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# **POLICY**

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| **TITLE:** | **DUAL USE RESEARCH OF CONCERN (DURC)** |
| **Policy Number:** | **IBC2017-001** |
| **Responsible Department:** | **DURC Committee** |
| **Policy Contact:****Designation:****E-Mail:** | **Vishwanath Venketaraman, Ph.D.****Chair, DURC Committee****vvenketaraman@westernu.edu** |
| **Approval Date:** | **2/3/17** |

**Purpose of Policy:** To identify certain types of research that could be conducted for harmful as well as benevolent purposes, herein described as Dual Use Research of Concern (DURC), and mitigate risks where appropriate.

**Policy Information:** As defined by the United States Government [Policy](https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) for Institutional Oversight of Life Sciences Dual Use Research of Concern, hereafter designated “DURC Policy”, DURC is “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 DURC Policy requires that institutions within the United States that receive federal funds to conduct or sponsor life sciences research AND conduct or sponsor research that involves one of more of the 15 agents or toxins listed in Section 6.2.1 of the DURC Policy, even if the research is not supported by U.S. government funds, establish an Institutional Review Entity (IRE) empowered to execute the requirements in Section 7.2.B.i-iii, v and viii of the DURC Policy.

To meet these requirements, WesternU has established as its IRE the [DURC Committee](http://www.westernu.edu/research/regulatory-affairs/research-biosafety/bin/research/iacuc/durc_committee.pdf). Pursuant to the DURC Policy, the scope of the DURC Committee’s oversight authority is limited to the use of 15 specific agents and toxins and seven categories of experiments listed and described in Sections 6.2.1 and 6.2.2 of the DURC Policy, respectively.

To be effective and comply with regulations, cooperation between the Institutional Biosafety Committee (IBC) and the DURC Committee is essential. Towards this end, the following policy will be in effect.

**Policy:**

1. All protocols submitted to the Institutional Biosafety Committee (IBC) shall be reviewed to determine if the protocol utilizes any of the agents listed in Section 6.2.1 of the DURC Policy. If the protocol does not utilize any of the agents listed, the IBC shall proceed with the protocol review. If the protocol does utilize any of the agents listed, the IBC shall suspend further review of the protocol and notify the Principal Investigator (PI) that the protocol shall be referred to the DURC Committee for review.

2. Upon receipt of a protocol, the DURC Committee shall verify if the protocol utilizes one or more of the covered agents.

3. If the DURC Committee determines that the protocol utilizes one or more of the covered agents, the Committee shall review the PI’s assessment of whether or not the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed in Section 6.2.2 of the DURC Policy and make a final determination of their applicability. If the Committee determines that the research in question does not involve one or more of the categories of experiments detailed in Section 6.2.2 of the DURC Policy, the research is not subject to additional review or oversight by the DURC Committee as described below but shall continue to be assessed by the PI. The Chair of the DURC Committee shall notify, in writing, the Chair of the IBC of this determination and the IBC shall continue its review of the protocol.

4. If the research is determined to fall within the scope of the DURC Policy, the DURC Committee shall determine if the research meets the DURC definition, i.e. “…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.” If it is determined that the research does not meet the definition of DURC, the research is not subject to additional DURC Committee oversight. The Chair of the DURC Committee shall notify, in writing, the Chair of the IBC of this determination and the IBC shall continue its review of the protocol.

5. **Within 30 calendar days** of the DURC Committee’s review of the research for DURC potential, WesternU **shall notify the appropriate U.S. Government funding agency of the Committee’s findings**, including whether it meets or does not meet the definition of DURC. For non-U.S. Government-funded research, the results of the review process shall be submitted to the NIH Program on Biosecurity and Biosafety Policy at DURC@od.nih.gov. Notifications shall include the following:

 i. Grant or contract number (if funded by the U.S. Government)

 ii. Name(s) of PI(s)

 iii. Name(s) of the agent(s) or toxin(s) in question

iv. Description of why the research is deemed to produce one or more of the experimental

 effects listed in the DURC Policy

 v. Name(s) of the investigator(s), if different from the PI, responsible for the performance of

 the DURC

 vi. Description of the DURC Committee’s basis for its determination.

6. **Research that is determined to be DURC may not be conducted until a risk mitigation plan has been submitted by the PI to the DURC Committee for review and approval.**

7. **Within 90 calendar days** of a determination that the research is DURC, a draft risk mitigation plan shall be submitted to the U.S. Government funding agency for final review and approval. For non-U.S. Government-funded research, draft risk mitigation plans shall be provided to the NIH Program on Biosecurity and Biosafety Policy at DURC@od.nih.gov. Once the funding agency has approved the mitigation plan, the Chair of the DURC Committee shall so inform the Chair of the IBC, in writing, and provide the IBC with a copy of the plan. At this point, the IBC shall continue its review of the protocol.

8. All DURC shall be conducted in accordance with the approved risk mitigation plan which shall be reviewed at least annually and modified as the DURC warrants.

9. The funding agency or the NIH Program on Biosecurity and Biosafety Policy (DURC@od.nih.gov) shall be **notified within 30 calendar days** of any change in the status of a DURC project, including if the project no longer meets the definition of DURC, or if changes have been made to the risk mitigation plans as such plans must be approved by the appropriate agency.

10. The Institutional Contact for Dual Use Research (ICDUR) is the Vice President for Research and Biotechnology who responds to questions regarding compliance with, and implementation of, the DURC Policy and who serves as a liaison between WesternU and the relevant program officers at the funding agencies or at the National Institutes of Health (NIH).

11. Records of DURC Committee reviews and completed risk mitigation plans shall be maintained for the term of the research grant or contract plus three years after its completion but for no less than eight years unless a shorter period is required by law or regulation.

12. Education and training on DURC shall be provided for persons conducting life sciences research with one or more of the agents listed in Section 6.2.1 of the DURC Policy. Records of such education and training shall be maintained for the term of the research grant or contract plus three years after its completion.

13. Instances of noncompliance with the DURC Policy, as well as mitigation measures undertaken to prevent recurrences of similar noncompliance, shall be reported **within 30 days** to the funding agency or to the NIH Program on Biosecurity and Biosafety Policy (DURC@od.nih.gov).

14. A PI may **appeal** a decision regarding research that is determined by the DURC Committee to meet the definition of DURC by submitting, in writing, to the Committee Chair an explanation of why they believe that the proposal does not meet the definition of DURC. **The Chair shall respond to the PI, in writing, within 10 business days of the receipt of the appeal, of the Committee’s final decision.**

15. If a Federal department or agency passes through funding from another Federal department or agency to support research involving any of the agents covered by the DURC Policy, the original funding agency shall be considered the U.S. Government funding agency and the ultimate recipient of the funds shall be considered the institution and, respectively, shall fulfill the requirements expected of each under the DURC Policy.

16. In cases of collaborations involving multiple institutions via a sub-award, the primary institution is responsible for notifying the funding agency of research that falls within the scope of the DURC Policy and, if that research is determined to be DURC, providing copies of each institution’s risk mitigation plan to the appropriate agencies. The primary institution should ensure that DURC oversight is consistently applied by all entities participating in the collaboration.