

Proposed Strategies for Minimizing the Potential Misuse of Information from Dual Use Life Sciences Research



**Report of the NSABB Working Group on
Oversight Framework Development
April 19, 2007**



Working Group Charge

- **Propose processes for the local and federal review and oversight of dual use life science research**
 - **Identify optimal features and characteristics of an effective and comprehensive oversight system**
 - **Delineate relevant attributes of local review and oversight entities**
- **Develop tools and guidances for these processes**



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Working Group Approach

- **Explore extant models of oversight of biomedical research**
 - **Recombinant DNA**
 - **Structure and function of IBCs**
 - **Human subjects research**
 - **Animal research**
- **Identify features relevant to oversight of dual use research**



Working Group Approach, cont.

- **Articulate principles for oversight of dual use research**
- **Identify:**
 - **Key features of an oversight system**
 - **Specific elements of oversight framework**
 - Purpose
 - Roles and responsibilities
 - Attributes
 - Tools needed for oversight
- **Consultation**



Draft Oversight Framework

- **Introduction**
- **Guiding principles for oversight**
- **Key features of proposed oversight system**
- **Roles and responsibilities**
- **Major steps in local oversight**
- **Criterion and considerations for identifying dual use research of concern**



Draft Oversight Framework, cont.

- **Evaluation of research for dual use potential**
- **Review of potential dual use research of concern: risk assessment, management**
- **Responsible communication of dual use research**
- **Considerations for code of conduct**
- **Outreach and education**
- **Appendices (Tools for oversight of dual use research)**



Introduction

- **Critical role of life sciences research**
- **Dual use research issue**
- **Calls to action**
- **US government response**
- **NSABB considerations**
- **Need for engagement of life sciences community**



Intro: Critical Role of Life Sciences Research

- **Life sciences research underpins:**
 - ❑ **Biomedical and public health advances**
 - ❑ **Improvements in agriculture**
 - ❑ **Safety and quality of food supply**
 - ❑ **Environmental quality**
 - ❑ **Strong national security and economy**



Intro: Dual Use Research Issue

- Information and tools developed to better the health, welfare, and safety of mankind also can be misused for harm
- Development of new technologies and generation of information with potential for benevolent and malevolent purposes = **dual use research (DUR)**
- A subset of DUR that has highest potential for generating information that could be misused = **DUR of concern (DURC)**



Intro: Calls to Action

- **Increasing recognition of need to consider possibility that new information from life sciences research could be subverted for malevolent purposes**
- **Growing acknowledgment—in US and abroad—of need to institute new biosecurity measures to minimize this risk**



Intro: US Government Response

- **Agreement that new biosecurity measures warranted**
- **USG launched a series of biosecurity initiatives, including establishment of NSABB**
 - **NSABB to recommend strategies for the efficient and effective oversight of federally funded dual use life sciences research**
 - **Consider both national security concerns and needs of the life sciences research community**



Intro: NSABB Considerations

- **Threat of misuse exists and consequences could be severe**
- **Response to threat of misuse of research findings must be carefully measured**
 - **Continued rapid progress of life sciences is paramount**



Intro: Need for Engagement of Life Sciences Community

- **Best way to address concerns:**
 - **Raise awareness of DUR issues**
 - **Strengthen culture of responsibility regarding DUR**
 - Opportunity for scientists to demonstrate responsibility and accountability
 - Help ensure free flow of science continues
 - **Broad consultation with scientific and security communities and public is essential**



Guiding Principles for Oversight of Dual Use Life Sciences Research

- Life sciences research, and the free and open communication of its results is essential to continued strong public health and other aspects of national security
- Oversight is appropriate because of the potential for misuse of information for harm
- Effective oversight will help maintain public trust
- Oversight must balance need for security with need for continued research progress
- Foundation is investigator awareness, peer review, local institutional responsibility



Guiding Principles, cont.

- **Responsible conduct and communication of DURC depends upon the individual**
- **Research results not always predictable, therefore need to periodically evaluate research for dual use potential**
- **Effective oversight requires:**
 - **Harmonized governmental approach**
 - **Broad awareness of DUR issues**
 - **Ongoing dialogue**



Guiding Principles, cont.

- **Responsible communication of DURC essential to public confidence in scientific community**
- **Need to periodically evaluate oversight system**
 - **Effectiveness**
 - **Impact on research enterprise**



Key Features of Proposed Oversight System

- **Federal guidelines**
- **Awareness**
- **Ongoing, mandatory education**
- **Evaluation and review of research for dual use potential**
- **Risk assessment and risk management**
- **Periodic evaluation**
- **Compliance**



Roles and Responsibilities

- **Researchers**
- **Institutions**
 - **Institutional review entity**
- **NSABB**
- **Federal government**



Roles and Responsibilities: **Researchers**

- **Most critical element in oversight system**
- **Be aware of DUR and DURC concepts**
- **Consider implications of their work**
- **Take steps to minimize misuse of research information**
- **Understand local and federal policies for DUR oversight**
- **Ensure training of self and research staff**
- **Assess work for DURC potential on ongoing basis**
- **Communicate DURC in a responsible manner**
- **Annually attest to assessing their work for DURC potential**



Roles and Responsibilities: Institutions

- **General responsibilities for oversight:**
 - **Ensure research conducted per applicable policies**
 - **Internal policies/practices should minimize negative impact of conduct of life sciences research**
 - Periodically evaluate for effectiveness and impact on research
 - **Assist PIs in complying with DUR policies**
 - Designate a point of contact for questions
 - Assist with identification of DURC, as needed
 - Establish appeals mechanism
 - Address requests to refer issues to federal level
 - **Educate employees on DUR issues, policies**
 - Can utilize educational materials developed by USG and others



Roles and Responsibilities: Institutions, cont.

- **Specific responsibilities for evaluation and review of research for DURC potential:**
 - ❑ **Establish mechanism for expert committee review (risk assessment/management) of research identified by PI as DURC**
 - ❑ **Appropriate expertise—standing or *ad hoc***
 - ❑ **Consider use of IBC (in-house, neighboring institution, commercial) or establish new committee for review of DURC**
 - ❑ **Review process should not encumber conduct of research that is not DURC**



Roles and Responsibilities: Institutions, cont.

- **Administrative responsibilities:**
 - ❑ **As required, register review mechanisms and update annually**
 - ❑ **Designate point of contact on DUR issues**
 - ❑ **Collect and maintain records of training, investigator attestations**



Roles and Responsibilities: **NSABB**

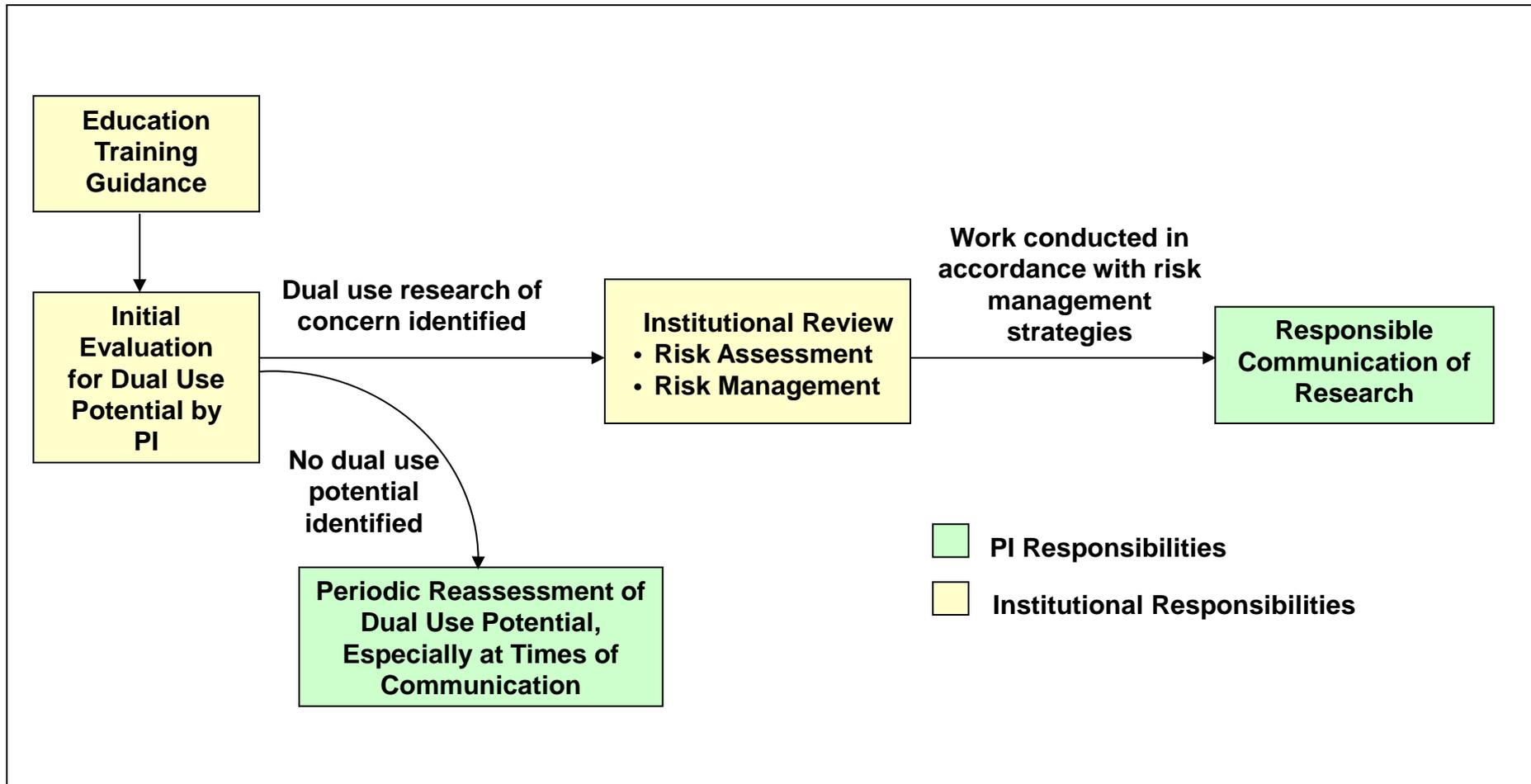
- **Continue to carry out functions specified in charter**
- **Periodically evaluate DUR oversight system**
 - **Effectiveness**
 - **Impact on research enterprise**
- **Serve as resource to research community, including scientific publishing community, on DUR issues**



Roles and Responsibilities: Federal Government

- **Develop and implement oversight policy that is efficient and effective**
- **Harmonization of:**
 - Oversight policy
 - Implementation of policy
 - Interpretation of policy
- **Evaluate oversight policy for effectiveness and impact on research enterprise**
- **Education and outreach**

Steps in Local Oversight of DUR





Key Considerations for Identifying DURC

- **Most life sciences research could be considered DUR—want to identify that subset with highest potential for misuse to threaten public health and safety**
- **Evaluation should be based on current understanding of ways information could be directly misused**
- **Scope of potential threat is important**
 - **E.g., broad potential consequences for public health rather than for individuals**



Key Considerations for Identifying DURC, cont.

- **Characterization of research as DURC should not be viewed pejoratively**
- **Evaluation of research for DURC potential is subjective**
- **Criterion will need to be periodically evaluated and modified as necessary to ensure relevance**



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 by others to pose a threat to:

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

Elements of national security



Considerations for Identifying DURC

- Applying the criterion is subjective and can be challenging
- To assist in application of the criterion, NSABB identified categories and examples of information, products, or technologies that, if produced by research, might make that research DURC:



Considerations for Identifying DURC, cont.

- **Enhance harmful consequences of a biological agent or toxin**
- **Disrupt immunity or effectiveness of an immunization without clinical/agricultural justification**
- **Confer to a biological agent/toxin resistance to clinically/agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies**



Considerations for Identifying DURC

- **Increase the stability, transmissibility, or the ability to disseminate a biological agent/toxin**
- **Alter the host range or tropism of a biological agent/toxin**
- **Enhance the susceptibility of a host population**
- **Generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent**



Evaluation of Life Sciences Research for Dual Use Potential

- **PI should conduct the initial evaluation of research for DURC potential**
 - **An independent assessment or consultation with other scientist(s) can be helpful**
 - **May be differences of opinion among experts**
- **NSABB recommends a formal, annual attestation by researchers that they have been evaluating their work for DURC potential**



Research that is Potentially DURC: Risk Assessment and Risk Management

- Institutional review should address:
 - ❑ Potential for, and ways in which, information could be misused to threaten aspects of national security
 - ❑ Likelihood of misuse
 - ❑ Potential impacts of misuse
 - ❑ Strategies for mitigating the risks of misuse
- NSABB tool: *“Points to Consider in Risk Assessment and Management of Research that is Potentially DURC”*



Responsible Communication of Research with Dual Use Potential

- **NSABB has developed a set of communications tools:**
 - ❑ Principles for the responsible communication of research with dual use potential
 - ❑ ***“Points to Consider for Identifying and Assessing the Risks and Benefits of Communicating Research Information with Dual Use Potential”***
 - Includes options for communication of such research
 - ❑ Considerations for the development of a communication plan for research with dual use potential



Code of Conduct: Key Premises

- **A code of conduct addressing dual use research is a key to promoting a culture of responsibility; a uniformly accepted culture of responsibility is key to the success of any oversight framework**
- **Codes of conduct articulate the shared values and standards of conduct that exist within a discipline or profession**
- **Codes serve an important educational role and promote responsible research conduct by defining the standards to which all members of society should strive**
- **Codes are typically developed by scientific societies, professional associations, and institutions**



“Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences”

- **Three sections:**

- **General considerations**

- Characterization of the dual use issue
- Description of codes and their purpose
- Possible uses of this guidance

- **Core responsibilities of life scientists with regard to dual use research of concern**

- A terse articulation of the most basic ethical responsibilities of life scientists

- **Specific responsibilities in the research process**

- Model standards of responsible research conduct applicable from the conceptualization of research through publication



Utility of the Code

- **Scientific societies and professional associations are encouraged to:**
 - ❑ **Adapt elements as appropriate to their memberships and research-related activities**
 - ❑ **Discuss a code on dual use research at annual membership meetings at part of its development and adoption**
 - Enhances awareness of the issue
 - Promotes general acceptance of the code
 - ❑ **Use the document for formal educational and training purposes**



Outreach and Education

- **Relevant activities by NSABB members and staff:**
 - ❑ **Consultations: focus groups, roundtables, expert panels**
 - ❑ **Presentations on dual use issue and NSABB activities**
 - ❑ **Exhibit on DUR and developing federal policy for scientific and professional conferences**
 - ❑ **Ongoing international dialogue**



Outreach and Education, cont.

- **Recommendations for outreach during federal policy making process:**
 - ❑ **Town-hall style regional meetings**
 - ❑ **Formal solicitation of public comment**
 - **Federal Register notice, docket for comments**
 - ❑ **Communication plan for rollout of federal policy**
 - ❑ **Intensive and ongoing educational campaign once policy developed**



Outreach and Education, cont.

- **Recommendations for ongoing educational and awareness-building strategies:**
 - ❑ **NSABB to have continuing advisory role in outreach and education strategies**
 - ❑ **Educational efforts on DUR should have a broad reach**
 - **Not just college and graduate level, but also high school and junior high school**
 - **International audiences**
 - **Commercial research environment**



Outreach and Education, cont.

- **Recommendations for ongoing educational and awareness-building strategies:**
 - **Institutions should routinely incorporate topic of DUR into content of NIH-mandated training programs**
 - **Federal government should stimulate development of educational materials by non-governmental organizations**