membership, including at least one member whose primary concerns are in non-scientific areas and at least one from outside the University, will be considered a quorum for the purposes of Board work. In cases where a member is unable to attend a meeting in person, he/she may participate by conference phone call.

At least a simple majority positive vote will be required among the Board members present (at least a quorum) for approval of a proposed investigation.

## Board Files

The files of the Institutional Review Board must contain records of the review process for individual cases including, but not limited to, attendance, minutes of discussions of substantive issues and their resolution, vote counts (for, against, or abstain), correspondence with investigators, and a sample of the form for written consent (when appropriate; see below) as approved by the Board.

The Review Board records will also contain a list of the members, written procedures for its activities, and documentation of continuing review activities. All records shall be retained for at least three years after completion of the approved research.

The files and records of the Institutional Review Board pertaining to any investigator(s) shall not be available to, nor any action of the Board referred to by any official, committee, or agency of the University nor to any other individual or organization, unless specifically required by law or by the written permission of the investigator.

# INFORMED CONSENT

## General

Informed consent in this policy means the knowing consent of an individual or his/her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other forms of constraint or coercion. The written informed consent statement shall be in language which is understandable to the subject or his/her representative.

The basic elements of information necessary to such consent include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental or novel.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk of physical harm, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

In general, if there is a chance of physical harm to persons who take part in a project, the following statement must be used (in accordance with the 1978 Federal regulations) when requesting the consent of subjects:

*I understand that the University will provide first aid medical treatment in the unlikely event of physical injury resulting from research procedures. Additional medical treatment will be provided in accordance with the University's determination of its responsibility to do so. The University does not, however, provide compensation to a person who is injured while participating as a subject in research.*

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

## Retention of Consent Forms

The investigator, where appropriate, shall retain in his file a complete set of written consent forms signed by the subject(s) or his/her (their) authorized representative(s). This treatment of informed consent records may be altered when written consent may be more appropriately retained in clinical files. A copy of the written consent form shall be given by the investigator to all persons who will be signing it.

## Modification of Consent Procedures

When a Board decides that it is not feasible to base informed consent on a written document signed by the subjects and therefore grants permission to modify the usual procedure, the Board must establish that:

1. risk to any subject is minimal;
2. waiver or alteration of written informed consent requirements will not adversely affect the rights and welfare of the subject;
3. use of written consent forms would surely invalidate research objectives of considerable immediate importance;
4. any reasonable alternative means for attaining these objectives would be less advantageous; and
5. when appropriate, subjects will be provided with additional information after participation.

The Board's reasons for permitting use of modified consent procedures must be fully documented in its records.

## Exculpatory Language

The informed consent agreement, written or oral, entered into by the subject or other qualified third-party representative of the subject's interests, should include no exculpatory language through which the subject is made to waive, or appears to waive, any of his legal rights, or to release the University or its agents from liability for negligence.

## Timeliness

An essential feature and requirement of this Policy is that approval of the Institutional Review Board must be obtained before any investigation or activity involving humans as subjects is started, and before a proposal for support from the outside or from within the University is processed (or if necessary within 30 days of submission to an external sponsor).

## EXAMPLES

Examples of some research or instructional activities which require prior approval by the Institutional Review Board (normal or expedited) are listed below although this list is not meant to be exhaustive:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - a. research on regular and special education instructional strategies, or
  - b. research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
2. Research involving survey, interview, or observation procedures where any of the following conditions exist:
  - a. responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
  - b. the subject's responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or
  - c. the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, even if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects can or cannot be identified, directly or through identifiers linked to the subjects.
4. Collection of: hair and nail clippings in a non-disfiguring manner, deciduous teeth and permanent teeth if patient care indicates a need for extraction, and excreta and external secretions including sweat.
5. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice including such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, etc.
6. Collection of blood samples.
7. Voice records made for research purposes such as investigations of speech defects.

8. Moderate exercise by healthy volunteers.
9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
10. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, even where the research investigator does not manipulate the subjects' behavior and the research will not involve stress to subjects.

# INSTRUCTIONS

## General

To obtain Institutional Review Board approval, please complete the attached four-page form entitled, "Request for Project Approval," attach the appropriate documents such as protocols, survey instruments, verbal explanations, and Informed Consent Forms, and submit ten (10) complete sets to the Chairperson of the Institutional Review Board. The 2004–05 Chairperson is Dr. Francis C. Dane (Science East 161). The names of future chairmen will be available in the offices of the President, Vice President for Academic Affairs, and the Director of Sponsored Programs.

During the first year, all proposals must be made using the four-page form. Renewals and revisions may be obtained by using the one-page expedited review form.

We regret the necessity for the extra effort and work involved in preparing these submissions which are necessary to meet Federal law. Any member of the Institutional Review Board will be happy to help you in preparing your submission.

## Effective Date of Implementation

These new regulations are effective immediately for:

1. Any proposal to be submitted to an outside sponsor.
2. Any new research effort involving human subjects not yet started.

In brief, before submitting a proposal or commencing a new research project involving human subjects, prior approval of the Institutional Review Board is necessary.

These new regulations are effective August 1, 1984, for:

1. Any classroom efforts falling under the guidelines for classes starting after August 1, 1984.
2. Any research projects involving human subjects for research projects in process which will not be completed by August 1, 1984.

In brief, prior approval of the Institutional Review Board is necessary for appropriate research projects continuing beyond August 1, 1984, and for all appropriate classes commencing in the Fall Semester of 1984 (and subsequently).

## Objections and Questions

Any questions about these guidelines and procedures should be directed to the Chairperson of the Institutional Review Board. This new procedure has been mandated by Federal Regulations and is subject to change based upon your contributions as long as they are consistent with Federal standards.

## Attachments

- Request for Project Approval Form
- Request for Project Renewal Form
- Consent Document Development Checklist

## NEW POLICY STATEMENT ON INFORMED CONSENT<sup>1</sup>

“Informed consent” means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power or choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

1. A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.
2. A description of any attendant discomforts and risks reasonably to be expected.
3. A description of any benefits reasonably to be expected.
4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject.
5. An offer to answer any inquiries concerning the procedures.
6. An instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

In addition, no such informed consent, oral or written, . . . shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his/her legal rights, including any release of the organization or its agents from liability for negligence.

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<sup>1</sup>Federal Register, Thursday, May 30, 1974, pp. 18917–18919.





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