

Introduction to Dual Use Research of Concern

Student Guide – draft2 – Sept. 2011





Introduction to Dual Use Research of Concern

Welcome & Introductions

Welcome to Introduction to Dual Use Research of Concern!





Introductions

- Instructors
- Students
 - What is your name?
 - Where are you from?
 - Something fun about yourself.

Slide 2

A yellow emoji with a smiling face, blue eyes, and a wide grin. It has a black arm and hand raised in a wave. A speech bubble above it contains the word "HELLO!" in red capital letters.



Action Plan (pg X)

By the end of this lesson, I would like to:

KNOW	FEEL	BE ABLE TO DO

Your learning doesn't stop with this lesson. Use this space to think about what else you need to do or learn to put the information from this lesson into practice.

What more do I need to know or do?	How will I acquire the knowledge or skills?	How will I know that I've succeeded?	How will I use this new learning in my job?

Use space on back, if needed

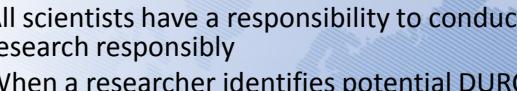




Introduction to Dual Use Research of Concern

Welcome & Introductions

Course Objectives



1. DURC is an issue relevant to all researchers
2. All scientists have a responsibility to conduct research responsibly
3. When a researcher identifies potential DURC, the project must undergo a review process to determine actual concern
4. Reviewing and determining DURC does not necessitate cessation of the project
5. Key to review of potential DURC is documentation and justification of conclusions and decisions

Briefly look over what the course will cover.





Introduction to Dual Use Research of Concern

Biorisk Management

Biorisk Management: the **AMP** Model



**Biorisk Management =
Assessment, Mitigation, Performance**

Record refresher notes on the AMP model and biorisk management.



Key Components of Biorisk Management

Define Biorisk Assessment:

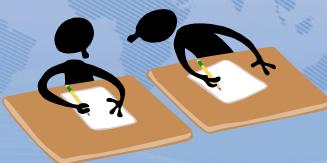


Key Components of Biorisk Management

Define Biorisk Mitigation:



Key Components of Biorisk Management



Performance

- The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.





Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

What is DURC to you? Exercise

- Individually, spend 10 minutes writing down in your notebook what types of experiments could be considered potentially DURC.
 - Consider the following question:
 - What about the experiment makes it Dual Use?
 - How could this information be misused?
- Discussion on your answers will follow as a large group.

Slide 15



What types of experiments could be considered Dual Use Research of Concern (DURC)?

What about the experiment makes it Dual Use?

How could information about the experiment be misused?



Introduction to Dual Use Research of Concern

Dual Use Research Refresher

- What is Dual Use? Traditional Definition -
 - “Goods and technologies are considered to be dual-use when they can be used for both civil and military purposes.”
 - » European Commission – Trade Website
<http://ec.europa.eu/trade/creating-opportunities/trade-topics/dual-use/>
 - “Dual-Use items’ shall mean items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices”
 - » Council Regulation (EC) No 428/2009

Slide 11

Defining & Identifying Dual Use Research of Concern

Historically, dual use has referred to technologies that can be used for both military and peaceful aims.

Concerns over dual use as used in this definition arose prominently during the Cold War and continue today and are captured in reference to Nuclear Weapons through the Nuclear Non-Proliferation Treaty.



Introduction to Dual Use Research of Concern

Dual Use Research Refresher

- What is Dual Use? Biology Specific-
 - “Biotechnology represents a ‘dual use’ dilemma in which the same technologies can be used legitimately for human betterment and misused for bioterrorism.”
 - “...the capacity for advanced biological research activities to cause disruption or harm, potentially on a catastrophic scale. Broadly stated, that capacity consists of two elements: (1) the risk that dangerous agents that are the subject of research will be stolen or diverted for malevolent purposes; and (2) the risk that the research results, knowledge, or techniques could facilitate the creation of “novel” pathogens with unique properties or create entirely new classes of threat agents.”

» National Academies of Science: *Biotechnology Research in an Age of Terrorism* (2004)

Slide 12

Defining & Identifying Dual Use Research of Concern

Biotechnology Research in an Age of Terrorism (commonly referred to as the “Fink Report” named after the committee chair Gerald Fink, Massachusetts Institute of Technology)

Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology

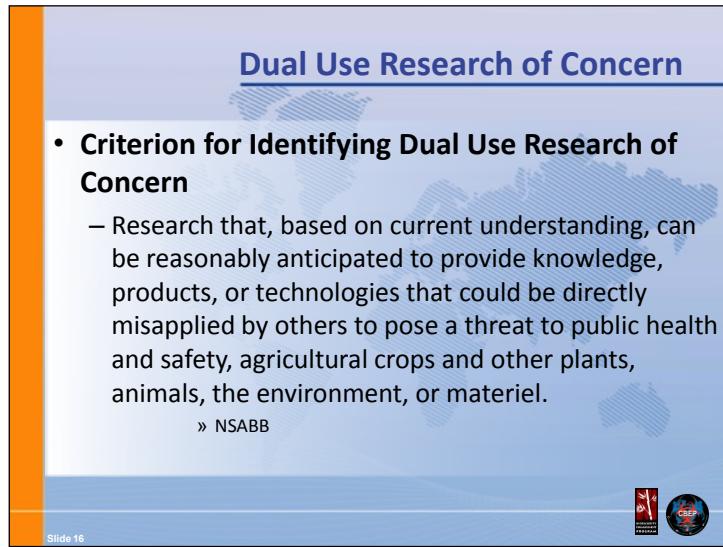
Chaired by Gerald Fink

Note the International Significance of the Fink Report:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

A slide titled "Dual Use Research of Concern" with a blue header and a world map background. It contains a bullet point about the criterion for identifying such research, followed by a quote from the NSABB. The slide is numbered "Slide 16" at the bottom left and features the CSEPP logo at the bottom right.

Dual Use Research of Concern

- Criterion for Identifying Dual Use Research of Concern**
 - Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misappropriated by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.

» NSABB

Slide 16

 CSEPP

Note the criterion for identifying Dual Use Research of Concern:

Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

Seven Categories of Experiments

1. Enhance the harmful consequences of a biological agent or toxin.
2. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification.
3. Confer 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. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.
5. Alter the host range or tropism of a biological agent or toxin.
6. Enhance the susceptibility of a host population.
7. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.

Look at your list from the previous page and look at this list of seven categories of experiments that might be considered DURC:

1. What is missing from your list?
2. What was included in your list that is not on this list?

Why is there a difference between your list and this list?



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

1. Enhance the harmful consequences of a biological agent or toxin

List other examples/notes:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

2. Disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification.

List other examples/notes:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

3. Confer 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.

- **Rationale:**
 - Anything that might compromise the ability to detect, treat, or prevent disease or illness (human or agricultural) caused by biological agents or toxins could result in a significant public health and/or economic burden.
- **Examples:**
 - Conferring doxycycline resistance to *Vibrio vulnificus* or conferring antibiotic resistance to agriculturally relevant microbes, such as rendering *Ralstonia sloanacearum* (a bacterium on the U.S. Department of Agriculture list of high-consequence organisms) resistant to rifampin.
 - Use of standard laboratory selection procedures with antibiotics using host-vector systems that do not present a significant risk to health or the environment – not likely to be dual use of concern.

List other examples/notes:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

4. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin.

List other examples/notes:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

5. Alter the host range or tropism of a biological agent or toxin.

- Rationale:
 - This could endanger a host population that normally would not be susceptible.
 - Prevention and therapy measures for the newly vulnerable host population may be lacking, possibly allowing for the uncontrolled spread of disease.
- Examples:
 - Converting non-zoonotic agents, altering the tropism of viruses, and expanding the varieties of the same plant that a pathogenic agent could infect.
 - Certain vaccine research and the development of animal models for infectious disease, which may involve alterations of the host range or tropism, are unlikely to constitute dual use research of concern as well as the attenuation of viruses for vaccine development.

Slide 19

List other examples/notes:



Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

6. Enhance the susceptibility of a host population.

- Rationale:
 - This could be used to compromise immune responses and enable the acquisition and spread of disease on an epidemic scale.
- Examples:
 - Creation of a stable recombinant Lactobacillus casei that could effectively block the host's ability to synthesize an important immune signal, such cytokines which may directly facilitate the evasion of normal host defenses.
 - Unlikely to be considered dual use of concern are research on the systemic exposure to immunostimulatory and immunosuppressive DNA and their effect on host susceptibility to local inflammatory challenge, studies to develop immunosuppressive drugs for cancer or transplantation.

Slide 20

List other examples/notes:

Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

7. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct biological agent.

List other examples/notes:

Introduction to Dual Use Research of Concern

Defining & Identifying Dual Use Research of Concern

Examples of Potential DURC

- Reconstruction of the 1918 Influenza Virus
- Publication of Complete 1918 Genome Sequence
- Synthesis of Poliovirus
- Insertion of Interleukin-4 in Mousepox Virus
- Generation of an avian flu variant that can spread (airborne) between mammals
- Any other examples come to mind?

List other examples/notes:



Introduction to Dual Use Research of Concern

Examples of Potential DURC

Examples of Potential DURC

Note the concerns that are involved with this report:

What are some actions you would take to prevent or reduce those concerns?

Introduction to Dual Use Research of Concern

Examples of Potential DURC

What To Consider? Activity

Do you need to consider just the seven categories?

When do you need to make these considerations?



Introduction to Dual Use Research of Concern

Examples of Potential DURC



Note that any list of experiments and/or categories are inherently inadequate to cover all the possible cases of potential DURC.



Introduction to Dual Use Research of Concern

What to do about DURC?

National Science Advisory Board for Biosecurity (U.S.)

- The Fink Report recommended the creation of a national Science Advisory Board for Biodefense. “We recommend that the Department of Health and Human Services create a National Science Advisory Board for Biodefense (NSABB) to provide advice, guidance, and leadership for the system of review and oversight we are proposing.”
- National Science Advisory Board for Biosecurity: *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (2007).
 - Described a subset of dual use **research that has the highest potential** for generating information that could be misused.

Slide 27

The logo for the National Science Advisory Board for Biosecurity (NSABB) features a stylized circular emblem with a red and blue color scheme, possibly representing a DNA helix or a molecular structure.

The NSABB recognized that almost all research can be identified as having a dual use potential.

Thus another layer of specificity was developed for those research programs that have the highest potential for generating malevolent dual use research

Introduction to Dual Use Research of Concern

What to do about DURC

What To Do?

- You have determined that you have potential DURC. What do you do about?
- In your group, construct a timeline covering the research project and determine what constraints need to be undertaken to reduce the concern.
- After 15 minutes, groups will present their findings to the larger group.

Possible actions as laid out by the AAAS Survey of Attitudes and Actions on Dual Use Research in the Life Sciences:

Change in Performance of research:

Change in Collaboration:

Change in research communications:

Possible Actions

- Change in Performance of Research
 - Decided against conducting a specific research project/experiment
 - Decided against seeking funding for a proposed research project
 - Decided to shift my research away from an area altogether
- Change in Collaboration
 - Decided against collaborating with particular scientists, postdocs, students, etc
- Change in Research Communications
 - Limited conversations about research
 - Decided against presenting research at a conference
 - Modified a conference presentation
 - Decided against submitting a manuscript to a journal
 - Modified a manuscript

Slide 29

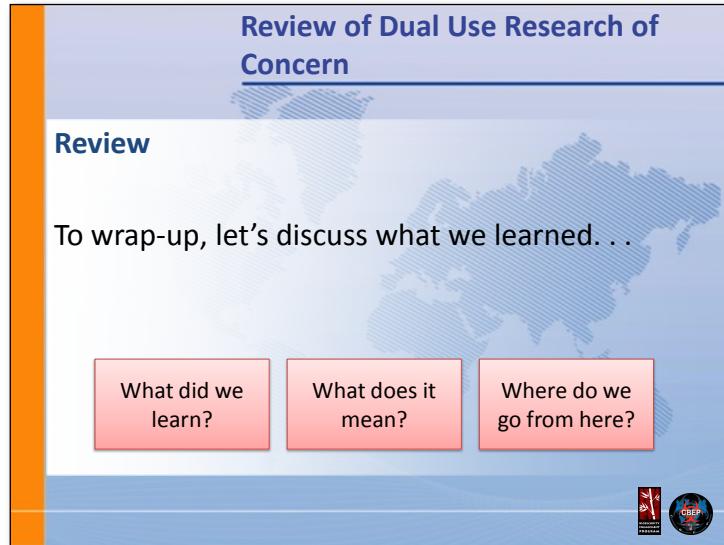


Expected answers for communication of potential DURC.



Introduction to Dual Use Research of Concern

Review



A slide titled "Review of Dual Use Research of Concern" with a world map background. The title is in a blue header. The main content is "Review" in bold. Below it is the text "To wrap-up, let's discuss what we learned...". At the bottom are three red boxes with white text: "What did we learn?", "What does it mean?", and "Where do we go from here?". The CHEF logo is at the bottom right.

Review of Dual Use Research of Concern

Review

To wrap-up, let's discuss what we learned...

What did we learn?

What does it mean?

Where do we go from here?





Introduction to Dual Use Research of Concern

Review

Review

- What is Dual Use Research of Concern?
- Who does it apply to?
- When does it apply for me?
- Who should be involved?

Slide 30





Introduction to Dual Use Research of Concern

Review

Review

1. DURC is an issue relevant to all researchers
1. All scientists have a responsibility to conduct research responsibly
1. When a researcher identifies potential DURC, the project must undergo a review process to determine actual concern
1. Reviewing and determining DURC does not necessitate cessation of the project
1. Key to review of potential DURC is documentation and justification of conclusions and decisions



Slide 32