# Ohio Administrative Code

## Rule 3341-7-10 Dual Use Research of Concern (DURC).

Effective: June 24, 2026

(A) Policy statement and purpose

(1) Statement of institutional authority

Bowling Green state university (BGSU) is committed to ensuring that life sciences research is conducted responsibly to prevent misuse of biological knowledge, materials, or technologies. BGSU requires that all research directly involving DURC-listed agents or toxins be submitted for review prior to initiation.

BGSU will utilize an institutional review entity (IRE) responsible for:

(a) Identifying potential DURC

(b) Assessing risks and benefits

(c) Developing and monitoring risk mitigation plans

(2) Purpose of the institutional review entity (IRE)

The purpose of the IRE is to:

(a) Ensure compliance with federal DURC oversight policies

(b) Review research that may constitute DURC

(c) Work with researchers to assess dual-use risks and benefits

(d) Develop, approve, and oversee DURC risk mitigation plans

(e) Provide ongoing monitoring of approved DURC research

The IRE operates under the authority of the vice president for research

(3) Governing principles

(a) Risk mitigation - Research should preserve scientific benefits while minimizing potential for misuse.

(b) Ethical responsibility - Researchers must understand the dual-use potential of their work and handle sensitive information responsibly.

(c) Regulatory compliance - BGSU adheres to federal DURC regulations and guidance, including:

(i) USG DURC policy

(ii) Companion guidance for DURC oversight

(iii) Select agent regulations

(iv) NIH guidelines for biosafety and recombinant DNA

(d) Proactive oversight - Potential DURC must be identified early and proactively managed.

(B) Policy definitions

(1) Dual use research of concern (DURC) - life sciences research that could reasonably be anticipated to enable misuse resulting in significant threats to public health, agriculture, national security, or the environment.

(2) Institutional review entity (IRE) - The IRE is an oversight committee established by the university to review life sciences research using one or more of the fifteen select agents and toxins listed above for dual use potential, as well as work with researchers to assess the risks and benefits of the DURC and to develop risk mitigation plans when appropriate. The IRE provides ongoing oversight for any life sciences research identified as DURC and on-going compliance with any risk mitigation measures put into place. The IRE shall review risk mitigation plans annually and modify the plans as necessary.

(3) Risk mitigation plan - a documented strategy to reduce potential for misuse while enabling beneficial research.

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

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

(C) Policy scope

(1) DURC agents and toxins

In accordance with federal policy, research directly involving non-attenuated forms of the following fifteen agents or toxins must be reviewed:

(a) Avian influenza virus (highly pathogenic)

(b) Bacillus anthracis

(c) Botulinum neurotoxin

(d) Burkholderia mallei

(e) Burkholderia pseudomallei

(f) Ebola virus

(g) Foot-and-mouth disease virus

(h) Francisella tularensis

(i) Marburg virus

(j) Reconstructed 1918 influenza virus

(k) Rinderpest virus

(l) Toxin-producing Clostridium botulinum strains

(m) Variola major virus

(n) Variola minor virus

(o) Yersinia pestis

(2) Experimental categories

DURC applies when work with one of the listed agents directly involves experiments that:

(a) Enhance harmful consequences

(b) Disrupt immunity or vaccine effectiveness

(c) Confer resistance to interventions or detection

(d) Increase stability, transmissibility, or dissemination

(e) Alter host range or tropism

(f) Enhance host susceptibility

(g) Reconstitute an eradicated or extinct agent

(3) IRE jurisdiction and authority

The IRE has the authority to:

(a) Review, approve, require modifications, or disapprove DURC research

(b) Determine whether research meets the DURC definition

(c) Require, approve, and monitor risk mitigation plans

(d) Suspend DURC research if conducted outside approved conditions

(e) Require corrective actions, recordkeeping, and follow-up reporting

(4) Principal investigator responsibilities

PIs must:

(a) Identify and promptly notify the IRE of any research

(b) involving DURC agents or experimental categories

(c) Not begin or continue DURC until a risk mitigation plan is approved

(d) Implement all risk mitigation measures

(e) Ensure all personnel receive required DURC training

(f) Communicate DURC findings responsibly

(g) Approved projects must undergo annual review to ensure the project still constitutes DURC and whether the existing risk mitigation plan is sufficient

(5) Review by Institution

(a) Research covered by this policy may be subject to additional review; however:

(b) No BGSU official may approve DURC research without IRE approval.

(c) Inappropriate attempts to influence the IRE process will be reported to the vice president for research.

(6) Funded research

If DURC-applicable research is supported by internal or external funding:

(a) DURC approval must be obtained before expending any research funds

(b) The funded project must correspond to the approved DURC protocol

(c) Federal notifications must be submitted as required

(7) Use of procedures

The IRE must maintain written procedures that follow:

(a) USG DURC policy

(b) Federal DURC review and reporting timelines

(c) Select agent regulations (where applicable)

Procedures will be posted by research integrity.

(8) Compliance

Noncompliance may result in:

(a) Suspension or termination of research

(b) Loss of research privileges

(c) Institutional disciplinary action

(d) Mandatory reporting to federal agencies

(e) Additional sanctions as required by law

(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 |
|---|---|
| Vice President for Research | Investigate concerns; enforce DURC requirements; ensure institutional compliance. |

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|---|---|
| Division of Research / Research Integrity | Maintain DURC procedures; coordinate reviews; file required federal notifications; maintain training and records. |
| Institutional Review Entity (IRE) | Review DURC submissions, issue determinations, and oversee risk mitigation plans. |
| Principal Investigators | Identify DURC, submit protocols, implement mitigation plans, ensure training and compliance. |

(E) Related university policies

(1) 3341-7-05 - research misconduct

(2) 3341-7-08 - protection of vertebrate animals

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

(F) Related government policies and guidance

(1) United States government policy for institutional oversight of life science dual use research of concern

(2) Oversight of life sciences DURC

(3) DURC companion guide

(4) Select agent regulations

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

(6) Biosafety in microbiological and biomedical laboratories sixth edition