HUMAN SUBJECTS PROTECTIONS POLICY
INSTITUTIONAL REVIEW BOARD (IRB)

I. Statement of Ethical Principles

Missouri Southern State University is committed to quality policy and procedures for the protection of humans as participants in research. The development of this policy was guided by the requirements of the code of Federal Regulations 45 CFR 46.

II. Applicability of Policy

All systematic research undertaken by Missouri Southern personnel or students in which human subjects participate is subject to review under this policy. The term “human subjects” is defined as 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. The federal definition for research is “a systematic investigation, including research development, testing and evaluation, designed to develop and contribute to generalizable knowledge (45 CFR 46).” This definition includes any surveys, tests, observations of people, or experiments which involve systematic data collection that could result in knowledge reported in professional meetings or publications. All research projects directed by MSSU faculty, staff, or students must receive Institutional Review Board (IRB) approval prior to collecting data.

Research conducted on the MSSU campus by researchers from other institutions may apply for approval by submitting the following documents: a copy of the original approved IRB application from an IRB with a Federalwide Assurance number (FWA), and supporting materials including all measures and procedures. External researchers who cannot provide an approved IRB with FWA number must submit an application using the MSSU process. The Chair of the IRB will review the documents and may approve the application or require further review by the full IRB committee.

Classroom curriculum projects, workshop evaluations, and administrative projects do not need IRB approval if they are not research; that is, if the results will not be distributed outside the classroom, institutional setting, or if they are used solely for program review or evaluation. If such projects may lead to generalizable information, through publication or dissemination of results, they must undergo review. Regardless of whether the project is subject to review, all personnel and students must adhere to ethical guidelines when conducting class projects with human participants.

III. Human Subjects Review Structure

A. Institutional Review Board Composition

The IRB is an administrative committee consisting of individuals with diverse backgrounds and the training necessary to evaluate human subjects research and its institutional, legal, scientific, and social implications. The members of the IRB are appointed by the Vice President of Academic Affairs and Provost for five year terms. Membership consists of the following:

a. Two faculty members from each of the academic schools; preferably these members will have experience with the Human Subjects Review Panels (previously called Departmental Review Panels); including

(1) At least one faculty member whose primary concerns are in scientific areas
(2) At least one faculty member whose primary concerns are in nonscientific areas

b. At least one individual from the community who is not an employee or member of the Board of Governors of the University or a family member of a University employee or Governor
c. Chair of the Student Research Committee
d. Director of Assessment and Institutional Research, ex-officio
e. Associate Vice President for Academic Affairs and Vice Provost, ex-officio

The Chair will be appointed from the current membership for a three-year term in the following manner: one year as chair elect; one year as chair; and one year as past chair. Membership will consist of both men and women.

B. IRB Responsibilities

1. The IRB shall review and have the authority to approve, require modification, or disapprove all research activities involving human subjects.
   a. Except when a research project is exempt or an expedited review is used, reviews will occur at a convened meeting at which at least 5 of the 9 IRB members are present, including at least one member whose primary concerns are in nonscientific areas.
   b. The IRB will periodically review the range of research approved under the exempt and expedited categories to assure compliance with policy.
2. The IRB shall develop policy and procedures for review of research involving human subjects. The policies and procedures shall be consistent with ethical standards and federal code regarding human subjects.
3. The IRB shall retain documentation of their review activities including copies of all research proposals reviewed, minutes of their meetings, copies of correspondence with the investigators, and records of continuing review. All records must be retained for 3 years after completion of a research project.
4. The IRB will provide written notice to principal investigators of the disposition of their proposals.
5. The IRB will conduct a continuing review of ongoing projects at least once a year.
6. IRB members should provide advice to investigators whose research involves human subjects.

C. IRB Meetings

The IRB will meet the second, sixth, tenth, and fourteenth week of the fall and spring semester, and the fourth week of the 8-week summer session.

D. Human Subjects Review Panels

Schools, departments, or programs may establish a Human Subjects Review Panel. Each Human Subjects Review Panel will:

1. Consist of at least two members who hold faculty, staff, or administrative positions at MSSU.
2. Establish guidelines in keeping with the IRB policies and their discipline’s professional guidelines
3. Provide the IRB with a copy of their guidelines and a list of their reviewers, and supply evidence of training certification for each member.
Trained members of the review panels will serve as reviewers for exempt projects within their
department, program, or area, and serve as one of the reviewers for expedited projects campus-
wide.

Reviewers are urged to complete their review within two business days. Upon completion the
reviewer will send a signed copy of the Human Subjects Review Application and associated
materials to the IRB manager.

E. Training Requirements

Members of the IRB, Human Subjects Review Panels, Faculty Research Advisors, and all MSSU
researchers, including students, faculty, and staff who submit an IRB application must complete the
online training provided by the Collaborative Institutional Training Initiative (CITI).

The specific CITI training required can be found on the MSSU IRB website. Certification will be
accepted for 3 years.

IV. Determining the Type of Research Review

The type of review that a research project undergoes is determined by the level of risks to the participants
and the types of participants involved in the research. There are three types of initial reviews for research,
exempt, expedited, and full. The researcher must evaluate risk and type of participants to determine which
type of review may be appropriate for the project. If the risk and participant type is appropriate for
exempt or expedited review, the researcher must determine if the research falls in one of the categories
under that type of review.

An IRBNet Administrator with the required human subjects ethics training may change the risk
level prior to assigning the application to reviewers.

Approval of research under these policies is for a one-year period, unless the IRB determines the risk is
sufficiently high to require more frequent review. Any research project that lasts for more than one year
must petition the IRB for continuing approval.

A. Level of Risk

Researchers should make every effort to minimize the amount of risk involved in the research design. The
IRB will evaluate the risk and determine if the risks are reasonable in relationship to the anticipated
benefits of the research to the subjects, if any, or the knowledge that may reasonably be expected to
result.

1. Less-than-minimal-risk is research in which there is no known physical, emotional, psychological, or
economic risk. This research can qualify as exempt if it does not involve a vulnerable population and falls
in an exempt category.

2. Minimal-risk is research that presents only the kind of risks encountered in daily life by most people
(e.g., moderate exercise testing, minor stress from psychological tests, or surveys involving sensitive
topics). This research can qualify as expedited if it does not involve a vulnerable population and falls in
an expedited category.

3. Greater-than-minimal-risk is research procedures that may include risk beyond that ordinarily
encountered by subjects (e.g., maximal exercise testing, stressful psychological testing, questions about
illegal activities). This type of research requires a full review.
B. Type of Participants

Vulnerable populations require a higher level of protection, thus a higher level of scrutiny for the research procedures. Prisoners, mentally disabled persons, and children are considered vulnerable because their ability to give truly voluntary and informed consent may be limited. Pregnant women are considered vulnerable in the case of research procedures that pose any hazard to the fetus.

C. Qualifications for Exempt Status

Exempt review is used for human subjects studies presenting less than minimal risk to non-vulnerable subjects. The categories of research that qualify for exempt review are listed below. Note that even if research falls into one of the general categories that is normally exempt, it is not exempt if it involves sensitive topics (e.g., recreational drug use, sexual practices, use of alcohol by minors, criminal behavior) or vulnerable participants (e.g., children, victims, persons with mental retardation). Exempt protocols are reviewed by an IRB Committee member selected by the IRB manager (see the section on Research Review Procedures). The researcher must not begin contacting research participants or collecting data until written approval is received from the IRB. This usually requires three working days for processing after the exempt projects are submitted. Research activities in which the only involvement of human subjects is in one or more of the following categories qualify for review under the exempt category:

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

Note: When video-recording and/or photography is used for data collection, the research no longer meets the exempt requirements. This is because information is recorded in such a manner that participants can be identified. Audio-recording may fit under this same category, depending upon how the recording is made and its intended use. If the recording is to facilitate accurate record keeping and will be erased following transcription, it may go in the exempt category. If it is to be used for purposes that would make the recording part of the reporting process it would not be exempt.

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 category (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 information, 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 that are conducted by or subject to the approval of supporting agencies, and which are designed to study, evaluate, or otherwise examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) 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, a) if wholesome foods without additives are consumed or b) 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 and approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

D. Qualifications for Expedited Status

Expedited reviews are used for research presenting minimal risk to non-vulnerable participants or less-than-minimal risk to vulnerable participants. Expedited reviews do not require a convened meeting of the IRB. Two reviewers, one from the Human Subjects Review Panel and one IRB member outside the department review the protocol (or two members of the IRB if no Human Subjects Review Panel exists). The reviewers will send the completed review to the IRB (See the section on Research Review Procedures). Research involving no more than minimal risk and in which the involvement of (non-vulnerable) participants is in one or more of the following categories may be reviewed through the expedited review procedure.

1. 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.)

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

3. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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.)

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 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.

5. 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.

6. 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.

7. 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.

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.

E. Full Review

Any research that does not meet the qualifications listed under exempt or expedited review will be reviewed by the IRB at a regular meeting.

V. Research Review Procedures

All applications, regardless of research level, will be submitted to the IRB Manager through IRBNet. The principal researcher should indicate the level of research review on the application. The researcher must not begin collecting data until the IRB approval is received.
A. Exempt Review

Human subjects research at the Exempt level of review only requires the approval of an IRB Committee member. Federal guidelines list six types of projects eligible for exempt review. In general, the exempt research is research that is less-than-minimal-risk for non-vulnerable adults.

B. Expedited Review

Research at the Expedited level of review requires the approval of two reviewers. One can be a member of the Department Review Panel, or, if there is no review panel, then both reviewers must be a member of the IRB. Federal guidelines list various types of projects eligible for expedited review. In general, expedited research is research that is of no more than minimal risk for non-vulnerable adults. This level cannot be used if the identification of subjects could reasonably place them at risk.

C. Full Review

Research not qualifying for expedited review will be reviewed by the full IRB Committee. Generally, research requires a full review if it is of greater than minimal risk, and/or is conducted with a vulnerable population. Proposals should be submitted one week prior to a scheduled meeting. Approval of a proposal by the IRB requires a majority vote of the members present at the meeting. The IRB manager will inform the researcher or research supervisor of the IRB decision through IRBNet.

D. Continuation or 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, by submitting an application to IRBNet. 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 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.

VI. Informed Consent Requirements

The participant should have sufficient knowledge and understanding of the elements of informed consent. To the extent possible, the participant should make an informed decision about whether or not to participate in the research. As a part of the process of obtaining informed consent, the following elements of consent should be considered.

A. Elements of Informed Consent

Informed Consent Forms should include the following elements.
1. A statement that the study involves research.
2. An explanation of the purposes of the research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. Identification of any procedures which are experimental.
6. A description of any reasonably foreseeable risks or discomforts to the subject.
7. A description of any benefits to the subject or to others which may reasonably be expected from the research.
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
10. 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.
11. 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.
12. 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. Documenting or Waiving Documentation of Informed Consent

When research presents a greater than minimal risk to the participants, a signed written Informed Consent Form must be retained with the research records for three years. A copy of the form must be given to the participant. Signed documentation of informed consent can be waived if 1) the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context or 2) the consent document would be the only record linking the subject and the research and the principal risk would come from a breach of confidentiality. The researcher still needs to provide the subject with the elements of consent so an informed decision is assured. This process is recommended for projects that require less than a full review because it preserves anonymity and eliminates the need to store the consent forms.

Informed consent may be waived or altered if the research meets all of the following conditions: 1) The research involves no greater than minimal risk. 2) It is not practicable to conduct the research without the waiver or alteration. 3) Waiving or altering the informed consent will not adversely affect the subjects’ rights and welfare. 4) Pertinent information will be provided to the subjects later, if appropriate. This category of waiver includes cases in which the investigator needs to withhold some information about the research, which if known by the participant would bias the result of the study. Ordinarily, the researcher will plan a debriefing session after completion of the individual’s participation to provide the missing information.

VII. Debriefing

When the informed consent procedures withhold information from the participants of the research or the research design involves deception, researchers should provide the participants additional information and correct any misperceptions that have been created. This information should be provided as early as possible, preferably at the end of participation, but at least by the conclusion of the research. When appropriate the researcher should provide the participants the opportunity to learn about the nature of the results and conclusions of the research.

VIII. Data Management

As per federal guidelines, all informed consent forms are to be stored in a secure location for 3 years. Electronic consent forms (e.g., Survey Monkey) are to be stored for 3 years.
The primary investigator is obligated to maintain the privacy and confidentiality of all data pertaining to human subjects. The researcher must explicitly state in the IRB application how participant data or other information will be stored in a way which protects the privacy and identity of the participants.

State what data, if any, will be shared with third parties. Data should only be released in a form which protects the privacy and identity of the participants involved.

Sensitive or non-confidential data has special considerations. This type of data should include a data destruction plan in the IRB application.

**IX. Research with Children**

Research involving children must be undertaken with care and meet strict ethical standards. Research with children is never considered exempt from IRB review, even if the same research procedures would be exempt with adult participants. It is anticipated that most research conducted with children will present minimal or less-than-minimal risk. Research involving more than minimal risk to children should be conducted only if sufficient potential benefits are anticipated. If research involving more than minimal risks with children is proposed, it must meet the special considerations specified in 45 CFR §46.405, or §46.406 to be approved by the IRB. For the purpose of these rules a —child is a person under the age of 18 or legally emancipated. When engaging in research with children the researcher may need to seek permission of the school district and parents or guardians as well as assent of the child. Permission of the school (superintendent or principal) is required for any research that takes place in a school setting or involves school records. Parental permission and child assent may be waived, if the research does not involve direct intervention with children or include personally identifiable information. Examples of such research include observations of public or classroom behavior and analysis of educational test or existing data recorded without personal identifiers. Projects that involve direct intervention with children require permission from the parent or guardian. In addition, assent from the child is required when appropriate.