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LAWRENCE BERKELEY NATIONAL LABORATORY DIRECTOR
MEDICAL CENTER CHIEF EXECUTIVE OFFICERS
VICE PRESIDENT--AGRICULTURE AND NATURAL RESOURCES

Dual Use Research of Concern Policy

Dear Colleagues:

Attached is the revised University of California Dual Research of Concern Policy. This policy shall apply to all research conducted at the University that may involve Dual Use Research of Concern (DURC), which is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be intentionally misused 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 policy was drafted by Academic Affairs and was widely distributed for comment and review.

The Dual Research of Concern Policy will be published online at http://policy.ucop.edu/ with an effective date of September 24, 2015.

Yours very truly,

Janet Napolitano
President

Attachment

cc: Division Leaders
Chief Human Resources Officers
Universitywide Policy Office

Dual Use Research of Concern

Responsible Officer:	Provost & EVP - Academic Affairs
Responsible Office:	RG - Research & Graduate Studies
Issuance Date:	9/24/2015
Effective Date:	9/24/2015
Last Review Date:	Not Applicable
Scope:	This Policy shall apply to all research conducted at the University that may involve Dual Use Research of Concern ("DURC"), which is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be intentionally misused 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. This Policy is intended to strengthen the University's institutional review and oversight of life sciences research to identify potential DURC, and to develop and implement risk mitigation where appropriate and as required by federal regulation. This Policy is intended to preserve the benefits of life sciences DURC while minimizing the risk that the output of such research could be used for harmful purposes.

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I. POLICY SUMMARY

This policy sets forth instructions for individuals and committees at the University of California who are responsible for the implementation of the University's requirements with respect to Dual Use Research of Concern ("DURC"). This policy is intended to strengthen the institutional review and oversight by the University of life sciences research to identify potential DURC and to develop and implement risk mitigation where appropriate, and as required by federal regulation. In so doing, this Policy is intended to preserve the benefits of life sciences DURC while minimizing the risk that the output of such research could be used for harmful purposes.

II. DEFINITIONS

A. **Dual Use Research**. Research conducted for legitimate purposes that can be utilized for both benevolent and harmful purposes.

B. **Dual Use Research of Concern ("DURC").** 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.[1]

C. **DURC Agents**: Agents and toxins specified by the U.S. Government as governed by its DURC policy. The below list of agents and toxins will be subject to revision to reflect future changes in federal DURC policy, but as currently defined, the following 15 agents and toxins, in any quantity, are governed by federal and University policy on DURC:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For 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.)

[1] The definition for Dual Use Research of Concern provided here is drawn from the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014) and what constitutes a "significant threat with broad potential consequences" is not further described in that policy, or in federal regulation. Under federal policy, the final determination of whether federally-funded life sciences research meets this definition will be made by the relevant U.S. Funding Agency on a case-specific analysis, and inconsideration of factors suggested at Section C.2.3 of the Companion Guide, and for *non*-federally-funded research, that determination will be made by the NIH.

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*

D. Experimental Effects of Concern: the following 7 categories of experiments:

1. Enhances the harmful consequences of the agent or toxin.
2. Disrupts immunity or 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 in the definition of DURC Agents above.

E. Principal Investigator. ("PI") A PI is an individual who is designated by UC to direct a project or program and who is responsible to the funding agency or UC for the scientific and technical direction of that project or program. There may be more than one PI on a research grant or project**.**

F. Institutional Review Entity ("IRE"). The campus committee charged with establishing and implementing internal policies and practices that allow for the identification and oversight of DURC, and that reviews proposed research that will utilize a DURC Agent. The committee shall be appointed by the Chancellor or Chancellor's designee and composed of 5 or more members, including at least 2 scientists with appropriate expertise, the campus ICDUR (defined below), the campus Biosafety Officer, and other members who can provide the IRE expertise with regard to ethics and compliance, export controls regulations and other know-how as determined by the campus.

G. Institutional Contact for Dual Use Research ("**ICDUR"):** The individual designated by the campus Chancellor or designee to be the institutional campus point of contact for researchers' questions relating to compliance with this Policy and to serve as the liaison with the relevant U.S. Government funding agencies.

H. **Risk Mitigation Plan**: A plan that describes the DURC-associated risks identified by the IRE, the specific risk mitigation measures to be employed, and how these measures address the identified risks.

I. **U.S. Funding Agency:** The U.S. Government agency that is funding the subject research. If a federal department or agency simply passes through funding from another federal department, agency or non-federal entity to support life sciences research involving one or more of the DURC Agents, the agency originally providing the funding shall be considered the U.S. Funding Agency. Where the agency providing funding is a non-federal entity NIH shall be considered the U.S. Funding Agency.

III. POLICY TEXT

PURPOSE AND SCOPE OF POLICY

A. Purpose

This policy is intended to comply with federal requirements for review of DURC to:

- strengthen the institutional review and oversight by the University of specifically defined life sciences research,
- identify potential DURC,
- develop and implement risk mitigation where appropriate,
- set forth instructions for individuals and committees at the University of California who are responsible for the implementation of the University's requirements with respect to DURC, and
- preserve the benefits of dual use life sciences research while minimizing the risk that the output of such research would be intentionally used for harmful purposes.

B. Scope

This policy shall apply only to life sciences research conducted at the University of California that may constitute Dual Use Research of Concern ("DURC").

C. Limitations

With regard to the implementation of federally required Risk Mitigation Plans (as defined) for DURC, a campus shall not implement a Risk Mitigation Plan that contains publication or citizenship[2] restrictions in violation of University policy.

[2] Please note that federal regulations may nonetheless impose citizenship restrictions. The DURC Agents specified under federal DURC policy are a subset of Select Agents, and there are some inherent citizenship restrictions in all Select Agent facilities. Each of the Select Agent regulations (42 CFR 73, 9 CFR 121 & 7CFR 331) require all

INVESTIGATOR RESPONSIBILITES

A. Before commencing research with DURC Agents, the Principal Investigator ("PI") shall must first make a determination about whether:
   1. The research directly involves non-attenuated forms of one or more of the potential DURC Agents; or
   2. The research with non-attenuated forms of one or more of the potential DURC Agents also produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or
   3. The PI concludes that his/her research may meet the definition of DURC. If research is determined not to meet the DURC criteria, it is the responsibility of the principal investigator to monitor his or her research on an ongoing basis and notify the IRE if anything changes that may alter the initial IRE determination.

B. The PI's assessment in regarding the above should be summarized in writing and this summary shall be registered and retained with the IRE via the ICDUR. The PI will provide the ICDUR with documentation in accordance with local campus policies and procedures, indicating the reasons for concluding that his/her research involves, or does not involve potential DURC, along with sufficient data to permit the IRE to complete the review required by Section IV., below.

C. If the IRE determines that the proposed research is DURC, the PI will be expected to:
   1. Collaborate with the IRE to develop the Risk Mitigation Plan.
   2. Conduct DURC in accordance with the final Risk Mitigation Plan (see section IV., below);
   3. Notify the ICDUR of any substantive change in the on-going conduct of the DURC;
   4. Notify the ICDUR if for whatever reason (e.g., changes in the research, new discoveries), he/she feels that the research should no longer be considered DURC;
   5. 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 research with one of more of DURC Agents have received appropriate education and training on DURC;

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individuals to obtain a FBI/CJIS Security Risk Assessment (SRA) to gain access to the facility. Among other reasons, the SRA approval will be denied if an individual is within the categories listed in 18 UCS 175b, one of which includes being an alien who is a national of a country as to which the Secretary of State has made a determination that the country has repeatedly provided support for acts of international terrorism. Therefore, currently, any individual who is a national or Iran, Sudan or Syria would be denied access to any Select Agent laboratory or its information simply by nature of their citizenship.

6. Be knowledgeable about and comply with all UC and federal policies and requirements for oversight of DURC; and
7. Communicate about the DURC in a responsible manner and in compliance with the approved risk mitigation plan.

CAMPUS/INSTITUTIONAL RESPONSIBILITIES

A. The campus shall ensure that no research with DURC Agents will be conducted unless the Principal Investigators conducting research with one of more of DURC Agents have received education and training on DURC. This education and training must be sufficient to allow them to undertake an initial assessment to determine whether the research they wish to undertake is potentially DURC.

B. Each campus shall establish the local IRE in compliance with this policy.

C. Each campus Vice Chancellor for Research shall designate an individual to serve as the ICDUR. The ICDUR will be the institutional point of contact for campus researchers' and administrators' questions relating to compliance with this Policy and will also be the liaison with the relevant U.S. Funding Agencies.

The ICDUR shall:

- As necessary, advise the PIs in conducting the life sciences research in accordance with federal and University policies when questions arise about whether their research may require further review of oversight as DURC.
- On behalf of the IRE, conduct an initial assessment of information provided by the PI to determine whether the research involves one or more of the 15 listed agents and if it involves one of the seven experimental effects.
- Upon determining that the research does involve one of the seven experimental effects, the ICDUR will notify the other members of the IRE which will then convene to assess the research to determine if it meets the DURC criteria. If the research is determined to not involve one of the seven experimental effects, the ICDUR will notify the IRE accordingly.
- Notify the relevant U.S. Funding Agency as to whether or not research involving one or more of the 15 agents and one or more of the seven experiments effects meets the definition of DURC within 30 calendar days.
- Ensure that the IRE reviews each DURC Risk Mitigation Plan annually;
- Ensure that education and training on DURC is available for individuals conducting research with one or more of the DURC Agents and that records of such education and training are retained for the term of the research grant or contract plus three years after its completion;
- Ensure that records of institutional DURC reviews and completed Risk Mitigation Plans are retained for no less than eight years, unless a shorter period is permitted by law or regulation;
- Notify the relevant Program Officer of the applicable U.S. Funding Agency within 30 calendar days of any change in the status of any DURC, including

whether such research has been determined by the IRE to no longer meet the definition of DURC. The notification should include details of any changes to an approved Risk Mitigation Plan, which must be approved by the U.S. Funding Agency.

- Report within 30 calendar days to the applicable U.S. Funding Agency instances of noncompliance with this Policy, as well as mitigation measures undertaken by the campus to prevent recurrences of similar noncompliance.
- Liaison with the National Institutes of Health ("NIH") on DURC that is non-federally-funded.
- Ensure that the campus can certify that it is, or will be, in compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern when applying for or accepting federal funding for life sciences research.

D. IRE Review Process

Based on the materials provided by the PI and ICDUR, along with any other relevant information, the IRE shall first determine whether the subject research directly involves non-attenuated forms of one or more of the DURC Agents.

Guidance on points to consider while making this assessment can be found in NIH's "Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the "Companion Guide"). The ICDUR may, on the IRE's behalf, consult the applicable U.S. Funding Agency or, if support for research does not come from a U.S. Funding Agency, consult the NIH Office of Biotechnology Activities, for advice about DURC.

In making its assessment, the IRE should examine descriptions of the research, the PI's assessment and other relevant information such as the project proposal, any project reports, any previous outcomes of Dual Use reviews and examples of similar research in the literature. When considering whether the research in question meets the definition of DURC, the IRE should identify the risks associated with the potential misuse of the knowledge, information, technologies or products (collectively, the "Research Output") that may be generated and assess the following:

- The ways in which the research output could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel or national security;
- The ease with which the research output might be misused and the feasibility of such misuse; and
- The magnitude, nature and scope of the potential consequences of misuse.

Guidance on points to consider while making this assessment can be found in the Companion Guide.

1. If the IRE determines the research is not DURC, the IRE Chair shall promptly advise the PI in writing that the research is not subject to DURC oversight under this policy or federal policy, and the ICDUR shall, within 30 days of the IRE's determination, notify the relevant U.S. Funding Agency.

2. If the IRE determines the research meets the definition of DURC, it will promptly so notify the PI and within 30 calendar days, the applicable US Funding Agency, and shall proceed to develop a Risk Mitigation Plan.

In order to determine the acceptable level of risk and the best mitigation strategies, the IRE should assess the potential benefits of the research and then weigh the risks and benefits.

The IRE may consider the PI's input in developing a draft Risk Mitigation Plan. The Plan should indicate the DURC-associated risks, the specific risk mitigation measures to be employed and how these measures address the identified risks. Strategies for mitigating risks[3] could include:

- Applying additional biosafety or biosecurity measures
- Modifying the experimental design or methodology
- Planning for medical countermeasures
- Educating and training research staff
- Developing a specific monitoring plan
- Not conducting certain aspects of the research, if doing so would result in a U.S. Funding Agency's imposition of publication or citizenship restrictions that contravene UC policy protecting freedom to publish or disseminate research results. For example, including such restrictions in a Risk Mitigation Plan could potentially jeopardize UC's Fundamental Research Exclusion (FRE) under export control regulations and require imposition of export controls requirements to the research, in violation of the above UC policies.

At the conclusion of its review of research that the IRE determines meets the definition of DURC, the IRE will submit its findings and its recommendations as to the elements of the draft Risk Mitigation Plan to the PI and to the Chancellor or designee.

Subject to locally established campus procedures, the PI shall have the right to make a timely appeal to the Chancellor or designee regarding the IRE's recommendation. In the event the PI appeals the IRE's recommendation, the

[3] Federal guidance on points to consider in drafting a Risk Mitigation Plan can be found in the Companion Guide.

Chancellor or designee shall be authorized to determine the merits of the PI's appeal and communicate that decision to the PI and the IRE.

The Chancellor or designee shall determine whether to act on the recommendations of the IRE, and is authorized to approve the institutional determination that the research is DURC and the institution's recommended Risk Mitigation Plan that are conveyed by the ICDUR to the U.S. Funding Agency. Within 90 calendar days following the final institutional approval of the draft Risk Mitigation Plan by the Chancellor or designee, the ICDUR shall submit such draft plan to the applicable U.S. Funding Agency for final review and approval. The ICDUR and the PI will respond to any questions or concerns that the U.S. Funding Agency may have regarding the draft Risk Mitigation Plan. Upon approval of the draft Plan by the U.S. Funding Agency, the IRE must communicate the final Risk Mitigation Plan to the PI and the ICDUR will collaborate with the PI to ensure its implementation.

For research determined to be DURC, the IRE shall review, at least annually, all active Risk Mitigation Plans at the University. In reviewing such Plans, the IRE will follow the guidance on points to consider in drafting a Risk Mitigation Plan that can be found in the Companion Guide. The IRE, working with the PI, shall modify the applicable Risk Mitigation Plan as needed to ensure that the Plan still adequately mitigates the risks associated with the DURC.

E. Subawards

Federal DURC policy requires that where elements of a potential DURC project are being carried out at multiple institutions through a subaward with a primary institution that directly receives the grant or contract from the U.S. Funding Agency, (the "Prime Institution"), the Prime Institution will be responsible for notifying the applicable U.S. Funding Agency of research that may constitute DURC and if such research is determined to be DURC, providing copies of each institution's Risk Mitigation Plan. The Prime Institution should also ensure that DURC oversight is consistently applied by all entities participating in the collaboration. If the Prime Institution's procedures or standards are less rigorous than the subawardee's, the more rigorous standard will be applied.

IV. COMPLIANCE / RESPONSIBILITIES

The campus Chancellor shall designate to the campus Vice Chancellor for Research responsibility for ensuring compliance with this policy.

V. PROCEDURES

Not Applicable

VI. RELATED INFORMATION

- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012) [http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf]
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014) [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf]
- Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the "Companion Guide") http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf.
- Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies http://www.phe.gov/s3/dualuse/Documents/12-case-studies-durc.pdf.
- Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf.
- National Institutes of Health ("NIH") Notice NOT-CD-15-017: NIH Implementation of the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern issued on November 21, 2014.

VII. FREQUENTLY ASKED QUESTIONS

Not Applicable

VIII. REVISION HISTORY

Issused as a new policy on September 24th, 2015.