

The University of Chicago
Office of Research Safety
**Institutional Oversight of Life Sciences Dual Use
Research of Concern (DURC)**

Policy & Procedure Manual

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1. Overview

Dual Use Research of Concern (DURC) is a subset of dual use research defined as: “life sciences 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.”

The University of Chicago Institutional Oversight of Life Sciences Dual Use Research of Concern Policy is based on recommendations and guiding principles from The United States Government (*March 2012 DURC Policy* and *September 2014 Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*).

The University of Chicago Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern articulates the practices and procedures required to ensure that DURC is identified at the institutional level and risk mitigation measures are implemented as necessary.

2. Purpose

The purpose of this Policy is to describe and provide guidance for the ongoing institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential DURC and mitigate risks where appropriate. This Policy delineates the roles and responsibilities of the University of Chicago Research Administration (URA), the University of Chicago Principal Investigators (PIs) engaged in research activity that can have DURC potential or that has been identified as DURC, and the University of Chicago DURC Task Force (UC-DTF).

The Policy seeks to preserve the benefits of life sciences while minimizing the risk that the knowledge, information, products, or technologies generated from such research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

3. Scope of Research that Requires Oversight

3.1 Agents and toxins

The 15 agents and toxins listed in this Policy are subject to the Select Agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal or plant health, or to animal or plant products.

Avian influenza virus (highly pathogenic)

Bacillus anthracis

Botulinum neurotoxin

For the purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.

Burkholderia mallei

Burkholderia pseudomallei

Ebola virus

Foot-and-mouth disease virus

Francisella tularensis

Marburg virus

Reconstructed 1918 Influenza virus

Rinderpest virus

Toxin-producing strains of *Clostridium botulinum*

Variola major virus

Variola minor virus

Yersinia pestis

3.2 Categories of experiments

Planned and on-going experiments, as well as data obtained from these experiments, should be evaluated for their potential to:

- Enhance the harmful consequences of the agent or toxin
- Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confer 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
- Increase the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alter the host range or tropism of the agent or toxin
- Enhance the susceptibility of a host population to the agent or toxin
- Generate or reconstitute an eradicated or extinct agent or toxin listed above

4. Compliance

As stated in the *September 2014 USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, non-compliance with this policy may result in suspension, limitation, or termination of United States Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the University of Chicago to other potential penalties under applicable laws and regulations. The University of Chicago is responsible, in accordance with its relevant statutory and regulatory authorities, for determining how best to ensure compliance with the oversight requirements set forth in the *September 2014 USG Policy* for research it funds.

5. Organizational Framework for Oversight of DURC

This Section describes the organizational framework for review of research with dual use potential and the oversight of DURC and articulates the roles and responsibilities of PIs, The University of Chicago and the funding agencies. Components of the review and oversight system for DURC include:

- PI should identify life sciences research that involves one or more of the 15 agents or toxins listed in Section 3.1 and/or produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 3.2.
- The University of Chicago DURC Task Force (UC-DTF), in conjunction with the University of Chicago Select-Agent Institutional Biosafety Committee (SA-IBC) and the University Research Administration (URA) review the PI assessment and/or written statement from USG funding agency or journal publisher to determine whether research that uses one or more of the agents or toxins listed in Section 3.1 also produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 3.2.
- PI submits a written statement that identifies the benefits of the research project while addressing each of the effects listed in Section 3.2.
- For research *not* meeting DURC definition and when all UC-DTF members are in agreement, assessment summaries and decisions can be captured and recorded by electronic communications (emails).
- For research that meets or is anticipated to meet DURC definition, UC-DTF will conduct a risk assessment to underpin the determination of DURC during a convened meeting.
- UC-DTF, in consultation with the PI, will identify the anticipated benefits of the research identified as DURC. The anticipated benefits will be considered in conjunction with the previously identified risks in order to develop a Risk Mitigation Plan (RMP) to guide the conduct and communication of the research project.
- UC-DTF, in conjunction with URA, will inform the relevant USG funding agency of the

results of the review process and, in instances when the research is determined to be DURC, provide the RMP to the USG funding agency.

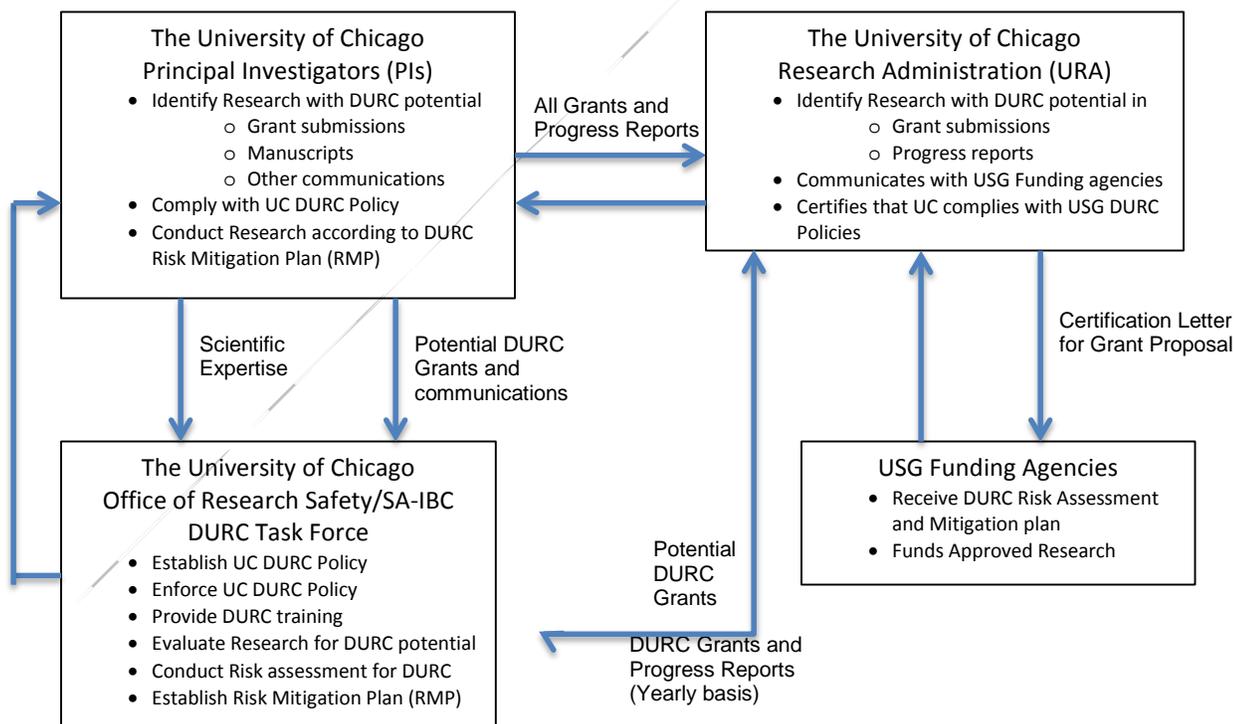
- Risk Mitigation Plans will be re-evaluated by the UC-DTF at least annually and modified as necessary for the duration of the research.
- The principal investigator, with endorsement by the UC-DTF, is responsible for ensuring that the DURC is conducted in accordance with the approved RMP.
- URA will certify that the University of Chicago investigators will comply with this Policy.

Special considerations:

For non-USG funded research, the organizational framework will remain as described above with the exception of notifying the funding agency, unless requested by the funding agency.

Research that has already been determined to be DURC under the *March 2012 DURC Policy*, and for which a RMP has already been developed, does not need a new risk mitigation plan under the *September 2014 USG Policy* but the existent risk mitigation plan will be subject to ongoing review and modification, as necessary, by the UC-DTF.

Figure 1 provides an overview of the process for institutional review of life sciences research within the scope of the Policy.



6. Responsibilities of Principal Investigators

- PIs are to notify the UC-DURC Task Force as soon as:
 - PI's research involves one or more of the agents or toxins listed in Section 3.1
 - PI's research with one or more of the agents or toxins listed in Section 3.1 also produces, aims to produce, or can be reasonably anticipated to produce one or more

- of the seven effects listed in Section 3.2; or
- PI's research that is within the scope of Section 3 may meet the definition of DURC.
- PI receives notification from USG funding agency or journal publisher that the grant or manuscript has been flagged for DURC.

The **notification must include the PI's assessment** of whether any research involving these agents or toxins produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 3.2.

- PIs will work with the UC-DTF to assess the risks and benefits of the proposed research and develop risk mitigation measures.
- PIs should conduct the research work in accordance with the provisions in the approved RMP.
- PIs should be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC.
- PIs should ensure that laboratory personnel (i.e., those under the supervision of laboratory leadership, including graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting life sciences research with one or more of the agents listed in Section 3.1 of this Policy have received education and training on DURC.
- PIs should communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved RMP.
- **Research that has been determined to be DURC should not be conducted until an approved RMP is in place.**
- **Publications or research communication materials (posters, presentations, lectures should not be published or disseminated until an approved RMP is in place.**

7. Responsibilities of The University of Chicago

- The University of Chicago should have policies and practices in place that enable PIs to identify and refer to the UC-DTF any life science research that requires institutional review.
- The University of Chicago should establish and maintain a DTF to execute institutional review of research for DURC potential.
- The University of Chicago should have policies and practices in place for institutional review and oversight of research.
- The University of Chicago Office of Research Safety should develop training tools and provide training on Dual Use Research to all members of the University that are expected to be knowledgeable about DURC.

7.1 Requirements for the University of Chicago DURC Task Force (UC-DTF)

As mandated by the *September 2014 USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, the University of Chicago Institutional Review Entity (IRE) for DURC has been established and is referred to as the University of Chicago DURC Task Force (UC-DTF).

The UC-DTF must meet the following criteria:

- Be composed of **at least 5 members**;
- Be sufficiently empowered by the University of Chicago SA-IBC to ensure it can execute the relevant requirements of the *Policy for Institutional DURC Oversight*;
- Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at the University of Chicago;
- Include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity.
- The UC-DTF may also include, or have available as consultants, at least one person

- knowledgeable in the institution's commitments, policies, and standard operating procedures;
- On a case-by-case basis, recuse any member of the UC-DTF who is involved in the research project in question or has a direct financial interest, except to provide specific information requested by the review entity; and
 - Engage in an ongoing dialogue with the PI of the research in question when conducting a risk assessment and developing a risk mitigation plan.

8. Requirements for the UC-DTF Review Process

The *USG Policy for Institutional DURC Oversight* requires the UC-DTF to undertake the following steps in its review of research:

- **Verify** that the research identified by the PI directly utilizes non-attenuated forms of one or more of the listed agents.
- **Review the PI's assessment** of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the experimental effects listed in Section 3.2 and the final determination of whether the research meets the scope of the *Policy for Institutional DURC Oversight*.
- For research that the UC-DTF determines meets the scope of the *Policy for Institutional DURC Oversight*, **conduct a risk assessment and determine whether the research meets the definition of DURC**. This assessment should involve the PI, as appropriate.

If the UC-DTF determines that the research *does NOT* meet the DURC definition, the research is not subject to additional institutional DURC oversight. The PI will be notified that the proposed work does not constitute DURC.

If the UC-DTF determines that the research *does* meet the DURC definition, the research is DURC, as defined in the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*, and is subject to DURC oversight. The UC-DTF will inform the PI of its findings and proceed with the review process:

- **Assess the benefits of the DURC** while also considering the risks identified during the review.
- **Develop a risk mitigation plan (RMP)** for the identified DURC. This plan should be based on the assessment of the risks and benefits performed in the previous step.
- **Inform**, in conjunction with URA, the relevant USG funding agency of the results of the review process and provide all research communication materials (Grants, abstracts, manuscripts, etc.) and the associated RMP to the USG funding agency.

It is anticipated that the DURC review process will be conducted **entirely** by the UC-DTF. USG funding agencies are not expected to provide routine reviews or assessments of DURC. However, situations may arise that require additional consultation with the USG funding agency. The University of Chicago may consult with the USG department or agency that is funding the research in question for advice on the review of research for DURC potential.

Such consultations will involve the institutional contact for dual use research, an individual designated by the institution to serve as a point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC and to liaise (as necessary) between the institution and the relevant USG funding agency. The funding agency program officers can provide guidance on DURC issues. Such consultations may be appropriate when, for example, the following conditions are present:

- The PI does not agree with the finding of the UC-DTF and the University of Chicago would like to request outside advice;
- The research in question represents a particularly complex case or appears to fall outside

- the scope of the *Policy for Institutional DURC Oversight* but still seems to present significant concerns; or
- Guidance is required to ensure a clear understanding of how the USG interprets the definition of DURC and related terms.

9. Monitoring processes

- **The UC-DTF will review, at least annually, all active risk mitigation plans at the University of Chicago.** If the research in question still constitutes DURC, the UC-DTF will modify the plan as needed. Review material can include, but is not limited to, SA-IBC protocol submissions, publications and other research communications or grant progress reports.
- As part of the University of Chicago **on-going review process** for DURC, the IBC AURA system will reset the DURC questions on the IBC SmartForm each time an amendment to an approved protocol is submitted. Submission will only be considered once the DURC questions have been answered by the PI.

10. Training policy

All University of Chicago Personnel authorized to work with agent listed in Section 3.1 are subject to the University of Chicago Select Agent Program Biosafety, Biosecurity and Incident Response Training Requirements, with the exception of PI working with Botulinum toxin below the threshold quantity. These training requirements include training on **Dual-Use Research of Concern**.

Training is provided annually and exams are given to verify that trainees have comprehended training material.

As a Tier-1 Select Agent registered entity, The University of Chicago is also engaged in a Personnel Suitability and Reliability Program for all its employees working with Agent listed in Section 3.1. This program relies, in part, on the adherence to a Code of Conduct for safe research; and reiterates the need for PIs and staff members to assess their work for DURC potential.

Together, these training sessions allow all participants of the University of Chicago Select Agent Program to actively identify DURC.

For PI working with Botulinum toxin below the threshold quantity, DURC awareness training is included in the required training for working with Biological toxins.

11. Records

Records falling under the jurisdiction of the University of Chicago Select Agent Program (training, access, clearance, etc.) are kept for three years according to 42. CFR part 73.

Any other records related to DURC (RMP, assessment, meeting minutes, etc.) will be kept according to IBC and SA-IBC record keeping policy.

Additional information and training on DURC, the *September 2014 USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, the *March 2012 DURC Policy* or the *University of Chicago Office Oversight of Life Sciences Dual Use Research of Concern Policy* is available upon request to the University of Chicago Office of Research Safety (773-834-2707).

Dual-Use Research of Concern (DURC) Task Force Member Roster

1. Joseph Kanabrocki, Ph.D., N.R.C.M.(S.M.) R.O.
Associate Vice President for Research Safety, Professor of Microbiology.
Institutional Biosafety Committee, Select Agent Institutional Biosafety Committee,
Research Safety Policy Council, Committee on Radiation Safety.
2. Sean Crosson, Ph.D.
Professor, Department of Biochemistry and Molecular Biology. Committees on
Microbiology and Genetics, Genomics and Systems Biology.
3. Dave Pitrak, MD.
Professor of Medicine, Chief, Section of Infectious Diseases & Global Health,
Chair of the Institutional Biosafety Committee.
4. Gopal Thinakaran, Ph.D.
Professor of Neurobiology. Committee on Molecular Medicine/MPMM,
Committee on Cellular and Molecular Physiology, Committee on Neurobiology.
5. Michael R. Ludwig,
Associate Vice President for Research Administration & Director,
Research Safety Policy Council.
6. Russell J. Herron,
Senior Associate General Counsel. Select Agent Institutional Biosafety
Committee, the BSD Institutional Review Board, the IRB Council, the Clinical
Research Policy Board and its Executive Committee, and the University of
Chicago Medical Center Compliance Committee.
7. R. Allen Helm, Ph.D., R.B.P., A.R.O.
Biological Safety Officer. Institutional Biosafety Committee, Select Agent
Institutional Biosafety Committee.
8. Anthony Wang, Ph.D., C.B.S.P., A.R.O.
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Institutional Biosafety Committee
9. Nicholas Noriea, Ph.D., A.R.O.
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Institutional Biosafety Committee.