Ohio Administrative Code

Rule 3342-10-02.1 Administrative policy regarding research involving human subjects.

Effective: October 15, 2016

(A) Purpose. The university, in the course of carrying out its teaching, research, and service missions, engages in research involving the use of human subjects across a wide array of academic disciplines and administrative functions. In order to protect the rights, well-being, and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of the university, the policies and procedures described in this policy have been established for the conduct of investigations and educational projects involving human subjects.

(B) Scope.

This policy shall apply to all activities conducted by, or under the auspices of the university, irrespective of the funding source, that meet the criteria for:

(1) "Research" involving "human subjects," as defined in the department of health and human service (DHHS) regulations 45 CFR pt. 46 as such regulations may be amended, and/or

(2) A "clinical investigation" involving "human subjects" or "subjects," as defined in U.S. food and drug administration (FDA) regulations in CFR Title 21, as such regulations may be amended. This includes graduate theses or dissertations.

(C) Implementation.

(1) All members of the university community, including all faculty, staff, and students engaged in research recognize and share in the responsibility for protection of the rights and welfare of human subjects.

(2) No research involving human subjects shall be initiated until approval or exemption has been granted by the institutional review board (IRB).

(3) Under the approved federal-wide assurance (FWA) provided by the university to DHHS, all research involving human subjects, and the oversight of such research shall be guided by the ethical principles set forth in the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," and performed in compliance with the regulations set forth by DHHS.

(4) For clinical investigations involving drugs, biologics, medical devices, and other test articles, the university shall comply with human subjects research regulations established by the FDA for clinical investigations.

(5) The university shall conform with other applicable federal, state and local laws and regulations germane to human subjects research.

(6) Investigations conducted by university students in connection with academic work must be supervised by a faculty member, who will refer such proposals to the IRB for review. For student research, the faculty advisor is assumed the principal investigator in regards to IRB applications.

(D) Authority and responsibility.

(1) The IRBs designated under the university's FWA are the principal mechanism by which the university reviews proposed research to ensure that it is planned and conducted in a manner consistent with applicable law and policy, and that the rights and welfare of human research participants are adequately protected. The responsibilities of the IRB include, but are not limited to:

(a) Reviewing, approving, exempting, requesting modifications to, or denying proposed research involving human subjects to ensure that it is planned and conducted in a manner consistent with applicable law and policy, and that the rights and welfare of human subjects are adequately protected. Notwithstanding the preceding, research that has been approved by the IRB may be subject to further review and approval or disapproval by the provost or the provost's designee. No university official, however, may approve research that has not been approved by the IRB.

(b) Conducting continuing review of research approved by the IRB, at intervals not less than once per year, including as necessary, observing, or having a third party observe, the consent process and investigational activity; or requesting and inspecting information related to human participant

research activity.

(c) Suspending or terminating approval of research activity that is not being conducted in accordance with the requirements established by the IRB for a particular research activity, has been associated with serious harm to research participants, or that is not otherwise in accordance with federal human subject research regulations or university policy.

(d) Reporting to appropriate university and federal officials, and as applicable, any department or agency head:

(i) Unanticipated problems involving risks to research participants or others and serious or continuing noncompliance with this policy or the requirements or determinations of the IRB.

(ii) Any suspension or termination of IRB approval.

(e) Contributing to the development and implementation of administrative policies and procedures consistent with federal regulations and best practices.

(2) Sponsored projects involving human subjects are subject to rule 3342-3-04.1 of the Administrative Code.

(3) The institutional official, by appointment from the provost, shall represent the university in providing assurance to the federal government that the university will comply with federal human subject research regulations, and shall be responsible for ensuring that all regulatory and programmatic requirements for the conduct of human participant research at the university are met.