Missouri Southern State University
Human Subjects Protections Policy
Institutional Review Board

Statement of Ethical Principles

Missouri Southern State University is committed to quality teaching and learning, scholarship, and community service. The University strives to fulfill its mission and objectives in an honorable and ethical manner. It is in this light that the University has developed policy and procedures for the protection of humans as participants in research. The development of this policy was guided by the ethical principles set fourth in the Declaration of Helsinki, the National Commission of the Protection of Human Participants of Biomedical and Behavioral research, and the requirements of the code of Federal Regulations 45 CFR 46.
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

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 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 fulfill the requirements of approval by submitting a copy of the IRB approval from their home institution to the MSSU IRB.

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.

External Researcher
Individuals from other institutions who wish to conduct research using MSSU students or personnel as participants must send proof of the approval of their research by their home institution's Institutional Review Board to IRB c/o Dr. Delores Honey, 3950 Newman Road, Joplin, MO 64801-1595 or honey-d@mssu.edu. If the home institution does not have a procedure for approving human research procedures, the individuals must submit the appropriate information to the MSSU IRB for review.

Human Subjects Review Structure

Institutional Review Board Composition

The IRB is an administrative committee consisting of diverse individuals with the background 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 for three year terms.

- Two representatives from each of the academic schools. Preferably, these members will come from the Departmental Review Panels.
- Two representatives whose primary concerns are in nonscientific areas.
- Two members will be from the community and not employees or members of the Board of Governors of the University or family members of a University employee or Governor.
- The Assistant Vice President for Assessment and Institutional Research (member by position).
- The Assistant Vice President for Academic Affairs (member by position).
- Membership will consist of both men and women.

IRB Responsibilities

- The IRB shall review and have the authority to approve, require modification, or disapprove all research activities involving human subjects.
    - Except when a research project is exempt or an expedited review is used, reviews will occur at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas.
    - The IRB will periodically review the range of research approved under the exempt and expedited categories to assure compliance with policy.
- 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.
- 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.
- The IRB will provide written notice to principal investigators of the disposition of their proposals.
- The IRB will conduct a continuing review of ongoing projects at least once a year.
- IRB members should provide advice to investigators whose research involves human subjects.

IRB Meetings

The IRB will meet at least once a semester to consider the status of reviews and policies. Additional meetings may be called when there are proposals that require full review.

Departmental Review Panels

Departments with a significant number of minimal risk research activities may establish a Departmental Review Panel. Departments that wish to establish a Departmental Review Panel may establish guidelines in keeping with the IRB policies and their discipline's professional ethical guidelines. Departments must supply the IRB a copy of their guidelines and a list of their reviewers along with a copy of the training certification for each member. Trained members of the review panels will serve as reviewers for exempt projects and as one of the reviewers for expedited projects. Reviewers are urged to facilitate the review process by completing their review within two working days. Upon completion of the review the reviewer will send a signed copy of the Human Subjects Review Application and associated materials to the IRB manager.

Training Requirements

Members of the IRB and all Departmental Review Panels must complete the online training module entitled: Human Participant Protections Education for Research sponsored by the National Institutes of Health. The submission of the certificate of completion available at the completion of the training module is to be printed and submitted to be maintained with the reviewer's qualifications for the IRB.
http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

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. Most of the research conducted at MSSU is expected to fall in the exempt or expedited categories. 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.

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.

- 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.
- 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.

- 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.

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. Research considered to be less-than-minimal-risk for nonvulnerable adults is considered as minimal-risk for vulnerable populations, thus only research on nonvulnerable adults qualifies for the exempt category.

Qualifications for Exempt Status

Exempt review is used for studies presenting less than minimal risk to nonvulnerable subjects.

Even research that you believe to be exempt must be reviewed under the exempt process to assure that it really is exempt from further review. 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 a Departmental Review Panel or reviewer 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 videotaping 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. Audiotaping 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.

Qualifications for Expedited Status

Expedited reviews are used for research presenting minimal risk to nonvulnerable 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 Departmental Review Panel and one IRB member outside the department review the protocol. The reviewers will send the completed review to the IRB manager, who will notify the principal investigator or supervisor of the results of the review. This may require up to one week for review after it is received by the IRB.

Research involving no more than minimal risk and in which the involvement of (nonvulnerable) participants is in one or more of the following categories may be

reviewed through the expedited review procedure. The categories in this list are exempt regardless of the age of the subject, except as noted.

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 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.)

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.

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.

Research Review Procedures

Exempt Review

Research projects that the principal researcher (and faculty research supervisor in the case of a student research) believes meet the qualifications for exempt status must be reviewed by a member of a Departmental Review Panel *(not the faculty research supervisor)* before the researcher begins contacting participants or collecting data. The researcher should send the application and associated documents to the Departmental Review Panel. If the researcher is not in a department that has a Departmental Review Panel, the researcher will send the Human Subjects Review Application and associated documents to the IRB manager, who will select a review panel member and forward the application and materials. If the reviewer confirms that the research is exempt, the reviewer will sign the application form and send the Human Subjects Review Application and associated documents to the IRB manager. The IRB manager will assign a number, inform the researcher or research supervisor in writing that the project is approved, and file the application. If the reviewer determines that the project does not meet the exempt criteria, the reviewer will notify the researcher with a recommendation for modification or resubmission for expedited or full review. Researchers should allow three days in their planning for the review process. The researcher must not begin collecting data until the written IRB approval is received.

Expedited Review

Research projects that the principal researcher (and faculty research supervisor in the case of a student research) believes meet the expedited review criteria must be reviewed by a member of the researcher's Departmental Review Panel *(not the faculty research supervisor)* and an IRB reviewer outside of the researcher's department. The researcher should submit the Human Subjects Review Application and associated documents to the Departmental Review Panel and to the IRB manager, who will assign a number and send the materials to an IRB reviewer outside of the researcher's department. If the researcher is not in a department that has a Departmental Review Panel the researcher should send the Human Subjects Review Application and associated documents with a request for two reviewers to the IRB manager, who will send the application and materials to two reviewers in separate departments. Each reviewer will send the completed signed application to the IRB manager. The IRB manager will inform the researcher or research supervisor in writing if the project is approved, or revision or full review is recommended and file the application. Researchers should allow one week in their planning for the review process. The researcher must not begin collecting data until the written IRB approval is received.

Full Review

If a research project requires a full review, the researcher must submit the Human Subjects Review Application and associated documents to the IRB manager requesting a full review. The IRB manager will send the application and materials to the IRB members for consideration at their next meeting. Proposals should be submitted at least three working days prior to a scheduled meeting. The IRB will meet the second and the sixth week of the fall and spring semesters. A majority of the IRB members must be

present for research to be reviewed. 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 in writing of the IRB decision.

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. 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.

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.

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.

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.

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.

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 waved, 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.