Stakeholder Engagement Workshop to Examine Institutional 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**

Speakers
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, National Institutes of Health
Joseph E. McDade, Ph.D., Chair, NSABB Working Group on Institutional DURC Policy Stakeholder Engagement

8:45 am – 9:15 am **SESSION I - Overview of the *USG Policy for Institutional Oversight of Life Science 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 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., Associate VP for Research Compliance, Kansas State University
Rebecca Moritz, M.S., Select Agent Program Manager & ICDUR, University of Wisconsin, Madison
Bruce Whitney, Ph.D., Chief Compliance Officer, Texas A&M University
Robert Ellis, Ph.D., CPSB, 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 governance structures, review bodies, or reporting mechanisms were put in place?
- What if any challenges have 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., NSABB member

Panelists:

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

David Pitrak, M.D., IBC Chair & IRE member, University of Chicago

Philip M. Potter, Ph.D., Associate Faculty 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 and additional IRE actions required under the policy?

Audience Discussion

12:30 pm – 1:30 pm **LUNCH**

1:30 pm – 2:00 pm

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

Moderator
Joseph E. McDade, Ph.D.

Speaker(s)
Dennis M. Dixon, Ph.D., Chief, Bacteriology and Mycology Branch, National Institute of Allergy and Infectious Diseases, NIH
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., NSABB member

Panelists:
Joseph Kanabrocki, Ph.D., NRCM(SM), Associate Vice-President for Research Safety & IRE Chair, University of Chicago
Rebecca Moritz, M.S., Select Agent Program Manager & ICDUR, University of Wisconsin-Madison
Adolfo Garcia-Sastre, Ph.D., Director, Global Health and Emerging Pathogens Institute, Mount Sinai School of Medicine

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 – 4:30 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/Panelists:
NSABB member/Institutional & Federal representatives

4:30 pm **Wrap-up of Day 1**

Speaker
Carrie D. Wolinetz, Ph.D.
Joseph McDade, Ph.D.

Day 2 - September 26, 2017

8:00 am – 8:15 am **Introduction**

Speaker
Carrie D. Wolinetz, Ph.D.
Joseph E. McDade, Ph.D.

8:15 am – 9:45 am **SESSION VII - Institutional Approaches: Raising Awareness and Educating 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

Moderator:
Jean L. Patterson, Ph.D., NSABB member

Panelists:
Brandy Nelson, M.S., CBSP, NRCM(SM), Biosafety Officer & ICDUR, University of Kentucky
Jennifer Perkins, M.A., CPIA, ICDUR, University of California, Los Angeles
Richard Frothingham, M.D., IRE Co-Chair, Duke Human Vaccine Institute, Duke University School of Medicine

Questions:
- What steps/programs have your institution implemented to raise awareness and educate personnel about their responsibilities under the policy?
- How is education and training regarding DURC integrated with other aspects of training/awareness at your institution?
- Is the training material developed by the USG useful? Did your institution develop its own education material?
- What strategies have been particularly effective at raising awareness and fostering a culture of responsibility at your institution?

Audience Discussion

9:45 am – 11:15 am **SESSION VIII – Researcher Perspectives on the Institutional DURC Policy**

Discussion of DURC policy implementation and associated experiences at the laboratory level

Moderator:

Marie-Louise Hammarskjöld, M.D., Ph.D., NSABB member

Panelists:

Christopher Ehrhardt, Ph.D., Asst. Professor, Virginia Commonwealth University

Balaji Manicassamy, Ph.D., Asst. 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 dual use and what, if any, steps have been taken to address potential DURC?
- Describe your experiences working with the IRE, ICDUR, funding agency and, if relevant, journal editors regarding dual use concerns.
- What, if any, benefits or challenges have 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 – 12:15 pm **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

Moderator/Panelists

NSABB member/Institutional & Federal representatives

12:15 pm – 12:30 pm **Closing remarks**

Speakers

Carrie D. Wolinetz, Ph.D.

Joseph E. McDade, Ph.D.

12:30 pm **Adjourn**