GEORGIA INSTITUTE OF TECHNOLOGY
POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES
DUAL USE RESEARCH OF CONCERN

1. BACKGROUND

1.1. 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 (DUR). Dual Use Research of Concern (DURC) is a subset of DUR 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."[1]

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

1.3. These definitions could potentially encompass a number of life sciences research projects at Georgia Tech (GT), however, the current scope of the US Government Policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and category of experiment to be deemed potential DURC:

Agents & Toxins	***Categories of Experiments***
• Avian influenza virus (highly pathogenic) • *Bacillus anthracis* • Botulinum neurotoxin[2] • *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*	• Enhances the harmful consequences of the agent or toxin • Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification • 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 • Increases the stability, transmissibility, or the ability to disseminate the agent or toxin • Alters the host range or tropism of the agent or toxin • Enhances the susceptibility of a host population to the agent or toxin • Generates or reconstitutes an eradicated or extinct agent or toxin listed in the column to the left

[1] United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014)

[2] For the 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.

2. PURPOSE

The purpose of this GT policy is to provide institutional review and oversight by GT of life sciences research to identify potential DURC and to develop and implement risk mitigation plans, where appropriate. In doing so, this policy seeks to preserve the benefits of life sciences DURC while minimizing the risk that the output of such research could be used for harmful purposes.

3. SCOPE

This policy applies to all research conducted at GT or by GT faculty members, staff or students that involves any of the 15 agents and toxins listed in 1.3 of this policy, regardless of the funding source.

4. RESPONSIBILITIES

4.1. Georgia Institute of Technology (GT)

GT has the following responsibilities:

4.1.1. Establishing and implementing policies and procedures that provide for the identification and oversight of DURC.

4.1.2. Establishing an Institutional Review Entity (IRE) that is made up of at least five members and comprised of persons with:

4.1.2.1. A breadth of expertise to assess the dual use potential of the range of relevant life sciences research conducted at GT; and

4.1.2.2. Knowledge of US Government policies and the understanding of risk assessment and risk management considerations, including biosafety and biosecurity.

4.1.3. Designating an Institutional Contact for Dual Use Research (ICDUR).

4.1.4. Certifying that GT will comply with the US Government Policy.

4.2. Office of Research Integrity Assurance (ORIA)

ORIA is responsible for administering the IRE.

4.3. Institutional Contact for Dual Use Research (ICDUR)

The GT Vice President for Research will serve as the ICDUR. The ICDUR has the following responsibilities:

4.3.1. Serving as the liaison, as necessary, between GT and the US Government funding agency or NIH (as applicable).

4.3.2. Serving as the point of contact for GT for questions regarding the implementation of and compliance with the institutional DURC policy.

4.4. Biological Materials Safeguards Committee (BMSC)

The BMSC is responsible for notifying the IRE of potential DURC identified during the BMSC protocol review process.

4.5. Institutional Biosafety Committee (IBC)

The IBC is responsible for notifying the IRE of potential DURC identified during the IBC protocol review process.

4.6. Institutional Review Entity (IRE)

The members and chair of the GT IBC will be used to form the IRE. Ad Hoc members will be added to the committee as needed.

The IRE has the following responsibilities:

4.6.1. Reviewing research projects that have been designated by the PI as potential DURC and conducting a risk assessment to determine if they are indeed DURC.

4.6.2. Notifying US Government funding agencies or the NIH (as applicable) within 30 calendar days that DURC has been identified.

4.6.3. Developing a Risk Mitigation Plan for the research while working with the PI.

4.6.4. Providing a draft of the Risk Mitigation Plan to the US Government funding agency or NIH (as applicable) within 90 calendar days.

4.6.5. Ensuring implementation of the approved risk management plan.

4.6.6. Reviewing all active approved risk management plans annually.

4.6.7. Notifying the US Government funding agency or NIH (as applicable) within 30 calendar days of any changes that would affect active risk mitigation plans or instances of non-compliance.

4.6.8. Maintaining records of DURC reviews and risk mitigation plans for at least the term of the research grant/contract plus three years but not less than eight years.

4.6.9. Providing education and training on DURC to research personnel.

4.6.10. Ensuring compliance with the policy among research personnel.

4.6.11. Meeting at least annually.

4.7. Principal Investigator (PI)

The PI has the following responsibilities:

4.7.1. Initially assessing DURC potential of life science research during the submission of registrations to the IBC or BMSC (as applicable).

4.7.2. Working with the IRE to develop a risk mitigation plan.

4.7.3. Conducting approved DURC in accordance with the approved risk mitigation plan.

4.7.4. Being knowledgeable about DURC policies and ensure that lab personnel are also knowledgeable about DURC policies.

4.7.5. Communicating DURC responsibly when publishing or presenting experimental findings as defined in the Risk Management Plan.

5. DURC Screening & Review Procedures

5.1. DURC Awareness Training:

5.1.1. DURC Module in General Biosafety Training: GT researchers are required to complete General Biosafety Training every three years as a prerequisite for IBC and BMSC approval. This training includes a module on DURC.

5.1.2. DURC Administration Training: Members of the IRE, BMSC, IBC, ORIA, Environmental Health and Safety (EHS) and the Office of Sponsored Programs are provided DURC Administration Training on a periodic basis.

5.1.3. DURC Information Posting:

A website, hosted by ORIA, provides the GT research community with up-to-date information on US Government DURC policy, training tools and GT-specific forms and procedures (including this policy).

A link to the GT DURC website is posted on the Environmental Health and Safety Website and the Research GT Portal.

5.2. DURC Potential Assessment:

5.2.1. The PI assesses DURC potential of their life science research by answering the following questions during the submission of research registrations to the BMSC or IBC (as applicable).

DUAL USE RESEARCH OF CONCERN (DURC) POTENTIAL ASSESSMENT

- 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 (DUR).
- Dual Use Research of Concern (DURC) is a subset of DUR 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 US Government released the US Government Policy for Oversight of Life Sciences Dual Use Research of Concern to establish the requirements for the oversight of DURC by the US GOVERNMENT. On September 24, 2014, the US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern was released to establish the requirements for institutional (i.e., non-US Government) oversight of DURC. The US Government considers these two policies to be complementary.
- These definitions could potentially encompass a number of life sciences research projects at Georgia Tech, however, the current scope of the US Government Policy has been limited to the following agents and toxins and categories of experiments. Research must involve both a listed agent/toxin and category of experiment to be deemed potential DURC.

1	**Agent or Toxin Involved in Project (check all that apply)** *Verify if this project directly involves non-attenuated forms of 1 or more of the 15 listed agents.* ☐ Avian Influenza (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* ☐ **NONE**

2	**Experimental Effects (check all that apply)** *Indicate whether the research project indicated above produces, aims or can be reasonably anticipated to produce any of the following experimental effects.* ☐ Enhances the harmful consequences of the agent or toxin. ☐ Disrupts the immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification. ☐ Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against the agent or toxin or facilitates its ability to evade detection methodologies. ☐ Alters properties of the agent or toxin in a manner that would enhance its ability to be disseminated. ☐ Alters the host range or tropism of the agent or toxin. ☐ Enhances the susceptibility of a host population to the agent or toxin. ☐ Generates or reconstitutes an eradicated or extinct agent or toxin listed in Question 6.2 of this form. ☐ **NONE** ***If you checked any of the above experimental effects, please explain:***

5.2.2. The BMSC and IBC notify the IRE when potential DURC has been identified during the respective registration review process.

5.3. Verification of DURC and Risk Assessment by IRE:

5.3.1. The IRE verifies that the PIs research involves any of the listed agents and/or toxins and makes a final determination of the applicability of the list of experimental effects.

5.3.2. The IRE conducts a Risk Assessment to determine if the research meets the definition of DURC. A template for conducting this risk assessment is available in the DURC Companion Guide prepared by the NIH on behalf of the US Government in Appendix 3.

5.3.3. The IRE notifies the appropriate US Government funding agency or NIH of the outcome of the risk assessment within 30 calendar days. A template for 30-day reporting is available in the DURC Companion Guide in Appendix 4.

5.4. Development of Draft Risk Mitigation Plan by IRE:

5.4.1. In the event that the IRE's Risk Assessment determines that the research meets the definition of DURC, the IRE evaluates the anticipated benefits and identified risks of the DURC to develop a Draft Risk Mitigation Plan. Guidance on how to develop a draft risk mitigation plan is available in Section D of the DURC Companion Guide.

5.4.2. IRE submits the Draft Risk Mitigation Plan to the US Government Funding Agency or NIH within 90 calendar days of the IRE's determination that the research is DURC.

5.5. Approval of Risk Mitigation Plan by US GOVERNMENT Funding Agency:

5.5.1. After receipt of Draft Risk Mitigation Plan, the appropriate US Government funding agency or NIH finalizes the plan within 60 calendar days for receipt of the draft of the plan.

5.5.2. GT implements the approved Risk Mitigation Plan and the PI conducts and/or communicates research according to the approved plan.

5.6. Annual Review of Risk Mitigation Plan:

5.6.1. Annually, the IRE reviews all active Risk Mitigation Plans.

5.6.2. As needed, the IRE should modify the Risk Mitigation Plan.

5.6.3. The IRE will notify the US Government Funding Agency or NIH within 30 calendar days of:

5.6.3.1. Any change in the status of DURC; and

5.6.3.2. Details of any changes to the risk mitigation plan.

6. REFERENCES

6.1. United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 2014)

6.2. United States Government Policy for the Oversight of Life Sciences Dual Use Research of Concern (March 2012)

6.3. Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern (September 2014)

6.4. GT IBC Website

6.5. GT EHS Website

7. SUPPORTING DOCUMENTS

7.1. BMSC DURC Potential Assessment Form

7.2. IBC Registration Form