POLICIES OF COLORADO STATE UNIVERSITY
UNIVERSITY POLICY

Policy Title: Dual Use Research of Concern
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Category: 7. Research

Policy Owner: Vice President for Research
Contact(s):
Research Integrity & Compliance Review Office (RICRO) Office of Research Collaboration and Compliance (ORCC)
Web: https://www.research.colostate.edu/ricro
https://www.research.colostate.edu/orcc/
Phone: (970) 491-1553

PURPOSE OF THIS POLICY
Despite its value and benefits, some research conducted for legitimate purposes may provide knowledge, information, products, or technologies that could be misused for harmful purposes. Such research is called “dual use research.” 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.” This Dual Use Research of Concern in the Life Sciences Policy articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level. Rand risk mitigation measures are implemented as necessary and consistent with the United States Government (USG) Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

APPLICATION OF THIS POLICY
This policy applies to all persons employed by or acting on behalf of the University.

DEFINITIONS USED IN THIS POLICY
“Dual use research” is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for both benevolent and harmful purposes.

“Dual use research of concern,” or “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.

“Institution” is Colorado State University.

“Institutional Contact for Dual Use Research,” or “ICDUR,” is a person designated by the institution to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of DURC as well as the liaison (as necessary) between the institution and the relevant federal funding agency.

“Institutional Review Entity” (IRE) is established by the institution to execute the requirements in the policy.

“Life sciences” pertains to living organisms (e.g., microbes, human beings, animals, and plants) and their products, including all disciplines and methodologies of biology such as agricultural science, plant science, animal science, bioinformatics, genomics, proteomics, synthetic 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 individual who is designated by the research institution to direct a project or program and who is responsible to the funding agency or the research institution for the scientific and technical direction of that project or program.

**POLICY STATEMENT**

Life sciences research performed at Colorado State University (CSU) is subject to institutional oversight. The purpose of this oversight is to preserve the benefits of such research while minimizing the risk that the knowledge, information, products, or technologies generated by DURC 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. As part of our institutional responsibility, CSU’s oversight complies with the March 2012 DURC Policy and the USG Policy for Institutional Oversight of Life Sciences DURC. Institutional oversight includes the identification of life sciences research
that raises dual use concerns as well as the implementation of measures to mitigate the risk that DURC may result in harm. Measures that mitigate the risks of DURC should be applied in a manner that minimizes, to the maximum extent possible, adverse impact on legitimate research, is commensurate with the risk, includes flexible approaches that leverage existing processes, and endeavors to preserve and foster the benefits of research.

**POLICY PROVISIONS**

**Applicability**

This policy and its oversight requirements apply to all life sciences research being performed at Colorado State University CSU, regardless of funding. Non-compliance with this Policy may result in suspension, limitation, or termination of life sciences research at the institution.

**Scope of Oversight Required Under this Policy**

1. **A. Covered agents and toxins (“CAT”)**

   2.1. Avian influenza virus (highly pathogenic)
   3.2. *Bacillus anthracis*
   4.3. Botulinum neurotoxin (in any quantity)
   5.4. *Burkholderia mallei*
   6.5. *Burkholderia pseudomallei*
   7.6. Ebola virus
   8.7. Foot-and-mouth disease virus
   9.8. *Francisella tularensis*
   10.9. Marburg virus
   11-10. Reconstructed 1918 Influenza virus
   12.11. Rinderpest virus
   13.12. Toxin-producing strains of *Clostridium botulinum*
   14.13. Variola major virus
   15.14. Variola minor virus
   16.15. *Yersinia pestis*
   17-16. Any other agent or toxin that may be identified by the USG Policy for Institutional Oversight of Life Sciences DURC

*Note: As scientific research and technologies continue to evolve, the definition of DURC may not be limited to the currently listed agents. In an attempt to be proactive, the Institutional Contact for Dual Use Research (ICDUR) may choose to classify other agents.*
and toxins or experiments for DURC review on a case-by-case basis, following a formal risk assessment. These agents will be classified as Institutional DURC, and may not require oversight by USG funding agency, as outlined in the policy.

B. Other Agents and Toxins (“OAT”)

1. Coronavirus
2. Rift Valley Fever
3. Chikungunya
4. African Swine Fever
5. Any other agents or toxins that may be identified by the CSU Vice President for Research for inclusion in this policy.

CB. Categories of experiments

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 above or creates a novel pathogen.

DC. Organizational Framework for Oversight of DURC

Generally, components of the oversight system for DURC include:

1. Identification by the Principal Investigator (PI) of life sciences research that falls within the scope of this policy;
2. An institutional review process for assessing whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed above, and, if so, determining whether the research meets the definition of DURC. This includes assessing the benefits and risks associated with its conduct and communication, developing a plan for mitigating identified risks, and ensuring that research is conducted in accordance with the risk mitigation plan;
3. Notification of the results of this review process and provision of the risk mitigation plan by the institution to the federal funding agency, or for non-federally funded research, to the National Institutes of Health (NIH) (which will receive for administrative purposes on behalf of all of the institution's federal funders) and annual assurance of compliance with the policy; and

4. Oversight by federal funding agencies and the USG as articulated in the *March 2012 DURC Policy* and the *USG Policy for Institutional Oversight of Life Sciences DURC*.

**Responsibilities of PIs**

PIs are to:

1. Notify the Institutional Review Entity as soon as:
   a. The PI’s research involves one or more of the agents or toxins covered by this policy;
   b. The PI’s research with one or more of the agents or toxins covered by this policy also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven effects listed in the experimental categories; or
   c. The PI’s research that is within the scope of this policy may meet the definition of DURC.

   **Note:** 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 the experimental categories.

2. Assess research for its DURC potential on an ongoing basis and notify the IRE when dual use concerns arise.

3. Work with the IRE to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures.

4. Conduct DURC in accordance with the provisions in the risk mitigation plan.

5. Be knowledgeable about and comply with all institutional and federal policies and requirements for oversight of DURC.
6. Ensure that laboratory personnel (e.g., graduate students, postdoctoral fellows, research technicians, laboratory staff, and visiting scientists) conducting research with one or more of the agents covered by this policy have received education and training on DURC.

7. Communicate DURC in a responsible manner. Be mindful that communication of research and research findings occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the risk mitigation plan approved by the appropriate federal funding agency.

Responsibilities of CSU

CSU will:

1. Establish and implement internal policies and practices that provide a mechanism for the identification and effective oversight of DURC.

2. When research is identified by a PI as utilizing one of the agents or toxins listed above, initiate an institutional oversight process that includes:
   
a. Verification that the research utilizes one or more of the agents or toxins listed above;
   
b. Determination of whether the research produces, aims to produce, or is reasonably anticipated to produce one or more of the effects listed above;
   
c. Determination of whether the research meets the DURC definition and is therefore DURC. If the institutional review determines that the research in question does not fall within the scope or does not meet the definition of DURC, the research can continue without additional DURC oversight;
   
d. Assessment of the dual use risks and the benefits of the research;
   
e. Development of a risk mitigation plan for DURC, as necessary;
   
f. Implementation of the risk mitigation plan. After a risk mitigation plan is developed, the research must be conducted in accordance with that plan and must be periodically reviewed by the institution to determine if additional modifications to the risk mitigation plan are appropriate. For research that has
been proposed but not yet initiated, the DURC component of the project should not be initiated until a risk mitigation plan is implemented;

g. Within 30 calendar days of the institutional review of the research for DURC potential, notification of the federal funding agency of any research utilizing a CAT that falls within the scope of the policy, including whether it meets or does not meet the definition of DURC. For non-federally funded research, notification may be made to NIH (which may in turn notify the appropriate federal funding agency, based upon the nature of the research); and

h. Within 90 calendar days from the time that the institution determined the research to be DURC utilizing a CAT, provide a copy of the risk mitigation plan to the funding agency for review – or for non-federally funded research, provision of the plan to NIH for review (or referral to the appropriate funding agency).

3. Ensure that internal policies establish a mechanism for the PI to refer a project to the IRE if, at any time, the PI’s work with one or more of the agents or toxins listed above also produces or can be reasonably anticipated to produce one or more of the seven effects listed above, or may meet the definition of DURC.

4. Designate the Vice President for Research as the Institutional Contact for Dual Use Research (ICDUR), as appointed by the Vice President for Research, to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of the policy and/or meets the definition of DURC. If questions arise regarding compliance, implementation of this policy, the USG Policy for Institutional Oversight of Life Sciences DURC, or the March 2012 DURC Policy, or when guidance is needed about identifying DURC or developing risk mitigation plans, the ICDUR serves as the liaison (as necessary) between the institution and the relevant program officers at the federal funding agencies, or for non-federally funded research, between the institution and NIH (or the appropriate federal funding agency to which NIH refers the institution).

5. Establish an Institutional Review Entity (IRE) to execute the requirements. The CSU extant committee (the Institutional Biosafety Committee [IBC], whose constitution meets the requirements outlined below), shall serve as the IRE. The IRE shall:

a. Be sufficiently empowered by the institution to ensure compliance with the institution’s dual use research policies.

b. Have sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility.
IRE members will be appointed by the Vice President for Research for three-year terms and may be reappointed. The committee will be comprised of at least five members, including the following roles:

i. **Core voting members:** ICDUR (serving as IRE Chair), Institutional Biosafety Committee (IBC) Chair, Select Agent Responsible Official (RO), and may include a Virologist, Bacteriologist, and/or Immunologist.

ii. **Ad hoc Consultants:** Based on the nature of the proposed research, the IRE may choose to include various subject matter experts (SMEs) in the review process. SMEs may include, but are not limited to, experts from the following fields:


b. Have knowledge of dual use issues, concerns, and related institutional and federal policies and understand risk assessment and risk management considerations. The review entity should be aware that a variety of risk mitigation measures are available and that designating research as DURC does not necessarily mean that the research should not be conducted or communicated.

c. Make its procedures for reviewing life sciences research for dual use potential accessible to the public. The posted policies of the institution should include an overview of the institution's procedures or review process but should not include details of particular cases or the minutes of the DURC review entity's proceedings.

d. On a case-by-case basis, recuse any member of the IRE 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.

e. Engage in an ongoing dialogue with the PI of the research in question when developing appropriate risk mitigation plans.

f. Maintain records of institutional DURC reviews and completed risk mitigation plans for three years.

6. Provide education and training on DURC for individuals conducting life sciences research that falls within the scope of this Policy. Institutions may also wish to
address dual use topics in existing courses on research ethics or the responsible conduct of research.

7. Maintain records of personnel training on dual use research for three years.

8. Report instances of noncompliance with this Policy, as well as mitigation measures undertaken by the institution to prevent recurrences of similar noncompliance, within 30 calendar days to the Federal funding agency or, for non-Federally funded research, to NIH (which will receive for administrative purposes on behalf of all of the institution’s Federal funders). Such notice is required for a non-compliance involving a CAT but optional for a non-compliance involving an OAT but optional for non-compliance involving institutional DURC.

9. As necessary, assist the PIs of life sciences research when questions arise about whether their research may require further review or oversight.

10. Establish an internal mechanism for PIs to appeal institutional decisions regarding research that is determined by the institutional review entity to meet the definition of DURC.

11. On an annual basis, provide a formal assurance to the Federal funding agencies that the institution is in compliance with all aspects of this Policy.

**COMPLIANCE WITH THIS POLICY**

Failure to comply with this Policy subjects the individual to potential criminal and civil penalties as well as University sanctions. Violations also subject the University to potentially serious sanctions, including loss of federal funding, and monetary penalties. The Research Integrity and Compliance Review Office (RICRO) Office of Research Collaboration and Compliance (ORCC) will facilitate compliance through management and administration of standard operation procedures drafted and approved by the IRE.

**REFERENCES**

[USG Policy for Institutional Oversight of Life Science Dual Use Research of Concern](https://example.com) – released September 24, 2014

[United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern](https://example.com) (“March 2012 DURC Policy”)

[Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Research of Concern](https://example.com)
Department of Health and Human Services (DHHS) general information on the USG Dual Use Research Policy

Institutional Biosafety Committee

Biosafety Office

CDC Biosafety in Microbiological and Biomedical Laboratories

CSU Policy: Export Control Policy

IBC Dual Use Research of Concern (DURC)

PROCEDURES, FORMS AND TOOLS

Institutional forms and procedures for review of research with DURC potential at CSU are available on the CSU/IBC DURC webpage.

A Companion Guide, entitled Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern, has been developed by the NIH.

APPROVAL

Approved by Anthony A. Frank, President, September 18, 2015

Revision approved by Lynn Johnson, Vice President for University Operations on February 17, 2020

Revision approved by Brendan Hanlon, Vice President for University Operations on