

Shawnee State University

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SU&JECT:	RESEARCH INVOLVING HUMAN SUBJECTS	RECOMMENDED BY:	
		APPROVED BY:	Board of Trustees

1.0 University Policy

To assure the protection of human subjects and to comply with Federal law including 45 CFR 46, Shawnee State University requires that, prior to contacting potential subjects, all research projects involving human subjects must be reviewed and approved by the University's Institutional Review Board for Human Subjects Research (IRB). For the purposes of this policy, the definitions and procedures of 45 CFR 46 are incorporated by reference. In cases of conflict between this policy and federal regulations, the federal regulations take precedence.

2.0 Applicability

This policy applies to all activities which, in whole or in part, involve research with human subjects if:

- 2.1 The research is sponsored by Shawnee State University, or
- 2.2 The research is conducted by or under the direction of faculty, staff, or students of Shawnee State University in connection with their institutional responsibilities, or
- 2.3 The research is conducted by or under the direction of faculty, staff or students of Shawnee State University using any property or facility of the University, or
- 2.4 The research involves the use of Shawnee State University's nonpublic information to identify or contact human research subjects or prospective subjects.

Graduate and undergraduate student research projects which meet the definition of research (see section 7.0) and are designed for dissemination beyond the classroom are covered by this policy. Student projects designed to provide research training which are not intended for dissemination beyond the classroom are not treated as research projects under this policy (see section 10.0 on student class projects).

3.0 Ethical Principles

The University is guided by ethical principles regarding all research involving humans as subjects. These principles have been set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research". These principles include respect for persons, beneficence (including minimization of risks and maximization of benefits), and justice. The Belmont report can be accessed at the following site: <http://ohsr.od.nih.gov/guidelines/belmont.html>.

4.0 Institutional Review Board

- 4.1 The Institutional Review Board for Human Subjects Research (IRB) for Shawnee State University has responsibility to oversee procedures for carrying out the University's commitment to protect human subjects in research. The IRB shall review and is authorized to approve, require modifications in (to secure approval), or disapprove all research activities using human subjects covered by this policy.

- 4.2** Composition: The IRB will consist of six voting members. Standing members of the IRB will include the General Counsel for the University, and two faculty representatives from each college. No two faculty members may be from the same department. One faculty member must have as their primary concern scientific areas and one faculty member must have as their primary concern nonscientific areas. The Provost will appoint one member of the IRB who is not affiliated or in any contractual relationship with Shawnee State University, and not in the immediate family of a person who is affiliated with the University.
- 4.3** The IRB may take action by majority vote at any meeting in which four voting members are present, provided at least one of those members has as their primary concern nonscientific areas.
- 4.4** The IRB has the authority to approve, require modification in (to secure approval), or disapprove all research activities covered by this policy. The IRB must review the written informed consent as part of the research approval process.
- 4.5** An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5.0 Submitting an application for review

Researchers who propose to conduct research involving human subjects shall prepare and submit an **Application for Approval of Research Involving Human Subjects** to the IRB. Applications must be approved prior to any subject recruitment or contact with subjects. Researchers must complete the required education program on research ethics for human subject's research prior to approval of an application (see section 3.0).

- 5.1** The Application Form and Instructions for completing the application may be obtained from the Provost's Office or downloaded from the following web site: www.shawnee.edu
- 5.2** The objective of IRB review is to determine whether the research is subject to this policy, and, if so, to ensure that the rights and welfare of the subjects are adequately protected and that all activities involving human subjects are in compliance with University policies and Federal regulations to assure that:
- 5.2.1** Selection of research subjects is equitable
 - 5.2.2** Informed consent is obtained and documented where appropriate
 - 5.2.3** Risks to subjects are minimized
 - 5.2.4** Risks are reasonable in relation to anticipated benefits to subjects and others
 - 5.2.5** Privacy and confidentiality are protected
 - 5.2.6** Data handling and safety monitoring provisions are adequate

- 5.2.7** Vulnerable subjects are provided special safeguards against undue influence or coercion to participate in the research.
- 5.3** If, after the initiation of research, it appears that a project should have had prior IRB review, the investigator or anyone with information about the project should contact the IRB Chair to determine ways to maximize human subjects protection for any aspects of the study that are still in process and to maintain confidentiality of existing data.
- 5.4** Expedited review. The Chair of the IRB or the Chair's designee who is a member of the IRB may provide an expedited review of research activities that pose minimal risks to the human subjects and is one included on the list of activities subject to the expedited procedures in 45CFR § 46.110. Any research activities afforded an expedited review will be reported to the full IRB by the reviewer. The full IRB may require a review of the research activities.

6.0 Applications

There are three types of applications:

- 6.1 New protocol.** All new research projects involving human subjects shall be reviewed by the IRB prior to beginning the project. For initial review by the IRB, investigators shall submit a signed original and three copies of an **Application for Approval of Research Involving Human Subjects**, including the cover page, research description and supporting materials as specified in the Instructions for Completing an Application for New Protocol Review. If the protocol is referred to the full IRB for review by the initial reviewers, the investigator will be contacted to submit additional copies of the protocol with any requested changes.
- 6.2 Revisions of approved protocol.** Any changes in an approved protocol, including subject population, study location, procedures, or project personnel must be reviewed and approved by the IRB prior to initiating changes. Investigators shall submit a signed original and three copies of a new **Application Cover Page**, a description of the proposed changes, and the revised protocol that incorporates the proposed changes.
- 6.3 Continuing project review.** All research involving human subjects must be re-reviewed periodically, at least every twelve months or more frequently as specified in the original approval notification. This applies to studies for which data are continuing to be collected or for which research data are being maintained with personal identifiers that can be linked to individual subject responses. For review of continuing projects, investigators shall submit a signed original and three copies of an **Application for Approval of Research Involving Human Subjects** including a status report and supporting materials as specified in the Instructions for Completing an Application for Continuing Project Review. Research projects, not eligible for continuing review because the project's approval has expired, may be submitted as a new protocol.

7.0 Definitions

- 7.1 Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.
- 7.2 Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the

- 7.3** individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
- 7.4** **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 7.5** **Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 7.6** **Informed Consent** a process in which the investigator provides adequate information about the risks and benefits of the research to give the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence

8.0 Research subjects under age 18

- 8.1** Consent from parent(s) or legal guardian(s) is required for children under age 18.
- 8.2** College students who are under age 18 must have parental or guardian consents to participate as research subjects.
- 8.3** In addition to parental or guardian consent, children should also be asked for their assent to participate in the research project in language appropriate to the subject's age and maturity.
- 8.4** Surveys, interview procedures, or participant observations are not eligible for exempt status when persons under age 18 are involved as subjects.

9.0 Responsibility of researchers for the conduct of research

- 9.1** Researchers shall obtain approval for proposed human subject's research prior to recruiting subjects or collecting data from subjects. This applies to preliminary and pilot studies which are developing or testing instruments and procedures, as well as the full study.
- 9.2** Researchers shall explain to subjects, prior to their decision about whether or not to participate, the objectives of the research, the procedures to be followed and the potential risks and benefits. Researchers shall not use individuals as subjects unless satisfied that they, and/or others legally responsible for their well-being, fully understand the consequence of participation and freely consent to participate in the research. The IRB may waive certain aspects of these requirements only when persuaded that the research cannot otherwise be done, that its potential value outweighs any harm to the subject, and that the subject is not exposed to unnecessary risk or harm in participating.
- 9.3** Researchers shall seek informed consent from subjects to participate only under circumstances that provide the prospective subject sufficient opportunity to consider and decide freely whether or not to participate. Subjects shall be given a copy of the informed consent materials to keep.
- 9.4** Researchers shall make clear to subjects that participation is voluntary and they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which the subject is otherwise entitled. Any payment to subjects must be reasonable and prorated with partial payment in the event subjects discontinue participation during the course of the study.

- 9.5** Researchers, assistants, support staff, and anyone else involved in the project shall respect the privacy of subjects. They shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.
- 9.6** Researchers shall obtain approval from the IRB prior to making any changes in the research procedures.

10.0 Student Researchers

- 10.1** Student research projects designed to add to generalizable knowledge through dissemination of results in publications or presentations beyond the classroom are covered by this policy on human subject's research. Faculty members who assign or supervise research conducted by students are responsible for ensuring that the proposed research is reviewed and conducted in accordance with University policy and the student is qualified to safeguard adequately the well-being of the subjects.
- 10.2** Class projects designed to provide hands-on experience or research training to students are not treated as research projects in this policy and do not require formal IRB. Projects in this category are expected to be confined to the specific class and end at the termination of that class. If it is anticipated that the research project will be used in other classes or published or presented beyond the classroom, the project should be submitted to the IRB for review. Faculty members who assign research learning experiences are responsible for assuring that people used in such projects are treated ethically. Faculty members must provide information to students on University policies and guidelines on human subject's research and develop class procedures in a manner that protects the privacy, dignity, and welfare of participants. Questions should be referred to the IRB Chair.