

Working Group Update on Institutional DURC Policy Stakeholder Engagement

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Chair, NSABB Working Group

CHARGE TO THE NSABB

- Conduct a series of regional meetings to solicit feedback from stakeholders about their experiences implementing the institutional DURC policy.
- The NSABB Working Group will take lead on planning the first stakeholder meeting by:
 - Identifying a meeting location
 - Developing the meeting format and agenda
 - Identifying meeting participants/panelists
 - Leading discussions at the meeting

NSABB WORKING GROUP ROSTER

Voting Members

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

Joseph Kanabrocki
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Theresa M. Koehler
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Non-Voting Federal Representatives

Gerald Epstein
White House Office of Science and Technology
Policy

Meg Flanagan
Department of State

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

APPROACH TO STAKEHOLDER ENGAGEMENT PLANNING

- Discuss overall vision and strategy for the stakeholder engagement effort
- Consider factors important for identifying/selecting:
 - Meeting location/venue
 - Meeting participants
 - Meeting format
 - Key topics to be addressed at stakeholder meetings

POTENTIAL ENGAGEMENT STRATEGIES

- Stand alone regional meeting in partnership with a hosting university or research institute
- Panel session as part of the regular program at scientific meetings/conferences in partnership with scientific societies, e.g. American Society for Microbiology, American Society for Virology
- Stand alone meeting co-located with and occurring the day before or after a scientific meeting/conference

POTENTIAL LOCATION/VENUE

Regions to Consider	Rationale, Pros, & Cons to Consider
<ul style="list-style-type: none">• East Coast• Midwest• Central• Mountain• West Coast	<ul style="list-style-type: none">• Does the venue conduct research subject to the institutional DURC policy?• What is the proximity of the venue to universities, medical schools, research institutions, and private companies that conduct research subject to the policy?• Does the venue have a Regional Biocontainment Lab?• Is the venue located in a city with a major hub airport for ease of travel?• Has the venue (or venue stakeholders) been involved in past USG engagement efforts?• Are any NSABB members affiliated with the venue?

POTENTIAL MEETING PARTICIPANTS

Summary of Responsibilities under the institutional DURC policy

Entity	Responsibilities
Principal Investigator (PI)	<ul style="list-style-type: none">• Identify research for IRE review, train personnel, continuously monitor research
Institutional Review Entity (IRE)	<ul style="list-style-type: none">• Review research to determine if the research is DURC and if so, develop a draft risk mitigation plan
Institutional Contact for Dual Use Research (ICDUR)	<ul style="list-style-type: none">• Serve as the point of contact for questions about the DURC policy• Serve as the liaison between the institution and USG, as needed
Institution	<ul style="list-style-type: none">• Establish policies and processes for administering the institutional DURC policy• Report outcomes of DURC review to funding agencies, as required
Funding Agency	<ul style="list-style-type: none">• Assist institutions in complying with institutional DURC policy• Work with institutions to finalize risk mitigation plans

POTENTIAL MEETING FORMATS

Format	Description
Lecture/Plenary	<ul style="list-style-type: none">• Presentation to audience by a single speaker• Questions and discussion after presentation
Breakout & Report Back	<ul style="list-style-type: none">• Divide audience into smaller groups• Each group considers topics independently• Groups report out and facilitate wider discussion on topics
Panel Presentation & Discussion	<ul style="list-style-type: none">• Group of panelists from multiple institutions discuss specific topic• Panelists could represent various roles/responsibilities (e.g., PI, IRE member, ICDUR, etc.)• Discussion with audience after panel
Open Forum for Questions & Comments	<ul style="list-style-type: none">• Participants ask questions and provide feedback on the policy• Questions could be posted in advance to facilitate audience participation through prepared comments.

POTENTIAL TOPICS TO EXPLORE AT STAKEHOLDER MEETINGS

- Best practices and common challenges regarding the policy
- Identifying DURC/applying the definition of DURC
- Administrative burden associated with implementing the policy
- Development and implementation of risk mitigation plans
- Developing training and guidance materials/programs for IREs, Pls, and staff
- Perceived strengths and limitations of the policy

NSABB DISCUSSION

- Engagement strategy options:
 - Stand alone meeting in partnership with research institution
 - Panel session at scientific meeting/conference in partnership with scientific society
 - Stand alone meeting co-located with scientific meeting/conference
- Approaches to identifying meeting locations/venues, participants, and format
- Key topics to be explored at stakeholder meetings