Establishing a Dual Use Research of Concern (DURC) review program at Columbia University

MABSA Symposium

June 11th 2015

Christopher Aston Ph.D.

Dual Use Research In The Life Sciences

Good science can be put to bad uses

Dual use research (DUR) is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized both for benevolent and harmful purposes

A little history:

2001 - Mouse Pox virus encoding immune-modulatory genes made more virulent

2002 - De novo synthesis of polio virus genome

2004 – Fink Report "Biotechnology Research in an Age of Terrorism: Confronting The "Dual Use" Dilemma"

2011 – Avian influenza H5N1 virus made more transmissible between ferrets

2014- Moratorium on Gain-of-Function Research (Influenza, SARS, and MERS)

2015 - Government Policy on Institutional Review of Life Science DURC takes effect

The USG Policy for Institutional DURC Oversight (September 2014)

- **Institutional oversight** of DURC is a critical component of a comprehensive oversight system that involves:
  - Principal Investigators (PIs)
  - Institutional Review Entity (IRE)
  - Institutional Contact for Dual Use Research (ICDUR)
  - Institution
  - United States Government (USG)

DURC at Columbia

Aug. 2012 - White Paper - DURC; A path forward for Columbia
Oct. 2012 - A policy recommendation for Columbia University
Mar. 2013 – Interim DURC Policy
Mar. 2015 – Final DURC Policy

Final – February 10, 2015

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

I. BACKGROUND

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."

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.

II. PURPOSE

http://evpr.columbia.edu

Columbia University in the City of New York

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH

SEARCH GO

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ABOUT

RESEARCH AT COLUMBIA

FACULTY AND STAFF
- QUICK GUIDE TO RESEARCH
- RESOURCES
- POLICIES

RESEARCHERS NEW TO COLUMBIA

RESEARCH COMPLIANCE TOPICS IN THE NEWS

NEWSLETTER

Policies

The Sponsored Projects Handbook contains all University policies related to the conduct of sponsored research; however, the following policies are often referred to by faculty and staff involved in research.

General Policies

Institutional Policy on Misconduct in Research

Principal Investigator Eligibility Policy

International Research and Service Projects: Risk Management Procedures

Guidelines for Short-term Visitors in Research-Related Activities

Sponsored Project Subaward Policy

Standard Operating Procedure for Medicare Approval of Device Trials

Memo concerning NSF Data Management Plan requirements

NSF Data Management Plan

Clinical Trials Monitoring Assistance Program for FDA Regulated Human Subjects Research

Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

http://ehs.columbia.edu/

CU Home

COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK

ENVIRONMENTAL HEALTH AND SAFETY

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Emergency Response

Sitemap

Vision Statement

Environmental Health & Safety (EH&S) provides expert guidance and timely service to the University Community through our commitment to health and safety. Employing best practices and collaboration, and by building long term relationships, we promote a productive and safety conscious work environment.

Mission Statement

Columbia University is committed to establishing and maintaining a healthy and safe work environment for our staff, students, neighbors and surrounding communities. Through the recognition, evaluation, and control of personal and environmental hazards, the University strives to eliminate individual risk and reduce the environmental impact of its activities. EH&S offers a broad range of services and actively develops partnerships with faculty and departmental personnel to ensure a safe work environment and compliance with University policy and applicable regulations in the most efficient manner possible. These endeavors are realized through programs such as personnel training, chemical hygiene plan, biological safety, environmental safety, fire safety, occupational safety, and asbestos and lead management in compliance with local, state and federal regulations.

Goals:

- Setting an example for effective health and safety programs;
- Minimizing risk of exposure to hazardous chemical, physical or biological agents;
- Minimizing risk of work related injury and illness;
- Minimizing risk to the environment; and
- Realizing these goals with a minimum burden on education and research activities.

Columbia University Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)

Emergency Email Alerts Archive

Please Note: C14 class is cancelled for this Friday: 4-24-15

Morningside Campus (MS) : (212) 854-8749
Medical Center (CUMC): (212) 305-6780 and (212) 305-0303

What Research is Subject to the Policy?

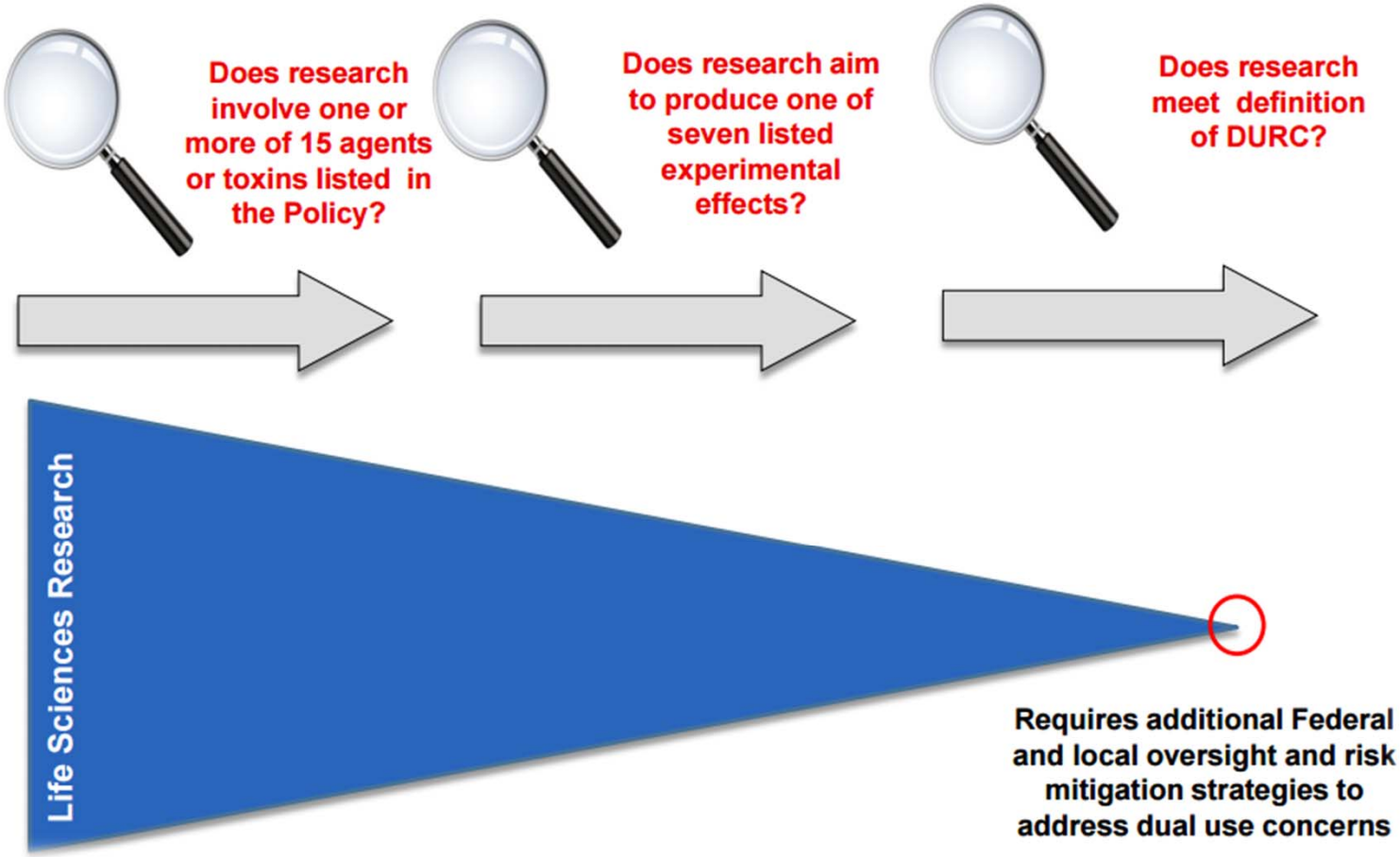
- **Research that directly involves any of the following 15 agents and toxins***
  - Avian influenza virus (highly pathogenic)
  - *Bacillus anthracis*
  - Botulinum neurotoxin (in any quantity)
  - *Burkholderia mallei*
  - *Burkholderia pseudomallei*
  - Ebola virus
  - Foot-and-mouth disease virus
  - *Francisella tularensis*
  - Marburg virus
  - Reconstructed 1918 Influenza virus
  - Rinderpest virus
  - Toxin-producing strains of *Clostridium botulinum*
  - Variola major virus
  - Variola minor virus
  - *Yersinia pestis*

* Except attenuated strains of the agents that are excluded from the Select Agent list and inactive forms of botulinum neurotoxin

What Research is Subject to the Policy?

- **Experimental effects**
  - 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 policy

Research Subject to the Policies



Overview of the Process for Institutional DURC Oversight

PI identifies research that involves any of the 15 listed agents

↓

Institutional Review Entity (IRE):
- Determines whether the research involves any of the 7 experimental effects;
- If so, conducts a risk assessment to determine whether the research is DURC; and
- If so, weighs the risks and benefits and develops a draft risk mitigation plan

↓

USG funding agency finalizes and approves risk mitigation plan

↓

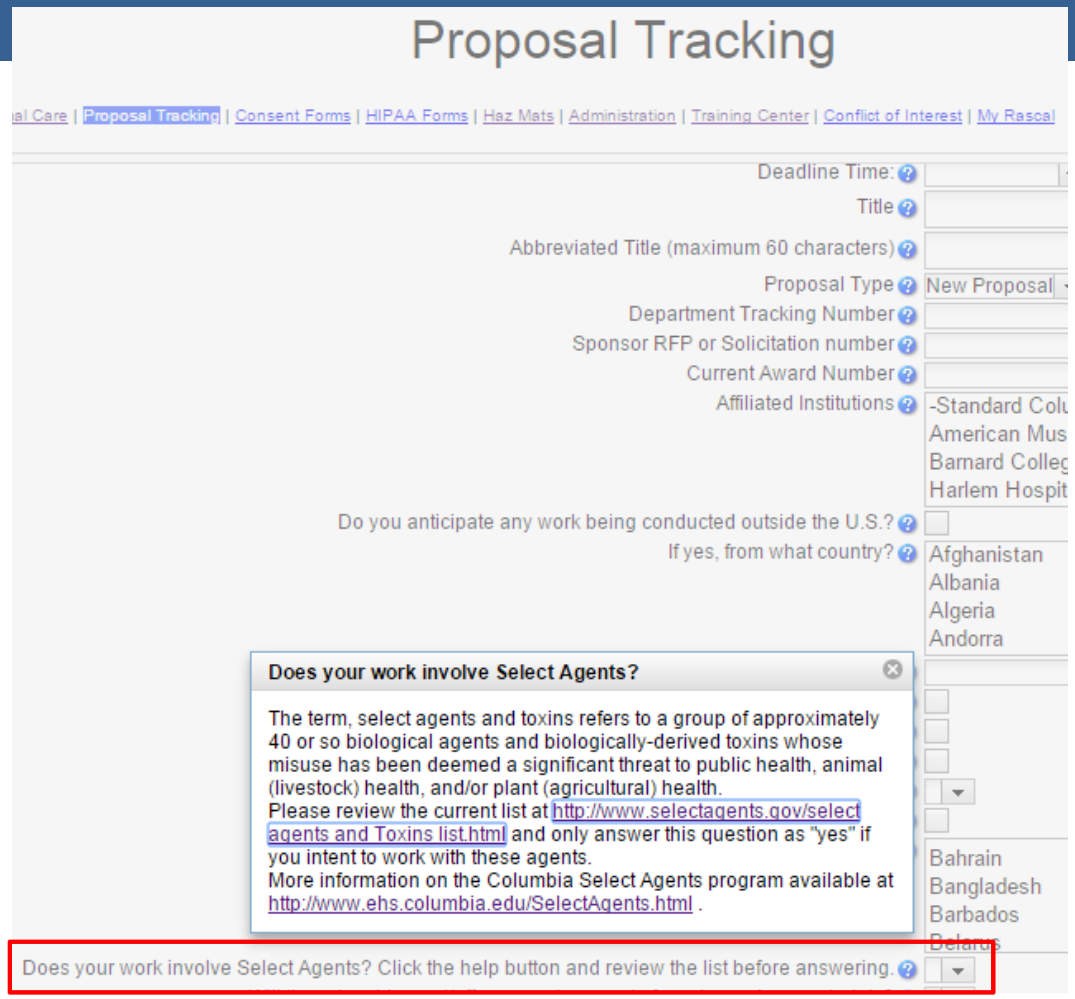
Institution implements approved risk mitigation plan and provides ongoing oversight

↓

PI conducts and communicates research according to risk mitigation plan

The PI's self-screening will be augmented by multiple checkpoints:

- Sponsored Projects Administration (SPA), which will include a question in the online grant proposal tracking application as to whether the proposed research involves a DURC Agent.
- Columbia Technology Ventures (CTV), which will ask the same question as part of its review of Material Transfer Agreements.
- Export Controls Officer
- Procurement, which processes Select Agent incl. *C. bot.* toxin purchases.
- IRB, who identify PIs using *C. bot.* toxin in human subjects.



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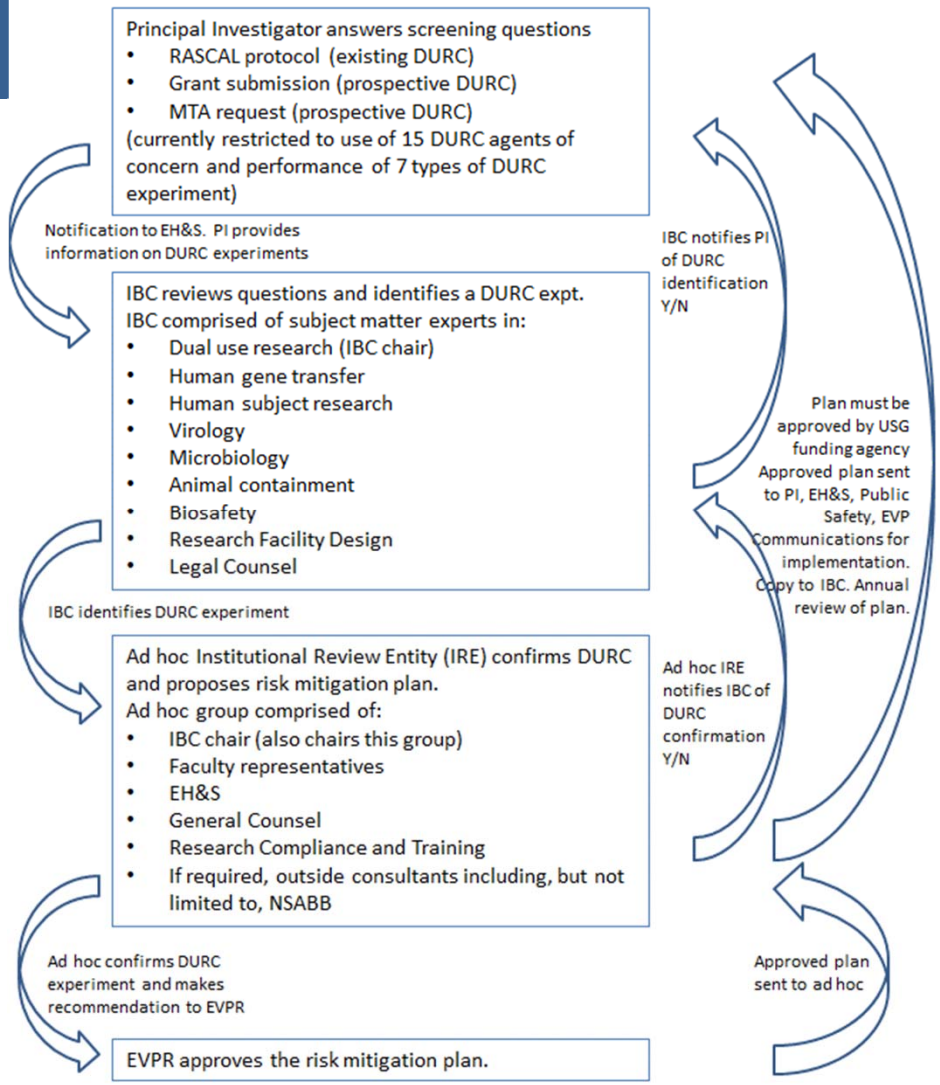
Flow diagram indicating review of Dual Use Research of Concern (DURC)



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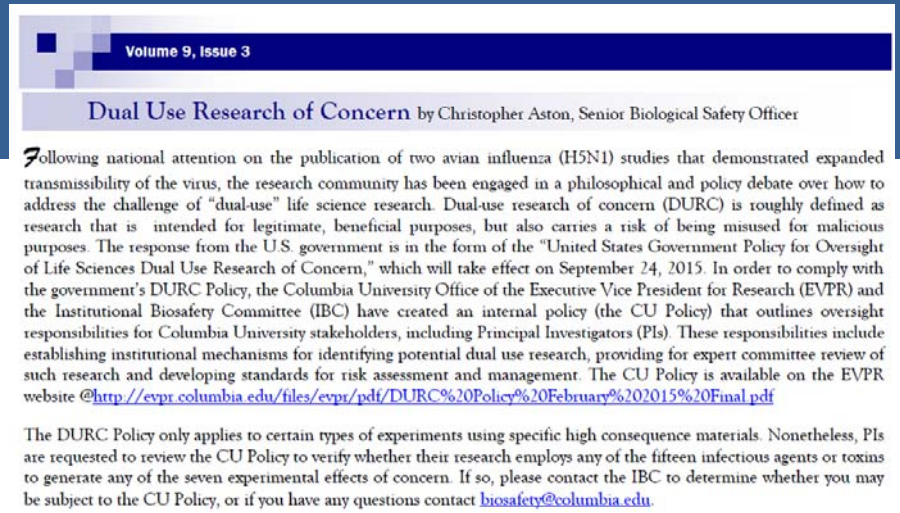
Management of DURC-Associated Risks

- **DURC risk mitigation strategies may 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.

Outreach and training:

- email to ~200 PIs working at BSL-2 or higher, as well as those who perform research with biological toxins
- Newsletter article
- EVPR handbooks (wee books)
- Posters and lobby monitors
- Revision to our online biosafety course TC0509

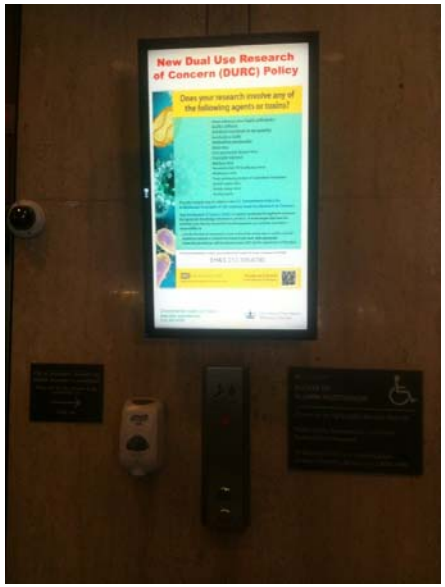


Volume 9, Issue 3

Dual Use Research of Concern by Christopher Aston, Senior Biological Safety Officer

Following national attention on the publication of two avian influenza (H5N1) studies that demonstrated expanded transmissibility of the virus, the research community has been engaged in a philosophical and policy debate over how to address the challenge of "dual-use" life science research. Dual-use research of concern (DURC) is roughly defined as research that is intended for legitimate, beneficial purposes, but also carries a risk of being misused for malicious purposes. The response from the U.S. government is in the form of the "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern," which will take effect on September 24, 2015. In order to comply with the government's DURC Policy, the Columbia University Office of the Executive Vice President for Research (EVPR) and the Institutional Biosafety Committee (IBC) have created an internal policy (the CU Policy) that outlines oversight responsibilities for Columbia University stakeholders, including Principal Investigators (PIs). These responsibilities include establishing institutional mechanisms for identifying potential dual use research, providing for expert committee review of such research and developing standards for risk assessment and management. The CU Policy is available on the EVPR website @http://evpr.columbia.edu/files/evpr/pdf/DURC%20Policy%20February%202015%20Final.pdf

The DURC Policy only applies to certain types of experiments using specific high consequence materials. Nonetheless, PIs are requested to review the CU Policy to verify whether their research employs any of the fifteen infectious agents or toxins to generate any of the seven experimental effects of concern. If so, please contact the IBC to determine whether you may be subject to the CU Policy, or if you have any questions contact biosafety@columbia.edu.



Dual Use Research of Concern (DURC)

- Dual Use Research of Concern (DURC) is life sciences research that, 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.
- Currently restricted to these agents and experiments……
- Principal Investigators must review the University Policy on DURC and self-screen their research. http://evpr.columbia.edu/files/evpr/pdf/DURC%20Policy%20February%202015%20Final.pdf
- Review of potential DURC is performed by the IBC, and an ad hoc committee convened by the EVPR. Please contact biosafety@columbia.edu for guidance.

FIFTEEN DURC AGENTS		SEVEN EXPERIMENTAL EFFECTS OF CONCERN
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	AND	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.

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Advice to share

- Start now
- Utilize the government FAQ and guides
- Identify and engage your stakeholders
- Educate your investigators


KEEP
CALM
AND
ASK
QUESTIONS