



Ohio Administrative Code

Rule 3362-5-26 Research involving human subjects.

Effective: September 2, 2022

(A) Purpose statement

(1) The purpose of this rule is to assure the protection of human subjects for all research projects involving human subjects and to ensure compliance with applicable federal, state, and local laws, including the Code of Federal Regulations, (CFR) Title 45, public welfare, department of health and human services, part 46, protection of human subjects (45 C.F.R. 46) as well as any subsequent changes to the federal policy for the protection of human subjects. The university will have an institutional review board for human subjects (IRB), which will serve to review all research projects involving human subjects. For the purposes of this rule, the definitions and procedures of 45 C.F.R. 46 are incorporated by reference. In cases of conflict between this rule and federal regulations, the federal regulations take precedence.

(2) The applicable federal regulations will be made available on the university's website.

(B) Applicability and ethical principles

(1) This rule applies to all activities which, in whole or in part, involve research with human subjects if:

(a) The research is sponsored by Shawnee state university; or

(b) The research is directed or conducted by university faculty or staff in connection with their institutional responsibilities; or

(c) The research is conducted by university students under the direction of university faculty or staff; or

(d) The research is conducted at the university or involves use of university property.



(2) Research projects that meet the definition of "research," as defined by in 45-CFR-46, and are designed for dissemination beyond the classroom are covered by this rule. The university may create a preliminary review process for research projects to determine whether such projects require IRB review.

(3) The university IRB and researchers subject to this rule are to be guided by the ethical principles set forth in the Belmont report ethical principles and guidelines for the protection of human subjects of research" (Belmont report), which is created by the national commission for the protection of human subjects of biomedical and behavioral research. The Belmont report will be made available on the university's website.

(C) Institutional review board

(1) IRB membership

(a) The IRB will consist of seven voting members from varying and diverse backgrounds with the professional competence and training necessary to review specific research activities. Six members will be university faculty or staff from varying disciplines including scientific and nonscientific backgrounds as well as undergraduate and graduate programs. Consideration will be given to diversity of gender, race and cultural backgrounds among the IRB members. One external member will be appointed and will not have any contractual relationship or other affiliation with Shawnee state university, and will not be an immediate family member of a person affiliated with the university.

(b) The term for each member will be three years and will commence at the beginning of a fall semester and end at the conclusion of the summer term of the final year of service. Appointments will be proportionately staggered. Members may serve more than one term.

(c) A majority of the voting members of the IRB constitutes a quorum.

(d) Outside assistance. The IRB may invite other individuals with competence in special areas to assist the IRB in the review of applications to conduct research. Such individuals are not permitted to



vote with the IRB.

(2) Appointment process

(a) Members. The provost and vice president for academic and student affairs will appoint the members of the IRB, in consultation with the university faculty senate and the IRB chairperson. In considering each appointment, the provost will review the existing composition of the IRB in light of the composition requirements of this rule and 45-CFR-46.

(b) Chairperson and chairperson-elect. The provost is responsible for appointing a chairperson and chairperson-elect from the IRB membership. The chairperson should have at least one year of service on an IRB, which may be at another institution. The terms for the chairperson and chairperson-elect will be for one year, and both may serve multiple terms. The roles and responsibilities of the chairperson and chairperson-elect shall be set forth in an accompanying procedure.

(D) Procedures

The provost is responsible for establishing procedures, subject to the president's approval, to ensure that the IRB and the university's research involving human subjects are in conformance with federal, state, and local laws. As part of the process in developing procedures, the provost may confer with members of the IRB and other university groups or individuals. Procedures will include, but not be limited to, the application process for students and faculty, standards and criteria for the IRB review and approval process, meetings of the IRB, an exempt or expedited review process, standards for record-keeping, requirements for informed consent, and other processes to ensure protection of human subjects and legal compliance.