Dual Use Research of Concern (DURC)

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U.S. Government Position

- Policy for USG review released 3/29/2012

- Policy for *Institutional Oversight* of Life Sciences Dual Use Research of Concern
  - Released: 9/24/2014; Effective: 9/24/2015*

- Pause in funding for gain-of-function research
  - MERS, SARS, and influenza viruses
  - NSABB and National Research Council
  - Effective: 10/17/2014
DURC Agents

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium
DURC Experimental Effects

1. Enhances the harmful consequences of the agent or toxin

2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification

3. Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies

4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin

5. Alters the host range or tropism of the agent or toxin

6. Enhances the susceptibility of a host population to the agent or toxin

7. Generates or reconstitutes an eradicated or extinct agent or toxin
DUR and DURC

Most life sciences research could conceivably be considered DUR (dual use research)

DURC definition:
- Based on current understanding
- Can be reasonably anticipated to provide knowledge, information, products, or technologies
- Could be directly misapplied to pose a significant threat
- Broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security
“It Takes a Village”

- Responsibility shared by researcher, publisher, institutional officials, local oversight bodies, and Federal government
  - Patterson, NIH, 2012

- Researchers are the most critical element in the oversight of dual use life sciences research
  - NSABB, 2011
DURC Review Process

► Principal Investigator
  ◦ Notify institution review entity of research that directly involves non-attenuated forms of the listed agents
  ◦ Identify if research produces, aims to produce, or is \textit{reasonably anticipated to produce} one or more of the seven experimental effects
  ◦ Notify institution if there are changes in research that may meet the definition of DURC

► Institution
  ◦ Establish policy and practices
  ◦ Establish institutional review entity (IRE) and institutional contact for DUR (ICDUR)
Institutional Review Entity (IRE)

- Review PI assessment of research
- Conduct risk assessment if research meets scope of USG Policy
- Determine if research meets DURC definition
- Report DURC to funding agency within 30 days
- Assess benefits and risks of DURC
- Develop \textit{draft} risk mitigation plan
- Review active risk mitigation plans at least annually
Assess *ways* in which research outcome could be misapplied
  ◦ Example: Who will have access to outcome?

Assess *ease* with which research outcome might be misused and *feasibility* of misuse
  ◦ Example: Require low or high degree of technical skill?

Assess *magnitude, nature, and scope* of the potential consequences of misuse
  ◦ Example: Are there current countermeasures to help mitigate the consequence?
Draft Risk Mitigation Planning

- Strategies
  - Biosafety and biosecurity measures
  - Existence or absence of countermeasures
  - Changes in design or conduct of research
  - Responsible communication of research findings
  - Education and training of research staff
  - Ongoing monitoring of DURC

- Must be submitted to funding agency within 90 days
DURC and Export Controls

- DURC agents are on the EAR CCL
- Fundamental research results are ordinarily published and shared broadly
- Restrictions on publication may affect status under EAR
  - Transfer of controlled technology outside the U.S. or as a deemed export
- ITAR (e.g., biological agents) may apply in some instances
- Export controls noted in risk assessment of H5N1DURC manuscripts (2011)
  - Casadevall, Endquist, Imperiale, Osterholm, et al., 2013
Resources

- *DURC Companion Guide*, NIH, September 2014
- NSABB *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility*, September 2011
- *Implementation of USG Policy for Institutional Oversight of Life Science DURC* – Case Studies
- USG training tools and materials (not yet available)
University of Maryland Baltimore and DURC

- DURC questions have been part of IBC protocol submissions
  - Conducted one non–listed agent review

- Current discussions with Institutional Official

- Develop and communicate institutional policy
  - Communicate and educate research community
    - DURC website, online training planned
  - Designate an Institutional Review Entity (IRE)
    - Institutional Biosafety Committee (IBC)
  - Develop procedures related to policy and IRE
    - Underway
  - Designate an institutional contact (ICDUR)
Institutional Biosafety Committee (IBC)

- Revisions to charter
- Revise DURC definition in IBC protocol submission process
- Addition of ad hoc members (e.g., legal counsel, scientific SMEs, Communications, Police)
- Assess role in development of risk mitigation plan
- Procedures needed for:
  - Assessing risks of DUR (e.g., ways, ease, magnitude, nature, scope, and consequences of misuse)
  - Assessing benefits of DUR
  - Process for monitoring DURC over the course of the research
ICDUR

▸ Chief Academic and Research Officer and Senior Vice President
   ◦ Also serves as Institutional Official

▸ Advisor will be Chair of Microbiology
   ◦ Attend IBC meetings with DURC reviews
   ◦ Advise IBC on institution’s view of risks and benefits
   ◦ Participate with IBC on risk/benefit analysis
   ◦ Key role in determining risk mitigation plan for communication of research findings
   ◦ Advise ICDUR in consultations with and reports to funding agencies
Challenges from the EHS Director Perspective

- Judgment of risk without evidence
- May discourage certain research
- May discourage new investigators
- Risk may outweigh significant benefits
- Restriction of open communication of research
- Consistency of approach between institutions with collaborative research projects
- Ongoing DURC monitoring by IBC
- Unexpected experimental outcomes that become DURC
- Immediate reporting by PI as soon as any DURC criteria are met
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