Official Memorandum of Action – MOA-16/12
Acceptance of the Dual Use of Research Concern Policy

Approval Date
19 May 2016

Implementation Date
Upon Administrative Approval

Name of Council/Committee
Research Policies Council

RECOMMENDATION:
Accept the Dual Use of Research Concern Policy as drafted by the Office of the Vice President for Research on May 12, 2016.
(see attached)

☑ Approve
☐ Disapprove
☐ Return to Council/Committee

Comments:

Paul Ciccarelli, Chair, Research Policies Council
5/19/16

☑ Approve
☐ Disapprove
☐ Other action

Comments:

Suzan F. Ayers, Faculty Senate President
8/12/16

☑ Approve
☐ Disapprove
☐ Other action

Comments:

Timothy J. Greene, Provost and Vice President for Academic Affairs
8/27/16

John M. Dunn, WMU President
8/30/2016

Received - 9/16

RECEIVED
AUG 31 2016
WMU PROVOST & ACADEMIC AFFAIRS
Western Michigan University

Dual Use of Research Concern Policy

Office for the Vice President of Research

August 29, 2016
Dual Use of Research Concern Policy

BACKGROUND AND PURPOSE

Dual use research is considered any legitimate research that generates new knowledge, information, technologies, or products that could be used for both benevolent and malevolent purposes. The U.S. Government further defined dual use of research concern (DURC) 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.”

The United States Government (USG) has adopted a policy of Dual Use of Research Concern that defines explicit guidelines for conducting and overseeing this type of research. On March 29, 2012, the USG released the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern [http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf] that established 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 [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf] was released that established the requirements for institutional (i.e., non-USG) oversight of DURC. According to the USG, these two Policies are to be seen as complementary to one another.

The purpose of this Policy is to lay out the processes that make up the institutional review and oversight by Western Michigan University of certain research to identify potential DURC and to develop and implement risk mitigation plans as needed. This Policy seeks to enable and preserve the benefits of life science DURC research while minimizing risks associated with the output of such research to the greatest extent possible. This Policy sets forth explicit instructions and guidance for individuals and committees at Western Michigan University who 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 Definitions section below) is subject to this Policy, regardless of the source of funding.

DEFINITIONS

Dual Use Research: Any legitimate research that generates new knowledge, information, technologies, or products that could be used for both benevolent and malevolent purposes.

Dual Use of Research 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.
**DURC Agents:** The following 15 agents and toxins referred to in the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern:

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

**Experimental Effects of Concern:** The following 7 categories of experiments referred to in the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern:

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.

**Institutional Biosafety Committee (IBC):** Western Michigan University’s Institutional Biosafety Committee.

**Institutional Contact for Dual Use Research (ICDUR):** The individual designated by the University to be the institutional point of contact for questions relating to compliance with this Policy and the liaison with the relevant USG funding agencies. The University has designated the Associate Vice President for research, Associate Director Research Compliance, and the Chair of the IBC together as the ICDUR.

**Institutional Review Entity (IRE):** Western Michigan University’s IRE is comprised of the Chair of the IBC, the Vice Chair of the IBC, the Associate Director of Research Compliance, the Associate Vice President for Research, the University Radiation Officer, and the Director of Environmental Health and Safety.
U.S. Funding Agency: The USG agency that is funding the subject research, or, if the research is not USG-funded, the USG agency designated by the NIH, based on the nature of the research. If a federal department or agency simply passes through funding from another federal department or agency to support life sciences research involving one or more of the DURC Agents, the agency originally providing the funding shall be considered the US Funding Agency.

POLICY REQUIREMENTS FOR THE PRINCIPAL INVESTIGATOR

Please see Appendix A for a detailed process chart developed by the USG [http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf]. The USG specifies that it is the responsibility of the Principal Investigator (PI) to submit for institutional review if any of the following criteria are met:

1. The PI’s research directly involves nonattenuated forms of one or more of the listed agents;
2. The PI’s research with nonattenuated forms of one or more of the listed agents also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects; or
3. The PI concludes that his or her research with nonattenuated forms of one or more of the listed agents that also produces, aims to produce, or can be reasonably anticipated to produce one or more of the seven listed experimental effects may meet the definition of DURC and should be considered (or reconsidered) by the IRE for its DURC potential.

If the Principal Investigator’s research meets any of the aforementioned criteria, he/she will notify the Institutional Review Entity (IRE) immediately, by contacting the Associate Director Research Compliance. The Principal Investigator will provide the Associate Director Research Compliance with documentation on how the determination of DURC was concluded. Additionally, the Principal Investigator will include all relevant data to assist the IRE in making a determination about DURC.

POLICY REQUIREMENTS FOR INSTITUTIONAL REVIEW

The overall process of the Institutional Review Entity consists of six steps which are described in detail below:

1. Verify the use of a nonattenuated agent.
   - The first step in review is to determine if one or more of the nonattenuated agents listed above are being used in the current research documents. If they are not, the research is not subject to additional institutional DURC oversight, and the entity does not need to continue with the assessment. If an agent is being considered for use, the IRE would continue with additional institutional review.

2. Review the PI’s assessment and determine if proposed research constitutes DURC.
   - The IRE will review the submitted materials and determine if the research produces, aims to produce, or is reasonably anticipated to produce one or more of the experimental effects listed above. At any time, the IRE can request additional information from the PI to help with the determination. If none of the listed experimental effects apply, the research is not subject to additional institutional DURC oversight, and the entity does not need to continue with the assessment.
3. Conduct a risk assessment to determine whether the research meets the definition of DURC.
   • The IRE will review the submitted materials to determine the level of risk associated with the project. The project will be assessed for:
     o The ways in which knowledge, information, technologies, or products from the research could be misused to harm public health and safety, agriculture, plants, animals, the environment, materiel, or national security.
     o The ease with which the knowledge, information, technologies, or products might be misused and the feasibility of such misuse.
     o The magnitude, nature, and scope of the potential consequences of misuse.
   • If the IRE determines the submitted project does not meet the definition of DURC, the research is not subject to additional institutional DURC oversight, and the entity does not need to continue with the assessment. If the IRE determines the research is DURC, as defined in the Policy for Institutional DURC Oversight and the March 2012 DURC Policy, it is subject to additional DURC oversight. The IRE will notify the USG funding agency within 30 days of the review.

4. Assess the benefits of DURC.
   • The IRE will determine potential benefits associated with the research. The IRE will use this information to aid in the development of the risk mitigation plan.

5. Develop a draft of the risk mitigation plan.
   • After reviewing both risks and benefits of DURC, the IRE will develop a risk mitigation plan. The mitigation plan will be submitted to the USG funding agency within 90 calendar days from the IRE DURC determination.
   • Section D.2 of the DURC companion guide suggests several strategies for mitigating risks:
     o Determine whether current biosafety measures are adequate.
     o Determine the applicability of existing countermeasures.
     o Develop a plan for responsibly communicating the findings of DURC.
     o Educate and train staff using available DURC educational tools.
     o Develop a plan for monitoring the DURC.
     o Do not conduct certain aspects of the DURC.

6. Review, at least annually, all active mitigation plans.
   • The IRE will review all active mitigation plans annually. Additionally, the IRE will report any changes in the status of the DURC project and/or any changes to the mitigation plan. Changes to the mitigation plan must be approved by the USG funding agency prior to implementation. Any changes will be reported to the USG funding agency within 30-calendar days of receiving the request of change and/or initial approval of the change from the IRE.

**ONGOING RESPONSIBILITIES**

**Responsibilities of the Principal Investigator**

- Conduct research in accordance with the mitigation plan.
- Notify the ICDUR of any additions to the research protocol including, but not limited to, use of additional nonattenuated agents, changes to the research protocol, inclusion of additional anticipated experimental effects, and any other substantive changes of the DURC research.
• Ensure all laboratory personnel are provided with adequate training and education of DURC research policies, as well as appropriate supervision of all research activities.
• Contact the IRE is at any time he/she feels research may be considered DURC, or may no longer be considered DURC.

Responsibilities of the Institutional Review Entity (IRE)

• The IRE will review, at least annually, all active risk mitigation plans at Western Michigan University. This review will consist of the abovementioned steps of initial review to continually assess the current state of the DURC, and, if needed, modify the risk mitigation plan to ensure it adequately mitigates the risks associated with the DURC to the greatest extent possible.

Responsibilities of the Institutional Contact for Dual Use Research (ICDUR)

• Ensure that the IRE reviews every mitigation plan at least annually.
• Provide education and training on DURC for researchers conducting research with one or more DURC agents, and maintain the records of such trainings for the duration of the granting term and three years following the close of the project.
• Maintain the records of institutional DURC reviews and completed risk mitigation plans for a minimum of eight years in total. All DURC reviews and mitigation plans must be maintained for at least three years following the close of the project.
• Notify the USG funding agency within 30 calendar days of any changes made to the DURC research protocol or risk mitigation plan. Similarly, the ICDUR will contact the USG funding agency if said research no longer qualifies as DURC within 30 calendar days of the determination.
• Report to the USG funding agency any instances of non-compliance or deviations from the current policy or risk mitigation plan within 30 calendar days of said instance of non-compliance. The ICDUR will work in conjunction with the IRE to determine future measures to avoid situations of non-compliance in the future.

For any additional information, or question about Dual Use Research, please contact the Institutional Contact for Dual Use Research at research-compliance@wmich.edu.
Appendix A: Process Flow Chart

Process for Institutional Review of Life Sciences Research within the Scope of the Policy

PI notifies the IRE as soon as:
- PI's research involves any of the agents listed in Policy Sec. 6.2.1
- PI's research with one or more of the above agents also produces or can be reasonably anticipated to produce one or more of the effects listed in Policy Sec. 6.2.2; or
- PI's research that meets the criteria in Policy Sec. 6.2 may meet the definition of DURC.
(Policy Sec. 7.1.A; CG Sec.B)

IF YES to any

Institution identifies whether USG funding agency has notified the Institution that the research is DURC under the March 2012 DURC Policy (Policy Sec. 7.2.B)

IF NO

IRE verifies that the research involves any of the listed agents, reviews PI's assessment, and makes final determination of the applicability of the list of experimental effects (Policy Sec. 6.2 and 7.2.B.1 -- II; CG Sec. C)

IF YES to both

IRE conducts a risk assessment to determine whether the research meets the definition of DURC
(Policy Sec. 4.C and 7.2.B.1ii; CG Sec. C)

IF NO

The research requires oversight under the Policy: IRE considers the previously identified risks and the anticipated benefits in order to develop a draft risk mitigation plan (Policy Sec. 7.2.B.v, CG Sec. C and D)

Institution works with the USG funding agency to complete the draft risk mitigation plan within 90 calendar days of the IRE's determination that the research is DURC (Policy Sec. 7.2.B.v -- VI; CG Sec. D)

USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan (Policy Sec. 7.2.B.vi)

Institution implements approved risk mitigation plan and provides ongoing oversight of DURC (Policy Sec. 7.2.B.vii -- IX; CG Sec. E)

PI conducts and/or communicates research according to risk mitigation plan (Policy Sec. 7.1; CG Sec. F)