Provost and Vice President for Academic Affairs
PROTECTION OF HUMAN SUBJECTS IN RESEARCH
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A. Purpose

1. Midwestern State University places a special importance on a faculty member's commitment to quality teaching, scholarship, and service to the university, the community, and the professions. As a part of the scholarship component, students, both graduate and undergraduate, are encouraged to engage, with their teachers, in research as part of their Midwestern State University experience. Research is therefore viewed as a means for both enhancing teaching and learning, and for growing and promoting Midwestern State University. Because faculty and students of the university may utilize human subjects from time to time in conducting research, safeguarding the rights and welfare of human subjects is of prime concern to Midwestern State University. All personnel engaged in any given study are accountable for any actions or inactions that might contribute to injury of any persons placed at risk. The university will maintain such reviews as necessary to minimize the risks of injury to human subjects and to ensure protection of their rights and welfare.

2. The fundamental responsibilities outlined above are meant to suggest a preventive attitude with respect to potential injury to human subjects at risk. However, to better ensure that all human subjects are adequately protected, authority is delegated and responsibilities are fixed as indicated below.

3. The purpose of this policy is to allow for the protection of human subjects involved in research conducted by Midwestern State University faculty, staff, and students in a manner consistent with federal regulations as stated in Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects (45 CFR 46; Revised January 15, 2009) or any future federal regulation relating to the Protection of Human Subjects in Research. In conjunction with these federal regulations, Midwestern State University has established an Institutional Review Board.

4. No research involving human subjects shall be undertaken unless the IRB has reviewed and approved such activity. This review shall determine whether these subjects will be placed at risk and, if so, whether:
    a. the risks to the subject 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 risks;
    b. the rights and welfare of any such subjects will be adequately protected; and
    c. legally effective informed consent will be obtained by adequate and appropriate methods.

B. Review

This policy will be reviewed by February 1 of each odd-numbered year by the Chair of the IRB and the Provost and Vice President for Academic Affairs, with recommendations for revision presented to the President by March 1.

C. Committee Make-up and Appointment

1. Federal Requirements

The IRB, in compliance with federal regulation 45 CFR 46.107, shall have at least five (5) members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by Midwestern State University. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The committee shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The committee shall, therefore, include persons knowledgeable in these areas. If the committee regularly reviews research that involves a vulnerable category of subjects, it shall include one or more individuals who are primarily concerned with the welfare of these subjects. The committee's make-up must also take the following factors into consideration.

a. The committee may not consist entirely of men or entirely of women, or entirely of members of one profession.
b. The committee shall include at least one member whose primary concerns are in nonscientific areas.
c. The committee shall have at least one member 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.
d. The committee may not have a member participating in its initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee.
e. The committee may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

2. Midwestern State University's Specifications

Membership of Midwestern State University's IRB will include:

a. One (1) member from the Wichita Falls community.
b. At least six (6) faculty members (one from each of the six colleges) from Midwestern State University and a Chairperson. Members of the committee will be appointed by the Provost from a list of candidates from each of the six colleges as recommended by the Dean of each college. Colleges that routinely conduct research with human participants and generate a higher volume of IRB

applications may request that the Provost appoint a second faculty member from that college to the committee. Members are appointed for 2-year terms.

c. The IRB chairperson will be selected from IRB members with at least one year of experience serving on the board and appointed by the Provost. Another faculty member from the Chairperson's college will be appointed to replace the Chairperson as the college representative to the IRB.
d. Members will complete the training described in Section H below before serving.

D. Applicability: Human Subjects Research Defined and Who Must Submit Protocols

1. The federal code defines research as: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge".

2. The federal code defines a human subject as: "living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information".

3. The IRB policies and procedures apply to all research involving human participants performed by Midwestern State University faculty, students, or staff under University auspices, whether carried out solely with University resources or with assistance of outside funds. Research is considered to be under University auspices if it involves one or more of the following:
    a. The research is sponsored by the University
    b. The research is conducted by, or under the direction of, any employee or agent of the University in connection with his or her employment with the institution, including the use of institutional letterhead.
    c. The research is conducted by, or under the direction of, any employee or agent of the University using any property or facility of the institution.
    d. The research involves the use of this institution's non-public information to identify or contact human research participants or prospective participants.

4. Student research that involves human participants and is intended to result in generalizable knowledge must also be submitted for review. For example, any student research intended for publication or dissemination such as presentation outside of the classroom, i.e. at a conference, must be reviewed. Student research involving human subjects must be supervised by a Midwestern State University faculty advisor who will assume responsibility for ensuring that all research procedures comply with all federal, state, and university policies designed to protect human subjects.

5. Instructors who routinely implement class projects which are not meant to result in publication nor wide dissemination, and involve no greater than minimal risk, do not need to have these protocols reviewed by the IRB. However, if the instructor believes that one or more of the projects may result in publication or wide dissemination, a

blanket IRB approval may be requested for the class as a whole. If instructors choose to complete a blanket application, please include the "Blanket IRB supplement" with IRB application. In addition, all materials used (i.e. surveys or interview questions) should be included.

E. Criteria for Categorization of Research

The IRB has incorporated into this policy the federal regulation's designations of "Research Exempt from Review" and "Research Suitable for Expedited Review." The category of "Research Subject to Full Committee Review" remains for research not suited to Exempt or Expedited Review. Information on the circumstances that qualify a research study for a particular review category is listed in the Code of Federal Regulations, Title 45, sections 46.101.2(b) and 46.110. The following criteria describe research to be considered in each of these categories.

1. Research Exempt from Review

The primary investigator and the department chair, in consultation with the IRB, are responsible for determining whether a research project falls within one of the following exempted categories:

a. The research will be conducted only in established or commonly accepted educational settings (like classrooms) and it involves normal educational practices such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
b. The research will be conducted using only questionnaire or interview survey methods and the subjects are elected or appointed public officials or candidates for public office.
c. The research is limited to the collection and study of data, documents, records, pathological or diagnostic specimens that are available to the public.
d. The research is limited to the collection and study of data obtained using only the following techniques and the data or information obtained will be recorded in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked with the subjects.
    (1) The data will be obtained through the use of educational tests (cognitive, diagnostic, aptitude, achievement, etc.); or
    (2) The data will be obtained by observing the public behavior of subjects; or
    (3) The data will be obtained using survey or interview procedures; or
    (4) The data will be obtained from existing documents, records, and pathological or diagnostic specimens.
e. The research is limited to the collection and study of data obtained by:
    (1) Observing the public behavior of the participants; or using survey or interview procedures.
    (2) The information collected about the subjects' behavior does not involve sensitive subjects such as illegal or immoral conduct, drug or alcohol abuse, sexual behavior, mental illness, or other possible personally embarrassing subjects;

(3) The information collected about subjects, if it became known to outsiders, could not reasonably be expected to place the subject at risk of civil or criminal liability, or be damaging to the subjects' social or financial standing or employability.

2. Examples of Research Suitable for Expedited Review

Most of the research projects that fall into this category of research have minimal or no risk for the subjects. Research suited for expedited review includes:

a. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.
   (1) 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.)
   (2) 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.
b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (1) 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
   (2) 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.
c. 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 subgingival 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.
d. 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 subject's 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.

e. 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. This listing refers only to research that is not exempt.)
f. Collection of data from voice, video, digital, or image recordings made for research purposes.
g. 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. This listing refers only to research that is not exempt.)

3. Research Subject to Full Committee Review

The category of "full Committee Review" remains for research not eligible for either Exemption or Expedited Review.

F. Informed Consent

1. No human subject research (including research deemed exempt from continuing IRB review) may be conducted without informing the human subject or the legally authorized representative of the risks, procedures, and discomforts of the research. Subjects should be clearly informed that their participation is voluntary. When appropriate, a statement illustrating the voluntary nature of the project should be included on written questionnaires. When research involves the use of minor participants, consent must be obtained from a parent or legal guardian. In addition, the minor participants over the age of 6 must provide their assent to participate, using a form appropriate for their age level.

2. Voluntary Informed Consent assures a person's right to exercise free power of choice regarding participation in research. The basic elements of information necessary for voluntary informed consent are:

a. A clear, responsible explanation of procedures and purpose in language appropriate for the subject group (with experimental procedures specifically identified).
b. A description of expected risks or discomforts.
c. A description of expected benefits.
d. A disclosure of alternative procedures available.
e. An offer to answer any questions raised by a subject regarding procedure, concerns, complaints, etc.
f. Freedom to withdraw/discontinue participation at any time, especially when the subjects are students enrolled in a class. Discontinuing participation will be without penalty and without loss of benefits which the subject is otherwise due.
g. Appropriate contact information for the researcher.
h. Maintenance of anonymity of subjects.
i. Maintenance of the confidentiality of subjects.
j. An explanation that any concerns regarding rights of the research subject should be directed to the chairperson of the IRB.

G. Protocol Submission and Processing for Review.

1. Investigators must submit, at minimum, the following items for review as part of a standard protocol submission:
    a. Application for Use of Human Subjects in Research protocol form
    b. Advertisement/recruitment materials that will be used to solicit participation in the study.
    c. Informed Consent documents reflecting the exact language that will be used to obtain participant consent. See IRB website for guidance on informed consent issues.
    d. Printed materials used for data collection (such as survey instruments or measures).
    e. Any relevant grant applications tied to the protocol request.

2. To facilitate the transfer of proposals, investigators are required to consolidate all of their material into one electronic file (completed application, any recruitment materials, consent form, and instruments such as interview questions, surveys, tests, experimental manipulations, etc.)

3. The College IRB representative serves as the intake-point for protocol submission, and forwards protocols to the IRB Chairperson for review. The IRB will review the protocol to confirm the research is exempt, eligible for expedited review, or subject to full board review.

4. The Chair of the IRB, upon receipt, will record the application and notify the principal investigator regarding the status of the proposal.

5. Data collection may begin as soon as the investigator has received committee approval. In the event that the reviewers do not approve the proposal, it will be forwarded to the full committee for review.

6. Research Subject to Full Committee Review
    a. Research projects not eligible for either exemption or expedited review, will be subject to full committee review.
    b. The committee meets on a monthly basis during each long semester to review proposals and policies. Additional meetings may be called as needed. The committee does not routinely meet or accept applications for full review during the summer.
    c. The investigator(s) may choose to be available for the committee meeting at which the project proposal will be reviewed in order to answer any questions the committee may have regarding the proposal. Attendance by the investigator(s) at this committee meeting is not required.

7. Continuation or renewal
    a. A project that has been determined to be exempt from IRB review does not require further review (e.g. annual continuing review) unless the relevant details of the project change in a way that makes the project ineligible for the exemption categories above.
    b. Projects that were approved under expedited or full review require annual renewal. Approval of research is good for a one year period. If the research is to continue beyond the approved time the researcher must request an extension. The request for extension must be reviewed at the same level of review as the original proposal. The researcher's request must include the following information.
        (1) The name of principal investigator(s) and title of the research project.
        (2) The number of participants that have been tested to date and the number of additional participants needed.
        (3) A description of any modifications that will be made to the procedures.
        (4) Any changes in anticipated risks or benefits.
        (5) A description of any adverse effect or participant complaints to date.
        (6) A brief summary of the findings to date.

H. Training

Individuals with projects subject to IRB review must complete a training course and provide documentation of certification. Online training from the National Institute of Health is available at http://phrp.nihtraining.com. A certificate of completion must be submitted for each of the primary investigators. It is recommended that all research assistants who will interact with participants or have access to identifiable data also complete the training. Training is required regardless of whether the project is internally funded, externally funded, or unfunded. Although subject to modification based on changing federal guidelines, training is currently required annually for each student investigator and recommended every 3 years for

faculty/staff.

I. Records

Federal regulations require all IRB records to be retained for at least three years, and records relating to the human subjects research conducted to be retained for at least three years after completion of the research. All records must be accessible for inspection and copying by authorized federal officials at reasonable times and in a reasonable manner.

J. Midwestern State University IRB Procedural Manual

Federal regulations at 45 CFR 46.103(b)(4) and (5) require institutions to have written IRB procedures for each of the following 7 areas:

1. Procedures which the IRB will follow for conducting its initial review of research;
2. Procedures which the IRB will follow for conducting its continuing review of research;
3. Procedures which the IRB will follow for reporting its findings and actions to investigators and the institution;
4. Procedures which the IRB will follow for determining which projects require review more often than annually;
5. Procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
6. Procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which the IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and
7. Procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and the Office of Human Research Protections (OHRP) of:
    a. Any unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems);
    b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
    c. Any suspension or termination of IRB approval.