UCLA Policy 995: Dual Use Research of Concern (DURC)

Issuing Officer:	Vice Chancellor for Research
Responsible Dept:	Office of Research Administration
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Supersedes:	New

I. PURPOSE & SCOPE

Dual use research refers to research conducted for legitimate purposes that can be utilized for both benevolent and harmful purposes. Effective oversight of dual use research involves identification of Dual Use Research of Concern (DURC) and its associated risks, and devising ways to mitigate these risks. The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (USG Policy) sets forth requirements for the ongoing review and oversight of DURC. The UC Office of the President has issued a DURC Policy for system-wide application of the USG Policy. This Policy incorporates and implements the UC and USG policies and outlines the responsibilities of those individuals and committees at UCLA who are accountable for executing the requirements of this Policy.

This Policy applies to Life Sciences research that involves the 15 agents and toxins and 7 categories of experimental effects of concern listed in this Policy.

II. DEFINITIONS

For the purposes of this Policy:

Dual Use Research of Concern (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, material, or national security.

Dual Use Review Entity (DURE) (referred to as "Institutional Review Entity" or "IRE" in the USG and UC policies) is a UCLA committee that establishes and implements internal policies and practices that allow for the identification and oversight of DURC and reviews proposed research that will utilize a DURC agent.

Institutional Contact for Dual Use Research (ICDUR) is an individual designated by the UCLA Vice Chancellor for Research to serve as point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between UCLA and the relevant USG funding agency.

Life Sciences are living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as aerobiology, agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, microbiology, synthetic biology, virology, molecular biology, environmental science, public health, modeling, engineering of living systems, and all applications of the biological sciences. The term is meant to encompass the diverse approaches to understanding life at the level of ecosystems, populations, organisms, organs, tissues, cells, and molecules.

Principal Investigator (PI) is an employee of UCLA (normally with an academic appointment), who is or becomes eligible under UCLA Policy 900, to submit a proposal for extramural support for a research, training, or public service project, who personally participates in the project to a significant degree, and who has primary responsibility for the scientific, technical, and administrative conduct, and reporting of the project, including financial matters. A Principal Investigator who is the head of a training or public service project may be known as a Project Director or Project Administrator.

III. POLICY STATEMENT

Research that uses any quantity of one or more of the agents or toxins listed below and produces, aims to produce, or can be reasonably anticipated to produce one or more of the effects of concern listed below, must be evaluated for DURC potential.

A. Agents and Toxins

1. Avian influenza virus (highly pathogenic)
2. Bacillus anthracis
3. Botulinum neurotoxin (in any quantity)
4. Burkholderia mallei
5. Burkholderia pseudomallei
6. Ebola virus
7. Foot-and-mouth disease virus
8. Francisella tularensis
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. Yersinia pestis

B. Categories of Experimental Effects of Concern

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. 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
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed under “Agents and Toxins,” above

UCLA has established the Dual Use Review Entity (DURE) and has appointed an Institutional Contact for Dual Use Research (ICDUR). Through the ICDUR, the DURE works with the PI to assess whether research that uses one or more of the agents or toxins also produces, aims to produce, or is reasonably anticipated to produce one or more of the seven categories of experimental effects of concern listed above.

For research anticipated to produce at least one of the seven effects, the DURE will conduct a risk assessment to determine whether the research meets the definition of DURC. Anticipated benefits of the research will be considered in conjunction with the previously identified risks in order to develop a draft risk mitigation plan to guide the conduct and communication of the DURC; this plan must be approved by the relevant USG funding agency, if applicable.

The ICDUR and DURE will adhere to the general procedures detailed in the UC DURC Policy and in compliance with the USG Policy.

IV. RESPONSIBILITIES

Principal Investigator (PI)

In accordance with the USG Policy, prior to initiating research, a PI is required to:

- Through the ICDUR, notify the DURE when the research involves one or more of the agents or toxins listed in Section III.A;
- Work with the DURE to determine if research produces one or more of the seven listed effects in Section III.B;
- Work with the DURE to assess the dual use risks and develop risk mitigation measures;
- Conduct DURC in accordance with the provisions in the risk mitigation plan;
- Be knowledgeable of, and comply with, all institutional, UC and USG policies, and requirements for DURC oversight;
- Ensure that laboratory personnel conducting DURC have received education and training on DURC as required by the DURE and any risk mitigation plans; and
- Following the above preparatory process, PIs must communicate DURC in compliance with the approved risk mitigation plan and maintain communication with the DURE related to any concerns or compliance with the approved mitigation plan.

Dual Use Review Entity (DURE)

Potential DURC will generally be identified during the UCLA Institutional Biosafety Committee (IBC) review process or via PI self-report. If research is determined to have a DURC potential, the ICDUR and DURE will implement the following steps:

- Notify the PI that the proposed work meets the criteria for DURC;
- Conduct a risk assessment on the proposed research;
- Develop a risk mitigation plan for the identified DURC using USG's risk mitigation template;
- Provide education and training for individuals conducting DURC, as needed;
- Review all active risk mitigation plans at least annually and modify as needed; and
- Maintain records of the institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years.

V. COMPLIANCE

As per the USG Policy, non-compliance with this Policy may result in suspension, limitation, or termination of USG funding, or loss of future USG funding opportunities for the non-compliant PI and of USG funds for other Life Sciences research at UCLA. Non-compliance may also subject UCLA to other potential penalties under applicable laws and regulations.

VI. REFERENCES

1. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. Release date: March 29, 2012;
2. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. Release date: September 24, 2015;
3. USG Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121);
4. Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern;
5. University of California – Policy: Dual Use Research of Concern;
6. UCLA Policy 900, Principal Investigator Eligibility.

Issuing Officer

/s/ James S. Economou

Vice Chancellor for Research

Questions concerning this policy or procedure should be referred to the Responsible Department listed at the top of this document.