



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

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Table of Contents

INTRODUCTION.....	5
TOWARD A GLOBAL DISCUSSION OF H5N1 COMMUNICATION.....	8
QUESTION ONE: WHAT ARE THE ATTRIBUTES OF H5N1 DURC THAT MAY WARRANT ALTERNATIVE VENUES OR MODES OF COMMUNICATION?	8
QUESTION TWO: IN LIGHT OF THE GLOBAL NATURE OF THIS RESEARCH, WHAT KEY ELEMENTS SHOULD UNDERPIN INTERNATIONAL DISCUSSIONS OF THE RESPONSIBLE COMMUNICATION OF HPAI H5N1 DURC?.....	10
MOVING FORWARD.....	12
APPENDICES	13
APPENDIX A – NSABB ROSTER.....	15
APPENDIX B – AN OVERVIEW OF THE NSABB’S DURC COMMUNICATION TOOL	19

DRAFT

Introduction

The open and unfettered communication of the findings and results of life sciences research is a fundamental principle of the scientific enterprise. It has fostered and nurtured the development of a scientific community whose culture is one of open debate, and it has fueled a progression of scientific developments that have had immeasurable benefit for the public's health, safety, and security. However, certain types of life sciences research, if openly communicated, could be misused to cause harm. In addition, some harm may be unintentional. For example, the very conduct of laboratory research with pathogens poses a risk of release of those organisms into the wider environment. In recognition of this "dual use dilemma" in the life sciences, the U.S. Government (USG) established the National Science Advisory Board for Biosecurity (NSABB) to provide advice to the USG regarding biosecurity oversight of dual use research, defined as "biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security."¹

The NSABB immediately recognized that much of life sciences research could be denominated "dual use;" it therefore identified a subset of that research that warranted particular scrutiny, "dual use research of concern" or "DURC," defining it as "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."² In describing DURC and recommending a paradigm for the oversight of such research,³ the NSABB has wrestled with the issue of how to communicate responsibly certain types of life sciences research that contain information that is potentially problematic from either a public health and safety or a national security perspective or that presents risks that cannot be adequately and responsibly managed. On several occasions, the NSABB has been tasked with reviewing unpublished manuscripts that present dual use concerns and recommending whether, and how, that research should be communicated.⁴ When making recommendations about communicating DURC, the NSABB considers an array of risks and benefits associated with communicating—and not communicating—the research in question. Over the course of its deliberations, the Board has developed a framework for assessing the benefits and risks of conducting work with DURC potential as well as the risks and benefits of communicating the important results of DURC, and an overview of this framework can be found in Appendix B.⁵

¹ U.S. Department of Health and Human Services, *Charter of the National Science Advisory Board for Biosecurity* (April 4, 2010), oba.od.nih.gov/biosecurity/PDF/NSABB-Charter_Signed_2012.pdf.

² NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007), oba.od.nih.gov/biosecurity/pdf/Framework_for_transmittal_0807_Sept07.pdf. The U.S. Government uses a modified version of this criterion as its definition in its policies for the oversight of DURC. See *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern* (March 29, 2012) oba.od.nih.gov/oba/biosecurity/pdf/united_states_government_policy_for_oversight_of_durc_final_version_032812.pdf.

³ NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007), oba.od.nih.gov/biosecurity/pdf/Framework_for_transmittal_0807_Sept07.pdf.

⁴ For example, in September 2005, the NSABB reviewed manuscripts submitted by Tumpey TM, Basler CF, Aguilar PV, et al. and Taubenberger JK, Reid AH, Lourens RM, et al. involving the reconstruction of the 1918 influenza virus and concluded that the research in question should be openly communicated.

⁵ NSABB, "Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential," in *Responsible Communication of Life Sciences Research with Dual Use Potential*, oba.od.nih.gov/biosecurity/pdf/Communication_Tools%20Dual_Use_Potential.pdf.

In the Fall of 2011, the NSABB was tasked by the USG to review two manuscripts already submitted for publication that identified genetic mutations introduced into the highly pathogenic avian influenza (HPAI) H5N1 virus that make the virus transmissible between mammals (ferrets) through the air. The NSABB was specifically charged with assessing the dual use research implications of the two unpublished manuscripts, considering the risks and benefits of communicating the research results, and providing findings and recommendations regarding the responsible communication of the research.

In the end, the NSABB considered the question of communication twice: in late 2011 when it reviewed the original manuscripts, and in March 2012 when it reviewed revised manuscripts by the same authors.⁶ In its 2011 review, after discussions that included influenza experts, the NSABB determined that both original manuscripts reported findings that met the criteria of DURC and made the unprecedented recommendation that the conclusions of the manuscripts should be published, but with redaction of experimental data that would enable replication of the experiments or production of these same viruses through other means.

The U.S. Government conveyed the NSABB's recommendations to the two journals poised to publish the manuscripts. The journal editors agreed to consider publishing the manuscripts without certain data, but only if there were a way in which to share the full experimental details and results with the relevant sectors of the global influenza surveillance and research communities. In recognition of the potential public health benefits and cognizant of the potential for misuse of the research findings, the U.S. Government began working to develop a mechanism to provide secure access to this information for individuals with appropriate credentials and affiliations who are prepared to help realize the potential benefits of this knowledge.

Four months later, in March 2012, the NSABB reconvened to review revised versions of the manuscripts, which contained new information as well as clarifications of information presented in the original manuscripts. During this meeting, the NSABB was presented with new epidemiological findings and discussed the relevance of the mutational data in the manuscripts for public health surveillance. The NSABB also received clarifications from one of the authors, notably that the mutated virus, while transmissible via respiratory droplets in the ferret model, was lethal only upon intratracheal or intranasal inoculation as was the case for the wild type virus. The Board also received a classified briefing from national security officials about security concerns associated with H5N1 research. In response to a question from the NSABB about the status of a controlled access mechanism, the Board was advised about USG efforts to identify a secure controlled access mechanism to effectively restrict communication of the experimental details of the research only to those who could use the information to benefit public health. The Board was informed that such a mechanism had not yet been identified but was still being explored. At the conclusion of this meeting, the Board unanimously recommended that the revised manuscript by Yoshihiro Kawaoka et al. be communicated in its entirety, and a majority of the Board recommended that the data, methods, and conclusions in the revised manuscript by Ron Fouchier et al. be communicated after appropriate scientific review and revision.⁷

⁶ NSABB, *National Science Advisory Board for Biosecurity Findings and Recommendations, March 29-30, 2012*, oba.od.nih.gov/oba/biosecurity/PDF/03302012_NSABB_Recommendations.pdf.

⁷ NSABB, *National Science Advisory Board for Biosecurity Findings and Recommendations, March 29-30, 2012*, oba.od.nih.gov/oba/biosecurity/PDF/03302012_NSABB_Recommendations.pdf.

Throughout the review of the manuscripts, the NSABB relied on two analytic tools that it earlier had developed for the identification and management of DURC. The first tool is the DURC criterion, which serves to facilitate a consistent determination of DURC.⁸ The second tool is the “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential” developed as part of the NSABB’s 2007 report on a proposed framework for the oversight of DURC.⁹ Although the majority of the NSABB ultimately recommended the open communication of the H5N1 manuscripts in question, the NSABB’s divided decision (12 to 6) in recommending the communication of one manuscript underscores the challenges of assessing risks and benefits, and highlights the fact that such assessments ultimately depend upon informed but subjective judgments.

The NSABB has consistently noted that DURC should not be a negative categorization and that most research that is designated as DURC should be conducted and can be responsibly communicated.¹⁰ Although only a small subset of life sciences research would be appropriately categorized as DURC (Figure 1), an even smaller subset of DURC crosses a threshold and would thus warrant an alternative venue or mode of communication (to include considerations of the content, timing, and distribution of the communication). Given the global nature of H5N1 research, and of the associated benefits and risks, the NSABB stressed the importance of an international dialogue on responsibly communicating HPAI DURC that approaches a threshold for considering alternative plans for communication. Indeed, this report is intended to advance the ongoing dialogue on the issue because, while this report is focused on the communication of HPAI H5N1 research, the Board’s recommendation are applicable to other strains of pandemic influenza and other infectious agents.

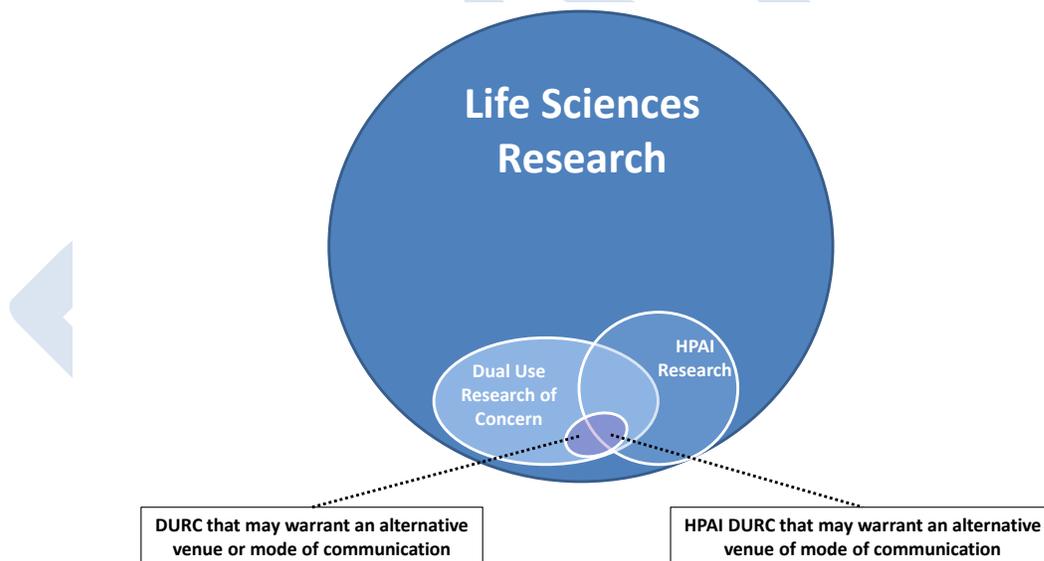


Figure 1. The NSABB defined dual use research of concern (DURC) as “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel.” NOTE: The diagram is not drawn to scale. DURC is a very small subset of life sciences research and DURC research that may warrant restricted communication is an even smaller subset. Likewise, HPAI DURC is a small subset of DURC and the amount of HPAI DURC that may require an alternative venue or mode of communication is likely small.

⁹ NSABB, “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential,” in *Responsible Communication of Life Sciences Research with Dual Use Potential*, oba.od.nih.gov/biosecurity/pdf/Communication_Tools%20Dual_Use_Potential.pdf.

¹⁰ See footnote 2.

Toward a Global Discussion of H5N1 Communication

In January 2012, a 60-day, voluntary moratorium on HPAI H5N1 transmissibility research was declared by 36 leading members of the international influenza research community,¹¹ a moratorium that since has been extended. Given the trajectory of HPAI research, and H5N1 research in particular, it is important to note that there will be additional instances of HPAI DURC that will require careful consideration. Thus, questions regarding the communication of HPAI DURC are likely to continue, and those questions will need to be considered not only by the NSABB, the National Institutes of Health (the funding source of the H5N1 research reviewed by the NSABB), and the departments and agencies across the U.S. Government that fund life sciences research, but also by other governments, international organizations, journal editors and publishers, other life sciences research funding entities, scientists, public health and public safety authorities, security authorities, legislators, and other stakeholders, particularly including the general public. Therefore, there is a critical need for global engagement concerning the responsible conduct and communication of HPAI DURC.

In recognition of the need for such discussion, the U.S. Government tasked the NSABB with addressing two key questions pertinent to a global discussion of HPAI DURC communication. First, what are the attributes of HPAI DURC that might warrant an alternative venue or mode of communication? Second, in light of the global nature of this research, what principles should underpin an international discussion promoting the responsible communication of HPAI DURC, and what should be the key questions addressed in that discussion?

The Board's answers to these questions are intended to foster an international dialogue about how to identify HPAI research that may warrant an alternative venue or mode of communication. An articulation of the attributes of a specific mechanism for controlling the access to the products of HPAI DURC is beyond the scope of this report and will require considerable further discussion within and among governments, science publishers, the scientific community at large, and the public regarding its feasibility and desirability. This report intends to contribute to the ongoing dialogue and precipitate a discussion of some of the challenging issues regarding how to responsibly communicate H5N1 DURC.

Question One: What are the attributes of H5N1 DURC that may warrant alternative venues or modes of communication?

Before identifying the attributes of H5N1 DURC that may warrant an alternative venue or mode of communication such as a manuscript, presentation, or personal communication, it is important to describe what is meant by the term. Altering or revising the venue or mode of communication may include: changes to the content of a communication (e.g., redacting information); changes to the timing of a communication, usually implemented as an embargo or delay of a communication; and/or changes to the planned distribution of a life sciences research communication. The NSABB previously has described strategies for responsibly communicating DURC that may entail altering the content,

¹¹ "Pause on Avian Flu Transmission Research," *SciencExpress*, published online January 20, 2012, www.sciencemag.org/site/feature/data/hottopics/biosecurity/Fouchier.Express.pdf. Also, "Pause on avian flu transmission studies," *Nature*, 481:443 (January 26, 2012; published online January 20, 2012), www.nature.com/nature/journal/v481/n7382/full/481443a.html.

timing, or distribution of a communication.¹² The Board recommends that the consideration of alternative plans for research communications should reside at the institutional level. However, given the global nature of HPAI H5N1 research, as well as the potential benefits to global health and the potentially global consequences if such research were to be misused, the conceptual framework guiding the communication of H5N1 DURC should be informed by national and international discussions.

H5N1 DURC that may warrant an alternative venue or mode of communication can be identified by the following four attributes:

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.

- A challenge in applying this attribute lies in the fact that the available scientific data are not always easily interpreted. For instance, there may be questions about how the results observed using a mammalian model will apply to humans. Or it may be unclear to what level the transmissibility or pathogenicity has been altered in a viral strain based on the experimental design or the assay used.
- Therefore, this attribute requires several judgments about the meanings of "increased transmissibility," "increased pathogenicity," "substantial harm," and "populations." In making such judgments, it is important to consider carefully all relevant information and data, including, for example, experimental findings from research involving these same or directly related viruses.
- The 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.

2. The timeframe for the risk of harm is the near-term.

- The harm to public safety and health, agriculture, wildlife, and the environment 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." As with Attribute 1, it is important to consider carefully all relevant information and data that may inform this judgment.

3. Countermeasures are either unavailable, limited in efficacy, availability, or sustainability, or are otherwise vulnerable.

- Currently available countermeasures for H5N1 are inadequate for responding to a widespread H5N1 public health emergency. Should this situation change, however, this could alter the determination regarding the extent to which a given body of H5N1 DURC should be communicated. It may be appropriate to delay the communication of a research finding until countermeasures have been developed or tested for efficacy, and made widely and readily available.

¹² NSABB, "Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential," in *Responsible Communication of Life Sciences Research with Dual Use Potential*, oba.od.nih.gov/biosecurity/pdf/Communication_Tools%20Dual_Use_Potential.pdf.

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

- There are challenges in assessing this attribute, and determining whether this attribute applies to a project will require judgment. The rapid evolution, proliferation, and dissemination of technology should be taken into account when making this judgment. Individuals may disagree on how readily information can be misused, but these determinations should be informed by evidence, data, and relevant expertise.

The following considerations are critical to understanding and appropriately employing the attributes of H5N1 DURC that may merit an alternative venue or mode of communication:

- The preceding attributes provide guidance for assessing H5N1 DURC; however, they should be used in conjunction with other relevant tools, including, for example, the NSABB's criterion for identifying DURC and the Board's seven categories of research that may warrant special scrutiny as DURC.¹³
- A pivotal question is whether a given body of H5N1 DURC must exhibit all four attributes in order to warrant an alternative venue or mode of communication. It is possible that a particular HPAI H5N1 study could exhibit some but not all of the attributes and still be judged to cross a threshold for considering alternative plans for communication. In such cases, the extent of the modifications to the communication may vary accordingly.
- The four attributes identified by the NSABB are interrelated and have synergistic effects. In the context of decisions about a given body of H5N1 DURC, one attribute may have decisive weight in the assessment; for example, a case in which the risks captured in Attribute 1 are so significant that it matters less whether the timeframe is immediate, near-term, or long-term, or whether the information could be easily misused. These determinations require a very thoughtful and evidence-driven process of analyzing the research and its implications and of weighing each attribute in conjunction with the others.

Question Two: In light of the global nature of this research, what key elements should underpin international discussions of the responsible communication of HPAI H5N1 DURC?

The need for an international discussion of how HPAI DURC should be responsibly communicated reflects 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. In developing its considerations for a global discussion of H5N1 DURC communication, the NSABB has sought to avoid becoming too specific and, therefore, prescriptive. The process of defining the attributes of HPAI DURC should be international in both scope and significance, and the Board has sought to provide recommendations that address the essential points and the principles.

As noted in the answer to Question 1, the Board recommends that the process of determining whether a given body of work merits an alternative venue or mode of communication should remain

¹³ NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007), oba.od.nih.gov/biosecurity/pdf/Framework_for_transmittal_0807_Sept07.pdf.

largely at the institutional level but that 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. While no international set of principles regarding the conduct or communication of H5N1 DURC exists to date, the NSABB expects that the continued dialogue in the scientific press as well as upcoming international meetings on the topic of HPAI DURC will be informative.

Institutions implementing a process for reviewing HPAI DURC communications may find it helpful to employ the communication tools developed by the NSABB, including the *Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential*.¹⁴ In formulating recommendations for the responsible communication of HPAI DURC, the review process should address the content, the timing, and possibly the extent of distribution of the information. Currently, decisions regarding the distribution of research information are binary: to openly communicate the information, as is traditionally done in the life sciences, or to significantly restrict the distribution, achieved, for example, by classifying the information. There exists to date no mechanism that would allow for controlled or limited access of HPAI DURC research findings to selected individuals on a “need to know” basis.

In light of the global nature of HPAI—specifically H5N1—research, the NSABB has considered the principles that should underpin an international discussion promoting the responsible communication of HPAI DURC and some key issues that should be part of that discussion. An effective discussion will guide and inform the decisions and actions of H5N1 investigators, public health authorities, journal editors and publishers, the public, national and international organizations, and policymakers throughout the world. Therefore, it should be founded on the principle of mutual benefit for global public health, safety and security.

Key elements of the international discussion should include:

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. (See the Board’s response to Question 1 for its description of these fundamental attributes.)
3. Discussion of alternative, feasible mechanisms for communicating HPAI DURC in a modified or delayed manner.
4. Discussion of the attributes of and possible mechanism for implementing controlled or limited access to the results of HPAI DURC. A mechanism for controlled access would fall between the two current options of classification and completely open communication.
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

¹⁴ NSABB, “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential,” in *Responsible Communication of Life Sciences Research with Dual Use Potential*, oba.od.nih.gov/biosecurity/pdf/Communication_Tools%20Dual_Use_Potential.pdf.

plan (e.g., communicate as-is; communicate with the addition of appropriate contextual information, an example being a description of biosafety and/or biosecurity management of the research in question; modify, abridge, or delay communication of information). Appendix A includes an overview of the risk/benefit analytic tool the NSABB has used when considering whether and how DURC results should be communicated. The figure in Appendix A has been adapted from the NSABB's communication tool in its 2007 report.

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. In this report, the NSABB aims to promote a discussion of some of the outstanding issues that need to be addressed by the international community. This report is not intended to provide answers to all of the questions regarding the communication of H5N1 DURC; those answers must be determined through further engagement by governments, public health authorities, researchers, journal editors and publishers, the public, and the international community. Rather, this report is intended to move the discussion forward by identifying some of the key elements required for future international discussions.

In this report, the Board has identified a set of attributes of H5N1 research and HPAI research in general that may warrant an alternative venue or mode of communication and has provided an overview of its communication tool that should serve as a springboard for further discussion about how to identify such research and communicate it responsibly. The NSABB continues to stress, however, that 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—that is, when the project is being conceived, reviewed, conducted, and any time aspects of the research are communicated—so that risk mitigation measures can be employed when necessary. 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. This is particularly so for research that can be reasonably anticipated to generate results that are described by the four attributes described above.

Appendices

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Appendix A – NSABB Roster

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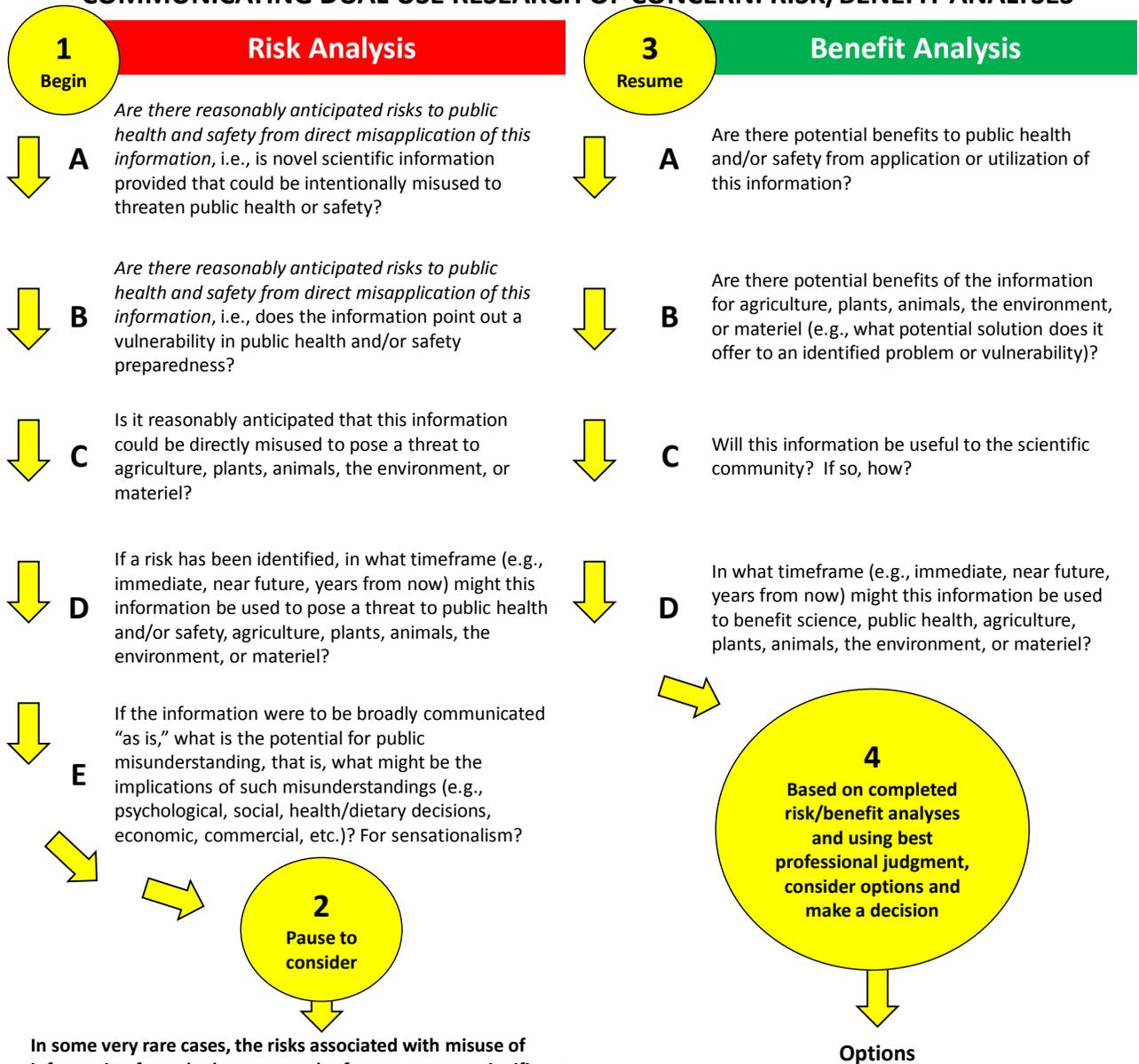
Appendix B – An Overview of the NSABB’s DURC Communication Tool

In the NSABB’s 2007 *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*, the Board developed a section titled “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential.”¹⁵ When asked by the U.S. Government to consider the communication of certain research communications, the NSABB has used that document to guide its risk/benefit analysis. Over the course of its deliberations, the NSABB has adapted this communication tool into the algorithm presented here. This adapted communication tool represents an overview of the thought-process and risk/benefit analysis that the NSABB employed when deliberating the H5N1 manuscripts.

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¹⁵ NSABB, “Points to Consider in Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential,” in *Responsible Communication of Life Sciences Research with Dual Use Potential*, oba.od.nih.gov/biosecurity/pdf/Communication_Tools%20Dual_Use_Potential.pdf.

COMMUNICATING DUAL USE RESEARCH OF CONCERN: RISK/BENEFIT ANALYSES



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**.

The conditions under which this could be the case is that 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 by resuming with steps 3A through 3D and step 4.

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

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