IOWA STATE UNIVERSITY
DUAL USE RESEARCH OF CONCERN
PROGRAM

I. BACKGROUND

”Dual use research is defined by the United States Government as “research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.” Dual use research of concern is a subset of this broader category. Dual use research of concern (DURC)is 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, material, or national security.” These definitions could potentially encompass a number of life sciences research projects at Iowa State University; however, the current scope of the policy has been limited to the specific agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and a listed category to be deemed DURC.”(1)

On March 29, 2012, the United States Government (USG) released the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) policy to establish the requirements for the oversight of DURC by the USG. On September 24, 2014, the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (the “2014 Policy”) policy was released to establish the requirements for institutional (i.e., non-USG) oversight of DURC. The USG considers these two policies to be complementary.

The following additional USG documents have been issued in connection with the 2014 Policy and provide guidance in understanding the regulations:

- Attachment A: Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern (the “Companion Guide”)
- Attachment B: Implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences DURC: Case Studies.
- Attachment C: Training on the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
- Attachment D: 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.

II. PURPOSE

The purpose of this Program is to evaluate the potential for and to mitigate risks associated with Dual Use Research of Concern (DURC) in Iowa State University (ISU) research programs. This is achieved by institutional review and oversight of current and proposed research at ISU to identify potential DURC and implementing risk mitigation where appropriate. This Program provides instructions for individuals and committees at ISU that are responsible for the implementation of the University’s requirements with respect to DURC. All research conducted at the University involving DURC Agents (as defined in Section III below) are subject to this Program, regardless of the source of funding.

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III. DEFINITIONS

For purposes of this Program, certain terms are defined as follows:

Dual Use Research: 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.

DURC: Dual use research of concern.

DURC Agents: the following 15 agents and toxins referred to in the 2014 Policy:

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For purposes of this Program, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
4. *Burkholderia mallei*
5. *Burkholderia pesudomallei*
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*

Experimental Effects of Concern: the following 7 categories of experiments referred to in the 2014 Policy:

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.

IBC: the Iowa State University Institutional Biosafety Committee

ICDUR: Institutional Contact for Dual Use Research, the individual designated by the University to be the institutional point of contact for questions relating to compliance with this Program and the liaison with the relevant funding source. The University has designated the Responsible Official (RO) as the ICDUR.

IRE: Institutional Review Entity

IV. PROGRAM REQUIREMENTS FOR PRINCIPAL INVESTIGATORS

A Principal Investigator (PI) must submit for institutional review his/her research that meets any of the following criteria:

- The research directly involves non-attenuated forms of one or more of the DURC Agents;
- The research with non-attenuated forms of one or more of the DURC Agents that also produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or
- The PI concludes that his/her research may meet the definition of DURC.

If a PI's proposed research meets any of the foregoing criteria, s/he will also assess whether the research produces, aims to produce or is reasonably anticipated to produce one or more of the Experimental Effects of Concern.

The ISU IBC application form and continuing/modification review application form (http://www.compliance.iastate.edu/ibc/forms/) contains screening questions pertaining to DURC.

V. POLICY REQUIREMENTS FOR INSTITUTIONAL REVIEW

The 2014 Policy requires an institution to designate a committee to execute the institutional review of potential DURC Research. At ISU, the DURC review is made up of two committee components: (1) the IBC and (2) IRE established by the Vice President for Research (VPR). The roles of the IBC and the IRE are delineated below.

1. Review by the IBC or the IBC Office

The first step of the review process is to verify that the research directly involves non-attenuated forms of one or more of the DURC Agents based on the information provided by the PI and any other relevant materials.

If it is concluded that the research does involve DURC Agents, the VPR will be notified for continuation of progress outlined in section 2 below. The PI will be notified of this determination.

The IBC will review any protocols that involve DURC Agents.

2. Review by the IRE and the VPR

After notification the Assistant Vice President for Research (AVPR), the AVPR will convene the IRE, whose members will include the IBC Chair, the RO/ICDUR, Biosafety Officer, Office for Responsible Research Director, Export Control Officer, and 2–3 selected faculty members with expertise in the area of the research. The choice of faculty members will be made by the Assistant Vice President for Research in consultation with the PI and the IBC Chair.

The first step of the IRE review process is to assess the risks of dual use and confirm whether the research is DURC. In so doing, it should examine descriptions of the research, the PI's assessments 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 will first identify the risks associated with the potential misuse of the knowledge, information, technologies or products (collectively, the "Research Output") that may be generated and will assess the following:

- The ways in which the Research Output could be misused to harm public health and safety, agriculture, plants, animals, the environment, material 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 Attachment A: Companion Guide. The applicable Funding Source may be consulted for advice.

If the IRE determined that the subject and aims of the research do meet the definition of DURC, the ICDUR will notify the PI promptly and, within 30 days will notify the applicable Funding Source. The initial notification to the Funding Source will include: the grant or contract number related to the USG-funded research; the name(s) of PI(s); the name(s) of the agent(s) listed in Section 3 of this program; and a description of why the research is deemed to produce one or more of the experimental effects listed in Section 3 of this program. The ICDUR shall also notify the Funding Source within 30 days of any determinations for these projects, including whether or not they meet the definition of DURC. Notifications for those projects deemed to meet the definition of DURC should include: the name of the investigator (if different from the PI) responsible for the performance of the DURC; and a description of the IRE's basis for its determination. If the IRE determines that the subject and aims of the research does not meet the definition of DURC, it is not subject to additional institutional oversight.

In order to determine the acceptable level of risk associated with the DURC and the best mitigation strategies, the IRE should assess the potential benefits of the Research and then weigh the risks and benefits. Guidance on points to consider in making this assessment can be found in Attachment A: Companion Guide.

The next step for the IRE is to develop a draft risk mitigation plan (the "Risk Mitigation Plan") in consultation with the PI. 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 include:

- Applying additional biosafety or biosecurity measures

- Modifying the experimental design or methodology
- Planning for medical countermeasures
- Determining a plan for responsibly communicating the research findings
- Educating and training research staff
- Developing a specific monitoring plan
- Not conducting certain aspects of the research

Guidance on points to consider in drafting a Risk Mitigation Plan and in creating a responsible communication plan can be found in Sections D and F of the Companion Guide. The applicable Funding Source may also be consulted for advice. At the conclusion of its review, the IRE will submit its findings and its recommendations on the elements of the draft Risk Mitigation Plan to the Assistant Vice President for Research. The Assistant Vice President for Research will decide whether or not to act on the recommendations of the IRE on whether the research constitutes DURC and the adequacy of the Committee's draft Risk Mitigation Plan. At this point, the Assistant Vice President for Research may require revisions to the draft Plan. The Assistant Vice President for Research's decision and any other institutional decision(s) regarding DURC may be appealed by the affected PI to the VPR.

3. Notification to the Funding Source

Within 90 calendar days following the final institutional approval of the draft Risk Mitigation Plan by the VPR, the ICDUR shall submit such draft Plan to the applicable Funding Source for final review and approval. The Funding Source must provide an initial response within 30 calendar days following receipt of the draft Plan. The ICDUR and the PI will work with the Funding Source to respond to any questions or concerns it may have regarding the draft Risk Mitigation Plan. The Funding Source must finalize the Plan within 60 days following receipt of the draft Plan. The VPR must also approve the final Risk Mitigation Plan.

4. Sub-awards

If elements of a potential DURC research project are being carried out at multiple institutions through a sub-award with a primary institution that directly receives the grant or contract from the Funding Source (the "Prime Institution"), the Prime Institution will be responsible for notifying the applicable Funding Source of research that may constitute DURC. If such research is determined to be DURC, the Prime Institution will obtain copies of each institution's Risk Mitigation Plan in order to review and send to the Funding Source. The Prime Institution should also ask that the level of DURC oversight is consistently applied by all entities participating in the collaboration. For example, if the Sub awardee Institution's procedures or standards are less rigorous than that of ISU, the more rigorous standard will be identified by ISU and asked to be applied by all parties in the agreement.

VI. ONGOING INSTITUTIONAL RESPONSIBILITIES

1. Responsibilities of the PI

The PI will:

- Conduct DURC Research in accordance with the final Risk Mitigation Plan;

- Notify the ICDUR of the addition of any DURC Agents or Experimental Effects of Concern, or any other substantive change in the conduct of the DURC Research;
- Notify the IBC if for whatever reason (e.g., changes in the research, new discoveries), s/he feels that the research should be reconsidered by the IBC because it might *constitute DURC, or is no longer DURC;*
- 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 education and training on DURC;
- Obtain FBI clearance for PI and staff if not already in place.

2. Responsibilities of the ICDUR

The ICDUR shall:

- Ensure that the IRE reviews each DURC Research Risk Mitigation Plan annually;
- Provide education and training on DURC for individuals conducting research with one or more of the DURC Agents and maintain records of such education and training for the term of the research grant or contract plus three years after its completion;
- Maintain records of institutional DURC reviews and completed Risk Mitigation Plans for no less than eight years, unless a shorter period is required by State law or regulation;
- Report DURC determinations of agent and category criteria to the Funding Source within 30 days.
- Notify the applicable Funding Source 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 Funding Source; and
- Report within 30 calendar days to the applicable Funding Source instances of noncompliance with this Program, as well as mitigation measures undertaken by the University to prevent recurrences of similar noncompliance.

3. Responsibilities of the IRE

The IRE shall review, at least annually, all active Risk Mitigation Plans at the University. If the research in question still constitutes DURC, the IRE, working with the PI, should modify the applicable Risk Mitigation Plan as needed to ensure that the Plan still adequately mitigates the risks associated with the DURC.

Attachment A: 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

Attachment B: 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

Attachment C: 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

Attachment D: 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.
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-017.html

REFERENCES

1. University of Kentucky Institutional Biosafety Committee Proposed Plan for Compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, 2015.