

# Update from the NSABB Working Group on Institutional DURC Policy Stakeholder Engagement

**Joseph E. McDade, Ph.D.**  
Chair, NSABB Working Group

# WORKING GROUP ROSTER

## 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

# NSABB TASK

- Help the U.S. government plan and host one or more meeting(s) to solicit feedback from stakeholders about their experiences implementing the *United States Government Policy for Institutional Oversight of Dual Use Research of Concern*.
- The NSABB Working Group reviewed the institutional DURC policy and other information to:
  - Identify a suitable meeting location
  - Identify appropriate meeting participants/panelists
  - Identify topics and questions to be addressed
  - Develop the meeting format and draft agenda

# STAKEHOLDER MEETING OVERVIEW

The purpose of the meeting is to engage stakeholders involved in implementation of the institutional DURC policy and solicit feedback regarding:

- Procedures and actions taken to implement the policy
- Experiences and challenges associated with implementing the policy and solutions/steps taken to address them
- Procedures for, and challenges associated with, reviewing research subject to the policy and identifying DURC
- Best practices and challenges associated 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

# STAKEHOLDER MEETING OVERVIEW

## Stakeholder Meeting Venue

September 25 – 26, 2017

Warwick Allerton Hotel, Chicago, IL



## Meeting Participants:

- Representatives from institutions subject to the US policy for institutional oversight of DURC including:
  - Senior research administrators
  - Institutional Review Entity (IRE) chairs and members
  - Institutional Contacts for Dual Use Research (ICDUR)
  - Research investigators
  - Biological Safety Officers and other relevant institutional officials
  - USG officials

# PANEL SESSIONS AND QUESTIONS FOR DISCUSSION

## Day I

- Session I: Overview of the *USG Policy for Institutional Oversight of Life Science Dual Use Research of Concern*
  - Review of the DURC issue and the U.S. government 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*

# PANEL SESSIONS AND QUESTIONS FOR DISCUSSION

## Day I

- Session IV: Risk mitigation: Funding agency perspective
  - 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

# PANEL SESSIONS AND QUESTIONS FOR DISCUSSION

## 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/Future Directions
  - Open discussion with meeting participants on experiences, challenges, and best practices regarding implementation of the institutional DURC policy



# STAKEHOLDER MEETING OUTCOMES

- The NSABB will develop a summary of the proceedings highlighting
  - Institution experiences
  - Challenges encountered and solutions found
  - Best practices for institutional oversight of DURC
- The Working Group envisions this will
  - Facilitate sharing of best practices among stakeholders
  - Inform future USG efforts to evaluate the institutional DURC policy
  - Inform consideration of whether/what additional stakeholder engagement activities are needed and on what specific topics

# NSABB DISCUSSION

The Working Group welcomes feedback from the Board on

- Meeting format and sessions
- Topics and questions to be addressed
- Other suggestions to enhance stakeholder engagement