Ohio Administrative Code

Rule 3341-7-13 Use of Regulated Biohazardous Materials.

Effective: July 16, 2026

(A) Policy statement and purpose

(1) Statement of institutional authority

Bowling Green state university (BGSU) is committed to ensuring that all activities, including but not limited to, research, instruction, and scholarly activities involving regulated biohazardous materials, recombinant or synthetic nucleic acid molecules, human or animal biological specimens, stem cells, and federally regulated toxins, are conducted in a safe, compliant, and ethically responsible manner.

BGSU requires that all activities involving regulated materials be reviewed and approved by the Institutional biosafety committee (IBC) prior to the initiation, purchase, synthesis, or transfer of such materials. Biohazardous materials not meeting the criteria managed under this policy are subject to oversight by environmental health and safety.

Requirements in this policy ensure compliance with:

(a) NIH guidelines for research involving recombinant or synthetic nucleic acid molecules;

(b) Biosafety in microbiological and biomedical laboratories (BMBL) sixth edition;

(c) Select agent regulations (7 CFR 331, 9 CFR 121, 42 CFR 73);

(d) Applicable federal, state, and local laws.

(2) Purpose of the institutional biosafety committee (IBC)

The IBC reviews, approves, and oversees research involving regulated materials to:

(a) Protect researchers, students, staff, and the local community from biological hazards;

(b) Ensure compliance with all biosafety regulations;

(c) Ensure facilities, procedures, equipment, and training meet required safety standards;

(d) Monitor the safe use, storage, and disposal of materials covered under this policy.

(3) Governing principles

The IBC is guided by the principles of:

(a) Risk minimization for personnel, students, the community, and the environment;

(b) Compliance with NIH, CDC, USDA, OSHA, and other biosafety regulatory bodies;

(c) Ethical responsibility in the conduct of biological research.

All research must follow the appropriate biosafety levels and work requiring biosafety level-2 (BSL-2) or higher may only proceed with prior IBC approval.

(B) Policy definitions

(1) Regulated materials: any substance requiring IBC oversight, including:

(a) Infectious agents requiring handling conditions at BSL-2 or higher.

(b) Infectious agents, classified as risk group 2 or higher, or toxic substances of biological origin used in conjunction with animals.

(c) Activities involving recombinant or synthetic DNA technology as defined by the NIH guidelines for research involving recombinant or synthetic nucleic acid molecules, section III-A-F (national institutes of health, office of science policy).

(d) Biological specimens (e.g., saliva, blood, urine, or tissues) collected from humans or non-human primates.

(e) HHS and USDA select agents and toxins, as defined in Federal Regulations 7CFR331, 9CFR121, and 42CFR Part 73.

(f) Biological specimens (e.g., saliva, blood, urine, feces, rumen contents, raw milk, or unfixed tissues) collected from animals including invertebrates requiring handling conditions above biosafety level 1.

(C) Policy scope

(1) IBC jurisdiction and authority

The IBC has full authority to review, approve, require modifications, or disapprove any research involving:

(a) Infectious agents (risk group 2 or higher);

(b) Recombinant or synthetic nucleic acids;

(c) Human or non-human primate biological specimens;

(d) Animal tissues requiring handling at BSL 2 or higher;

(e) Select agents or regulated toxins;

(f) Stem cells and related regulated biological materials.

The IBC may:

(i) Suspend or terminate research not in compliance;

(ii) Monitor ongoing approved work;

(iii) Conduct for-cause reviews or inspections;

(iv) Require corrective actions prior to resuming activities.

(2) Review by institution

Research may require additional institutional review; however, no BGSU official may approve a project involving regulated materials if the IBC has not approved it.

(3) Funded research

Externally or internally funded research may not expend funds involving regulated materials until IBC approval has been granted. Funded proposals must correspond to the approved IBC protocol.

(4) Use of procedures

The IBC shall maintain and follow written procedures for the review and oversight of research involving recombinant or synthetic nucleic acid molecules, biological agents, and other biohazards. These procedures are used to conduct initial and ongoing reviews, communicate committee determinations, address incidents or noncompliance, consider appeals of IBC decisions, and implement any restrictions, modifications, or suspensions of

approval. IBC procedures are consistent with the NIH guidelines, biosafety in microbiological and biomedical laboratories (BMBL) standards, and applicable select agent regulations, and are published through the division of research.

(5) Compliance

All BGSU researchers must adhere to this policy. Violations may result in:

(a) Suspension or termination of research protocols;

(b) Revocation of laboratory access;

(c) Disciplinary actions under university policies;

(d) Mandatory reporting to federal agencies if required.

Concerns regarding biosafety noncompliance may be reported confidentially to the division of research.

(6) Research

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

(7) Institutional biosafety committee (IBC)

A federally registered committee responsible for the review and oversight of research involving regulated materials.

(8) Principal investigator (PI)

The individual responsible for the intellectual direction and administrative oversight of the project.

(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
IBC chairperson, research/director of research Integrity	Ensure compliance with federal regulations, policy and procedures. Report inappropriate influence attempts to the vice president for research.
Vice president for research	Investigate concerns; evaluate biosafety program and IBC workload annually.
Environmental health & safety	Provide biosafety expertise in safe laboratory practices, containment, and waste management; conduct laboratory inspections; support incident response and reporting; and assist with biosafety training.
Principal investigators (PIs)	Submit protocols, ensure staff training, maintain compliance with IBC approval, report changes or incidents.
Research integrity	Coordinate IBC reviews, maintain records, provide biosafety training and guidance.

(E) Related university policies

(1) 3341-7-07 - Protection of human subjects.

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

(3) 3341-7-09 - Use of controlled substances for non-therapeutic purposes.

(4) 3341-7-11 - Export control.

(F) Related government policies and guidance

(1) NIH guidelines for research involving recombinant or synthetic nucleic acid molecules

(2) Biosafety in Microbiological and Biomedical Laboratories (BMBL) sixth edition

(3) Select agent regulations (7 CFR 331, 9 CFR 121, 42 CFR 73)

(4) CDC and USDA biosafety regulation