Ohio Administrative Code

Rule 3341-7-07 Protection of human subjects.

Effective: July 16, 2026

(A) Policy statement and purpose

(1) Statement of institutional authority

Bowling Green state university (BGSU) has provided a federal wide assurance *(FWA0003853) to comply with the common rule (45 CFR Part 46, Subpart A) and all applicable subparts governing the protection of human research participants, BGSU requires that all research projects involving human subjects, as defined by the federal regulations (45 CFR 46.102(d)(f)), regardless of the source of support or location of the performance site, be reviewed and approved by the institutional review board (IRB) prior to the initiation of the research project. The IRB is under the authority of the vice president for research and the division of research.

(2) Purpose of the IRB

The purpose of the IRB is to protect the rights and welfare of human subjects participating in research. The IRB reviews and oversees research with human subjects to assure that the ethical principles described in the "Belmont Report," a publication of the "National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research" are being followed, and that the research complies with federal regulations that pertain to human subject protections common rule (45 CFR 46) and other pertinent regulations, guidance, state, and local laws.

(3) Governing principles

The IRB is guided by the ethical principles in the Belmont report. The following principles are defined in the Belmont report:

(a) Respect for persons - Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.

(b) Beneficence - The benefits to participants and to the importance of knowledge must outweigh the risks to participants.

(c) Justice - Selection of subjects is equitable and is representative of the group that will benefit from the research.

In addition to the Belmont report, the institutional review board (IRB) operates in compliance with the common rule (45 CFR 46), which establishes requirements for IRB membership, review procedures, informaed consent, and protections for vulnerable populations.

(B) Policy definitions

(1) Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

(2) A 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 (45 CFR 46.102(f)).

(3) Principal investigator (PI) - The individual responsible for the intellectual direction and administrative oversight of the project.

(C) Policy scope

(1) IRB jurisdiction and authority

The IRB has the authority to review research with human subjects when, but not limited to:

(a) The research will be conducted by BGSU faculty, staff, or students.

(b) The research is under the direction of a BGSU faculty or staff member.

(c) The research is conducted by investigators at institutions in which there is an institutional authorization agreement in place with BGSU.

(d) BGSU is the awardee institution (i.e., received an award through a grant, contract, or cooperative agreement), but all activities with human subjects will be carried out by employees or agents of another institution.

(e) The research involves the use of BGSU's non-public information to identify or contact human research participants.

The IRB has the authority to approve, require modifications, or disapprove research activities with human subjects. The IRB has the authority to suspend or terminate approval of research with human subjects are not being conducted in accordance with the IRB approved protocol or when research has been associated with unexpected serious harm to participants.

All IRB activities will be conducted in accordance with the common rule (45 CFR 46), including requirements for initial and continuing review,

expedited review for minimal risk research, and reporting obligations for unanticipated problems, serious or continuing noncompliance, and suspensions or terminations of IRB approval.

(2) Review by institution

Research covered by this policy may be subject to additional review and approval or disapproval by officials of BGSU. However, those officials may not approve research with human subjects if it has not been approved by the IRB.

Inappropriate attempts to influence the IRB process, individual IRB members, or office of research compliance staff will be reported to the vice president for research and economic development. The vice president for research and economic development will investigate and appropriately respond to these concerns, and has the authority to limit or remove an investigator's privilege to conduct research after due process.

(3) Funded research

If research with human subjects is being internally or externally funded, the protocol must be reviewed and approved by the IRB prior to expenditure of any grant funds. The funded grant proposal must substantially correspond to the IRB approved protocol.

(4) Use of procedures

The IRB shall maintain and follow written procedures governing all aspects of IRB review and oversight. These procedures are used to conduct initial and continuing review of research, communicate IRB determinations to investigators and the institution, manage unanticipated problems involving risks to subjects or others, review serious or continuing noncompliance, consider appeals of IRB decisions, and implement any suspension or termination of IRB approval. All IRB procedures are consistent with the common rule (45 CFR 46.103(b)(4)(5)) and are made available to researchers through a link on the division of research website.

(5) IRB authorization agreements

The HSRB can serve as the IRB of record for other institutions and can rely on another IRB for review and continuing oversight when there is an IRB authorization agreement in place as an effort to avoid duplication of effort. This is at the discretion of the BGSU HSRB and will only be done in cases where the other institution has a valid federal-wide assurance.

(6) Compliance

All university personnel and students shall cooperate fully with the procedures implemented by the university IRB to provide protection to human subjects.

Violations of law, regulation, or university policies respecting human subject protections will be considered serious matters, which may warrant sanctions or more serious action, such as suspension of research protocols, termination of research protocols, and loss of research privileges, as the situation may warrant, including investigation for scientific misconduct in accordance with established policies.

(D) Policy provisions

(1) Responsible office

The division of research is responsible for the oversight and implementation of this policy.

(2) Implementation of policy

Who	Task
IRB chairperson, director of research integrity	Ensure compliance with federal regulations, policy and procedures to protect human subjects' participation in research. Report to the vice president for research any inappropriate attempts to influence the IRB process.
Vice president for research	Investigate and act on reports of inappropriate attempts to influence IRB process. Evaluate on an on-going basis the IRB for adherence and compliance with federal, state, and local policy and regulation.

(E) Related university policies

(1) 3341-7-05 Research misconduct.

(2) 3341-7-08 Protection of vertebrate animals.

(3) 3341-7-13 Biohazardous materials in research, instruction, and scholarly activities.

(F) Related government policies and guidance

(1) "Protection of Human Subjects," Title 45 C.F.R., Pt. 46. 2009 ed.

(2) "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research."

(3) "Guidance on Engagement of Institutions in Human Subjects Research."