

Dual Use Research of Concern (DURC)

RP-11-006



About This Policy

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Responsible University Office:

Office of Research Compliance

Responsible University Administrator:

Vice President for Research

Policy Contact:

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Related Information

* [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)

Related Forms

* [IBC Protocol Form](#)

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This policy applies to all Indiana University faculty, staff, and students involved in life science research using one or more of the listed biological below. (See [Definitions: Non-attenuated Agents and Toxins of Concern](#))

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It is the policy of Indiana University that all research projects involving biological agents or toxins specified in the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (“Policy for Institutional DURC Oversight”) are subject to review and approval by the institution prior to project initiation. Dual Use Research of Concern means research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

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Reason For Policy

This policy complies with the federal Policy for Institutional DURC Oversight which applies to institutions receiving federal funding to conduct certain types of life science research. The policies are intended to preserve the benefits of life sciences while ensuring safe research practices and mitigating risks.

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Procedure

A. Obligation of Researchers to Identify Research that May Constitute DURC

A Principal Investigator (“PI”) must identify research that involves Nonattenuated Agents and Toxins of Concern that could meet the definition of an Experiment of Concern. The PI must submit this information on a protocol form that is reviewed by the applicable campus Institutional Biosafety Committee (IBC). If an activity is determined by the DURC Committee to qualify as DURC, the PI must also work with the institution through the DURC Committee to develop a risk mitigation plan and ensure that all laboratory personnel are educated and trained on DURC.

B. Institutional Review

The local campus IBC shall review the PI-submitted protocol and forward to the IU DURC Committee (i) any work involving Non-attenuated Agents and Toxins of Concern that may involve an Experiment of Concern, or (ii) any other research protocol which the IBC believes should be reviewed by the DURC Committee. The local IBC may provide input and make any recommendations to the DURC Committee.

The DURC Committee shall review the proposed research against the standards set forth in the Policy for Institutional DURC Oversight and any other applicable regulations. If the research is determined to meet the definition of DURC, the DURC Committee must develop a risk mitigation plan with the PI. All risk mitigation plans and associated research protocols must be reviewed at least annually. Additional ad hoc members may be added as needed based on the research under review.

The DURC Committee will ensure that education and training on DURC is completed by individuals conducting life science research with a Non-attenuated Agent or Toxin of Concern.

C. Reporting and Plan

Within 30 days of the initial review, the institution, through the Office of Research Compliance, will provide the outcome of the DURC Committee review to the appropriate USG funding agency (or NIH, for non-USG funded research). This should include all information required by the Policy for Institutional DURC Oversight.

Within 90 days of the DURC committee review, the institution will provide the draft risk mitigation plan for final review and approval to the USG funding agency (or NIH, for non-USG funded research).

D. Records

The Policy for Institutional DURC Oversight requires that all records of DURC review and completed risk mitigation plans must be kept for three years after the completion of the project, but no less than eight years after the review or completion of the mitigation plan. The Office of Research Compliance shall keep the DURC and associated records in accordance with his and any other recordkeeping requirements.

E. Noncompliance

Any noncompliance with the approved risk mitigation plan or regulations will be reported to the appropriate USG funding agency (or NIH, for non-USG funded research) within 30 days. In addition, the institution may impose additional sanctions on the PI or lab based on the noncompliance issues found.

F. Appeals

Disputes regarding interpretation of this policy or decisions made by the DURC Committee are referred to the Vice President for Research, who may: deny the appeal, or request that parts of a previous decision by the DURC Committee be reconsidered by the committee. The DURC Committee shall reconsider the determination after receiving input from the Vice President for Research and the local campus IBC. After this reconsideration, the subsequent decision of the DURC Committee shall be final.

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Definitions

Dual Use Research of Concern means research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

DURC Committee is the committee responsible for oversight at Indiana University subject to this Policy and the federal Policy for Institutional DURC Oversight. The Committee will be comprised of:

- Indianapolis IBC Chair
- Bloomington IBC Chair,
- Indianapolis Biosafety Manager,
- Bloomington Biosafety Officer
- Director IU University Environmental Health and Safety
- Executive Director of RIICE
- Representative from one of the campus occupational health programs

Ad hoc members may be utilized to ensure familiarity with the subject matter of the research.

Non-attenuated Agents and Toxins of Concern means those so defined by federal policy, which may be updated periodically, including but not limited to:

- Avian influenza virus,
- Bacillus anthracis,
- Botulinum neurotoxin,
- Burkholderia mallei,
- Burkholderia pseudomallei,
- Ebola Virus,
- Foot-and-mouth disease virus,
- Francisella tularensis,
- Marburg virus,
- Reconstructed 1918 Influenza virus,
- Rinderpest virus,
- Toxin-producing strain of Clostridium botulinum,
- Variola major virus,
- Variola minor virus, and

- *Yersinia pestis*.

Experiments of Concern are research that produces, aims to produce or can be reasonably anticipated to produce one or more of the following experimental effects:

- enhances the harmful consequences of the agent or toxin;
- disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
- confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;
- increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
- alters the host range or tropism of the agent or toxin;
- enhances the susceptibility of a host population to the agent or toxin;
- generates or reconstitutes an eradicated or extinct agent or toxin listed under agents and toxins of concern.

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Sanctions

University faculty, staff, and students that are found to be in violation of this policy may be subject to restrictions from conduct or research and/or sanctions under other university policies.

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History

This policy was established in 2015