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# **NSABB Meeting July 13, 2006**



# **Meeting Agenda**

- **Dual Use Criteria Working Group Report**
- **Communications Working Group Report**
- **Codes of Conduct Working Group Report**
- **Lunch**
- **Public Comment**
- **Synthetic Genomics Working Group Report and Presentations by Panelists:**
  - **Mark Hemphill (CDC)**
  - **John Mulligan (Blue Heron Biotechnology, Inc.)**
  - **Ralph Baric (University of North Carolina)**
- **International Working Group Report**
- **Next Steps**

# Approving NSABB Working Group Products

- **Consider**

Approval of the **Criteria,**  
**Communication** and **Codes**  
Working Group products as  
components of a framework for  
addressing dual use research of  
concern.

# Life Sciences Research

Criteria

## Dual Use Research of Concern

Risk Assessment

Review Process

Risk Management

Guidelines for Oversight of Dual Use Research

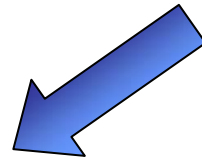
Training and Education

Responsible Communication of Dual Use Research

Code of Conduct for Life Science Researchers

## Vote on Components

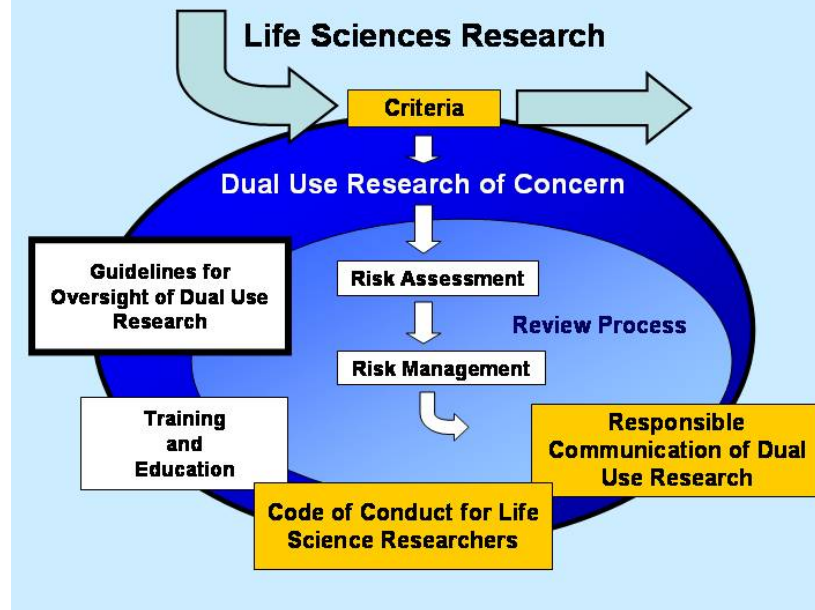
Criteria for Dual Use Research	<input checked="" type="checkbox"/>
Code of Conduct	<input checked="" type="checkbox"/>
Communication Tools	<input checked="" type="checkbox"/>



## Send Framework to USG



## Further Develop Oversight Framework



## USG Seeks Broad Input from Scientific Community and Public



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# Draft Criteria for Identifying Dual Use Research of Concern



Dennis Kasper  
Chair  
Dual Use Criteria Working Group



# **NSABB Charge**

- **The NSABB Charter states that the NSABB is to:**  
  
**“Develop criteria for identifying dual use research and research results.”**

# **Dual Use Criteria Working Group Members**

## **NSABB Voting Members**

**Dennis L. Kasper, M.D. (Chair)**  
**Arturo Casadevall, M.D., Ph.D.**  
**Barry J. Erlick, Ph.D.**  
**John A. Gordon GEN, USAF (Ret.)**  
**Michael J. Imperiale, Ph.D.**  
**Mark E. Nance, J.D.**  
**Michael T. Osterholm, Ph.D., M.P.H.**  
**David A. Relman, M.D.**  
**James A. Roth, D.V.M., Ph.D.**  
**Andrew A. Sorensen, Ph.D.**  
**William O. Studeman VADM, USN (Ret.)**  
**Anne K. Vidaver, Ph.D.**

## **Agency Representatives**

**Kenneth A. Cole, Ph.D. (DoD)**  
**Brenda Cuccerini, Ph.D. (DVA)**  
**Dennis Dixon, Ph.D. (NIH)**  
**Susan Elizabeth George, Ph.D. (DHS)**  
**Maryanna Henkart, Ph.D. (NSF)**  
**Peter R. Jutro, Ph.D. (EPA)**  
**Stuart L. Nightingale, M.D. (DHHS)**  
**Anthony Macaluso, Ph.D. (NIH)**  
**Gerald Parker, Ph.D., D.V.M. (DHHS)**  
**Scott Steele, Ph.D. (DoJ)**  
**David G. Thomassen, Ph.D. (DoE)**  
**Ronald A. Walters, Ph.D. (Intelligence  
Community)**



# **The Issues**

- **Dual use biological research is legitimate research that could be misused to threaten public health or other aspects of national security**
- **The dual use potential of certain biological research requires consideration of new biosecurity measures**
- **The challenge is to reduce the likelihood that biological research knowledge, products or technologies could be misapplied while minimizing the impact to scientific inquiry**

# Criteria and Dual Use Research of Concern

- Criteria are needed to identify that research which should be considered *of concern* because of the likelihood that it could produce knowledge, products or technologies that could be misapplied to pose a threat to national security

# **Key Concept: National Security**

- **Components of national security include:**
  - ❑ **Public health**
  - ❑ **Agriculture**
  - ❑ **Plants**
  - ❑ **Animals**
  - ❑ **Non-biological resources (materiel)**
  - ❑ **Environment**

# **Criteria and Dual Use Research Oversight**

- **Application of the criteria to determine dual use potential of research is the initial step in an oversight system the NSABB will be developing**

# Overarching Principles

- Dual use concerns pertain to misapplication of information or technologies resulting from the research, *not* the conduct of the research itself
- A designation of research as “dual use research of concern” simply means that it *may* warrant special consideration regarding conduct and oversight
- It does *not* mean, a priori, that the work should not be performed or that the results should not be published

# **Working Group Outreach Activities**

- **Outreach to peers by Working Group members**
- **Presentations at scientific meetings and conferences (e.g., ASM)**
- **Roundtable of stakeholders (including editors, scientists)**

# **Feedback**

- **Constructive and generally positive**
- **Suggestions for clarifying wording of the criteria**
- **Questions on the guidance and oversight framework**

# Revisions to Criteria

- **Emphasize: the threshold for dual use research of concern requires that misapplication of the research results**
  - **Could be directly misapplied (Immediacy)**
  - **Would have broad consequences (Scope)**



# **Revisions to Criteria**

- **Emphasize: the evaluation of dual use potential should be based on**
  - **A current understanding regarding the implications of the research results**
  - **A reasonable anticipation that research results could be misapplied**

# **Draft Criteria for 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 misapplied by others to pose a threat to:**

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

# **Research Areas of Concern**

**Careful consideration should be given to knowledge, products, or technologies that:**

- a) Enhance the harmful consequences of a biological agent or toxin**
- b) Disrupt immunity or the effectiveness of an immunization without a clinical and/or agricultural justification**
- c) 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**
- d) Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin**
- e) Alter the host range or tropism of a biological agent or toxin**
- f) Enhance the susceptibility of a host population**
- g) Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent**

# **Criteria for Dual Use Research of Concern**

- **The criteria will require periodic review and modification in response to scientific advances**

# **Guidance and Oversight Framework**

- *To be determined*
- **NSABB has established a Working Group to make a recommendation on**
  - **The attributes and key components of an oversight framework**
  - **Specific guidance for the various steps within the oversight process**

# **Recommendation to the NSABB**

- **The Criteria Working Group has developed the Draft Criteria for Identifying Dual Use Research of Concern**
- **The Working Group believes the criteria are at the point that broader public input is appropriate**
- **The Working Group requests that NSABB consider approving these criteria as a component of an oversight framework for addressing dual use of concern**