**3356-10-14 Use of human subjects.**

Responsible Division/Office: Office of Research Services

Responsible Officer: Provost and Vice President for Academic Affairs

Revision History: June 1999; December 2010; June 2016;

September 2021

Board Committee: Academic Excellence and Student Success

**Effective Date:** **September 2, 2021**

Next Review: 2026

(A) Policy statement. The university is committed to the protection of the rights, well-being, and personal privacy of all human subjects in research in conformance with, but not limited to, relevant federal and state regulations. All research projects conducted under university auspices involving human subjects, samples or data obtained from them, directly or indirectly, with or without consent must follow university procedures and receive approval from the institutional review board (“IRB”), regardless of funding or funding source.

(B) Purpose. To promote research best practices that meet high ethical standards and adhere to all applicable federal and state laws for research involving human subjects.

(C) Scope. This policy applies to all faculty, staff, and students involved in human subjects research at the university.

(D) Parameters.

(1) The director of research services annually forms an IRB committee composed of both university and non-university personnel.

(2) The IRB committee provides oversight and monitors all research involving human subjects in accordance with federal regulations (45 C.F.R. 46, 21 C.F.R. 50, and 21 C.F.R. 56), “The Belmont Report” of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Food and Drug Administration human research ethical codes, and university policy to protect the rights and welfare of human subjects while participating in research.

(3) The IRB is charged with:

(a) Maintaining review procedures for research projects and programs that utilize human subjects.

(b) Reviewing all research involving human subjects. This review process includes authority to approve, require modification, disapprove, suspend or terminate activities that fall within its jurisdiction.

(c) Conducting continuing review of approved and ongoing research, including requiring progress reports, observing the informed consent process, auditing study conduct and progress.

(E) Procedures.

(1) The IRB has established procedures that are in accordance with federal and state regulations. These procedures and other information concerning human subjects issues and procedures are available in the office of research services or online at <https://ysu.edu/office-research-services/human-subjects-research-irb>.

(2) All human subjects studies should be prepared and submitted to the office of research services via the electronic submission system for processing and reviewing.