

# Dual Use Research of Concern: The March 29 Policy

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# DUR vs. DURC

- **Dual use research (DUR)** = legitimate research that yields information or technologies that could be misused for malevolent purposes
  - NOTE: Most life sciences research conceivably could be considered DUR in that it has *some* potential to generate information that could be eventually misused
- Goal is to identify the subset that has highest potential for generating information that could be readily misused = *dual use research of concern (DURC)*

# Dual Use Research of Concern (DURC) Defined

“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.”

# DURC: Risk Mitigation Strategies

- Management of DURC may entail a variety of possible strategies, for example:
  - Changes in the design or conduct of research
  - Applying specific biosecurity and/or biosafety measures
  - Monitoring of research for findings with additional DURC potential

# USG Policy on Oversight of DURC

- **Issued by** the Administration on March 29, 2012 following an interagency policy process
- **Purpose:** To establish regular review of USG funded or conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to:
  - mitigate risks as appropriate; and
  - collect information needed to inform the development of an updated policy, as needed, for the oversight of DURC.

# Step 1: Identification of research involving any of the 15 agents or toxins listed

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
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*

**Step 2:** Identification of research that produces, aims to produce, or is reasonably anticipated to produce any of the listed effects

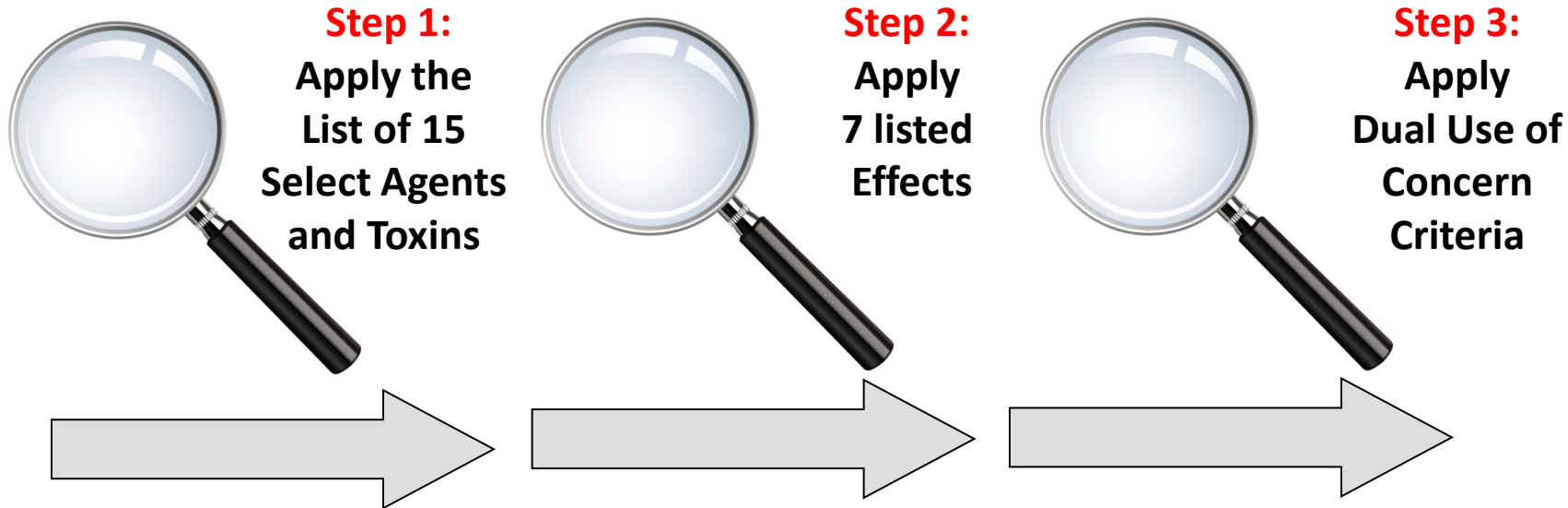
1. Enhances the harmful consequences of the agent or toxin;
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or 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; or
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section III.1

# Step 3: Determination of whether the research is DURC

## *Dual Use Research of Concern*

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.





Federally Funded Life Sciences Research

Requires additional Federal and local oversight and risk mitigation strategies to address dual use concerns

# Risk Assessment

- For projects that fall within the scope and that are determined to meet the definition of DURC, Federal departments and agencies will:
  - Assess the **risks and benefits** of such projects, including how research methodologies may generate risks and/or whether open access to the knowledge, information, products, or technologies generates risk
  - Develop, in collaboration with the institution or researcher, a **risk mitigation plan** to apply any necessary and appropriate risk mitigation measures



# Risk Mitigation

- Risk mitigation measures may include, but are not limited to:
  - **Modifying the design** or conduct of the research
  - Applying specific or **enhanced biosecurity or biosafety** measures
  - **Evaluating existing evidence of medical countermeasures** (MCM) efficacy, and where effective MCM exist, including that information in publications
  - **Regularly reviewing**, at the institutional level, emerging research findings for additional DURC

# Risk Mitigation, *continued*

- Risk mitigation measures may include, but are not limited to:
  - Requesting that institutions **notify funding departments or agencies** if additional DURC is identified, and propose modifications to the risk mitigation plan, as needed
  - **Reviewing annual progress reports** from Principal Investigators to determine if DURC results have been generated, and if so, flagging them for institutional attention
  - Determining the **venue and mode of communication** of the research (addressing content, timing, and possibly the extent of distribution of the information)

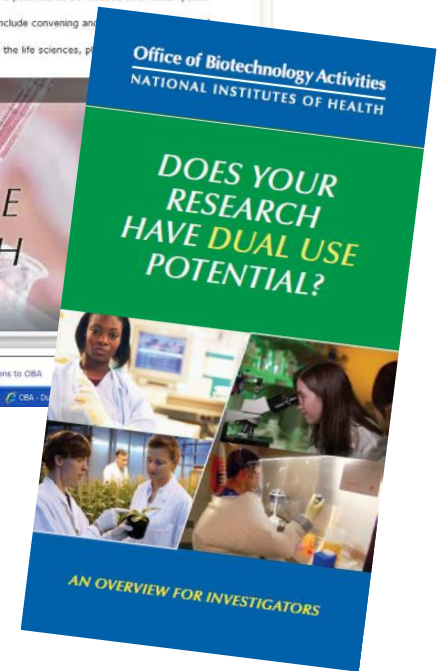
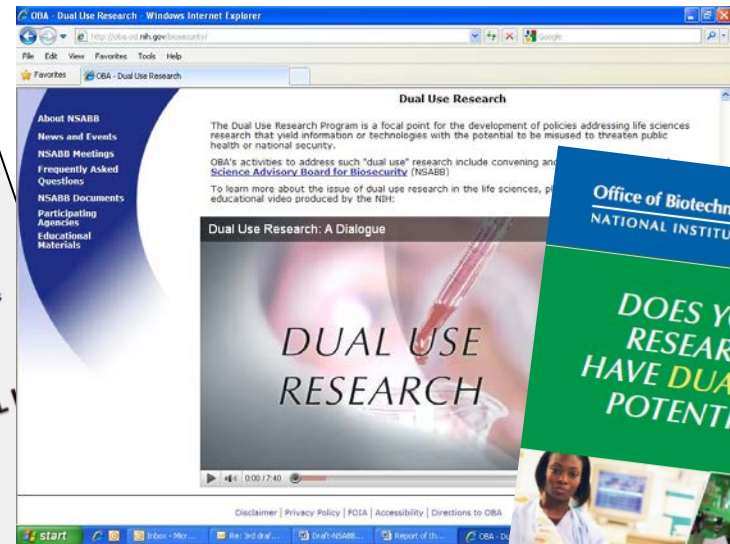
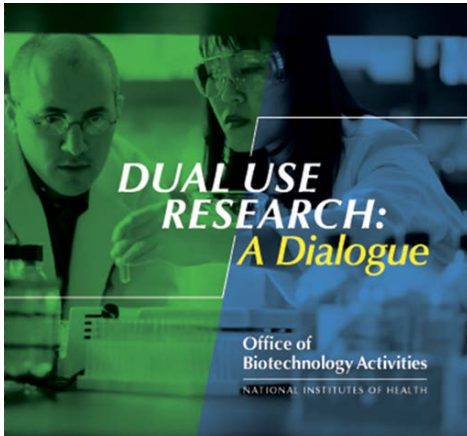
# Risk Mitigation, *continued*

- If the risks posed by the research cannot be adequately mitigated with the measures described, Federal departments and agencies will determine whether it is appropriate to:
  - Request voluntary redaction of the research publications or communications
  - Classify the research, in accordance with National Security Decision Directive/NSDD-189
  - Not provide or terminate research funding

# Current Risk Mitigation Measures

- **Biosafety**
  - NIH Guidelines for Research Involving Recombinant DNA Molecules
  - Biosafety in Microbiological and Biomedical Laboratories (BMBL)
  - Select Agent Regulations
- **Biosecurity**
  - Personnel Reliability Programs
  - Select Agent Regulations
- **Occupational Health and Safety**

# Educational Tools on DURC



[oba.od.nih.gov/biosecurity/biosecurity.html](http://oba.od.nih.gov/biosecurity/biosecurity.html)

[www.phe.gov/s3](http://www.phe.gov/s3)