Saint Mary-of-the-Woods College

Institutional Review Board

Policy and Procedures for the Protection of Human Subjects

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The Saint Mary-of-the-Woods College (SMWC) Institutional Review Board (IRB) is responsible for creating and implementing policies and procedures for the protection of human subjects involved in research. The policies and procedures are based on the Code of Federal Regulations established by the Department of Health and Human Services, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (June 23, 2005). The purpose of the IRB is to safeguard and protect from harm those persons who volunteer to be subjects in research conducted at or sponsored by SMWC faculty, staff, or students. The IRB ensures that: risks to subjects are minimized, risks are reasonable in relation to anticipated benefits, subject selection is equitable, informed consent is documented, and data are kept confidential and safe. Any research involving human subjects must be submitted to, reviewed by, and approved by the IRB before data collection begins.

DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, 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) in order for obtaining the information to constitute research involving human subjects.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Moderate risk means that participation in the research may induce distress, significant fatigue, or need for extensive debriefing or explanation due to some deception involved in the research.

High risk means that participation in the research might include potential danger or more severe levels of distress.

IRB MEMBERSHIP AND RESPONSIBILITIES

1. The IRB will consist of at least five members with varying backgrounds to promote complete and adequate review of research activities. At least four of the members will be SMWC faculty or staff. At least one member will be a community member who is not otherwise affiliated with SMWC and who is not a part of the immediate family of a person who is affiliated with the College.

   The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB membership will be inclusive of both women and men. In its discretion, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

2. The Vice President for Academic Affairs or his/her designee will serve as member and chair of the IRB. The IRB chair will be responsible for:

   a. maintaining membership of the IRB consistent with federal regulations (45 CFR §46.107)
   b. receiving proposals
   c. conducting initial reviews
   d. calling meetings
   e. recording and distributing minutes
   f. sending letters of notification regarding approval/disapproval to investigator(s).

3. The IRB will meet at least once during each of the fall and winter semesters. Additional meetings will be held as needed.

4. IRB application materials and copies of notification letters will be stored in the Office of Academic Affairs.

LEVELS OF REVIEW

The IRB has established three levels of review for approval: 1) exempt, 2) expedited, and 3) full board review.

Exempt. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be considered exempt (45 CFR §46.101b):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited. Research activities that involve no more than minimal risk, minor changes in previously approved research during the period (of one year or less) for which approval is authorized, and research that has been approved by the IRB of another institution may be considered for expedited review.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure (63 FR 60364-60367, November 9, 1998).

Applicability:

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following Research Categories (see below), may be reviewed by the IRB through the expedited review procedures authorized by 45 CFR §46.110 and 21 CFR §56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.

3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4. The expedited review procedure may not be used for classified research involving human subjects.

5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

Research Categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is

cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

    Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

    Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise,

muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR §46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR §46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full board review. Research not eligible for review as exempt or expedited will undergo a full board review as described in the Procedures section.

PROCEDURES

1. Investigators are asked to send a completed Human Subjects Review Form A, and an Exempt Review Form B or Expedited Review Form C, if applicable, to the Chair of the IRB seven business days in advance of the published meeting date. If the investigator is a student, the student must have his/her research advisor review and approve the proposal

prior to submission to the IRB. The following questions must be addressed in the materials submitted for review:

a. Who are the investigators, including the faculty supervisor, for student research?

b. What is the research question and what is its significance/rationale?

c. When and where will the research be conducted?

d. Who are the subjects and how will they be recruited and assigned to experimental groups?

e. What specifically will the subjects be doing in the study? Include a copy or thorough description of the instruments and/or protocol(s).

f. What level of risk is involved? Use the categories: low or minimal risk, moderate risk, or high risk. If more than minimal risk is involved, a detailed explanation of the prospect of direct benefit to the individual subjects is needed. Moderate risk might include distress or significant fatigue during the task or need for extensive debriefing or explanation due to some deception involved in the research. High risk might include potential danger or more severe levels of distress due to participation in the research.

g. What procedures will be used for obtaining informed consent? How will subject confidentiality be protected? Include a copy of the consent form (and assent form for subjects under the age of 18).

h. What procedures will be used to provide feedback and/or debriefing to subjects following completion of their participation in the study?

2. The Chair of the IRB will review each proposal to determine the appropriate level of review (exempt, expedited, or full board review).

a. Research proposals that appear to be **exempt** will be reviewed by the Chair of the IRB or his/her designee. Research proposals meeting one or more of the categories listed on the Exempt Review Form will be exempt from further review and the investigator will be notified within ten business days of receipt of the proposal.

b. Research proposals not exempt from the review process but meeting one or more of the categories for **expedited review** will be reviewed by the Chair of the IRB or his/her designee and one additional IRB member. The investigator will be notified within ten business days of receipt of the proposal with one of the following categories of response: approved, approved pending changes, or disapproved (resubmit).

c. Research proposals requiring **full board review** will be reviewed and discussed at a regularly scheduled IRB meeting. A majority of IRB members must be present. Research proposals must be approved by a majority of the IRB members present at the meeting. The IRB will respond in writing to the investigator within ten business days of the scheduled meeting with one of the following categories of response: approved, approved pending changes, or disapproved (resubmit).

3. The IRB will use the following **criteria to review and approve proposals**:

   a. Risks to subjects are minimized:

      i. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

      ii. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

   b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   c. Selection of subjects is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, persons who have mental disabilities, or persons who are economically or educationally disadvantaged.

   d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR §46.116.

   e. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR §46.117.

   f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with mental disabilities, or persons who are economically or educationally disadvantaged, additional safeguards have been included in the study to protect the rights and welfare of these subjects, in accordance with 45 CFR §46, Subparts B, C, and D.

4. The IRB has the sole authority for granting approval of the **content of consent documents**. If changes are made to the consent documents, they must be submitted to the IRB for review prior to use. The IRB will determine that the following elements are included in consent documents:

    a. **Required Elements of Consent Documents**:

        i. 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;

        ii. A description of any reasonably foreseeable risks or discomforts to the subject;

        iii. A description of any benefits to the subject or to others which may reasonably be expected from the research;

        iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

        v. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

        vi. For research involving more than minimal risk, 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;

        vii. 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; and

        viii. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without

penalty or loss of benefits to which the subject is otherwise entitled.

b. **Additional Elements of Consent Documents**. When appropriate, one or more of the following elements of information shall also be provided to each subject:

i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

ii. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

iii. Any additional costs to the subject that may result from participation in the research;

iv. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

v. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

vi. The approximate number of subjects involved in the study.

5. The IRB will approve **procedures for documentation of consent**, in accordance with 45 CFR §46.117, as follows:

a. Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b. Except as provided in paragraph (c) of this section, the consent form may be either of the following:

i. A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

ii. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the

short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

c. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

   i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

   ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

6. When the study involves children as research subjects, the IRB will assure that the following additional requirements for **permission by parents or guardians and for assent by children** are met:

   a. The IRB will determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR §46.116 of Subpart A.

   b. The IRB will determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted (research not involving greater than minimal risk or

research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject). Where research involves greater than minimal risk and no prospect of direct benefit to individual subjects, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

c. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.