Policy Name: **Institutional Review Committee for the Protection of Human Subjects**	**Date Approved**: 12/12/2023
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I. Purpose/Policy Statement/Applicability

Missouri Western State University is committed to excellence in teaching, research, and public service. Accordingly, the University is committed to the conduct of these activities with the highest possible ethical standards. For projects involving humans as subjects of research and research-related projects, the University is guided by the ethical principles regarding research involving humans as subjects as set forth in the Declaration of Helsinki, the Nuremberg Code, and the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled Ethical Principles and Guidelines for the Protection of Human Subjects in Research: The Belmont Report. In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations will be followed for all applicable federally funded research.

II. Definitions and Procedures

Missouri Western State University affirms the need for academic freedom in the conduct of research and the value of well-designed, responsible activities which involve human subjects. At the same time, it recognizes its basic responsibility to assure the protection of human subjects involved in such research. To this end, it has adopted the following statement of policy:

A. Investigations involving human subjects conducted at or sponsored by Missouri Western State University must:
   - adhere to the Belmont Principles, and
   - comply with the Nuremberg Code or one of the ethical codes developed by the various professional associations, and
   - adhere to the policies and procedures set forth in this document.
   - undergo review and receive approval from the Committee on the Use of Human Subjects in Research, Missouri Western State University's Institutional Review Board (IRB).

B. Participation of human beings as subjects in research governed by this policy must be voluntary, i.e., it must occur as the result of free choice, without compulsion or obligation.
   1. Both the rights of such individuals to be protected against injury or invasions of their privacy and their interests as members of a free society in preserving their dignity are recognized as major concerns and must be protected. Therefore, research involving human subjects should be undertaken only with the voluntary consent of the subject or, if the subject lacks the capacity to consent, with the consent of his or her authorized representative.
   2. Where vulnerable populations (intellectually disabled, or physically disabled persons, individuals with limited civil freedom, pregnant women, fetuses, or children) are subjects in research, special care must be taken to assure that consent for participation is obtained in accordance with applicable statutes and regulations. The consent of authorized representatives is usually required for subjects who have diminished

capacity to consent. The assent of the subjects themselves is usually required as well as the consent of their representatives.

3. The investigator must respect the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligation to protect this freedom requires careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to, situations in which research participation is required as a condition of employment or in which the participant is a student, employee or client of the investigator.

C. Adequate standards for informed consent must be satisfied.
    1. Disclosure generally includes: the research procedures; their purposes, risks and anticipated benefits; alternative procedures where therapy is involved; and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. The extent and nature of information should be such that persons, knowing that the procedures are neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, subjects should understand clearly the range of risk and the voluntary nature of participation.
    2. In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold information from the subject. However, information should not be withheld if withholding it would affect a reasonable person's decision to participate or damage his or her subsequent self-esteem. Information which places subjects at risk should never be withheld for the purpose of eliciting the cooperation of the subjects, and truthful answers should always be given to direct questions about the research.

       Incomplete disclosure is only justified if it is clear that:
        - Incomplete disclosure is truly necessary to accomplish the goals of the research and
        - there are no undisclosed risks to subjects that are more than minimal, and
        - where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

D. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.
    1. Comprehension is the third essential element in informed consent. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and terminology used as well as the subject's physical and mental state. Investigators are responsible for ascertaining that the subject has comprehended the information.

E. Adequate provision must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information.
    1. Confidentiality provisions must meet reasonable standards for protection of privacy and comply with applicable laws. Identifiable information must not be disclosed outside the research group unless the subjects expressly agree otherwise.
    2. In addition to being voluntary as described above, disclosure and comprehension are essential elements of the consent process.

F. The selection of subjects must be equitable.
    1. Recruitment and selection of participants must be equitable (fair or just) within the confines of the study. In making this assessment the investigator should consider the purposes of the research and the setting in which the research will be conducted. The benefits and burdens of research must be fairly distributed.

G. The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances.
    1. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where the professional-client or faculty-student relationship is converted into an investigator-subject relationship, special care must be taken to assure that the subject feels completely free to decline to participate. Where access to subjects is gained through cooperating institutions or individuals, care should be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

H. Any compensation made to subjects should not be large enough to constitute excessive inducement for participation of the subjects.

I. Projects involving human subjects should be carefully designed to minimize risk to the subjects.

J. All research involving human subjects conducted at or sponsored by Missouri Western State University must be submitted for prior review and timely periodic review after approval, in accordance with the policies and procedures of the Committee on the Use of Human Subjects in Research (CUHSR). Furthermore, changes in approved research may not be initiated without prior review.

Policy Implementation

Missouri Western State University will maintain an Institutional Review Board (IRB) composed of at least 5 members that will be responsible for reviewing and approving all research involving human subjects. The CUHSR will operate in accordance with a set of standard operating procedures reviewed and updated/ approved on an annual basis.