# DURC Identified: Time to Develop a Risk Mitigation Plan

**Dennis M. Dixon, PhD**
Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
NIAID, NIH, HHS

**September 2017**
**DURC Stakeholder Engagement Workshop**

National Institute of Allergy and Infectious Diseases

# NIH Implementation of the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern

Notice Number: NOT-OD-15-017

Key Dates

**Release Date:** November 21, 2014

Related Announcements

None

Issued by

National Institutes of Health (NIH)

- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
  - Effective Date: September 24, 2015

- United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern
  - Released March 29, 2012

# Three Key Steps for DURC Assessment

**United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern**

*Effective September 2015*

- One of the 15 agents and toxins.
- One or more of the 7 key experiments/“effects”
- Impact/consequences.

# Resources for Development of Risk Mitigation Plans

**United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern**
*Released March 2012*

i. Modifying the design or conduct of the research
ii. Applying specific or enhanced biosecurity or biosafety measures
iii. Evaluating existing evidence of MCM efficacy, or conducting experiments to determine MCM efficacy against the agents or toxins resulting from DURC, and where effective MCM exist, including that information in publications

# Resources for Development of Risk Mitigation Plans

**United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern**
*Released March 2012*

iv. Referring the institution to available DURC educational tools such as: https://osp.od.nih.gov/biotechnology/nsabb-reports-and-recommendations/

v. Regularly reviewing, at the institutional level, emerging research findings for additional DURC

vi. Requesting that institutions notify funding departments or agencies if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed

# Resources for Development of Risk Mitigation Plans

**United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern**
*Released March 2012*

vii. Determining the venue and mode of communication (addressing content, timing, and possibly the extent of distribution of the information) to communicate the research responsibly

viii. Reviewing annual progress reports from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention and applying potential mitigation measures as described above, as necessary

# Resources for Development of Risk Mitigation Plans

**United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern**

*Released March 2012*

ix. If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:

a) Request voluntary redaction of the research publications or communications

b) Classify the research:

i. In accordance with the National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations

ii. Departments and agencies may consider whether to refer classified research to another department or agency for funding

c) Not provide or terminate research funding

# Resources for Development of Risk Mitigation Plans

**A Companion Guide to the DURC Policies**
***Published September 2017***

D. Developing a Draft Risk Mitigation Plan: Guidance for Institutional Review Entities

F. Guidance for Responsible Communication of DURC Findings

# Risk Mitigation Plan Development: A Shared Endeavor

> Institutions should work with both the PI and USG funding agency, or for non-Federally funded DURC, the NIH-designated USG agency (per Section 7.E) to develop a risk mitigation plan.
>
> *Institutional DURC Policy – Effective September 2015*

- NIAID's Experience/Approach
  - Institution and PI develop a draft risk mitigation plan and share it with NIAID
  - NIAID reviews the draft risk mitigation plan and, in accordance with a Memorandum of Understanding, shares it with CDC and USDA for evaluation of the sufficiency of the biosecurity and/or biosafety measures
  - NIAID shares its suggestions, as well as feedback from CDC/USDA, with the institution

# Thank you

Institutions have the discretion to consider other categories of research for DURC potential and may expand their internal oversight to other types of life sciences research as they deem appropriate, but such expansion would not be subject to oversight as articulated in this policy.

*Institutional DURC Policy – September 2014*

Such guidance may also be applied more broadly to research that is not within the scope of these policies but may warrant review for dual use potential and special oversight, and it may be used by others within the scientific community (e.g., journal editors) that are not subject to these policies.

*A Companion Guide to the DURC Policies – September 2017*