

National  
Science  
Advisory  
Board for  
Biosecurity



Attributes of Highly  
Pathogenic Avian Influenza  
H5N1 Research that May  
Warrant Alternative Venues  
or Modes of Communication

A Report of the National Science Advisory Board for  
Biosecurity

November 2012

***Draft Report for  
discussion by the  
National Science Advisory  
Board for Biosecurity***

**November 27, 2012**

# Working Group Roster: Voting Members

- Arturo Casadevall, MD, PhD - *Chair*
- Joseph Kanabrocki, PhD, CBSP
- Kenneth I. Berns, MD, PhD
- Paul S. Keim, PhD
- Murray Cohen, PhD, MPH, CIH
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- Susan A. Ehrlich, JD, LLM
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- David A. Relman, MD
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# Overview of Report

- **Introduction**
- **Toward a Global Discussion of HPAI H5N1**
- **Question 1 – What are the attributes of HPAI H5N1 DURC that may warrant alternative venues or modes of communication?**
- **Question 2 – What key elements should underpin international discussions of the responsible communication of HPAI H5N1 DURC?**
- **Moving Forward**
- **Appendix**

# ***Introduction***

## **The NSABB's Process & Approach**

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# Introduction

## The “Dual Use Dilemma”:

- **The open and unfettered communication of the findings and results of life sciences research is a fundamental principle of the scientific enterprise.**
- **However, certain types of life sciences research, if openly communicated, could be misused to cause harm. In addition, some harm may be unintentional.**

# The NSABB's Starting Points

- **NSABB Criterion for Identifying DURC**

- Research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied to pose a threat to:

- Public health
    - Agriculture
    - Plants
    - Animals
    - Environment
    - Materiel

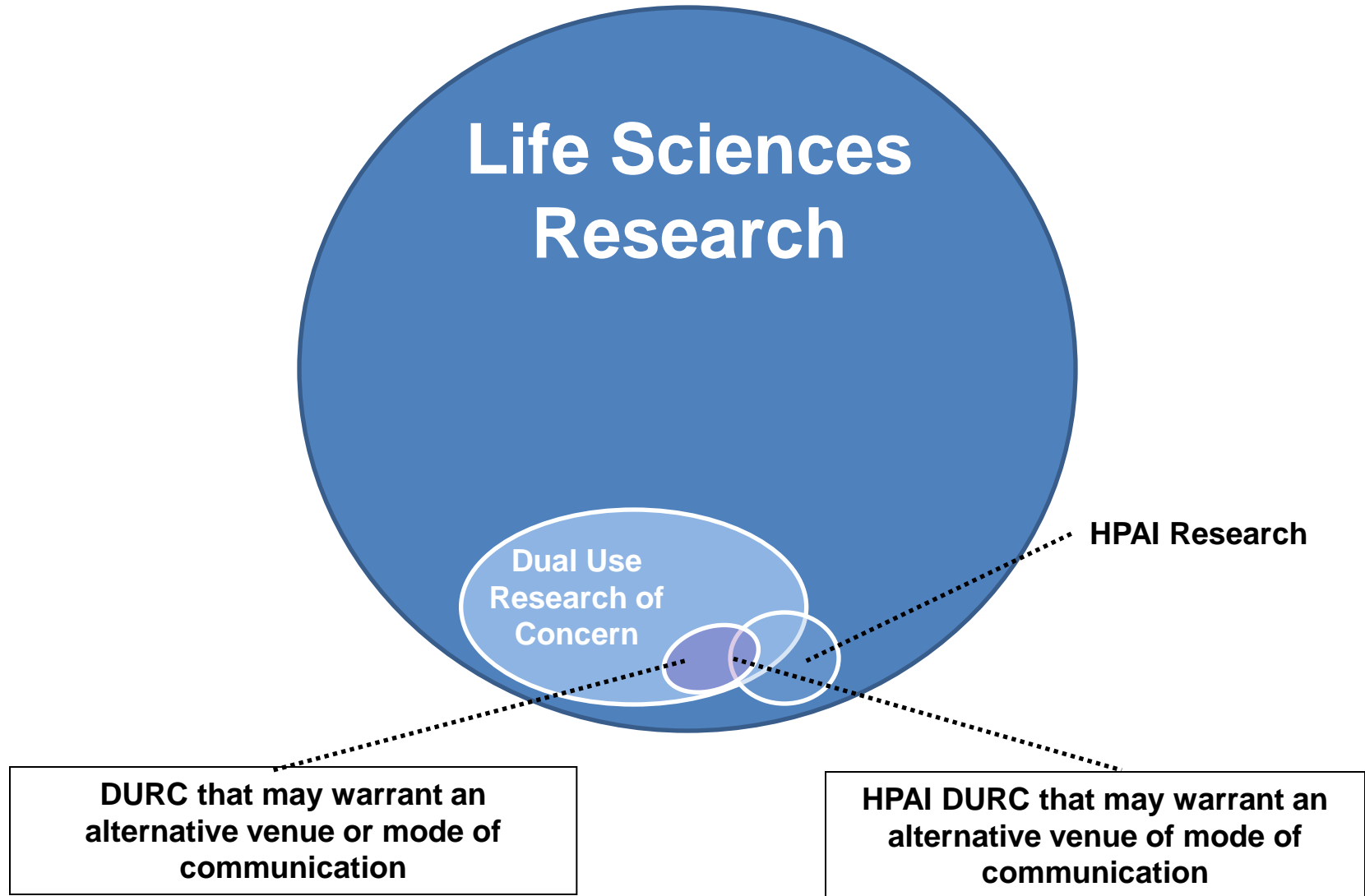
**Elements of national security**

- ***The NSABB's Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential***

# The NSABB's Guiding Premises

- **DURC should not be a negative categorization**
  - **Most research that is designated as DURC should be conducted and can be responsibly communicated.**
- **A small subset of life sciences research would be appropriately categorized as DURC**
  - **An even smaller subset of DURC crosses a threshold and would thus warrant an alternative venue or mode of communication**
- **Likewise, Highly Pathogenic Avian Influenza (HPAI) DURC is a very small subset of DURC and the amount of HPAI DURC that may require an alternative venue or mode of communication is likely very small.**

# HPAI DURC Communications



Note: Diagram not drawn to scale.



***Toward a Global Discussion of HPAI  
H5N1 Communication***

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# Toward a Global Discussion of HPAI H5N1 Communication

- **HPAI H5N1 DURC has exhibited attributes that may warrant the consideration of alternative modes or venues for communication.**
- **Given the trajectory of HPAI research, and HPAI H5N1 research in particular, it is important to note that there will be additional instances of HPAI DURC that will require careful consideration.**
- **Questions regarding the communication of HPAI DURC are likely to continue.**
- **Therefore, there is a critical need for global engagement concerning the responsible conduct and communication of HPAI DURC.**

# NSABB Global Engagement Working Group: Charge

**Formulate a set of recommendations and responses to these questions:**

- 1. What are the attributes of HPAI H5N1 DURC that might warrant an alternative venue or mode of communication?**
- 2. In light of the global nature of this research, what principles should underpin an international discussion promoting the responsible communication of HPAI DURC? What should the key questions addressed in that be?**

## ***Question One:***

**What are the attributes of HPAI DURC that might warrant an alternative venue or mode of communication?**

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# Attributes of HPAI H5N1 DURC that may Warrant an Alternative Venue or Mode of Communication

- 1: The research results in the generation of viral strains with increased transmissibility, pathogenicity, and/or other comparable attributes that pose the risk of substantial harm to populations of mammals or other animals.**
  - Challenge: Available scientific data are not always easily interpreted.
  - Requires judgment about meaning of "increased transmissibility," "increased pathogenicity," "substantial harm," and "populations."
  - Populations at risk of respiratory infection are mammalian and/or avian; the threat posed is a threat to public safety and health, agriculture, wildlife, and/or the environment.

# Attributes of HPAI H5N1 DURC that may Warrant an Alternative Venue or Mode of Communication

## **2: The timeframe for the risk of harm is the near term.**

- The harm could be realized within a timeframe ranging from the immediate to the near-term future, that is, not in the distant future.
- Applying this attribute also will require judgment about the meaning of “near-term.”

# Attributes of HPAI H5N1 DURC that may Warrant an Alternative Venue or Mode of Communication

- 3: Countermeasures are either unavailable or limited in efficacy, availability, sustainability, or are otherwise vulnerable.**
- Currently available countermeasures for HPAI H5N1 are inadequate for responding to a widespread HPAI H5N1 public health emergency.
  - Changes in countermeasure availability could alter the determination regarding the extent to which a given body of HPAI H5N1 DURC should be communicated.
  - Delay the communication of a research finding may be appropriate.

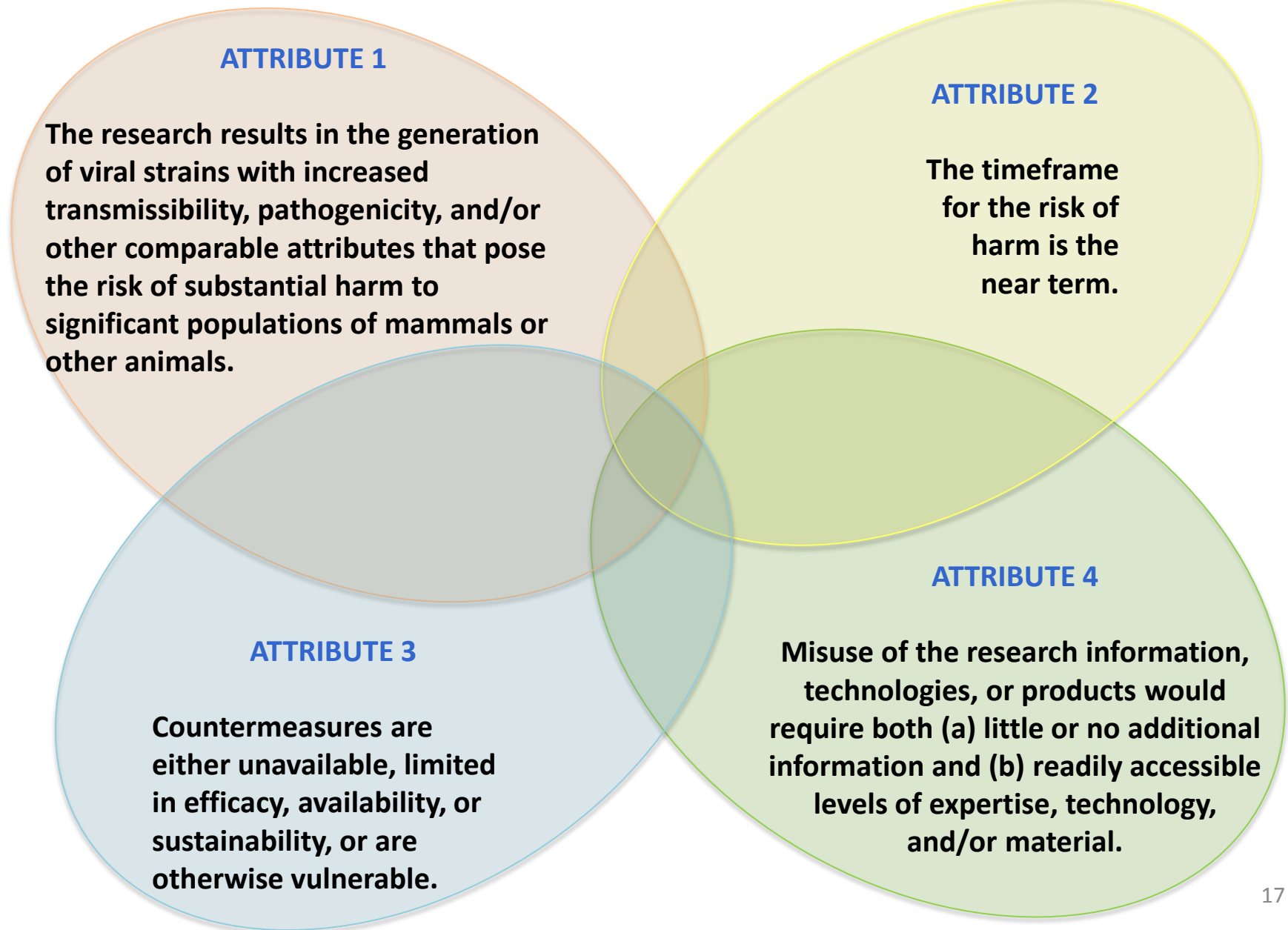
# Attributes of HPAI H5N1 DURC that may Warrant an Alternative Venue or Mode of Communication

**4: Misuse of the research information, technologies, or products would require (a) little or no additional information and (b) readily accessible levels of expertise, technology, and/or material.**

- The rapid evolution, proliferation, and dissemination of technology should be taken into account.
- Individuals may disagree on how readily information can be misused, but these determinations should be informed by evidence, data, and relevant expertise.



# **Recommended Attributes of HPAI H5N1 DURC that may Warrant an Alternative Venue or Mode of Communication**



## ***Question Two:***

**In light of the global nature of this research, what principles should underpin an international discussion promoting the responsible communication of HPAI DURC? What should the key questions addressed in that be?**

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# **An International Discussion of the Responsible Communication of HPAI DURC**

- **The discussion should reflect the global reach of HPAI research and the associated risks to global human and animal health if that research or information derived from it were misused.**
- **The process of defining the attributes of HPAI DURC communications will have to be international in both scope and significance.**
- **The process of determining whether a given body of work merits an alternative venue or mode of communication should remain largely at the institutional level**
  - **These decisions should be guided by a set of principles that have been informed by discussions within and with the national and international scientific communities.**

# Key Elements of An International Discussion of the Responsible Communication of HPAI DURC

- 1. A broadly based assessment of the risks vs. benefits of HPAI research to alter the host range, both for specific experiments and more generally for these types of experiments.**
- 2. An identification of the fundamental attributes of HPAI DURC that may warrant an alternative venue or mode of communication.**

# Key Elements of An International Discussion of the Responsible Communication of HPAI DURC

- 3. Discussion of alternative, feasible mechanisms for communicating HPAI DURC in a modified or delayed manner.**
- 4. Discussion of the attributes and possible mechanism for implementing controlled or limited access to the results of HPAI DURC.**
  - Such a mechanism for controlled access would fall between the two current options of classification and completely open communication.**

# Key Elements of An International Discussion of the Responsible Communication of HPAI DURC

5. Discussion of an analytic framework that facilitates identification of these attributes.
  - Such a framework might include a set of criteria for assessing the risks and benefits of communicating the research and guidance for determining an associated communication plan, for example:
    - communicate as is;
    - communicate with the addition of appropriate contextual information;
    - modify, abridge, or delay communication of information.

# Moving Forward

- **The challenge of responsibly communicating HPAI DURC is a global one, and finding a solution that both mitigates risks and allows for the advancement of influenza research will require global input and cooperation.**
  - **Further engagement by governments, public health authorities, researchers, journal editors and publishers, the public, and the international community is needed.**
  - **this report is intended to move the discussion forward by identifying some of the key elements required for future international discussions.**

# Moving Forward

- **As we move forward with consideration of HPAI H5N1 and HPAI research in general that may warrant an alternative venue or mode of communication, the NSABB continues to stress:**
  - **Research projects should be reviewed for their DURC potential well before the time of communication of research findings and outcomes.**
  - **Projects should be reviewed on an ongoing basis, throughout the course of the research lifecycle.**
  - **Risk mitigation measures may include using an alternative approach to address the same scientific question. It is particularly important to consider research for its DURC potential when the project is still in its early stages or being conceptualized so that such alternative approaches can be adopted at the outset if warranted.**

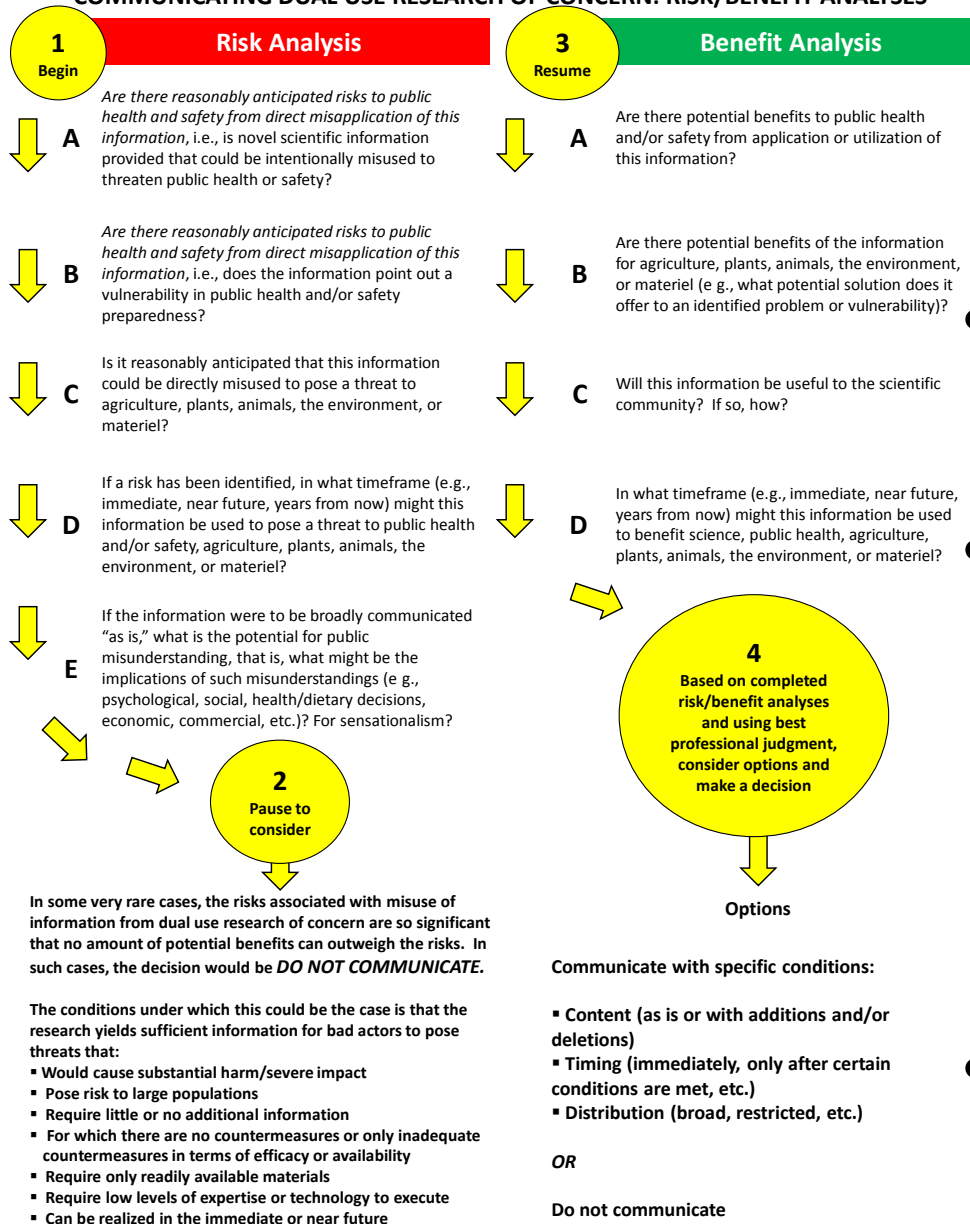


# *Appendix*

## The NSABB's Modified Communication Tool

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## COMMUNICATING DUAL USE RESEARCH OF CONCERN: RISK/BENEFIT ANALYSES



If this is not the case, then complete the risk/benefit analyses by resuming with steps 3A through 3D and step 4.

# Communicating Dual Use Research of Concern: Risk/Benefit Analyses

## Process map of the NSABB's Communication Tool

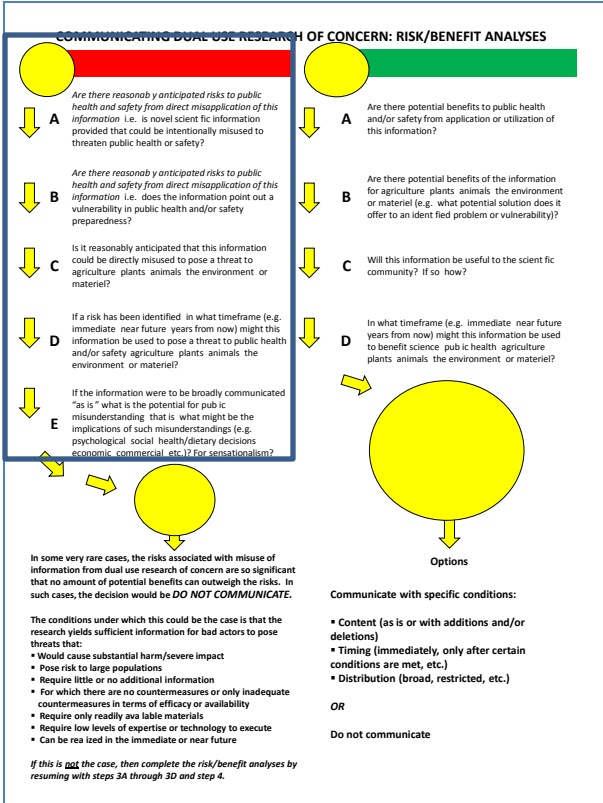
### Four step process:

1. Risk Analysis
2. Pause to Consider
3. Benefit Analysis
4. Consider option and make decision

- Includes an added step (#2) based on NSABB experience with manuscript reviews

**1  
Begin**

# Risk Analysis



**A**

**Are there reasonably anticipated risks to public health and safety from direct misapplication of this information, i.e., is novel scientific information provided that could be intentionally misused to threaten public health or safety?**



**B**

**Are there reasonably anticipated risks to public health and safety from direct misapplication of this information, i.e., does the information point out a vulnerability in public health and/or safety preparedness?**



**C**

**Is it reasonably anticipated that this information could be directly misused to pose a threat to agriculture, plants, animals, the environment, or materiel?**



**D**

**If a risk has been identified, in what timeframe (e.g., immediate, near future, years from now) might this information be used to pose a threat to public health and/or safety, agriculture, plants, animals, the environment, or materiel?**

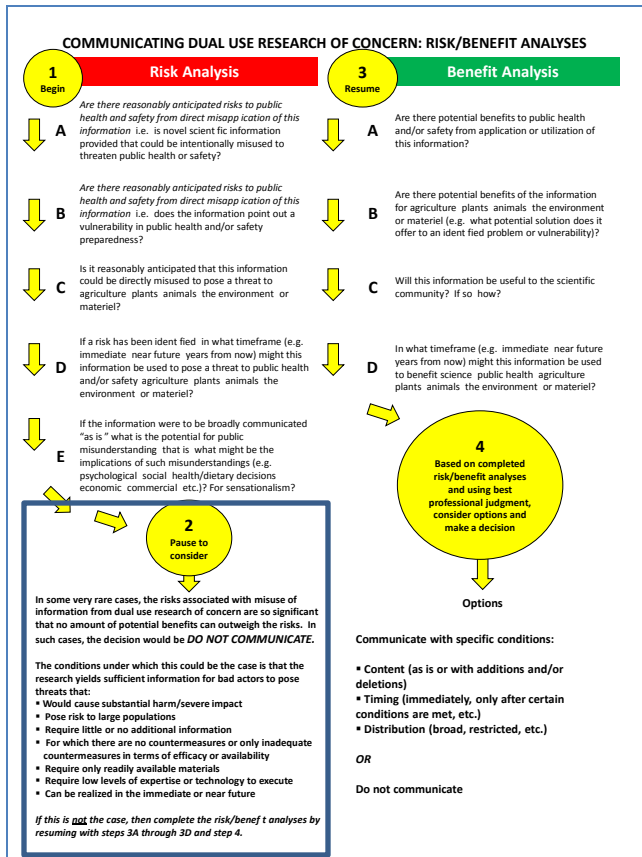


**E**

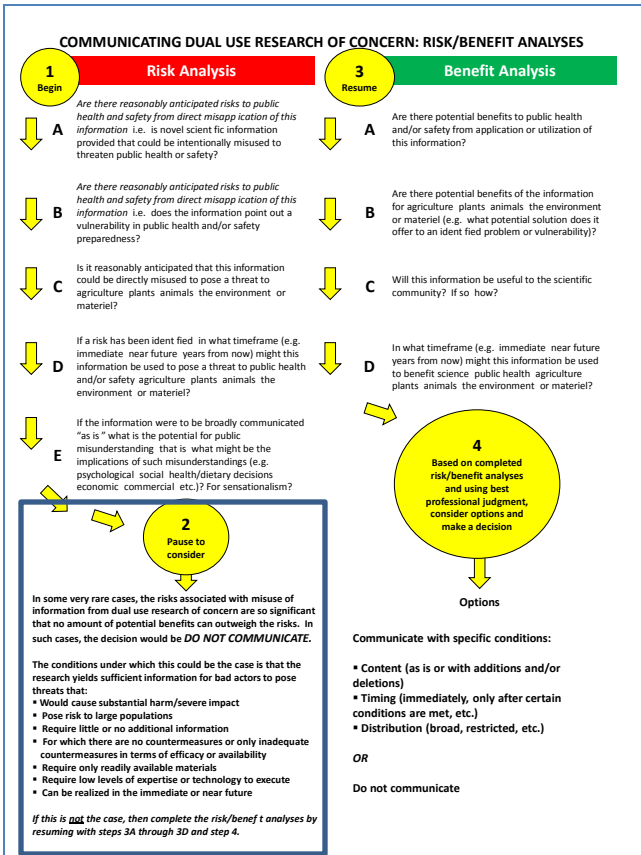
**If the information were to be broadly communicated “as is,” what is the potential for public misunderstanding, that is, what might be the implications of such misunderstandings (e.g., psychological, social, health/dietary decisions, economic, commercial, etc.)? For sensationalism?**

# 2 Pause to consider

In some very rare cases, the risks associated with misuse of information from dual use research of concern are so significant that no amount of potential benefits can outweigh the risks. In such cases, the decision would be ***DO NOT COMMUNICATE.***



# 2 Pause to consider



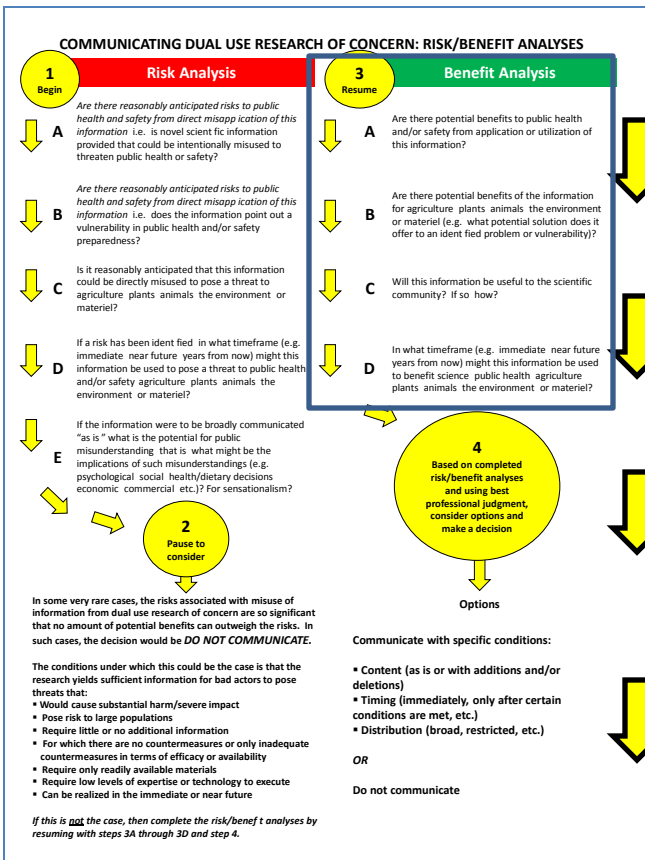
The conditions under which this could be the case: The research yields sufficient information for bad actors to pose threats that

- Would cause substantial harm/severe impact
- Pose risk to large populations
- Require little or no additional information
- For which there are no countermeasures or only inadequate countermeasures in terms of efficacy or availability
- Require only readily available materials
- Require low levels of expertise or technology to execute
- Can be realized in the immediate or near future

*If this is not the case, then complete the risk/benefit analyses.*

# 3 Resume

# Benefit Analysis



A

Are there potential benefits to public health and/or safety from application or utilization of this information?

B

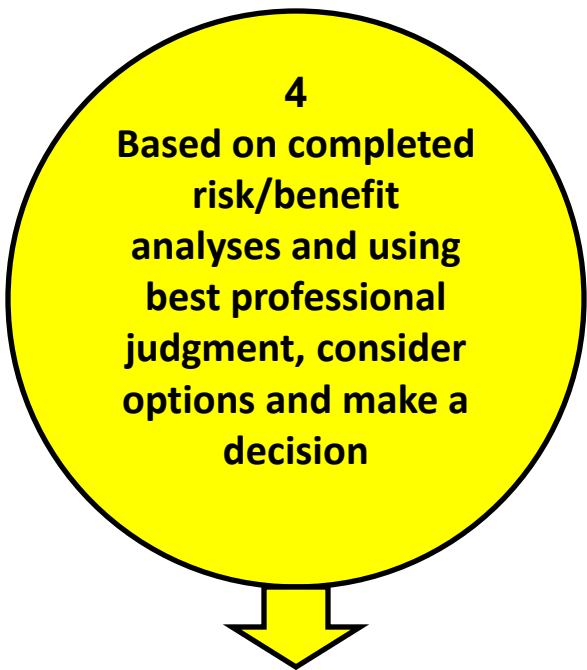
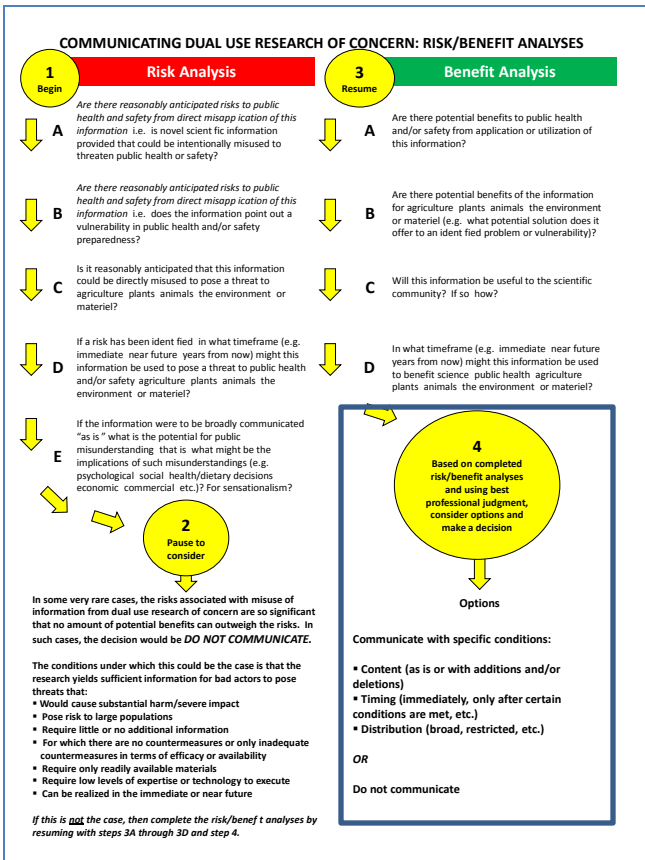
Are there potential benefits of the information for agriculture, plants, animals, the environment, or materiel (e.g., what potential solution does it offer to an identified problem or vulnerability)?

C

Will this information be useful to the scientific community? If so, how?

D

In what timeframe (e.g., immediate, near future, years from now) might this information be used to benefit science, public health, agriculture, plants, animals, the environment, or materiel?



Options

Communicate with specific conditions:

- Content (as is or with additions and/or deletions)
- Timing (immediately, only after certain conditions are met, etc.)
- Distribution (broad, restricted, etc.)

OR

Do not communicate