1. BACKGROUND

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."

- 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 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) was released to establish the requirements for institutional (i.e., non-USG) oversight of DURC. The USG considers these two Policies to be complementary.
- Other additional USG documents that have been issued in connection with the 2014 Policy and provide guidance in understanding the regulations are listed in the Section 5 of this Policy.

2. PURPOSE

The purpose of this Policy is to strengthen the institutional review and oversight by Emory University of research to identify potential Dual Use Research of Concern (DURC) and to develop and implement risk mitigation plans when appropriate. This Policy seeks to preserve the benefits of life sciences DURC research while minimizing the risk that the output of such research would be used for harmful purposes. This Policy sets forth explicit instructions for individuals and committees at Emory 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 Section 3 below) is subject to this Policy, regardless of the source of funding.

3. DEFINITIONS

Attenuated: Forms of DURC Agents listed in the Select Agent and Toxin Exclusions list as "Attenuated Strains of HHS and USDA Select Agents and Toxins", and are not subjected to any manipulation that restores or enhances its virulence or toxic activity.

Directly Involves: All disciplines and methodologies of research of which the subject is in whole or in part a DURC Agent, except research that, in relation to the DURC Agent, solely involves (a) the use only of genes from any of the DURC Agents; (b) *in silico* experiments (e.g., modeling experiments, bioinformatics approaches) involving the biology of the listed agents; or (c) research related to the public, animal, or agricultural health impact of any DURC Agent (e.g., modeling the effects of a toxin,

developing new methods to deliver a vaccine, developing surveillance mechanisms for a DURC Agent).

Dual Use Research (DURC): as defined in Section 1.

DURC Agents: the following 15 agents and toxins listed in the 2014 Policy:
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*

Experimental Effects of Concern:
The following 7 categories of experimental effects are listed 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 DURC Agent.

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. Emory University has designated the Biosafety Officer/Associate Director of the Research Safety Program in Environmental Health and Safety as the ICDUR.

Institutional Review Entity (IRE): The committee established by Emory University to review potential DURC. The committee acting as an IRE for Emory University at any point in the DURC review under this Policy shall be composed of at least five members and (a) be sufficiently empowered by Emory University to ensure it can

execute its responsibilities under this Policy; (b) include persons with sufficient breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at a given research facility; (c) include persons with knowledge of relevant USG policies and understanding of risk assessment and risk management considerations, including biosafety and biosecurity, and may also include, or have available as consultants, at least one person knowledgeable in Emory University's commitments, policies, and standard operating procedures; (d) on a case by case basis, recuse any member of the IRE who is involved in the subject research or has a direct financial interest, except to provide specific information requested, and (e) engage in an ongoing dialog with the Principal Investigator (PI) of the subject research when conducting a risk assessment and developing a risk mitigation plan.

Research Health and Safety Committee (RHSC): The Emory University Research Health and Safety Committee (RHSC) provides recommendations for safety policy for approval by the President or his/her designee, on matters relating to biosafety/chemical safety for all types of research (e.g. basic animal, human) including the control of health hazards associated with the intramural use of microbial agents and toxins, of hazardous chemicals, as well as other workplace, facility, or environmental hazards to faculty, staff and students that may be associated with University activities.

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.

4. SCOPE

This program is inclusive of Emory University employees, faculty, staff, students, volunteers, contractors, and others who act on behalf of Emory University are involved in research potentially defined as DURC.

5. REFERENCES

5.1. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (2014) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf

5.2. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (2012) http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf

5.3. 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.

5.4 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.

5.5 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.

5.6 See also the National Institutes of Health ("NIH") Notice NOT-OD-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.

6 RESPONSIBILITIES

6.1 POLICY REQUIREMENTS FOR PRINCIPAL INVESTIGATORS

A Principal Investigator (PI) must notify the IRE as soon as any of his/her research (or future research during the grant writing phase) may meet any of the following criteria:

1. The research Directly Involves non-Attenuated forms of one or more DURC Agent;

2. The research that Directly Involves non-Attenuated forms of one or more DURC Agent produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern; or

3. The PI's research that Directly Involves non-Attenuated form of one or more DURC Agent and produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern may meet the definition of DURC.

The PI's notification to the IRE shall be performed by contacting Environmental Health and Safety Office (EHSO) and providing the RHSC with documentation indicating the reasons for his/her conclusion that his/her research involves potential DURC, and providing sufficient data to permit the RHSC to complete the review required by Section 6.6 below. The PI's self-screening will be assisted by EHSO's Biosafety Notice of Intent (NOI) application for protocol submission which will include a section of DURC.

6.2 POLICY REQUIREMENTS FOR INSTITUTIONAL REVIEW

At Emory University, the IRE is made up of two committee components: (1) the RHSC and (2) an *Ad Hoc* committee (an Ad Hoc Committee) established by the Vice President for Research Administration (VPRA). Each of the components shall meet the definition of IRE as described in this Policy. The roles of the RHSC and the Ad Hoc Committee are delineated below.

A. Role of the RHSC

1. When the RHSC is notified by the PI of following a PI's self-assessment, the RHSC shall identify whether a USG Funding Agency has notified Emory that the research is DURC under the USG March 2012 Policy, in which case the IRE shall ensure implementation of the approved risk mitigation plan and provide ongoing oversight in accordance with this Policy.
2. A USG Funding Agency has not notified Emory that the research is DURC under the March 2012 Policy, the RHSC reviews the subject research to verify whether it Directly Involves non-Attenuated forms of one or more of the DURC Agents, and whether the subject research produces, aims to produce or can reasonably be anticipated to produce one or more Experimental Effects of Concern. This review is based upon the materials provided via the PI's self-screening and other materials as may be deemed relevant by the RHSC.

    i. If the RHSC determines that the subject research does not meet the foregoing criteria, the RHSC will notify the PI that further review for DURC by the acting IRE is not presently required, but that the PI is still required to continually self-assess provide notification if a change in the subject research may potentially alter the DURC analysis.

    ii. If the RHSC concludes that the subject research does Directly Involve one or more non-Attenuated DURC Agents and Experimental Effects of Concern, the RHSC will refer the review to the Ad Hoc Committee, and notify the PI that it has done so.

The RHSC has the discretion to confer with the relevant program officer at the applicable US Funding Agency regarding whether any research may constitute DURC.

B. Review by the Ad Hoc Committee

1. Promptly after notification from the RHSC, the VPRA will convene an Ad Hoc Committee, whose members will include appropriate internal and/or external experts in accordance with the IRE composition requirements(Section 3), the Vice President and Executive Director of EHSO, the RHSC Chair (s) and representatives of EH&S and the Offices of the General Counsel, and Public Safety.

    i. The choice of members will be made by the VPRA in consultation with the PI and EH&S.

2. The **Ad Hoc Committee review process is to assess the risks of dual use and determine whether the research is DURC**. In doing so, 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 Ad Hoc Committee 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:

i. 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;
ii. the *ease with which* the Research Output might be misused and the feasibility of such misuse; and
iii. the *magnitude, nature and scope* of the potential consequences of misuse.

(Guidance on points to consider while making this assessment can be found under references 5.3- Section C.3 of the Companion Guide. The applicable US Funding Agency may be consulted for advice).

i. If the Ad Hoc Committee determines that the subject research does not meet the definition of DURC, it is not subject to additional institutional oversight and the Chair of the Ad Hoc Committee will promptly notify the PI and, within 30 days, the applicable USG Funding Agency. Notification shall include the information identified in Section 7.2.iv of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. For non-USG funded research, notification should be made to the NIH which will refer the notification to an appropriate agency based on the nature of the research.

   Notification to the PI will convey that further review for DURC by the acting IRE is not presently required, but that the PI is still required to continually self-assess provide notification if a change in the subject research may potentially alter the DURC analysis.

ii. If the Ad Hoc Committee concludes that the subject research does meet the definition of DURC, it will promptly notify the PI and within 30 calendar days, the applicable USG Funding Agency, and shall proceed to develop a risk mitigation plan. Notification shall include the information identified in Section 7.2.iv of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. For non-USG funded research, notification should be made to the NIH which will refer the notification to an appropriate agency based on the nature of the research. Research that has been determined to be DURC should not be conducted until an approved Risk Mitigation Plan is in place.

The Chair of the Ad Hoc Committee and/or the ICDUR may consult with the USG Funding Agency with respect to the Committee's determination as to 6.2.B.2.i-ii.

iii. The Ad Hoc Committee's decision and any other institutional decision regarding DURC may be appealed by the affected PI to the Provost. The Provost will have the final word as to all institutional decisions regarding DURC that have been appealed.

3. Development and Implementation of Risk Mitigation Plan

In order to determine the acceptable level of risk associated with the DURC and the best risk mitigation strategies, **the Ad Hoc Committee shall assess the potential benefits of the research and weigh the risks and benefits**. Guidance on points to consider in making this assessment can be found in Section C.3.2 of the Companion Guide.

The Ad Hoc Committee shall work with the USG Funding Agency 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, E, and F of the Companion Guide.

At the conclusion of its review, the Ad Hoc Committee will submit its findings and its recommendations as to the elements of the draft Risk Mitigation Plan to the VPRA.

The VPRA shall review the adequacy of the Committee's draft Risk Mitigation Plan and may require revisions to the draft Plan. In doing so, the VPRA is bound by the same guidance contained in this Policy, the 2014 Policy, and Companion Guide in reviewing and making such revisions.

C. Notification to the USG Funding Agency of Draft Risk Management Plan

1. Within 90 calendar days following the Ad Hoc Committee's determination that the research is DURC, the ICDUR shall submit the draft Risk Management Plan to the applicable USG Funding Agency for final review and approval. In the case

of non-USG funded research, the draft Risk Management Plan should be provided to the USG agency designated by NIH (per Section 6.1.B.2.ii above).

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.

2. The USG Funding Agency must finalize the Plan within 60 days following receipt of the draft Plan.

D. Subawards

1. 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 US Funding Agency (the Primary Institution), the Primary Institution will be responsible for notifying 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.

2. The Primary Institution should also ensure that DURC oversight is consistently applied by all entities participating in the collaboration.

7. ONGOING RESPONSIBILITIES

7.1. Responsibilities of the PI

The PI shall:

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

B. 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;

C. Notify the RHSC if for whatever reason (e.g., changes in the research, new discoveries), he/she feels that the research should be reconsidered by the RHSC because it might constitute DURC or is no longer DURC;

D. 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;

E. Be knowledgeable about and comply with all institutional and USG policies and requirements for oversight of DURC; and

F. Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved Risk Mitigation Plan.

7.2. Responsibilities of the ICDUR

The ICDUR shall:

A. Ensure that the RHSC reviews each DURC Research Risk Mitigation Plan annually;

B. 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;

C. Maintain records of institutional DURC reviews and completed Risk Mitigation Plans for no less than eight years, unless a shorter period is required by law or regulation;

D. Notify the applicable US Funding Agency within 30 calendar days of any change in the status of any DURC, including whether such Research has been determined by the RHSC 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 USG Funding Agency. Such notification should be made to the USG Funding Agency or, in the case of non-USG funded research, to the USG agency designated by NIH;

E. Report within 30 calendar days to the applicable US Funding Agency instances of non-compliance with this Policy, as well as mitigation measures undertaken by the University to prevent recurrences of similar noncompliance; and

F. Make information about the process for review of research subject to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern available upon request, as consistent with applicable law.

7.3. Responsibilities of the RHSC

The RHSC shall:

A. Review, at least annually, all active Risk Mitigation Plans at the University. In reviewing such Plans, the RHSC will follow the same procedures as are described in Section 6.6 (A) of this Policy. If the research in question still constitutes DURC, the RHSC, 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.

B. Research that has already been determined to be DURC under the March 2012 DURC Policy, and for which a Risk Mitigation Plan has already been developed, does not need a Risk Mitigation Plan but the extant Risk Mitigation Plan will be subject to ongoing review and modification, as necessary.

END OF DOCUMENT