

# Stakeholder Engagement Workshop on Implementation of the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*

September 25-26, 2017

Warwick Allerton Hotel  
Tip Top Tap South Conference Room  
701 N Michigan Ave., Chicago, IL

## AGENDA

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### Day 1 - September 25, 2017

8:00 am – 8:30 am      Registration

8:30 am – 8:45 am      Welcome and Introduction

**Speaker**

*Carrie D. Wolinetz, Ph.D., Acting Chief of Staff & Associate Director for Science Policy, National Institutes of Health*

8:45 am – 9:15 am      **SESSION I - Overview of the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern**

**Speaker**

*Carrie D. Wolinetz, Ph.D.*

9:15 am – 10:45 am      **SESSION II – Establishing an Institutional Framework for Governance of Dual Use Research of Concern and an Institutional Review Entity**

*Discussion of approaches taken by institutions to establish and implement a system for institutional oversight of DURC*

**Moderator**

*Samuel S. Edwin, Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention*

**Panelists**

*Cheryl Doerr, M.S., M.A., Associate VP for Research Compliance, ICDUR, IRE & IBC member, Kansas State University*

*Rebecca Moritz, M.S., CBSP, SM(NRCM), Select Agent Program Manager & ICDUR, University of Wisconsin, Madison*

*Bruce Whitney, Ph.D., Chief Research Compliance Officer, Texas A&M University System*

*Robert Ellis, Ph.D., CBSP, Director of Biosafety, Colorado State University*

**Questions:**

- Briefly describe your approach to policy implementation, highlighting any key features or experiences.
- What offices/personnel were/are involved in initial and ongoing implementation activities?
- What new or modified institutional policies, governance structures, review bodies, or reporting mechanisms were put in place?
- What if any challenges has your institution experienced with policy implementation and what were the solutions/steps taken to address them?

**Audience Discussion**

**10:45 am – 11:00 am**    **BREAK**

**11:00 am – 12:30 pm**    **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*

**Moderator**

*Joseph Kanabrocki, Ph.D., SM(NRCM), Professor of Microbiology; Associate Vice-President for Research Safety, & IRE Chair, University of Chicago*

**Panelists**

*Andrew S. Pekosz, Ph.D., Professor & IRE member, Johns Hopkins Bloomberg School of Public Health*

*David Pitrak, M.D., Professor of Medicine; Chief, Section of Infectious Diseases, IBC Chair & IRE member, University of Chicago Medical Center*

*Philip M. Potter, Ph.D., Associate Member & IRE Chair, St. Jude Children's Research Hospital*

**Questions:**

- Briefly describe the composition and operation of your IRE and the procedures in place for initiating project review.
- What is the relationship between the structure and functions of the IRE and the IBC at your institution?
- What is the scope of research reviewed by the IRE and what are the parameters used to determine whether research is anticipated to produce one or more of the 7 experimental effects and/or meet the definition of DURC?
- What challenges have you experienced regarding the review and assessment of projects for potential DURC, or other IRE responsibilities required under the policy?

**Audience Discussion**

**12:30 pm – 1:30 pm**    **LUNCH**

1:30 pm – 2:00 pm

**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*

**Moderator**

*Jessica Tucker, Ph.D., Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy, Office of Science Policy, National Institutes of Health*

**Panelists**

*Dennis M. Dixon, Ph.D., Chief, Bacteriology and Mycology Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

*Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety, Centers for Disease Control and Prevention*

2:00 pm – 3:30 pm

**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*

**Moderator**

*Theresa M. Koehler, Ph.D., Chair, Department of Microbiology and Molecular Genetics, University of Texas Medical School at Houston*

**Panelists**

*Joseph Kanabrocki, Ph.D., SM(NRCM), Professor of Microbiology; Associate Vice-President for Research Safety, & IRE Chair, University of Chicago*

*Rebecca Moritz, M.S., CBSP, SM(NRCM), Select Agent Program Manager & ICDUR, University of Wisconsin-Madison*

*Adolfo Garcia-Sastre, Ph.D., Professor; Director, Global Health and Emerging Pathogens Institute, Icahn School of Medicine at Mount Sinai*

**Questions:**

- Describe the process and expertise involved in the development and implementation of risk mitigation plans.
- How is the potential for “information risk” considered and addressed?
- What has been your experience interacting with funding agencies and/or scientific journals on mitigating risks?
- What challenges and/or best practices associated with developing or implementing risk mitigation plans have you encountered?

**Audience Discussion**

3:30 pm – 3:45 pm

**BREAK**

3:45 pm – 4:45 pm

**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*

**Moderator**

*Gerald L. Epstein, Ph.D., Assistant Director for Biosecurity and Emerging Technologies, National Security and International Affairs Division, White House Office of Science and Technology Policy*

4:45 pm – 5:00 pm

**Wrap-up of Day 1**

**Speaker**

*Joseph E. McDade, Ph.D., Deputy Director (Ret.), National Center for Infectious Diseases, Centers for Disease Control and Prevention*

**Day 2 - September 26, 2017**

8:00 am – 8:15 am

**Introduction**

**Speaker**

*Joseph E. McDade, Ph.D.*

8:15 am – 9:45 am

**SESSION VII - Institutional Approaches to Raising Awareness and Educating Personnel about DURC**

*Discussion of institutional approaches to educating staff, IRE members, investigators, and laboratory personnel about dual use issues and various roles/requirements under the policy*

**Moderator**

*Jean L. Patterson, Ph.D., Scientist; Chair, BSL-4 Task Force, Texas Biomedical Research Institute*

**Panelists**

*Brandy Nelson, M.S., CBSP, SM(NRCM), Biosafety Officer & ICDUR, University of Kentucky*

*Jennifer A. Perkins, M.A., CPIA, Director, Research Safety & Animal Welfare & ICDUR, University of California, Los Angeles*

*Richard Frothingham, M.D., CBSP, Associate Professor of Medicine & IRE Co-Chair, Duke University School of Medicine*

**Questions:**

- What steps/programs has your institution implemented to raise awareness and educate personnel about their responsibilities under the policy?
- How are education and training regarding DURC integrated with other aspects of training/awareness at your institution?
- Is the training material developed by the U.S. Government useful? Did your institution develop its own education material?

- What strategies have been particularly effective at raising awareness and fostering a culture of responsibility regarding dual use issues at your institution?

#### **Audience Discussion**

**9:45 am – 11:15 am**

#### **SESSION VIII – Research Investigator Perspectives on Implementation of the Institutional DURC Policy**

*Discussion of DURC policy implementation and associated experiences at the laboratory/research conduct level*

#### **Moderator**

*Marie-Louise Hammarskjöld, M.D., Ph.D., Professor of Microbiology, Immunology and Cancer Biology; Associate Director, Myles H. Thaler Center, University of Virginia School of Medicine*

#### **Panelists**

*Christopher J. Ehrhardt, Ph.D., Assistant Professor, Virginia Commonwealth University*

*Balaji Manicassamy, Ph.D., Assistant Professor, University of Chicago*

*Daniel R. Perez, Ph.D., Professor, University of Georgia College of Veterinary Medicine*

#### **Questions:**

- At what point(s) in the research life-cycle do you consider your research for potential DURC and what, if any, steps have been taken?
- Describe your experiences working with the IRE, ICDUR, funding agency and, if relevant, journal editors regarding the potential for research to be DURC.
- What, if any, benefits or challenges has you or your lab experienced stemming from DURC policy implementation?
- Has the policy fundamentally altered the way you think about or approach your research?

#### **Audience Discussion**

**11:15 am – 11:30 am**

**BREAK**

**11:30 am – 12:30 pm**

#### **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*

#### **Moderator**

*Jessica Tucker, Ph.D.*

**12:30 pm – 12:45 pm**

#### **Closing Remarks & Adjourn**

#### **Speaker**

*Carrie D. Wolinetz, Ph.D.*