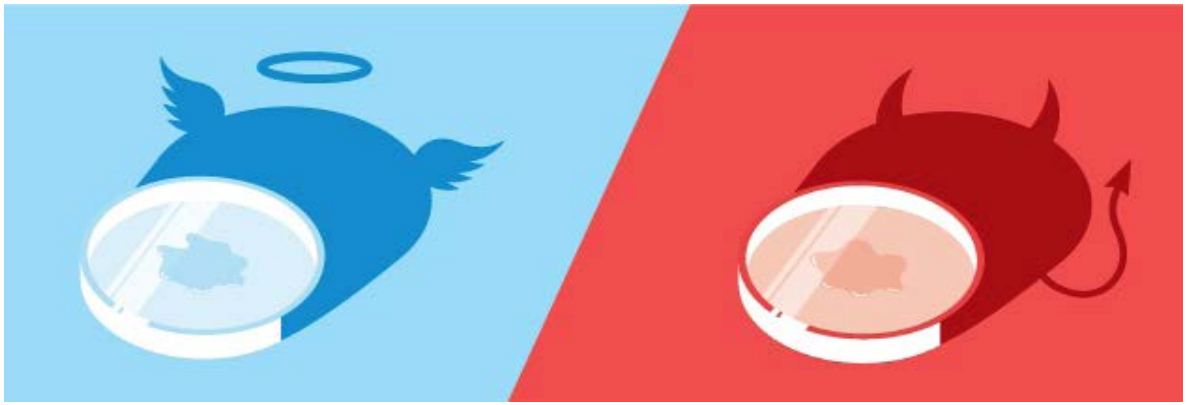
Implementation of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

Stakeholder Engagement Workshop

September 25-26, 2017

The Dual Use Dilemma



Good science** can be misused for **bad purposes

Legitimate life sciences research can be used for both benevolent and malevolent purposes

Key challenge: *How to facilitate beneficial biological research while mitigating the risks of misuse?*

Source of Image: Nature, *J. KRZYSZTOFIAK*

Previous Stakeholder Engagement on the Institutional DURC Policy

- USG Policy for Institutional Oversight of Life Sciences DURC released September 2014
  - Effective date: Sept. 2015
- 2015 OSTP and NIH Stakeholder meeting

2015 Stakeholder Meeting Goals

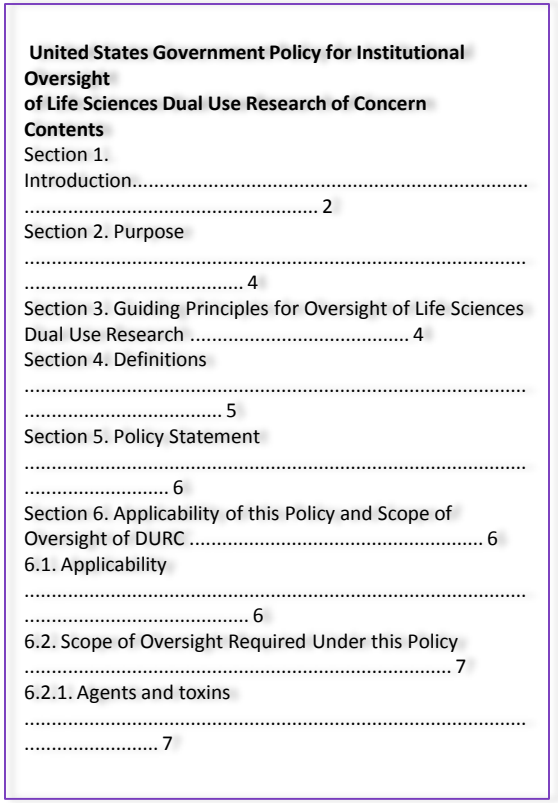
- Outreach to institutions about key responsibilities under the policy
- Learn about the experiences of institutions
- Identify challenges in implementing the policy

➢ USG issued a statement that addressed the most prevalent questions raised during the meeting

Why are we here today?

To gather feedback and perspectives of institutions and facilitate information exchange regarding:

- Approaches taken to implement the policy
- Experiences associated with policy implementation and steps taken to address any challenges encountered
- Procedures established for reviewing research and identifying DURC
- Experiences with developing and/or implementing risk mitigation plans
- Best practices and novel strategies for managing DURC
- Effective strategies for educating and training investigators and staff about DURC issues



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

Agenda Overview

Day 1

- **Session I: Overview of the *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern***
  - *Review of the DURC issue and the USG policy for institutional oversight of DURC*

- **Session II: Establishing an Institutional Framework for Governance of Dual Use Research and an Institutional Review Entity**
  - *Discussion of approaches taken by institutions to establish and implement a system for institutional oversight of DURC*

- **Session III: Institutional Processes for Identifying and Reviewing Research Subject to the Policy**
  - *Discussion of institutional approaches to and experiences with identifying and evaluating research subject to the policy*

Agenda Overview

Day 1 (cont.)

- **Session IV : Risk Mitigation: Federal Agency Perspectives**
  - *Discussion of federal agency approaches to working with institutions to develop risk mitigation plans for research identified as DURC*

- **Session V: Institutional Approaches to Developing and Implementing Risk Mitigation Plans**
  - *Discussion of institutional approaches to the development and implementation of risk mitigation plans for research determined to be DURC*

- **Session VI: Open Forum for Stakeholder Input**
  - *Open discussion with meeting participants on experiences, challenges, and best practices regarding implementation of the institutional DURC policy*

Agenda Overview

Day 2

- **Session VII: Institutional Approaches: Raising Awareness and Education about DURC**
  - *Discussion of institutional approaches to educating staff, IRE members, investigators, and laboratory personnel about the dual use issue and their roles/requirements under the policy*

- **Session VIII: Researcher Perspectives on the Institutional DURC Policy**
  - *Discussion of DURC policy implementation and associated experiences at the laboratory level*

- **Session IX: Open Forum for Stakeholder Input**
  - *Open discussion with meeting participants on experiences, challenges, and best practices regarding implementation of the institutional DURC policy*

NSABB Working Group

NSABB Voting Members

Joseph E. McDade (Chair)
Centers for Disease Control and Prevention (Ret.)

Marie-Louise Hammarskjöld
University of Virginia School of Medicine

Joseph Kanabrocki
University of Chicago

Theresa M. Koehler
University of Texas Medical School at Houston

Francis L. Macrina
Virginia Commonwealth University

Jean L. Patterson
Texas Biomedical Research Institute

I. Gary Resnick
Los Alamos National Laboratory

Federal Agency Representatives

Dennis Dixon
National Institutes of Health

Samuel Edwin
Centers for Disease Control

Gerald Epstein
White House Office of Science and Technology Policy

Meg Flanagan
Department of State

Andrew Ford
National Institutes of Health

Wendy Hall
Department of Homeland Security

Janelle Hurwitz
Department of Health and Human Services

Theresa Lawrence
Department of Health and Human Services

Christopher Park
Department of State