

3341-7-07 Protection of Human Subjects.

Applicability	All activities related to research with human subjects
Responsible Unit	Vice President for Research and Economic Development
Policy Administrator	Office of Research Compliance

(A) Policy Statement and Purpose**(1) Statement of Institutional Authority**

Bowling Green State University (BGSU) has given assurance via a Federal wide Assurance (FWA00003853) that it will comply with the Department of Health and Human Services regulations for the protection of human research participants (45 CFR Part 46). 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 Human Subjects Review Board (HSRB) prior to the initiation of the research project. The HSRB is under the authority of the Vice President for Research and Economic Development.

(2) Purpose of the HSRB

The purpose of the HSRB is to protect the rights and welfare of human subjects participating in research. The HSRB 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 (45 CFR 46) and other pertinent regulations, guidance, state, and local laws.

(3) Governing Principles

The HSRB 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.

(B) Policy

(1) HSRB Jurisdiction and Authority

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

(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 HSRB.

Inappropriate attempts to influence the HSRB process, individual HSRB 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 HSRB prior to expenditure of any grant funds. The funded grant proposal must substantially correspond to the HSRB approved protocol.

(4) Use of Procedures

The HSRB must maintain and follow written procedures consistent with applicable laws and regulations such as the "Belmont Report", 45 CFR 46, and the university's federal-wide assurance. These procedures will be available to all researchers through a link at the Office of Research Compliance 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 HSRB to provide protections 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 accord with established policies.

(7) Policy Definitions

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

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information (45 CFR 46.102(f)).

(8) Responsible Officer

The Office of Research Compliance is responsible for the oversight and implementation of this policy.

(9) Implementation of Policy

WHO	TASK
HSRB Chairperson, Research Compliance Officer	Ensure compliance with federal regulations, policy and procedures to protect human subjects participating in research. Report to the Vice President for Research and Economic Development any inappropriate attempts to influence the HSRB process.
Vice President for Research and Economic Development	Investigate and act on reports of inappropriate attempts to influence the HSRB process. Evaluate on an on-going basis the Human Research Protections Program for adherence and compliance with federal, state, and local policy and regulation. Evaluate (at least yearly) the HSRB workload in regard to timely and thorough review.

(10) Related University Policies

- (a) Policy on Misconduct in Research
- (b) Federal wide Assurance (FWA) for the Protection of Human Subjects for Institutions Within the United States: Update or Renewal for FWA Number: FWA00003853

(11) Related Government Policies and Guidance

- (a) “Protection of Human Subjects,” Title 45 Code of Federal Regulations, Pt. 46. 2009 ed. (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>)
- (b) 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 (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>)
- (c) “Guidance on Engagement of Institutions in Human Subjects Research” (<http://www.hhs.gov/ohrp/policy/engage08.html>)

Registered Date: May 6, 2015