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

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.