Dual Use Research of Concern

Boston University and Boston Medical Center
Scope of Presentation

The goal of this presentation is to provide an awareness on the dual use dilemma as it relates to academic research. The specific aims are to provide understanding of:

- The historical and regulatory perspective of Dual Use Research of Concern.
- Potential ethical and legal concerns.
- Understanding of the regulations governing life science research.
- Familiarity of the DURC criteria.
- Steps by the Institution to address the issue of DURC.
Regulations Governing Life Science Research

Understanding regulations that governs academic research will help understand the DURC Concept.
Dual Use Research of Concern (DURC)

Definition of DURC*

“Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel”.

*Source: National Science Advisory Board for Biosecurity (NSABB)
Historical Term of “Dual Use”

The military has used the term “dual use” for several years to refer to technology that could be used in peacetime as well as in war.

An example is “nuclear power” or “satellite technology”.

Agents as Weapons Historical Perspective

Agents have been used as weapons:
• 1346 – Tartars used plague infected corpses to infect their enemies
• 1915 – live stocks were infected with Anthrax and Glanders during WWI
• 1950 to 1970 – ignited the test and development of bioweapons
• 1972 – Biological Weapons Convention prohibited R&D of bioweapon
• 1979 – approximately 100 people were exposed and 64 died in Sverdlovsk, Russia from an accidental release of anthrax.
• 1984 – 750 became infected with Salmonella in Oregon after eating from salad bars contaminated by Rajneeshee cult.
• 1995 – Sarin gas was released in a Tokyo subway station by cult group
2001 Anthrax attacks

On September, 2001, letters containing anthrax spores were mailed to several news media places and federal government offices. The incident killed five people and infected seventeen others.
Governance of Research and Biosecurity

Dr. Thomas Butler was arrested and convicted for mishandling *Yersinia pestis* in research.

Dr. Bruce Ivins noted Anthrax researcher was investigated as a suspect in the Anthrax letters attack. He committed suicide before he was formally charged.
The United States Government recognized that information gained from life sciences research could potentially be misused in a way that could threaten public health and safety, agricultural crops and other plants, animals, the environment, or materiel. It therefore charged the National Science Advisory Board for Biosecurity (NSABB) to develop a framework for the oversight of “Dual Use Research of Concern” (DURC).
Dual Use Biosecurity Dilemma

Science and Nature magazines published two papers (Tumpey 2005 and Taubenberger 2005) that described the complete gene sequence of the 1918 flu virus as reconstructed by scientists at the U.S. Armed Forces Institute of Pathology and the Centers for Disease Control and Prevention (CDC).
The information and knowledge acquired from research work with pathogens could be used for malicious ends as well as legitimate purposes.

Dual Use Biosecurity Dilemma
National Science Advisory Board for Biosecurity (NSABB)

2004 NSABB Charter

• A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
• Guidelines for the identification and conduct of research that may require special attention and security surveillance;
• Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research;
• Materials and resources to educate the research community about effective biosecurity;
• Strategies for fostering international collaboration for the effective oversight of dual use biological research.
Experiments Identified by NSABB

NSABB identified 7 categories of research that:

1. Enhances the harmful consequences of a biological agent or toxin;
2. Disrupts the immunity or the effectiveness of an immunization without clinical and/or agricultural justification;
3. Confers to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies;
4. Increases the stability, transmissibility, or the ability to disseminate a biological agent or toxin;
5. Alters the host range or tropism of a biological agent or toxin;
6. Enhances the susceptibility of a host population; or
7. Generates a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.
In July 2009, BU-BMC Advisory Committee on DURC issued its report with the following key recommendations to be implemented in two phases:

**Phase I**

- Initial education and training for BU/BMC
  - Provide awareness training to faculty and staff on DURC.
- Set up an interim review and decision process for DURC related research
  - Research proposals submitted to the IBC are screened for DURC.
  - Interim body will review and make decisions on research proposals covered under DURC.
Phase II

• Develop and implement an institutional policy

(It is critical that the policy not unnecessarily curtail the research mission of the institutions.)

– Training and Education:

• Formal training and education structures in place
• Educate to understand DURC criteria
• Recognize research experiments with DURC implications
BU/BMC Advisory Committee on DURC

Recommendations: (Continued)

Phase II

• Develop and implement an institutional policy
  – Review of Research
    • Review of research through the appropriate channels
      – Institutional Biosafety Committee (IBC)
      – Laboratory Safety Committees (LSC)
      – Institutional Animal Care and Use Committee (IACUC)
      – Others
The IBC screens the research proposal if it meets the DURC criteria. Proposals that meet any of the criteria is submitted to the DURRC.

DURRC reviews research proposals previously screened and determine if the proposal is DURC. The committee provides recommendations to on actions to be taken.

The Principal Investigator reviews the research proposal and see if it meets any of the DURC criteria.
Phase II

- Review of Research
  - Review by the Dual Use Research Review Committee (DURRC)
    - Proposal is DURC
    - Risk assessment and benefits analysis
    - Possible actions:
      - Allow research to continue unfettered
      - Modify research so it no longer a DURC
      - Allow the study to continue with constraints
      - Do not allow the research to move forward
Things to Consider

• Part of the research may be a concern to national security
• Research may fall into any of the DURC criteria
• Information to be obtained may be used for malevolent purposes.
• DURC may apply to non-select agents.
• Responsibilities of PI’s and researchers to determine if proposed work is DURC.
• Responsibilities of PI’s and researchers to understand the laws governing life science research.
• Participate in the discussion and policy making process.
Federal Regulation and NSABB

- The federal government has not yet adopted recommendations by NSABB.
- Additional guidelines will likely be developed for institutions to follow.
- Although the regulation is not yet in place, the institution should begin to address the dilemma in the event that such research may take place.
- The institution should determine what entity would be in charge to help govern and address the dilemma.
- NSABB’s recommendations would assist the institution to determine research projects that may be sensitive to the dual use dilemma even if the regulation is never implemented.