

# Working Group on Communication of Dual Use Research Results, Methods, and Technologies





# Communication Working Group Charge

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- **Identify issues and examine options and strategies for the responsible communication of dual use research information**
- **Develop principles and tools to facilitate careful, consistent decisions about how to responsibly communicate information with biosecurity implications**



# Working Group Roster

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## Voting Members:

- P. Keim (Chair)
- A. Casadevall
- L. Enquist
- D. Franz
- J. Gordon
- D. Kasper
- S. Lemon
- M. Nance
- T. Shenk
- A. Sorensen
- S. Ehrlich

## Federal Agency Representatives:

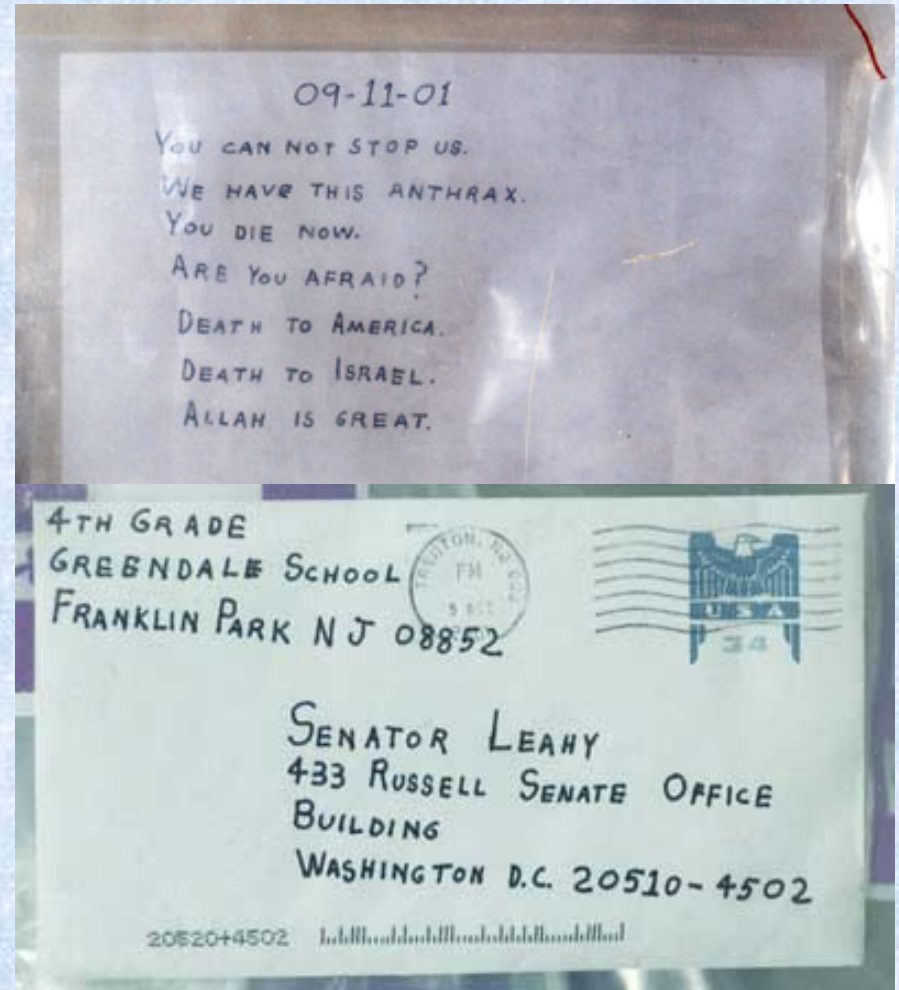
- B. Cuccherini (VA)
- D. Dixon (NIH)
- T. Lomax (NASA)
- B. Lushniak (FDA)
- S. Nightingale (HHS)
- S. Steele (DoJ)
- M. Schmolesky (State)
- R. Walters (Intel.)



# What's The Problem?

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- Increasing concerns about the potential for misuse of life science research information for bioterrorism purposes



# Calls to Action

...cial desegregation  
...ship; young people  
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...noun  
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**Science**  
7 October 1998

**RESEARCH ARTICLE**

**Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus**

Thomas H. Tamura,<sup>1,2</sup> Christopher F. Basler,<sup>1</sup> Fabiana N. Aguilón,<sup>1</sup> Neil Berg,<sup>1</sup> Nikola Balmori,<sup>1</sup> David S. Jones,<sup>1</sup> Nancy L. Cox,<sup>1</sup> Josephine H. Katz,<sup>1</sup> Jeffrey K. Taubenberger,<sup>1</sup> Peter Paley,<sup>1</sup> Adam S. de Waure,<sup>1</sup>

The pandemic influenza virus of 1918, which is estimated to be the most lethal major influenza virus in the world, has been reconstructed in the laboratory. We used reverse genetics to generate the influenza virus genome and reconstructed the pandemic virus by reverse genetic rescue of the reconstructed virus genome in a contemporary human influenza A virus cell. The reconstructed virus was able to produce an influenza pandemic wave of similar magnitude to that of the 1918 pandemic virus. The reconstructed virus was able to produce an influenza pandemic wave of similar magnitude to that of the 1918 pandemic virus. The reconstructed virus was able to produce an influenza pandemic wave of similar magnitude to that of the 1918 pandemic virus.

**Classified?**

**Table 1. Phylogenetic relationships of the 1918 virus to other influenza A viruses.**

Strain	Year	Location	Genotype
1918	1918	Spain	H1N1
1968	1968	Hong Kong	H3N2
1997	1997	Hong Kong	H5N1
2003	2003	Guinea	H5N1
2005	2005	Indonesia	H5N1
2009	2009	Mexico	H1N1
2013	2013	Guinea	H7N9
2017	2017	China	H5N1

- Increasing calls for consideration of the security implications of dual use research findings

# **Journal Editors and Authors Group statement on the consideration of biodefense and biosecurity**

**We recognize that the prospect of bioterrorism has raised legitimate concerns about the potential abuse of published information, but also recognize that research in the very same fields will be critical to society in meeting the challenges of defense.**

**Fundamental is a view, shared by nearly all, that there is information that, although we cannot now capture it with lists or definitions, presents enough risk of use by terrorists that it should not be published.**

**Scientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues.**

**Editorial**

***Nature* 421:771 (2003)**

# **“Do no harm: reducing the potential for the misuse of life science research”**

**Research institutions and funding agencies need to consider how to build on existing processes for reviewing research projects to ensure that risks of misuse are assessed in an appropriate and timely manner.**

**2004 Report of the Royal Society-Wellcome Trust**

# **“Science and Security in an Age of Terrorism”**

**The scientific, engineering, and health research community should work closely with the federal government to determine which research may be related to possible new security threats and to develop principles for researchers in each field.**

**Alberts, Wulf and Fineberg**

**Presidents of the National Academies**

**October 18, 2002**



**“US officials urge biologists to vet publications for bioterror risk”**

**“The science community ought to come up with a process before the public demands the government do it for them.”**

*Parney Albright (OSTP)*

**Report on NAS meeting ‘Scientific Openness and National Security’  
*Nature* 421:197 (2003)**

# **“Risks and benefits of dual-use research”**

**“It is important to develop clear guidelines about what research is considered sensitive, what is expected of researchers whose work produces dual-use outcomes, and how the government should in practice respond without losing the priceless virtue of open scientific scrutiny.”**

***Nature 435:7044 (2005)***



# How Does One Know If There Are Security Concerns?

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**“I’ll know it when I see it”**

**vs.**

**Systematic and comprehensive evaluation**

- **Guidance and tools will:**
  - **Facilitate consistent and well-considered approach**
  - **Demonstrate to the public that scientists recognize, and are being responsive to, concerns about the security implications of their work**



# Current Tasks

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- **Develop for consideration by the NSABB:**
  - **Principles for the responsible communication of dual use research findings**
  - **Statement regarding the importance of communicating findings from life sciences research**



# Current Tasks

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- **Framework for identifying and assessing the security implications of communicating dual use research information**
- **Options for how and when to communicate information**
- **Elements of a comprehensive plan for communicating dual use research findings that have security implications**



# **Overarching Principles**

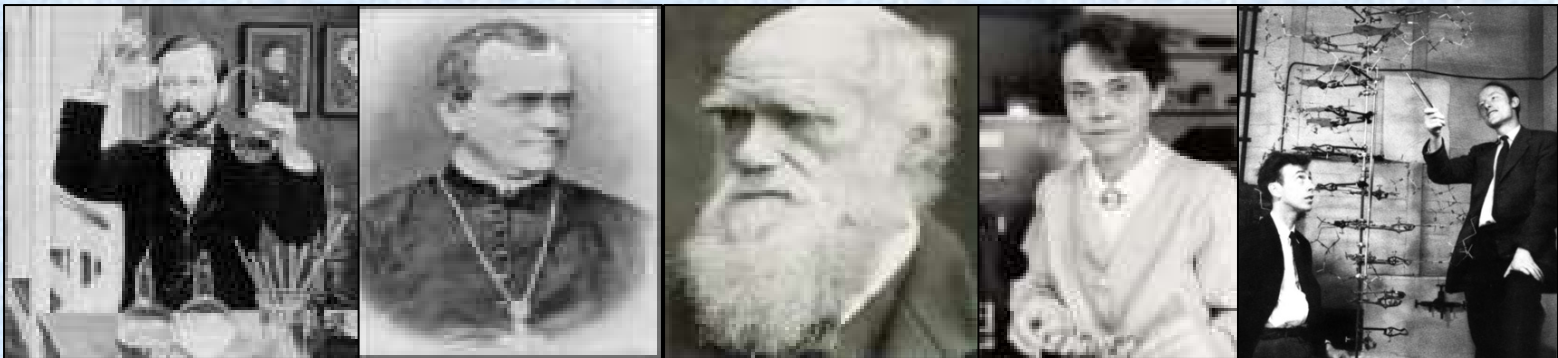
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**Principles that underpin the responsible communication of dual use research findings**

# Overarching Principles

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- **Communication is vital for scientific progress**



1. **The open and unfettered sharing of information and technologies has been a hallmark of the life sciences and has fostered a steady stream of scientific advances that underpin public health and safety, a strong and safe food supply, and a healthy environment.**
2. **Progress in the life sciences relies heavily upon the communication of research findings, so that they can be both validated, and built upon.**



# Overarching Principles

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- **Communicate research to the fullest extent possible**
  - **Restriction of scientific communication is a rare exception**

**3. To ensure the continued advancement of human, animal, plant, and environmental health, life sciences research should be communicated to the fullest extent possible. Consequently, any restriction of scientific communication should be the rare exception rather than the rule.**



# Overarching Principles

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## ■ Need for Balance



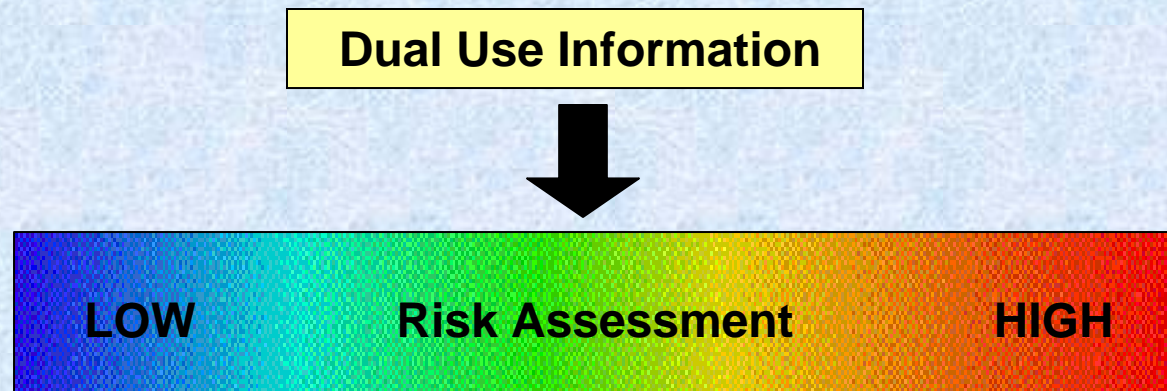
4. There is, however, a need for reasonable balance in decisions about the communication of dual use research. It is important to recognize the potential for deliberate and malevolent misuse of dual use research findings and to consider whether the disclosure of certain information might pose a significant threat to national security.



# Overarching Principles

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- **Need to assess risks and benefits of communicating information**



5. If the communication of dual use research does pose potential security risks, the logical next step is a risk-benefit analysis of communicating the information.



# Overarching Principles

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- **Consider a range of communication options**
  - **The decision to communicate information is not necessarily binary**

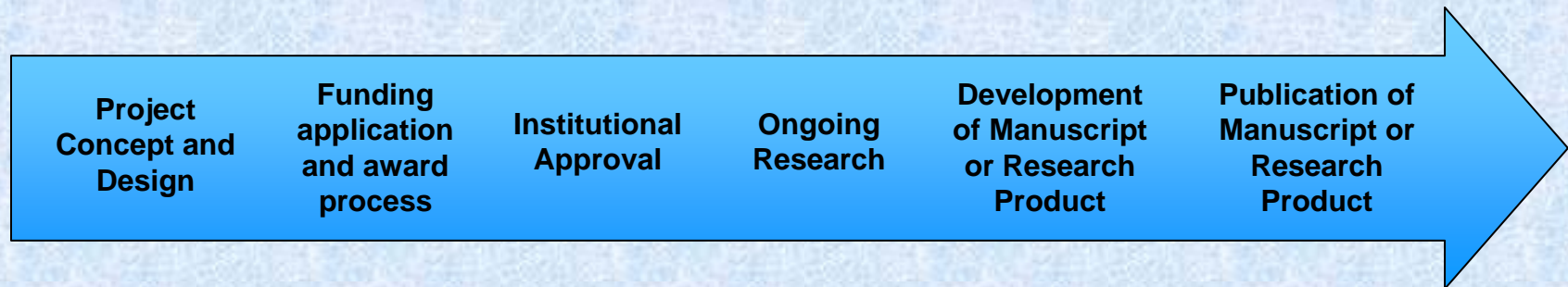
6. After weighing the risks and benefits of communicating dual use research, the decision regarding communication is not necessarily a binary (yes/no) one. Rather, a range of options for communication should be identified and considered. These options could range from full and immediate communication, to delayed and/or modified communication, to restricted/no communication, and could be recommended singly or in appropriate combinations on a case-by-case basis, depending on the nature of the dual use finding and the potential risks associated with its communication.



# Overarching Principles

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- **Communication occurs throughout the research process**



7. Paradigms for the responsible communication of dual use research should also take into consideration that the communication of dual use research occurs at multiple points throughout the research process, i.e. at points well upstream of the publication stage. Thus it is important to apply principles and practices of responsible communication at these early stages as well.



# Overarching Principles

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- **Need to consider what is communicated, and the way in which it is communicated**
  - **Potential for public concern and misunderstanding should be minimized**

8. It is important to consider not only what is communicated, but also the way in which it is communicated. Investigators and sponsors of potentially dual use research should recognize that the communication of dual use information is likely to raise biosecurity concerns, not only within the general public, but also within the scientific community. Consideration should be given to the potential for public concern and misunderstanding and sensationalism. Thought should be given to the need for the inclusion of contextual and explanatory information that might minimize such concerns and misunderstanding.



# Communication Tools

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- **Framework**
  - **Identifying and assessing the risks and benefits of communicating dual use research information**
- **Options**
- **Communication Plan**



# Risk/Benefit Assessment Framework

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- **Possible uses:**

- **Review**

- Research proposals
    - Manuscripts
    - Presentations (oral, abstract, posters)
    - Internet postings

- **Education tool**

- Raise awareness of DUR issues within the scientific community
    - Ethics training



# **Risk/Benefit Assessment Framework**

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- **Possible users:**
  - **Investigators**
  - **Students**
  - **Institutional biosecurity review entity**
  - **Proposal and manuscript reviewers (pre and/or post submission)**
  - **Government policy makers**





# **Risk/Benefit Assessment Framework**

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## **■ Key Elements**

- General Overview of Information**
- Risk Analysis**
- Benefit Analysis**
- Risk vs. Benefit Assessment**
- Formulation of Recommendation  
Regarding Communication**



# **Risk/Benefit Assessment Framework**

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- **General Overview of Information**
  - **What information is provided and to what extent is it novel?**
    - **E.g., is the information already publicly available?**



# Risk/Benefit Assessment Framework

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## ■ Risk Analysis

- Are there potential risks to public health from application or utilization of this information? (E.g., does the information point out a vulnerability in public health preparedness?)
- Could this information be intentionally misused to pose a threat to national security (other than public health)? (E.g., is novel scientific information provided that could be intentionally misused to threaten plant or animal health?)
- If a risk has been identified, in what time frame (e.g., immediate, near future, years from now) might this information be used to pose a threat?



# Risk/Benefit Assessment Framework

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## ■ Risk Analysis (cont.)

- If the information were to be broadly communicated “as is,” what is the potential for:
  - Public misunderstanding
    - What might be the implications of such misunderstandings, e.g., psychological, social, health/dietary decisions, economic, commercial etc.?
  - Sensationalism
    - In what way might it result in widespread concern or even panic about public health or other safety/security issues?



# **Risk/Benefit Assessment Framework**

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- **If no risk is identified, further communication review is not necessary**
- **If a risk has been identified, complete the benefit analysis**



# **Risk/Benefit Assessment Framework**

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## **■ Benefit Analysis**

- Are there potential benefits to public health from application or utilization of this information?**
- Are there potential benefits of the information for national security?**
- Will this information be useful to the scientific community?**
- If a benefit has been identified, in what time frame (e.g., immediate, near future, years from now) might these benefits be realized?**



# **Risk/Benefit Assessment Framework**

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- **Risk vs. Benefit Assessment**
  - **Based on the risks and benefits identified, and considering the time frame in which these might be realized:**
    - **Do the benefits of communicating the information outweigh the risks?**
    - **Do the risks outweigh the benefits?**



# **Risk/Benefit Assessment Framework**

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- **Formulation of Recommendation Regarding Communication**
  - **What are the recommendations with respect to the content, timing and extent of distribution of the information?**





# Communication Tools

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- Framework
- Options
- Communication Plan

# Options for Communication

- Spectrum of options – can be used in combination

<b>Content</b>	Communicate as is	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
	Addition of contextual Information		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
	Modify or remove substantive information			<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
<b>Timing</b>	Communicate immediately	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
	Delay communication				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
<b>Distribution</b>	No limit on distribution	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Limit distribution on a 'need to know basis'						<input checked="" type="checkbox"/>
	Don't communicate						



# Communication Tools

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- **Framework**
- **Options**
- **Communication Plan - a critical part of decision to communicate**
  - **Not only what is said, but how it is said**
  - **Promotes public understanding and trust**



# **Communication Plan**

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- **Elements of a communication plan**
  - **Important to speak to:**
    - **The public health significance of the research findings**
    - **How the new information or technology will be useful to the scientific community**
    - **The biosafety measures in place as the research was carried out**
    - **The dual use aspects of the information and that careful consideration was given to the biosecurity concerns in the decision to communicate**



# Communication Plan

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- **Vehicles for addressing these points:**
  - **Editorials**
    - **Scientific journals**
    - **Popular press**
  - **Press release**
    - **Opportunity to provide:**
      - **Contextual information regarding issues that may be of concern to the public and**
      - **Scientific perspectives on the importance of the findings**



# Communication Plan

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- **Vehicles (cont.):**
  - **Press conference**
    - Usually for the most significant and/or sensitive findings
    - Opportunity for direct interaction with the media
  - **Qs & As / Talking points**
    - Helpful tool for scientists and communications staff

# Concerns

## Scientific Community

- Red tape and restraints on communication slow progress
- Restricting communication -- starting down a slippery slope to censorship?



## Public

- Need for more effective oversight of dual use research
- Laws and regulations may be necessary



# Next Steps

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- **Seek broader input on communication tools, revise as necessary**
  - **Possible fora:**
    - **Focus groups**
    - **Workshops at professional meetings**
- **Promote acceptance of the communication tools**
  - **Scientific community**
  - **General public**






# Challenges

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- **Requires comprehensive education about dual use research concerns**
  - **Need to coordinate efforts with other working groups**
  - **Need to clearly explain how the tools fit into the oversight paradigm. E.g.,:**
    - **Purpose of the tools**
    - **Who are the users of the tools**
    - **How will the tools be used**
    - **When will the tools be used**



# Still to Come

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- **Strategies for review of work products containing information with national security implications**
  - **Where and how should dual use research communications be reviewed?**
    - E.g., Institutional or regional committee with appropriate expertise
    - Oversight of research not initially identified as dual use