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SOUTHWEST MINNESOTA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY FOR RESEARCH USING HUMAN SUBJECTS

1. Introduction

The Institutional Review Board (IRB) at Southwest Minnesota State University is a standing committee of the university that is composed of faculty, staff, and an administrator. The purpose of the IRB is to ensure that research is conducted in an ethical manner. The members of the IRB are responsible for protecting the dignity, rights, and welfare of human research participants. The Chair of the IRB is responsible for providing information and application materials to researchers and for organizing meetings of the IRB as needed.

The Institutional Review Board is composed of one (non-voting) dean; three SMSUFA members that include one science faculty; and one MAPE, AFSCME, or MSUAASF member. These members will review proposals for research and determine if the human participants will be adequately protected from harm. Before conducting any research, an investigator should submit an application with the summary of the proposed research to the IRB chair. The “Application to Conduct Research Using Human Participants” contains a checklist and set of questions, which will be used to determine the level of review that is appropriate. Copies of the application forms are provided on the IRB website.

Additional information and an online training program about ethical procedures for research using human participants can be found at the website for the Office of Extramural Research at the National Institutes of Health, <http://phrp.nihtraining.com>.

Contact the IRB Chair for additional information. Contact information is posted on the IRB website.

(Portions of this policy were adapted from the IRB Policies of St. Cloud State University and Minnesota State University Mankato.)

2. Human Participants

According to the *Code of Federal Regulations* Title 45, Part 46, all research that is supported by federal funding must have a review process in accordance with a prescribed set of ethical guidelines. Furthermore, the faculty of Southwest Minnesota State University has adopted these guidelines as a requirement for all research using human participants. It is recognized that free inquiry and investigation are among the most fundamental of scholarly values, yet it is also expected that researchers affiliated with the university comply with this review process. It is further understood that researchers will adhere to appropriate ethical standards in their own fields.

As defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), research is a systematic investigation designed to develop or contribute to generalizable knowledge. This includes both publishable and non-publishable scholarly endeavors. Any activity that meets this definition and involves human participants must pass through the institutional review process. Human participants are considered “involved” in research if a) there are interactions with people that would not occur in the absence of the research project, or b) personal information is made public in such a way that specific individuals can be identified and recognized.

Generally, most student projects or assignments that are not intended to advance the state of knowledge in a field (classroom activities, laboratory exercises, or field assignments) are not reviewed by SMSU’s IRB. Faculty are responsible for:

- Evaluating students' proposed projects to determine whether the projects fall under the definition of "research" and meet the criteria for IRB review (see 2.1. Classification of Risk and Level of Review and the “Application to Conduct Research Using Human Participants”)

AND

- Providing supervision and guidance to students during the execution of all projects involving human subjects, regardless of whether the projects require IRB review.

When faculty are uncertain about whether their students' projects constitute research and require IRB review, they should contact the IRB Chair. If the IRB Chair believes the project is subject to IRB review, the student researcher must submit an application to SMSU's IRB and receive written approval before recruiting human subjects.

Student projects involving human subjects that meet **either** of the criteria below must always be submitted for IRB review.

- Externally funded projects

OR

- Projects involving vulnerable populations, including minors* (except when engaged in public activities in which the investigator does not participate, such as non-participatory observations of playground or classroom interaction), pregnant women, fetuses, prisoners, people with mental or cognitive handicaps, or individuals who cannot communicate in a language known by the student conducting the project.

* Officially registered SMSU students under the age of 18 who participate in minimal-risk classroom research activities are not considered a vulnerable population.

2.1. Classifications of Risk and Levels of Review

Research can be classified into three categories depending on the level of risk to human participants. For these purposes, “risk” is defined as the potential for physical or psychological harm. The three classifications are: a) No risk, b) minimal risk, and c) greater than minimal risk. These correspond to three levels of review: a) exempt, b) expedited review, and c) full review.

2.2. Exempt

Research that involves no risk to human participants is considered exempt from full IRB review, according to federal code. This category includes the following types of research:

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

2.3. Expedited Review

All research involving only “minimal risk” may be handled by the expedited review. “Minimal risk” means that the probability of harm to human participants is no greater than that encountered in daily life. If the researchers are uncertain about whether an action constitutes risk, the chair of the IRB should be consulted.

An expedited review shall be conducted by one or more IRB members who are designated by the Chair to conduct the review. The IRB member(s) conducting the expedited review may exercise

all of the authorities of the full committee except that the reviewer(s) may not deny the research. The reviewer(s) shall refer any research proposals that seem ethically questionable to the full committee for review.

The expedited review may only be used when the following conditions are met, as assessed on the application form:

- a) Participants are not identifiable to anyone other than the researchers by their responses.
- b) Participants are not at risk of criminal or civil liability, damage to employability, or undue embarrassment if their responses became known outside the research project.
- c) The research does not deal with sensitive aspects of participants' behavior (e.g. illegal conduct, drug or alcohol use, sexual behavior).
- d) Participants will not be videotaped or audiotaped in such a way that their responses or appearance will be made public.
- e) The research does not deal with participants who are minors outside of a regular classroom or educational setting.
- f) There is no deception.
- g) Participants are free to withdraw from the study at any time.
- h) Participants or their legal guardians have given their voluntary consent.
- i) There are no physical or psychological risks that are greater than those found during daily activities or routine psychological testing.

All non-exempt research is subject to continuing review at least annually.

2.4 Full Review

Risks greater than "minimal risk" as defined above will require a review by a convened meeting of the full IRB. No less than 50% of the IRB membership is required to be present at this meeting. The IRB shall determine if:

- a) Risks to participants are minimized by using procedures consistent with sound research design and which do not unnecessarily expose participants to risk.
- b) Risks to participants are reasonable in relation to the anticipated benefits of the research.
- c) Appropriate methods are in place to obtain informed consent from participants and/or parental participation if necessary.

- d) Any deception used is necessary for the phenomenon under investigation, and justified by the scientific gains that will result from the research.
- e) Participants' right to privacy is protected. All non-exempt research is subject to continuing review at least annually.

2.5. Informed Consent

Ethical standards require that researchers strive to protect their participants from harm. Participants are best protected by being fully informed about the nature of the research activity in which they are being asked to participate, and then allowed to decide voluntarily whether they want to be a participant. In seeking informed consent, the following information should be provided to the participant:

- a) A statement that the study involves research, an explanation of the purpose of the research and who is conducting the research, the expected duration of the participant's participation, and a description of the procedures to be used.
- b) A description of any reasonably foreseeable risks or discomforts to the participant.
- c) A description of any benefits to the participant or others which may be reasonably expected from the research.
- d) A statement regarding anonymity or confidentiality, and how it will be maintained.
- e) An explanation of whom to contact for answers to pertinent questions about the research (usually the investigators).
- f) A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. Participants should also be reassured that they can discontinue participation at any time without penalty or loss of benefits.

In general, written consent must be obtained if greater than minimal risk is present. Participants must be informed and provide their consent if they are going to be videotaped or audiotaped. In the case of minors or other vulnerable participants (e.g. developmentally disabled individuals), permission is required from both the child and the parent or guardian. Informed consent is not invariably required. In the case of surveys and questionnaires that do not involve sensitive subjects or minors, return of the questionnaire can be considered as implying consent. However, a cover letter or statement must be included which contains the elements of consent and information about the survey so that individuals can decide to participate or not. Natural observation of public behavior does not require informed consent.

2.6. Data Security

Researchers need to provide a statement regarding secure archiving and storage of the data.

2.7. Overview of the IRB Approval Process

Researchers seeking approval from the Institutional Review Board should follow these steps:

- 1) Obtain a copy of this policy statement and the “Application to Conduct Research Using Human Participants” at the IRB website.
- 2) Be familiar with the policy statement and other ethical guidelines appropriate in the relevant field of research.
- 3) Fill out the “Application to Conduct Research Using Human Participants” completely.
- 4) Submit a copy of the completed application via the instructions on the IRB website.
- 5) Wait for review to be completed at regularly scheduled meetings. Research should not begin until written approval is received. The IRB may approve, deny with explanation, or approve with conditions.
- 6) Begin research or resubmit the proposal with any changes requested by the IRB.