

Responsibly Communicating Dual Use Research of Concern: Lessons Learned from NSABB

Carrie Wolinetz, PhD
Associate Director for Science Policy
National Institutes of Health



National Institutes of Health
Office of Science Policy

National Science Advisory Board for Biosecurity

- **Federal Advisory Committee**
- **Established in 2004**
- **NSABB advises:**
 - Secretary of HHS
 - Director of NIH
 - Heads of Federal entities that have an interest in life science research
- **Membership**
 - Up to 25 voting members with broad expertise
 - Non-voting Federal agency *ex officio* members



National Science Advisory Board for Biosecurity

“...to provide, as requested, advice, guidance and leadership regarding biosecurity oversight of dual-use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biological threat to public health and/or national security.”

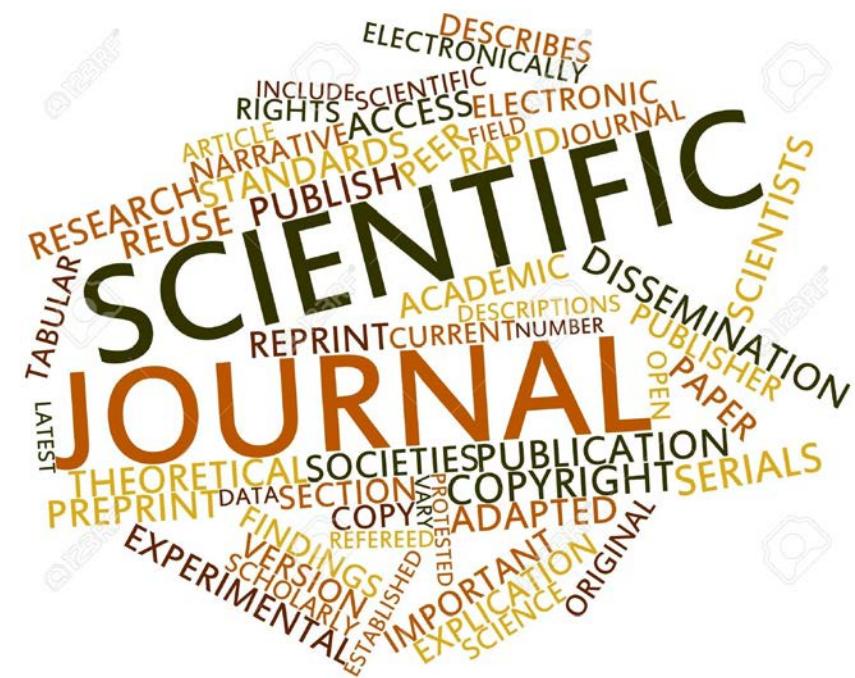
-NSABB Charter

NSABB Recommendations and Activities

- **Proposed Framework for the Oversight of Dual Use Life Sciences Research (2007)**
 - Criteria for identifying dual use research of concern
 - Guidance for assessing risks and responsibly communicating dual use research of concern
- **Biosecurity concerns related to synthetic biology (2006, 2010)**
- **Enhancing personnel reliability and a culture of responsibility (2009, 2011)**
- **Outreach and education strategies (2008, 2011)**
- **Codes of conduct for scientists and laboratory workers in life sciences research (2007, 2012)**
- **Gain-of-function research involving pathogens with pandemic potential (2016)**
- **International engagement on dual use research issue**

NSABB Engagement with Journal Editors

- Session on communicating dual use research at inaugural NSABB meeting (2005)
 - Scientific communication plenary and breakout session at 3rd International Roundtable Meeting (2008)
 - Two Journal Review Policies Working Groups of the NSABB; engaged with journal editors, surveyed policies and procedures used by journals for reviewing dual use research (2006, 2010)

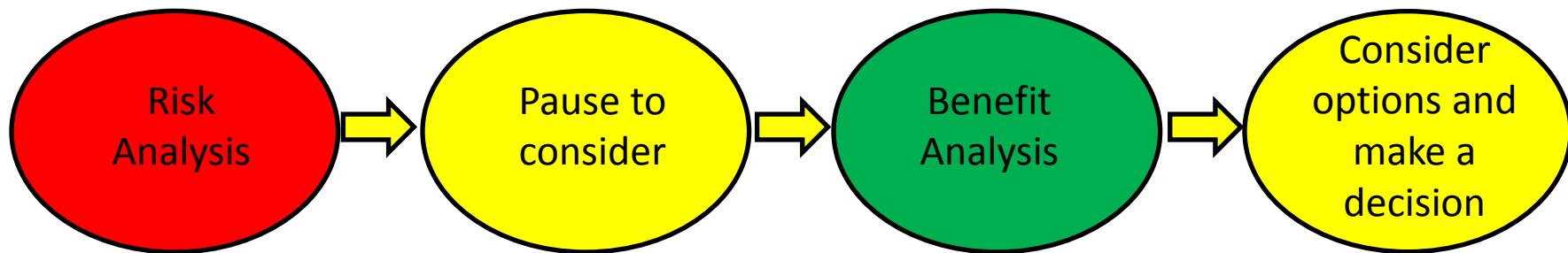


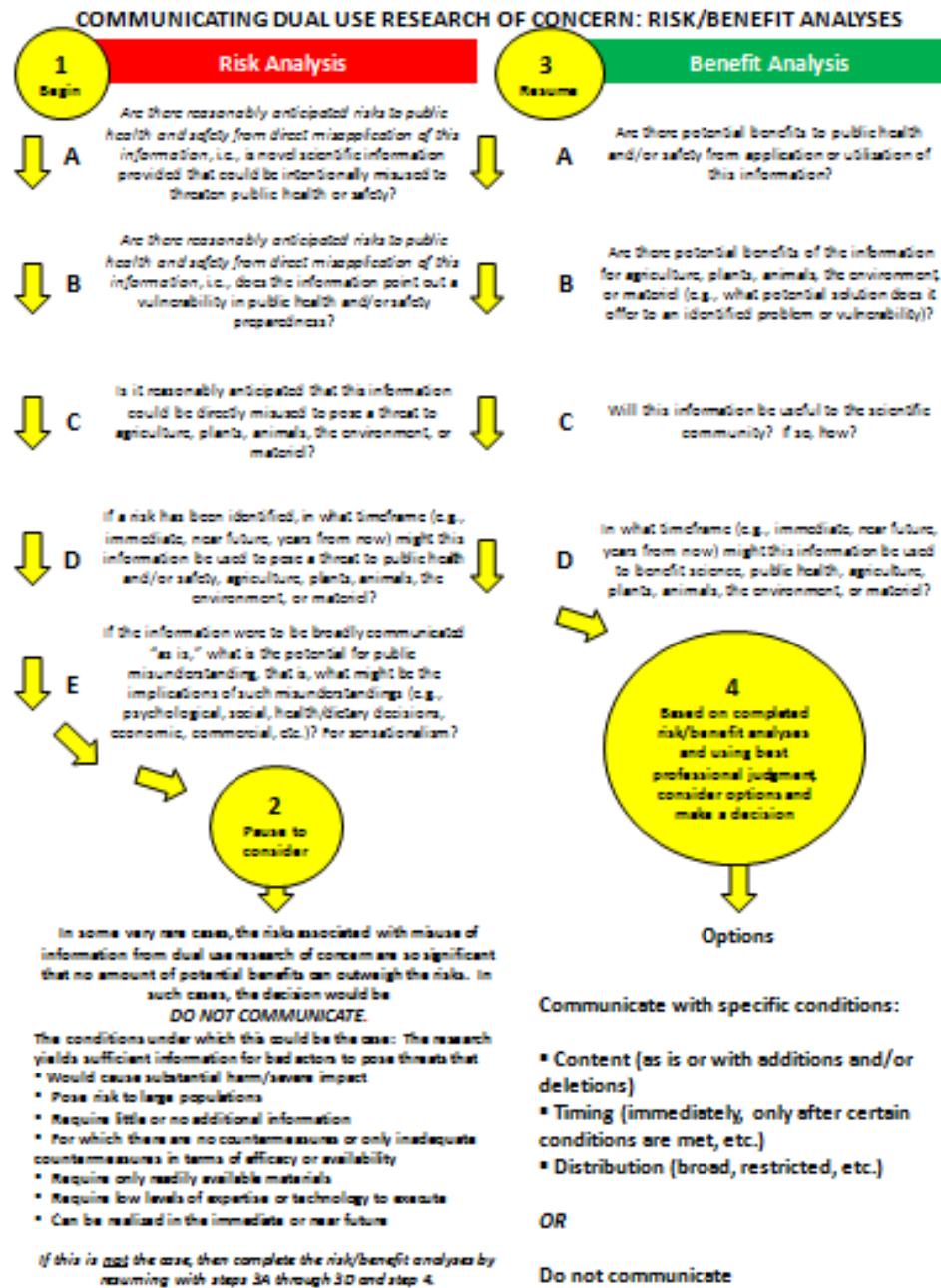
NSABB Manuscript Reviews

- Since 2004, NSABB has been asked by USG to review six manuscripts involving potential DURC to provide advice on how to responsibly communicate
- Lessons learned
 - First manuscripts were reviewed when NSABB had just been established
 - Informed the Board's recommendations on identifying and communicating DURC in its 2007 report
 - Review of H5N1 manuscripts in 2011 demonstrated the first example of research that some would suggest warranted redaction
 - Tested policy frameworks
 - Raised questions about whether research *can* be redacted, *should* be redacted, or whether a “restricted access” mechanism was feasible
 - Shifted the policy discussion about managing risks from the communication stage to the funding stage

NSABB Analytic Framework for Communicating DURC

- NSABB developed a communication framework to guide its review of DURC manuscripts
- Decisions to communicate were not viewed as binary (communicate/do not communicate)
- Communication strategies included altering content, timing, or distribution; including editorial or other accompanying information; etc.





NSABB Analytic Framework for Communicating DURC: A Process Map for Assessing Risks and Benefits

Risk Analysis

1
Begin

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?



A

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?



B

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



C

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?

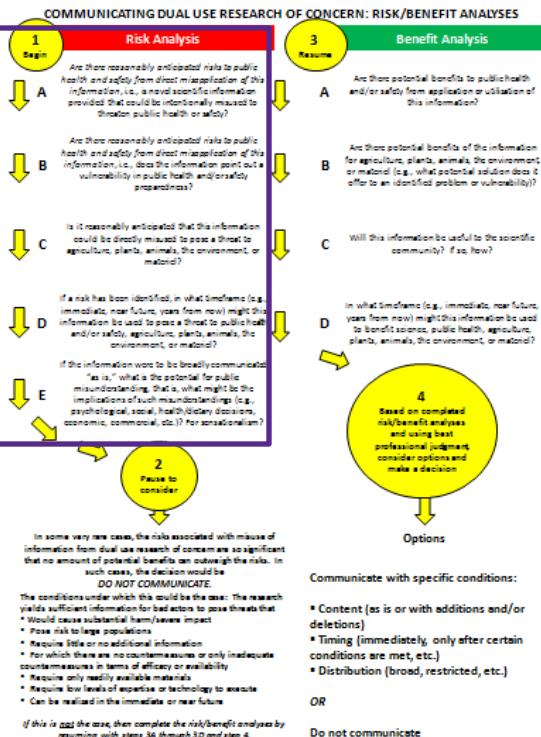


D

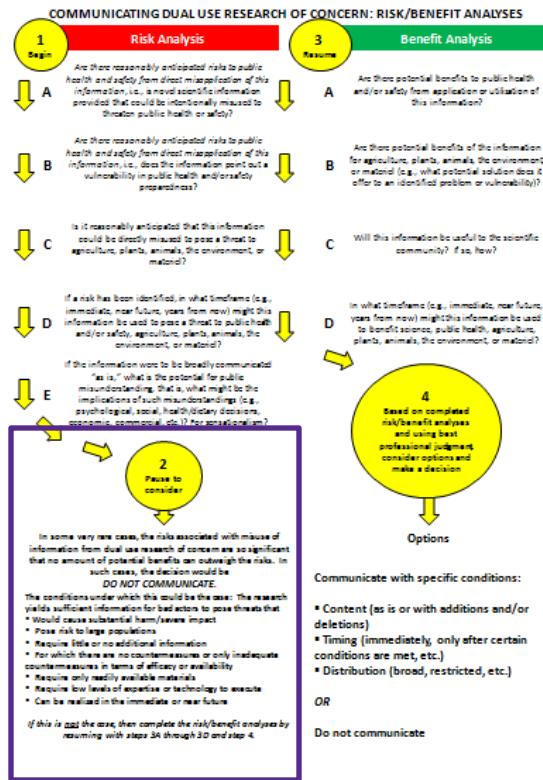
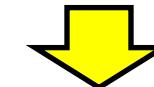
If the information were to be broadly communicated “as is,” what is the potential for public misunderstanding, that is, what might be the implications of such misunderstandings (e.g., psychological, social, health/dietary decisions, economic, commercial, etc.)? For sensationalism?



E



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

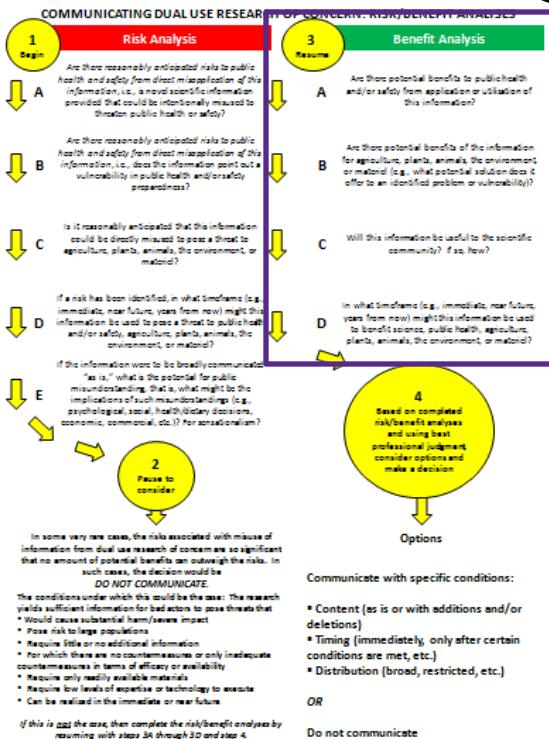
DO NOT COMMUNICATE

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 by resuming with steps 3A through 3D and step 4.

Benefit Analysis



3 Resume

A

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

B

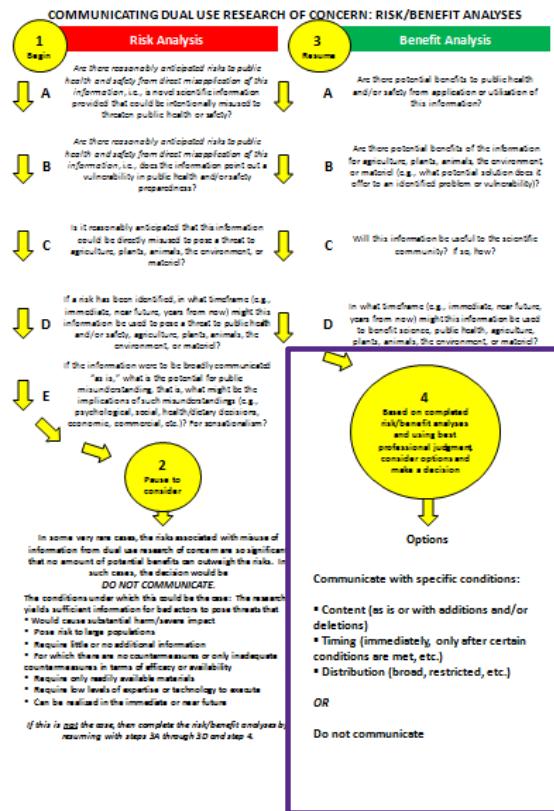
Are there potential benefits of the information for agriculture, plants, animals, the environment, or materiel (e.g., what potential solution does it offer to an identified problem or vulnerability)?

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?



4
Based on completed risk/benefit analyses and using best professional judgment, consider options and make a decision



Options

Communicate with specific conditions:

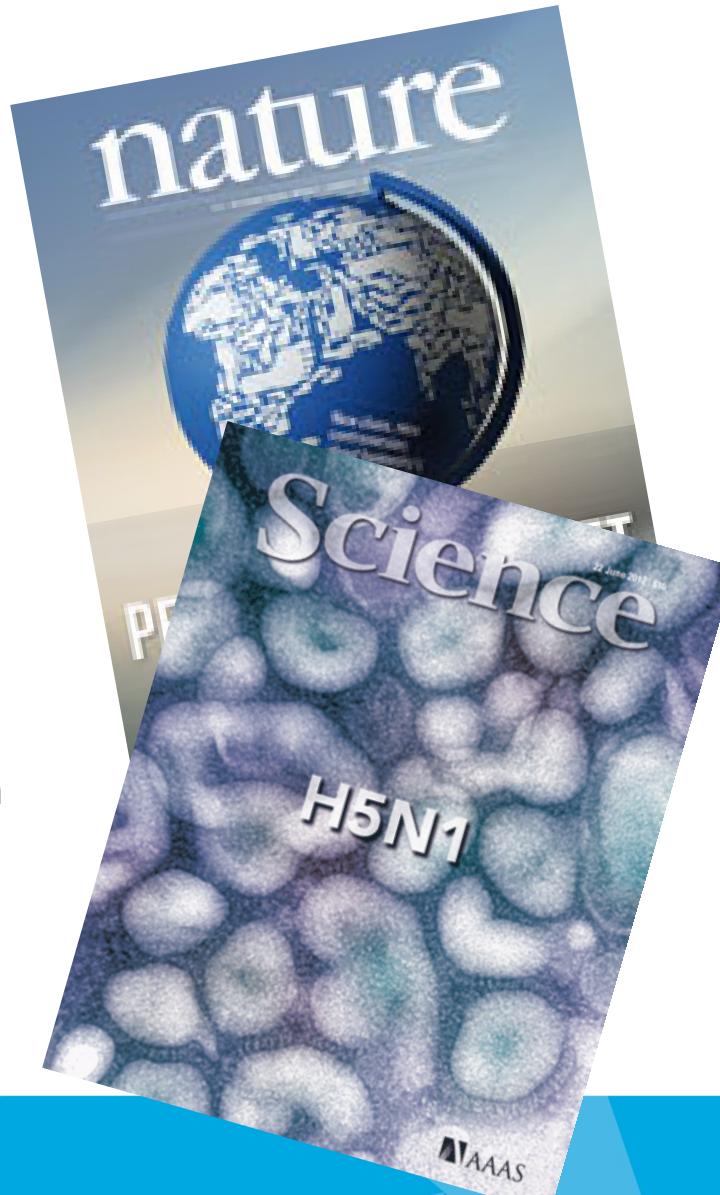
- **Content (as is or with additions and/or deletions)**
- **Timing (immediately, only after certain conditions are met, etc.)**
- **Distribution (broad, restricted, etc.)**

OR

Do not communicate

Unprecedented (Initial) Call for Redaction by NSABB

- **NSABB, November 2011:**
 - Neither manuscript should be published with complete data and experimental details
 - The conclusions of the manuscripts should be published but without experimental details and mutation data
- **NSABB review of revised manuscripts, March 2012:**
 - The revised Kawaoka manuscript should be communicated in full
 - The data, methods, and conclusions presented in the revised Fouchier manuscript should be communicated, but not as currently written
 - The U.S. Government should expeditiously develop a mechanism to provide controlled access to sensitive scientific information



USG Efforts to Develop Restricted Access Mechanism

Aim

- To create a mechanism that would:
 - Restrict the widespread distribution of scientific information that could be directly misused to cause harm (e.g., manuscripts)
 - Provide access to the complete, unredacted scientific information to vetted individuals with a legitimate need to know



USG Efforts to Develop Restricted Access Mechanism

Key Questions

- What information needs to be restricted?
- Who decides that the information should be restricted?
 - Who decides which individuals have a legitimate need to know?
- What mechanism can be utilized/developed to protect the information from unauthorized disclosure?

USG Efforts to Develop Restricted Access Mechanism

Examples of Potential Solutions

- Classification of the research
- Central repository, either physical or digital, within or outside of the USG, could be created to store sensitive information; access could be granted to individuals with a legitimate need
- Agency or organization, within or outside of the USG, could serve as stewards of the information; could convene experts to make determinations about whether the information should be restricted and to whom it could be shared
- USG could provide guidance on when to redact information or restrict communication but journals and individual investigators would make final decisions about whether and how to share the information

Significant challenges



- **Freedom of Information Act**
 - How can restricted information be protected from compelled disclosure, if that information is held by the USG?
- **First Amendment Issues**
 - What limits can be placed on future uses of restricted information once it is released to one individual?
- **Authority for a Restricted Access Program**
 - Under what authorities can the USG control the information? What recourse exists for noncompliance?
- **Export Control Requirements**
 - What is the applicability of the Export Control Requirements and must licenses be obtained?

But wait, there's more...



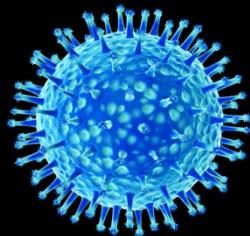
- **Screening Authority**
 - Does any Federal agency have sufficient statutory authority to conduct background checks for individuals seeking access to restricted information?
- **Review Committee Member Liability**
 - Can individuals appointed to determine if information should be restricted be indemnified against legal action?
- **Local Issues**
 - Would restricted information be subject to state, local, and university policies regarding transparency and open access?
- **International Issues**
- Should decisions about restricting access to information be made by international bodies? If so, is that feasible? Practical?
- **How useful is restricted information?!**

A Focus on Funding Decisions and Ongoing Oversight

- Two USG DURC policies issued (2012, 2014)
- Focus on identifying DURC by Federal funders and research institutions at the outset of a project and over the course of its conduct
- Policies and *Companion Guide* also list communication strategies, including classification or choosing to restrict, limit distribution, or delay

If the risks posed by the research cannot be adequately mitigated with the measures above, Federal departments and agencies will determine whether it is appropriate to:

- (a) Request voluntary redaction of the research publications or communications³;
- (b) Classify the research:
 - (i) In accordance with National Security Decision Directive/NSDD-189, departments and agencies will make classification determinations within the scope of their classification authorities and appropriate classification guidelines or may consult with other departments and agencies to make these determinations.
 - (ii) Departments and agencies may consider whether to refer classified research to another department or agency for funding.



A Proposed Framework for Guiding HHS Funding Decisions about Highly Pathogenic Avian Influenza H5N1 Gain-of-Function Research

December 17-18, 2012 | Natcher Conference Center | National Institutes of Health | Bethesda, Maryland

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

A Focus on Funding Decisions and Ongoing Oversight

- *HHS Framework* (Feb. 2013) requires multi-disciplinary, Department-level, **pre-funding review and approval** for research that is reasonably anticipated to generate certain avian influenza viruses that are transmissible in mammals via the respiratory route



Guiding HHS Funding Decisions

Under HHS Framework, research proposals that are anticipated to produce certain mammalian-transmissible avian influenza strains are reviewed and must be in line with the following principles in order to be funded:

1. Such a virus could be produced through a **natural evolutionary process**;
2. The research addresses a **scientific question with high significance** to public health;
3. There are **no feasible alternative methods** to address the same scientific question in a manner that poses less risk than does the proposed approach;
4. **Biosafety risks** to laboratory workers and the public can be sufficiently mitigated and managed;
5. **Biosecurity risks** can be sufficiently mitigated and managed;
6. The **research information is anticipated to be broadly shared** in order to realize its potential benefits to global health; and
7. The research is supported through **funding mechanisms that facilitate appropriate oversight** of the conduct and communication of the research

NSABB Recommendations on Funding GOF Research of Concern

There are many types of GOF studies and not all of them have the same level of risks. Only a small subset of GOF research—GOF research of concern (GOFROC)—entail risks that are potentially significant enough to warrant additional oversight.

*Research proposals involving GOF research of concern entail significant potential risks and **should receive an additional, multidisciplinary review, prior to determining whether they are acceptable for funding.** If funded, such projects should be subject to ongoing oversight at the federal and institutional levels.*

Some thoughts from NIH...

- A restricted access mechanism for DURC has not been developed and appears to be quite difficult
- At present, “classification” appears to be the only mechanism for restricting access and protecting information
- NIH does not and likely will not conduct classified research
- It is assumed that NIH-funded research will be openly published
- Is a restricted access mechanism feasible? If so, is it *desirable*?
- Focus on funding decisions

Resources

- **Science, Safety, Security (S3)**
 - <http://www.phe.gov/s3/Pages/default.aspx>
- **NIH Office of Science Policy**
 - Website: <http://osp.od.nih.gov/>
 - NSABB: <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb>
 - Blog: <http://osp.od.nih.gov/under-the-poliscope>
 - Twitter: <https://twitter.com/cwolinetznih>
 - Subscribe to the OSP listserv by sending an email to LISTSERV@list.nih.gov with “Subscribe OSP_News” in the message body



Bringing Science Policy Into Focus