CORNELL UNIVERSITY POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN

Effective date: Sept 24, 2015

Contents

1. Purpose

Despite its value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called Dual Use Research. Dual Use Research of Concern (DURC) is a subset of Dual Use Research and 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, materiel, or national security."

Cornell University is committed to conducting research with potential DURC agents in a manner that preserves the benefits of life sciences DURC research while minimizing the risk that the output of such research would be used for harmful purposes, and in full compliance with the rules and regulations governing the use of these agents. This Policy outlines the principles and procedures for institutional review and oversight by Cornell University ("Cornell" or the "University") of research identified as potential DURC and to develop and implement risk mitigation where appropriate.

2. Scope of Research covered under the policy

This policy applies to research that involves both (1) one or more of the 15 agents or toxins listed in the

HHS Policy (the "DURC Agents") and (2) must produce, aim to produce, or can be reasonably anticipated to produce one or more of the 7 categories of experiments listed in the Health and Human Services (HHS) Policy (the "DURC Experiments"). (See lists below)

3. Background

On March 29, 2012, the U. S. Government (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] 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") [http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf] 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 that have been issued in connection with the 2014 Policy and provide guidance in understanding the regulations:

- 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.

See also the 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

4. Definitions

Dual Use Research of Concern (DURC) Agents: 15 agents and toxins referred to in the 2014 DURC USG Policy[1]:

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.)
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*

[1] http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

Experimental Effects of Concern: The following 7 categories of experiments referred to in the 2014 USG DURC 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 Cornell University Institutional Biosafety Committee

IRE: Institutional Review Entity

ORIA: Office of Research Integrity and Assurance

ICDUR: Institutional Contact for Dual Use Research, who is 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 Institutional Official for the IBC, who is also the Senior Vice Provost for Research, as the ICDUR.

US 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.

Select Agent Program: Cornell University has a Select Agent Program. Since all the DURC agents are also Select Agents, this policy complements the controls and structures, already established in Cornell's Select Agent Program, with the DURC specific requirements.

5. Responsibilities of PIs

- Notify the IBC when the research involves one or more of the agents or toxins listed[2].
- Work with Biosafety Officer and IBC to determine if research produces one or more of the seven listed effects[2]
- Work with the IBC 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 and USG policies and requirements for DURC oversight.
- Ensure that laboratory personnel conducting DURC have received education and training.

6. Responsibilities and Review Process of the IBC

During the initial IBC protocol review/assessment process, the IBC will determine if any of the PI's proposed work meets the criteria for DURC. If the IBC deems any research to fall under DURC oversight, the following steps will be implemented:

- Notify the PI that the proposed work meets the criteria for DURC.
- Notify the USG of the proposed work[3]

[2] http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

[3] *Notification template on Page 49 of: http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf*

- Conduct a risk assessment on the proposed research using USG's risk assessment template.[4]
- Develop a risk mitigation plan for the identified DURC using USG's risk mitigation template.[5]
- Provide education and training for individuals conducting DURC, as needed.
- Review all active risk mitigation plans at least annually. If the research still constitutes DURC, the IBC should modify the plan as needed.
- 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.

7. Risk Mitigation Measures

- Consider changing the timing, mode, or venue of communication for DURC to outside entities.
- Establish a mechanism for pre-publication or pre-communication review by the institution and/or appropriate USG funding.
- Consider the need to redact specific information in light of security concerns.
- When communicating the DURC, emphasize the biosafety and biosecurity measures that were in place throughout the course of the research.
- Emphasize the public health or broader significance of the DURC. For example, describe specifically how the findings inform the development of countermeasures, disease surveillance, preparedness, and response efforts.
- Provide additional training that addresses risks or concerns that are unique to the DURC in question.
- Require that research staff receive refresher training on a more frequent basis rather than the required annual refresher training.
- Review the DURC in question at more frequent time intervals.

8. Notification to the USG and Finalization of the DURC Risk Mitigation Plan

Within 90 calendar days following the final institutional approval of the draft Risk Mitigation Plan by the IBC, the ICDUR shall submit such draft Plan to the applicable USG Funding Agency for final review and approval[6]. The USG Funding Agency must provide an initial response within 30 calendar days following receipt of the draft Plan. The ICDUR and the PI will work with the USG Funding Agency to respond to any questions or concerns it may have regarding the draft Risk Mitigation Plan. If research is funded by a USG Funding Agency, it must finalize the Plan within 60 days following receipt of the draft Plan. The IBC must also approve the final Risk Mitigation Plan. DURC research may begin only after (1) the USG funding agency, and the IBC have granted approvals, and (2) the necessary permits have been issued by the USDA and any other regulatory agency for the use of the Select Agent and the RO has determined that the research can begin.

9. **Subawards**

If elements of a potential DURC Research project are being carried out at multiple institutions through a subaward with a primary institution that directly receives the grant or contract from the US Funding Agency (the "Prime Institution"), Cornell will notify the applicable US 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. If Cornell's procedures or standards are less rigorous than the subawardee's, or vice versa, the more rigorous standard will be applied.

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[4] Page 66 of the document: http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

[5] Page 35 of the document: http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

[6] Appendix 4 of this document: http://www.phe.gov/s3/dualuse/Documents/durc-companion-guide.pdf

Appendix 1

Cornell University's framework for the review, approval and ongoing management of research that is potentially Dual Use Research of Concern (DURC)

PI Self Assessment Step 1:
Does the research involve any of the 15 agents listed in the DURC policy?

No → Not a select agent. PI should follow the standard IBC process

Yes

PI Self Assessment Step 2:
Does the research with one of the agents produce or can be reasonably expected to produce one or more of the seven outcomes listed in this policy?

No →
- Research may not be DURC but is subject to Select Agent Regulations.
- PI should contact the Biosafety officer and the IBC office to start the process for institutional review.

Yes

Research is potential DURC
PI Informs the IBC office and the Biosafety officer, complete the assessment form Appendix 2 of this document

Yes

Director ORIA:
- Checks with Office of Sponsored Programs(OSP) if the USG funding agency funding this research has indicated that the research is DURC under the March 2012 DURC policy, and if so, contact the USG agency for advice on Risk Mitigation approaches
- Informs the Chair of the IBC (which serves as the Institutional Review Entity (IRE)) and the ICDUR of the proposed research

Yes

The Chair of the IBC and the ICDUR assemble a DURC review subcommittee that is Chaired by the Chair of the IBC, and comprises individuals with the appropriate scientific, technical and institutional expertise to conduct a risk assessment and advise the IBC on whether the research meets the definition of DURC using Appendix 3 of this document. The subcommittee makes a recommendation to the IBC which will make the final decision on applicability.

Does the proposed research meet the definition of the DURC?

No → The ICDUR notifies appropriate USG funding agency of outcome within 30 calendar days using the template provided in Appendix 4 of the companion guide.

Yes

The research requires oversight under the DURC Policy
ICDUR notifies appropriate USG funding agency of outcome within 30 calendar days of being notified by the PI, using the template provided in Appendix 4.
The DURC review subcommittee conducts a Risk -Benefit Assessment based on template provided in the companion guide (Policy Sec. 7.2.B.v; *CG* Sec. C and D) and a draft risk mitigation plan (Policy Sec. 7.2.B.v; *CG* Sec. C and D) in consultation with the USG funding agency, and in conformance with the University's Select Agent program.
The IBC reviews and approves the plan within 90 days of the initial determination that the research is potentially DURC.

NOTE: The use of any of the agents on the DURC list is subject to review, approval and inspections by the Select Agent program and the BSL3 program (if appropriate). These reviews will happen concurrently. The IBC will approve the conduct of the research only when the risk mitigation program meets the requirements of all three programs (SA, BSl3 and the DURC).

The ICDUR communicates the draft risk mitigation plan to the USG funding agency within 90 days of the initial determination that the research is potentially DURC

USG funding agency finalizes the risk mitigation plan within 60 calendar days of receipt of the draft plan

Upon approval of the use of the select agent by the Select Agent Program by the USDA APHIS and by the University's Select Agent Program and other institutional approvals, the IBC may grant approval for the DURC to be conducted in accordance with the approved risk mitigation program.

Institution implements approved risk mitigation plan and IBC 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

The IBC reviews the risk mitigation plan at a minimum on an annual basis or more frequently as determined in the risk mitigation program

September 2015

Appendix 1: Definitions to Assist in the Consideration of the Categories of Experimental Effects

These definitions[19] were developed by the National Science Advisory Board for Biosecurity (NSABB) to assist in the consideration of the NSABB's categories of experiments that describe information, products, or technologies that, if produced from life sciences research, might define that research as meeting the criterion for being DURC. The definitions have been reproduced below to assist institutions, IREs, and individuals in the consideration of the categories of experimental effects included in the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*.

Biological agent: As is consistent with 18 U.S.C. § 178, "any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of causing - (A) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; (B) deterioration of food, water, equipment, supplies, or material of any kind; or (C) deleterious alteration of the environment."

Clinically and/or agriculturally useful prophylactic or therapeutic interventions: Includes first- or second-line prevention and treatment measures or alternative therapeutics used with special populations (e.g., pregnant women and pediatric patients) in the form of vaccines, antibiotics, antivirals, antiparasitics, antibodies, herbicides, fungicides, algaecides, insecticides, etc. "Agriculture" encompasses all methods of production and management of livestock, crops, vegetation, and soil. Therefore, useful prophylaxes and therapeutics would include herbicides, fungicides, algaecides, insecticides, rodenticides, etc.

Dissemination: The process by which infectious diseases or toxins are dispersed. The same routes of entry pertinent to the natural spread of diseases are also relevant when their etiologic agents are delivered intentionally (e.g., inhalation of biological agent disseminated as an aerosol or ingestion of a biological agent disseminated through a water supply).

Eradicated agent: A biological agent that has been exterminated through surveillance and containment resulting in the permanent reduction to zero of the worldwide incidence in the transmission of the agent and the infection/disease it causes; intervention measures are no longer needed. Eradicated agents are thought to no longer exist in circulation in plants, animals, or the environment. Note: Reconstituted eradicated agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade diagnostics, or those for which there is no known immunity.

Extinct agent: These agents are thought to no longer exist in nature or in the laboratory.

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[19] *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information,* National Science Advisory Board for Biosecurity, 2007.

Harmful consequences: The ability of a biological agent or toxin to critically alter normal biological functions, inflict damage on public health resources, materiel, and public safety. This would include augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated.

Host population: A collection of organisms that constitutes a specific group or occurs in a specified habitat. In the context of the DURC definition, this phrase implies that the misapplication of the knowledge, products, or technologies derived from the research has the potential to broadly impact a population of host organisms.

Host range: The number of different species or populations that can become infected by a biological agent, causing disease in the host or allowing the host to become a carrier.

Immunity: Encompasses all aspects of host immunity (e.g., active, adaptive, adoptive, passive, innate, and immune modulators).

Immunization: Refers to the active or passive induction of immunity through inoculation (e.g., natural inoculation or vaccination) with an immunizing agent or with antibodies; this includes antitoxins and toxoids.

Novel agent: An agent that has not existed previously and is considered unique based on its biological or other properties and traits (e.g., genotype and phenotype). Novel agents of concern are those for which there are no known or widely available prophylactic or therapeutic interventions, those that could evade detection, or those for which there is no known immunity.

Small interfering RNA (siRNA): Also known as "short interfering RNA" or "silencing RNA"; a class of RNA molecules that play a variety of roles in biology; most notably, siRNA is involved in the RNA interference (RNAi) pathway where the siRNA interferes with the expression of a specific gene.

Stability: The ability of a biological agent to remain viable when exposed to various environmental factors, including temperature, relative humidity, atmospheric pollution, and sunlight. Stability also includes persistence in a host.

Toxin: As is consistent with 18 U.S.C. § 178, "the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever the origin and method of production, and includes: (A) any poisonous substance or biological product that may be engineered as a result of biotechnology that is produced by a living organism; or (B) any poisonous isomer or biological product, homolog, or derivative of such a substance."

Transmissibility: The ease with which an agent spreads from host to host or from vector to host, e.g., via arthropod vectors.

Tropism: The specificity of a biological agent or toxin for a particular host tissue or cell.

Appendix 2: Template for Notifying the IRE of Research That Requires Institutional Review

Note on this template: This template is designed to assist principal investigators (PIs) in conducting initial reviews and ongoing assessments of research that may be subject to DURC oversight. This template includes information that may be useful for the institutional review entity (IRE), should it be called upon to review the research.

The use of this template by institutions is optional. Institutions may choose to utilize this template as a starting point for developing their own materials or tools based on the specific issues or needs of the institution.

The *Policy for Institutional DURC Oversight* requires PIs at institutions subject to the Policy[20] to notify the IRE as soon as:[21]

A. The PI's research directly involves nonattenuated[22] forms of one or more of the listed agents; or

B. 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

C. 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.

This notification must include the PI's assessment of the applicability of any of the seven listed experimental effects. More information on the identification and assessment of research that requires institutional review can be found in **Section B** of the *Companion Guide*.

Each institution is responsible for establishing and implementing its own internal policies and practices that provide for the identification and effective oversight of DURC. This includes establishing a mechanism for the PI to immediately refer a project to the IRE, when applicable. The institution may require the use of a specific form and/or additional supporting documentation (e.g., project proposals, progress reports).

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[20] The *Policy for Institutional DURC Oversight* and its oversight requirements apply to the following institutions: (1) USG departments and agencies that fund or conduct life sciences research, (2) institutions within the United States that receive USG funds to conduct or sponsor life sciences research and conduct or sponsor research, regardless of source of funding, that involves 1 or more of the 15 agents or toxins listed in the Policy, and (3) institutions outside the United States that receive USG funds to conduct or sponsor research that involves 1 or more of the 15 agents or toxins listed in the Policy.

[21] *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, http://www.phe.gov/s3/dualuse/Pages/default.aspx, Section 7.1.A.

[22] The 15 agents and toxins listed in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the March 2012 DURC Policy.

Template for Notifying the IRE of Research That Requires Institutional Review

1. Contact Information

1.1 Principal Investigator (PI)

Name (Last, First, MI):	
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

1.2 Person Preparing This Document (If Not the PI)

Name:	Phone number:
Email:	Fax:

2. Project Information

Please identify any life sciences research you conduct at this institution that directly involves nonattenuated forms of one or more of the agents listed below (please use a separate form for each identified project). If none of the agents are identified, your research is *not* subject to institutional DURC oversight. However, PIs should be aware that, if at any time, research is initiated that involves any of the below listed agents, he or she will need to immediately notify the institutional review entity (IRE) (or appropriate institutional authority), per the policy of this institution.

2.1 Project Title(s)

2.2 Agent or Toxin Involved in Project (Check All That Apply)

- ☐ Avian influenza virus (highly pathogenic)
- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxin (any quantity)
- ☐ *Burkholderia mallei*
- ☐ *Burkholderia pseudomallei*
- ☐ Ebola virus
- ☐ Foot-and-mouth disease virus
- ☐ *Francisella tularensis*
- ☐ Marburg virus
- ☐ Reconstructed 1918 influenza virus
- ☐ Rinderpest virus
- ☐ Toxin-producing strains of *Clostridium botulinum*
- ☐ Variola major virus
- ☐ Variola minor virus
- ☐ *Yersinia pestis*

2.3 Type of Funding Source(s) for This Project

- ☐ Department/institutional funds
- ☐ Foundation
- ☐ Federal funds
- ☐ Business /industry
- ☐ Other

If project is supported with Federal funds, name of funding agency and grant or contract number:

3. Training of Laboratory Personnel

The *Policy for Institutional DURC Oversight* requires that all 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 nonattenuated forms of 1 or more of the 15 listed agents have received education and training on DURC. Please indicate below the names of all laboratory personnel involved in this project and include the titles and dates of any DURC training.

Name	Title/Role	Title of DURC Training	Completion Date(s)

(Please insert more rows as necessary.)

4. Assessment by the PI for Experimental Effects

PIs are required to assess whether any research directly involving nonattenuated forms of 1 or more of the 15 listed agents produces, aims to produce, or is reasonably anticipated to produce 1 or more of the experimental effects listed in Section 6.2.2 of the *Policy for Institutional DURC Oversight* (relisted below). Note: the research and this assessment must be submitted to the IRE for review regardless of whether any of the following experimental effects apply.

☐ Enhances the harmful consequences of the agent or toxin.

If checked, please explain below:

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.

If checked, please explain below:

☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.

If checked, please explain below:

☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.

If checked, please explain below:

☐ Alters the host range or tropism of the agent or toxin.

If checked, please explain below:

☐ Enhances the susceptibility of a host population to the agent or toxin.

If checked, please explain below:

☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 2.2 of this form.

If checked, please explain below:

As a reminder, if there is a change in this research with respect to the applicability of any of the seven experimental effects, or if the PI, for any reason, thinks the research needs to be reconsidered by the IRE for DURC potential, the PI should submit this form again to the IRE with his/her revised assessment.

Appendix 3: Template for Assessment by the IRE of Research for DURC Potential

Note on this template: This template is designed to assist the institutional review entity (IRE) in its review and assessment of research for DURC potential. Such a review is initiated after a principal investigator (PI) identifies research directly involving nonattenuated forms of 1 or more of the 15 listed agents. This template guides IREs through the process of verifying that research meets the scope of the *Policy for Institutional DURC Oversight*, determining whether the research is DURC, and considering the risks and benefits of any identified DURC.

The use of this template by institutions or IREs is optional. Institutions may choose to utilize this template as a starting point to develop their own materials or tools based on the specific issues or needs of the institution.

The *Policy for Institutional DURC Oversight* requires that all research identified by a PI as directly involving nonattenuated[23] forms of 1 or more of the 15 listed agents be reviewed by an IRE. The responsibilities of the IRE in completing this step of the review process are as follows:[24]

- Verify that the research identified by the PI directly involves nonattenuated forms of one or more of the listed agents.
- Review the PI's assessment and make a final determination of the applicability of the listed experimental effects.
- If the research is assessed to meet the scope of the *Policy for Institutional DURC Oversight*, conduct a risk assessment and determine whether the research meets the DURC definition; the IRE should then immediately notify the appropriate institutional authority of the review outcomes.
- If the research meets the DURC definition, the IRE must consider both the identified risks and anticipated benefits, and it should then draft a risk mitigation plan (see **Sections C and D** of the *Companion Guide*).

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[23] The 15 agents and toxins listed in this Policy are subject to the select agent regulations (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121), which set forth the requirements for possession, use, and transfer of select agents and toxins, and have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. It is important to note, however, that the Federal Select Agent Program does not oversee the implementation of this Policy or the March 2012 DURC Policy.

[24] *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, http://www.phe.gov/s3/dualuse/Pages/default.aspx, Section 7.2.B.

Template for Assessment by the IRE of Research for DURC Potential

1. Contact Information

1.1 Institutional Review Entity

Name of entity:	Date(s) of review:
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

1.2 Person Preparing This Document

Name:	Phone number:
Email:	Fax:

2. Project Information

2.1 Principal Investigator

Name (First, Last, MI):	
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

2.2 Project Title(s)

2.3 Review(s) of Research by PI

Please list prior dates of reviews or assessments by the PI of research for DURC potential. For each date, please include a copy of the review or assessment.

Date

2.4 Agent or Toxin Involved in Project (Check All That Apply).

Please verify that this project directly involves nonattenuated forms of 1 or more of the 15 listed agents.

- ☐ Avian influenza virus (highly pathogenic)
- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxin (any quantity)
- ☐ *Burkholderia mallei*
- ☐ *Burkholderia pseudomallei*
- ☐ Ebola virus
- ☐ Foot-and-mouth disease virus
- ☐ *Francisella tularensis*
- ☐ Marburg virus
- ☐ Reconstructed 1918 influenza virus
- ☐ Rinderpest virus
- ☐ Toxin-producing strains of *Clostridium botulinum*
- ☐ Variola major virus
- ☐ Variola minor virus
- ☐ *Yersinia pestis*

3. Assessment by the IRE for Experimental Effects

Please indicate whether the research project identified above produces, aims to produce, or can be reasonably anticipated to produce any of the following experimental effects. The IRE should review descriptions of the research in question, the PI's assessment of the applicability of the categories of experiments, and other relevant information, as warranted. Examples of materials to consider include the project proposal, any project reports, any outcomes of previous reviews for dual use, and examples of similar research in the literature.

☐ Enhances the harmful consequences of the agent or toxin.

If checked, please explain below:

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.

If checked, please explain below:

☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.

If checked, please explain below:

☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.

If checked, please explain below:

☐ Alters the host range or tropism of the agent or toxin.

If checked, please explain below:

☐ Enhances the susceptibility of a host population to the agent or toxin.

If checked, please explain below:

☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 2.4 of this form.

If checked, please explain below:

If *none* of the above experimental effects applies, the research does not meet the scope of the *Policy for Institutional DURC Oversight,* and the IRE does not need to continue with this assessment. The PI should be informed that if at any time the reviewed research produces or can be reasonably anticipated to produce a previously unanticipated experimental effect listed in Section 6.2.2 of the Policy, or if the reviewed research may meet the definition of DURC, he or she will refer it again to the IRE for review.

4. Risk Assessment by the IRE and Determination of DURC

The *Policy for Institutional DURC Oversight* defines DURC as follows:

> *Life sciences research that can be reasonably anticipated, based on current understanding, 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.*

When considering whether the research in question meets the definition above, the IRE should first identify the risks associated with the potential misuse of the information, technologies, or products that may be generated. Although risk assessments may be either quantitative or qualitative, the assessment process outlined below is qualitative in nature and requires the consideration and judgment of the IRE on the following:

- 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.
- The *ease with which* the knowledge, information, technologies, or products might be misused and the feasibility of such misuse.
- The *magnitude, nature, and scope* of the potential consequences of misuse.

4.1 Points to Consider in Assessing Research for Its Dual Use Potential

Consider the points below to assess the potential risks associated with conducting the research in question or communicating its results. These points address some of the aspects of potential DURC that could be considered, but they are not exhaustive – IREs should augment these points to fit their needs and the research under consideration. This risk assessment is intended to assist IREs in determining whether the research in question meets the definition of DURC. In cases where the research is determined to be DURC, this assessment will also inform the subsequent process of identifying strategies for mitigating those risks.

1. **The ways in which knowledge, information, technologies, or products from the research could be misused.** Address the following questions and considerations regarding the nature and disposition of the knowledge, information, technology, or products that could be generated by the research under consideration:

   a. What types of knowledge, information, technology, or products are anticipated to be generated through the research?

   b. How will the results or products of the research in question be shared or distributed? *Knowledge, information, technology, or products that are freely available and widely distributed may be more easily accessed by individuals with harmful intent.*

      – Who will have access to the knowledge, information, technology, or final products?

– Will it be shared openly or remain within the laboratory?

c. What is the novelty of the information provided by the research or of the research methods? *Research that adds novel information or consolidates information in novel ways may be of greater concern, whereas information that is already widely available is generally of lower concern.*

– Have the results of the research been previously described or shared?

– If so, at what venues and in what detail?

– How readily available are these results?

d. Are the products of the research under consideration applicable to other more common or less pathogenic organisms or agents? *Knowledge, information, technology, or products generated from research that could be applied to more commonly available organisms to increase their associated risks may be of greater concern.*

e. Does the research highlight vulnerabilities in existing countermeasures or public health or agricultural infrastructure?

– Does the research highlight weaknesses in the ability to prepare for and respond to disease outbreaks that could impact public, agricultural, or environmental health?

– Does the research consolidate existing information in ways that highlight vulnerabilities in public health and/or safety preparedness?

2. **The ease with which the knowledge, information, technologies, or products might be directly misused and the feasibility of such misuse.** IRE members are not expected to have expertise in national security, but IRE members and investigators in general are in a good position to make technical assessments about how readily and in what ways certain knowledge, information, technologies, or products obtained from research might be misused. Address the following questions and considerations regarding factors that impact the likelihood of misuse, including technical feasibility, level of expertise, necessary reagents, or the need for additional scientific advances or technologies.

a. Consider the technical expertise and/or physical resources that would be needed to apply the knowledge, information, technology, or product for malevolent purposes. *The risk of misuse may be lower for knowledge, information, technologies, or products that would be expensive, difficult to procure, or that require a high degree of technical skill to facilitate such misuse.*

   – Would it require a low or high degree of technical skill and sophistication to use the information from dual use research for harmful purposes?

   – Would its misuse require materials, equipment, or reagents that are expensive or difficult to procure?

b. Consider whether the products of the research in question could be directly misused to pose a threat to public health and safety, agriculture, plants, animals, the environment, materiel, or national security. *The risk of misuse may be higher for research information that can be directly misused than for research information that requires significant additional scientific advances to facilitate its misapplication.*

   – Can the products, information, or technologies generated from the research be directly misapplied? If so, how?

   – If not, do these outcomes of the research need to be combined with other knowledge, information, technology, or products in order to pose a threat? If so, is that other information already available?

c. Consider the time frame in which information from the research might be misused. *Information that can be misused in the near term may be of greater concern.*

   – Is there concern about immediate or near-future potential use, or is the concern about misuse in the distant future?

d. Given your responses to the preceding questions, how readily could the knowledge, information, technology, or products from the research be used to threaten public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security?

3. Potential consequences of misuse. When considering the potential consequences of the misuse of scientific knowledge, information, technology, or products obtained from research, think broadly about the potential impacts on public health, agriculture, the environment,

and/or the economy from the intentional misapplication of the results from the research in question. In general, information that could be misused to harm large populations of humans, plants, or animals; cause public panic; or require costly response efforts would be considered a greater risk.

a. Consider the nature of the potential consequences (e.g., harm to the economy, the environment, agriculture, or public health; public terror) that might result from misuse of the research results in question. *Information that could be misused to harm numerous sectors of society or the environment may be of greater concern.*

b. Consider the scope and magnitude of the potential consequences. *Research or research information that could be misused to cause severe harm, disease, or consequences is generally considered to be of greater concern.*

   – Could the impact on people, plants, and/or animals be considered minor, moderate, or major?

c. Consider the available countermeasures. *Adequate countermeasures may help to decrease concern about the consequences of misuse. Countermeasures may include drugs, biological products, public health practices, pesticides, or devices intended for diagnosis, detection, mitigation, prevention, or treatment.*

   – Are there currently any countermeasures to help mitigate the potential consequences?

   – Are they readily available?

4.2 Apply the DURC Definition

The IRE should consider the identified risks in determining whether the research in question meets the definition of 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."*

If the IRE determines that the research *does not* meet the DURC definition, the research is not subject to additional institutional DURC oversight. However, the institution must still notify the appropriate USG funding agency of the findings of the institutional review. If significant concerns about dual use remain, the ICDUR should be informed. The ICDUR and the IRE may choose to consult with a representative of the USG department or agency that is funding the research in question.

If the IRE determines that the research *does* meet the DURC definition, the research is DURC, as defined in the *Policy for Institutional DURC Oversight* and the *March 2012 DURC Policy*, and is subject to additional DURC oversight. The IRE should inform the PI of its findings and proceed with the review process, which includes the development of a draft risk mitigation plan. The institution must notify the appropriate USG funding agency of the IRE's findings within 30 calendar days of review.

5. Risk-Benefit Assessment of DURC

For research that has been identified as DURC, it is important to assess the research for its anticipated benefits and to weigh those benefits with the risks identified in Step 4. This process will help determine the acceptable level of risk and inform the most appropriate mitigation strategies. The IRE should use the answers to Step 4 and Step 5 in developing a risk mitigation plan for conducting the research and communicating its findings.

5.1 Points to Consider in Assessing the Benefits of the DURC

The benefits inherent to scientific research are many. Such benefits may impact various sectors of society and be realized over different time frames. The points below address *some* of the aspects of the research that could be considered, but they are not exhaustive – IREs should augment these points to fit their needs and the research under consideration.

a. Are there potential benefits to the public's health and/or safety from the research?

b. Are there potential benefits of the research for agriculture, plants, animals, the environment, materiel, or national security?

   – What potential solution does it offer to an identified problem or vulnerability?

c. Will this research be useful to the scientific, public health, or public safety communities? If so, how?

d. Because scientific research can have broad impacts, it is important to consider the scope of the potential benefits.

   – Will the knowledge, information, or technology generated from the research be broadly applicable (e.g., to human health, multiple scientific fields, populations of organisms)?

– What populations of plants or animals might be positively affected?

e. If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might this research benefit science, public health, agriculture, plants, animals, the environment, materiel, or national security?

5.2 Points to Consider for Weighing the Risks and Benefits of the DURC

This can be the most challenging step in the risk-benefit assessment; it is often described as a step that entails "weighing" or "balancing" the risks with or against the benefits of DURC. This language, however, suggests that risks and benefits can be quantified and that they are commensurable. This is rarely, if ever, the case.

The process of weighing the risks and benefits of DURC is an exercise in making defensible, rational judgments in the midst of unavoidable uncertainty. Uncertainty can best be managed by ensuring that the process draws on the expertise and perspectives of a group of individuals of diverse backgrounds and experience. Discussion and debate within such a group can help to (a) identify and mitigate the biases that individuals inevitably bring to the challenges of this sort, (b) uncover often implicit assumptions in arguments, (c) scrutinize and test the basis for judgments, and (d) yield conclusions that represent a consensus (literally, "a thinking together") and are optimally defensible.

a. Could the information of concern be more readily applied to improvements in surveillance or to the development of countermeasures than to malevolent applications? What reasons or evidence support the answer to this question?

b. What is the time frame in which potential benefits or anticipated risks might be realized?

c. How might the potential benefits and the anticipated risks be distributed across different populations (humans and animals)?

– Who or what will be the likely beneficiaries of the potential benefits? Will the potential benefits be distributed equally or disproportionately across different populations? (Here, it will be helpful to keep in mind that, for example, human populations may differ in

terms of size: The potential benefits may accrue to a large or, alternatively, to a small number of individuals. Or, human populations may differ along socioeconomic or cultural lines: The potential benefits may accrue to or have little impact on a vulnerable or low-resourced population versus a well-resourced population.)

– Who or what will bear the anticipated risks? Is it likely that one or more specific populations will bear the burden of the anticipated risks?

– Is it likely that the distribution of the anticipated risks and the potential benefits will be fair or just?

d. Considering the anticipated risks in tandem with the potential benefits, are the risks of such a feasibility and magnitude that they warrant proceeding after developing and implementing a risk mitigation plan? Are the potential benefits of significant magnitude to warrant proceeding despite the risks? What is the most responsible way to proceed? For the vast majority of cases of DURC, an appropriate risk mitigation plan can be developed and effectively implemented.

Appendix 4: Template for 30-Day Reporting of Research That Meets the Scope of the *Policy for Institutional DURC Oversight*

Section 7.2 of the *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* outlines the responsibilities of federally funded research institutions for the oversight of research with DURC potential. This oversight process begins with identification by the principal investigator (PI) of research involving any of the 15 agents listed in the Policy. Any such research must be referred to the institutional review entity (IRE) along with the PI's assessment of whether the research involves any of the seven listed experimental effects. When an IRE determines that research directly involving nonattenuated[25] forms of any of the 15 listed agents also involves 1 or more of the 7 experimental effects, the institution must report this information within 30 calendar days to the appropriate USG funding agency, as described in Section 7.2.B.iv, below. This reporting template is intended for the institutional contact for dual use research (ICDUR) and is designed to assist the institution in meeting the 30-day reporting requirement.

Section 7.2.B.iv:

> *Within 30 calendar days of the institutional review of the research for DURC potential, notification to the USG (US Government) funding agency of any research that involves 1 or more of the 15 listed agents and 1 or more of the 7 listed experimental effects (Section 6.2), including whether it meets or does not meet the definition of DURC. For non-USG-funded research, notification should be made to the National Institutes of Health, which will in turn refer the notification to an appropriate USG funding agency, based upon the nature of the research (per Section 7.E). This initial notification should include: the grant or contract number related to the research (if the research is funded by the USG); the name(s) of PI(s); the name(s) of the agent(s) listed in Section 6.2.1 of the Policy; and a description of why the research is deemed to produce one or more of the experimental effects listed in Section 6.2.2 of the Policy. For research that is determined by the IRE to meet the definition of DURC, the notification should also 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.*

[25] The only forms of the agents or toxins listed in the USG DURC policies that are considered by the USG to be attenuated and therefore not subject to the requirements of these policies, can be found in the Select Agent and Toxin Exclusions list under "Attenuated Strains of HHS and USDA Select Agents and Toxins" at http://go.usa.gov/8rwQ.

Reports of federally funded research should be submitted directly to the relevant USG funding agency.

Reports of non-USG-funded research should be submitted to the National Institutes of Health via one of the following:

1. U.S. mail, courier service, or facsimile to:
   Attention: Institutional DURC Oversight Policy Reporting
   NIH Program on Biosecurity and Biosafety Policy
   6705 Rockledge Drive, Suite 750
   Bethesda, MD 20892-7985
   (For all non-USPS US Postal Service deliveries use Zip Code 20817)
   Telephone 301-496-9838
   Fax 301-496-9839

2. Email: DURC@od.nih.gov

Template for 30-Day Reporting of Research That Meets the Scope of the *Policy for Institutional DURC Oversight*

Date of Report: _____

1. Contact Information

1.1 Institutional Contact for Dual Use Research (ICDUR)

Name:	Phone number:
Email:	Fax:

1.2 Person Completing This Form (If Different from ICDUR)

Name:	Phone number:
Email:	Fax:

2. Project Information

2.1 Principal Investigator (PI) or Other Scientist Responsible for This Research

Name (Last, First, MI):	
Mailing address:	Phone number:
	Fax:
	Email:
Department (if applicable):	

2.2 Funding Source(s)

U.S. Government agency funding this research *(If more than one source, list all that apply. For non-USG-funded research, please provide the name of the funding entity and point of contact)*:
Grant/contract number *(For non-USG-funded research, please provide a project identifier)*:

2.3 Project Title(s)

2.4 Project Description (Non-USG-Funded Research Only)

If the project is not supported with U.S. Government funds, please provide sufficient detail describing the nature of this research (*e.g., description of agent and how it is to be used, animal models, methods and procedures, biosafety and biosecurity measures*) that will allow for complete and accurate review by the designated USG funding agency. Alternatively, this information may be provided as supplemental material *(see Section 4)*.

3. Institutional Review

3.1 Institutional Review Entity

Name of entity:	Date(s) of review:
Mailing address:	Phone number:
	Fax:
	Email:

3.2 Agent or Toxin Involved in Project (Check All That Apply)

- ☐ Avian influenza virus (highly pathogenic)
- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxin (any quantity)
- ☐ *Burkholderia mallei*
- ☐ *Burkholderia pseudomallei*
- ☐ Ebola virus
- ☐ Foot-and-mouth disease virus
- ☐ *Francisella tularensis*
- ☐ Marburg virus
- ☐ Reconstructed 1918 influenza virus
- ☐ Rinderpest virus
- ☐ Toxin-producing strains of *Clostridium botulinum*
- ☐ Variola major virus
- ☐ Variola minor virus
- ☐ *Yersinia pestis*

3.3 Assessment by the IRE for Experimental Effects

Please indicate whether the research produces, aims to produce, or can be reasonably anticipated to produce any of the experimental effects listed below. Check all that apply.

☐ Enhances the harmful consequences of the agent or toxin.

If checked, please explain below:

☐ Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification.

If checked, please explain below:

☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates its ability to evade detection methodologies.

If checked, please explain below:

☐ Alters properties of the agent or toxin in a manner that would enhance its stability, transmissibility, or ability to be disseminated.

If checked, please explain below:

☐ Alters the host range or tropism of the agent or toxin.

If checked, please explain below:

☐ Enhances the susceptibility of a host population to the agent or toxin.

If checked, please explain below:

☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section 3.2 of this form.

If checked, please explain below:

3.4 Determination by the IRE of Whether the Research Meets the Definition of DURC

Please provide the IRE's rationale for why the research does or does not meet the definition of DURC. The *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* defines 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."

4. Supplemental Materials

Please provide as attachments any additional information relevant to this research that may aid in the USG funding agency's review and assessment of this research, particularly any elements the IRE used during its institutional review process. These may include the following:

- Project proposals
- Progress reports
- Scientific abstracts
- Published manuscripts
- Assessment by the PI for dual use
- IRE meeting minutes
- Institutional biosafety committee meeting minutes
- Risk assessments
- Safety inspections

Appendix 5: Export Controls and DURC – Guidance for Institutions and Principal Investigators

1. What are export controls?

Export controls are a mechanism by which the United States regulates the export of controlled goods and activities to ensure consistency with U.S. foreign policy and national security interests, U.S. law, and its international commitments. This includes prohibiting the export of any goods, technology,[26] or services that would assist anyone in acquiring the capability to develop, produce, stockpile or use weapons of mass destruction (WMD). To implement this prohibition, the United States regulates the transfer of certain technology and materials to foreign parties (including individuals) by requiring export licenses.

2. Which export regulations apply to DURC?

It is expected that most DURC that is subject to export controls would be controlled under the Export Administration Regulations (EAR) administered by the Department of Commerce, Bureau of Industry and Security. There are generally two types of export transactions: (1) transferring controlled material or technology outside the United States; and (2) transferring controlled technology to non-U.S. persons who are within the United States which is considered a "deemed export."

However, under certain circumstances, the International Traffic in Arms Regulations (ITAR) may apply to DURC items (including materials and information). For information on these controls, see Title 22, Code of Federal Regulations, Parts 120 through 130 (ITAR) - including but not limited to: Part 121.1 Category XIV "Toxicological Agents, Including Chemical Agents, Biological Agents and Associated Equipment," and, Part 120.11 "Public Domain." For further assistance, please see www.pmddtc.state.gov. Note that the order of precedence for export controls first requires a determination of whether an item is ITAR-controlled. If it is not ITAR-controlled, DURC may be subject to the EAR. The remainder of this guidance document applies only to the EAR.

Please note that this guide includes discussion on certain aspects of the EAR and may not include all the details associated with the control of an item. For more details on the application of controls and compliance with these controls, please review the applicable regulations, including those listed in Question 8.

3. How do EAR export controls apply to research identified under the USG DURC Oversight policies?

The fifteen agents listed in the USG DURC Oversight policies are all included on the EAR control list (For the complete list, see Part 774 of the EAR available under the "Regulations" tab on the Bureau of Industry and Security homepage at www.bis.doc.gov.) This means that transfers of these materials and/or information or technology

[26]The EAR define "technology" as specific information necessary for the "development", "production", or "use" of a product (Part 772).

related to their development, production, or manipulation are subject to the EAR and may require an export license or a deemed export license.

To foster scientific advances, certain information and technology are exempted from this export license requirement as described in Question 4 below, including information that is in the public domain, information resulting from fundamental research, and information that is normally published. This information is not subject to the EAR.

Note: Identification of research as DURC has no direct bearing on whether or not an export license is required. However, certain risk mitigation measures (e.g., the imposition or acceptance of restrictions on publication) MAY affect whether the research is subject to the EAR. Institutions and researchers should be aware of this possibility. Assistance is available from the Department of Commerce, Bureau of Industry and Security for determining licensing and other requirements. Please see www.bis.doc.gov.

4. What types of information are not subject to the EAR (15 CFR Parts 734.7-10)?[27]

- Information resulting from fundamental research (see details below).
- Publicly available information: generally accessible to the interested public in any form.
- Printed books.
- Educational information: released by instruction in catalog courses and associated teaching laboratories of academic institutions.
- Information contained in patent applications.
- Technology that is subject to other export regulations (see Question 8).

5. What is considered fundamental research under the EAR (15 CFR Part 734.8)?

Fundamental research is described in the EAR as "basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community." The techniques used during the research are normally publicly available or are part of the published information. (Please note: The fundamental research exclusion does not apply to physical objects such as pathogens or equipment.)

> **Example:** Researchers from two universities, one in the U.S. and the other in the United Kingdom (UK), are collaborating on a project that involves vector identification for Marburg virus. There are no restrictions on publication of findings generated from the research. Therefore, the research would be considered fundamental and the information resulting from this research, such as the results and methods, are not subject to the EAR. There would be no "deemed export" required for foreign nationals working at the U.S. university and no export license required for discussing research methods and outcomes between the two universities. However, an export license would be required for the export of the Marburg virus samples to the UK university.

[27]The items listed here are not an exclusive list. For additional information, please see 15 CFR Parts 734.7-10.

6. What types of research are NOT considered fundamental research under the EAR (15 CFR Part 734.8)?

Research is not considered fundamental research when the Laboratory, Company, University or researcher restricts the publication of the outcome of the research or restricts the publication of the methods used during the research. The following are examples of research that is not considered fundamental and information that becomes subject to the EAR:

- Proprietary research.
- Any research methods or outcomes of government-funded research for which a decision has been taken to specifically restrict publication. Only the information that is redacted would become subject to the EAR; the remainder of the research methods and outcomes that have not been subject to restriction would be considered information resulting from fundamental research.
- Any research methods or outcomes of government-funded research that have been communicated in violation of any condition that may exist in the funding instrument that requires prepublication security review of the research communication. (Government funding agencies have the discretion to require future prepublication security review of the methods or outcomes of research without changing the fundamental nature of the research as it is being conducted.)
- Research methods or outcomes that an investigator voluntarily decides should not be communicated widely because of a decision that has been taken to specifically restrict publication. Only the information that is redacted would become subject to the EAR; the remainder of the research methods and outcomes that have not been subject to a decision taken to restrict publication would be considered information resulting from fundamental research.

  Example: Government-funded researchers studying *Bacillus anthracis* accept national security prepublication review of their research. If the group complies with the review requirement and does not communicate this research without the required reviews, their research remains fundamental research. However, any of the information resulting from this research for which a decision is taken to restrict from publication due to DURC concerns will become subject to the EAR. Research methods and outcomes from the same project that are not subject to a decision taken to restrict publication would remain information resulting from fundamental research and not subject to the EAR.

Specific decisions taken to restrict publication, regardless of the source of the decision, would mean that the technology not published is technology subject to the EAR. This decision is not retroactive so it would not impose a license requirement for exports of the information that have already taken place, but may trigger a license requirement for future exports of the information and future deemed export licenses as necessary.

If you have questions about whether or not your research is considered fundamental research, then you or someone designated by your institution should contact Kimberly Orr at the Department of Commerce at Kimberly.orr@bis.doc.gov.

7. Do the Export Administration Regulations restrict my ability to publish the results of my research?

Export Administration Regulations are not export "bans." They do not and should not impede legitimate academic freedom and information exchange that are unrelated to chemical and biological weapons, to include

patent applications or the publication of fundamental research in the public domain. There is no export license required to publish information (see Supplement #1 to Part 734 Section A, Question A:1, available under the "Regulations" tab on the Bureau of Industry and Security homepage at www.bis.doc.gov). You must review contract or grant clauses to ensure you do not violate any national security controls that may be required by the funding agency.

8. In addition to the EAR, are there other classes of exports that are regulated?

In addition to the EAR, other departments and agencies have jurisdiction over certain other classes of exports, including:

- The State Department's ITAR addresses goods, technology, and services that are controlled as 'defense ar-ticles' or 'defense services,' including technology that could be a subset of DURC. For additional details regarding the ITAR, please see www.pmddtc.state.gov.
- The Department of the Treasury, Office of Foreign Assets Control (OFAC) administers controls against cer-tain countries (Iran, North Korea, Cuba, Syria, etc.), individuals, and entities that are subject to sanctions affecting exports, imports, and financial dealings. For additional details, please see www.treasury.gov/ resource-center/sanctions/.
- The U.S. Nuclear Regulatory Commission, the Department of Energy, and the Patent and Trademark Office also control certain exports. For a summary of these agencies' controls, see Part 734.3 of the EAR, available under the "Regulations" tab on the Bureau of Industry and Security webpage at www.bis.doc.gov.