National Science Advisory Board for Biosecurity

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**

Working Group Members

- Dennis Kasper (Chair)
- Arturo Casadevall
- Susan Ehrlich
- Lynn Enquist
- Barry Erlick
- Mike Imperiale
- Paul Keim
- Stan Lemon
- David Relman
- Jim Roth
- Andrew Sorensen
- Anne Vidaver
- Ken Cole (DoD)
- Brenda Cuccherini (DVA)
- Dennis Dixon (DHHS/NIH)
- Maryanna Henkart (NSF)
- Peter Jutro (EPA)
- Jan Nicholson (DHHS/CDC)
- Mary Mazanec (DHHS/OS)
- Caird Rexroad (USDA)
- Scott Steele (EOP)

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**

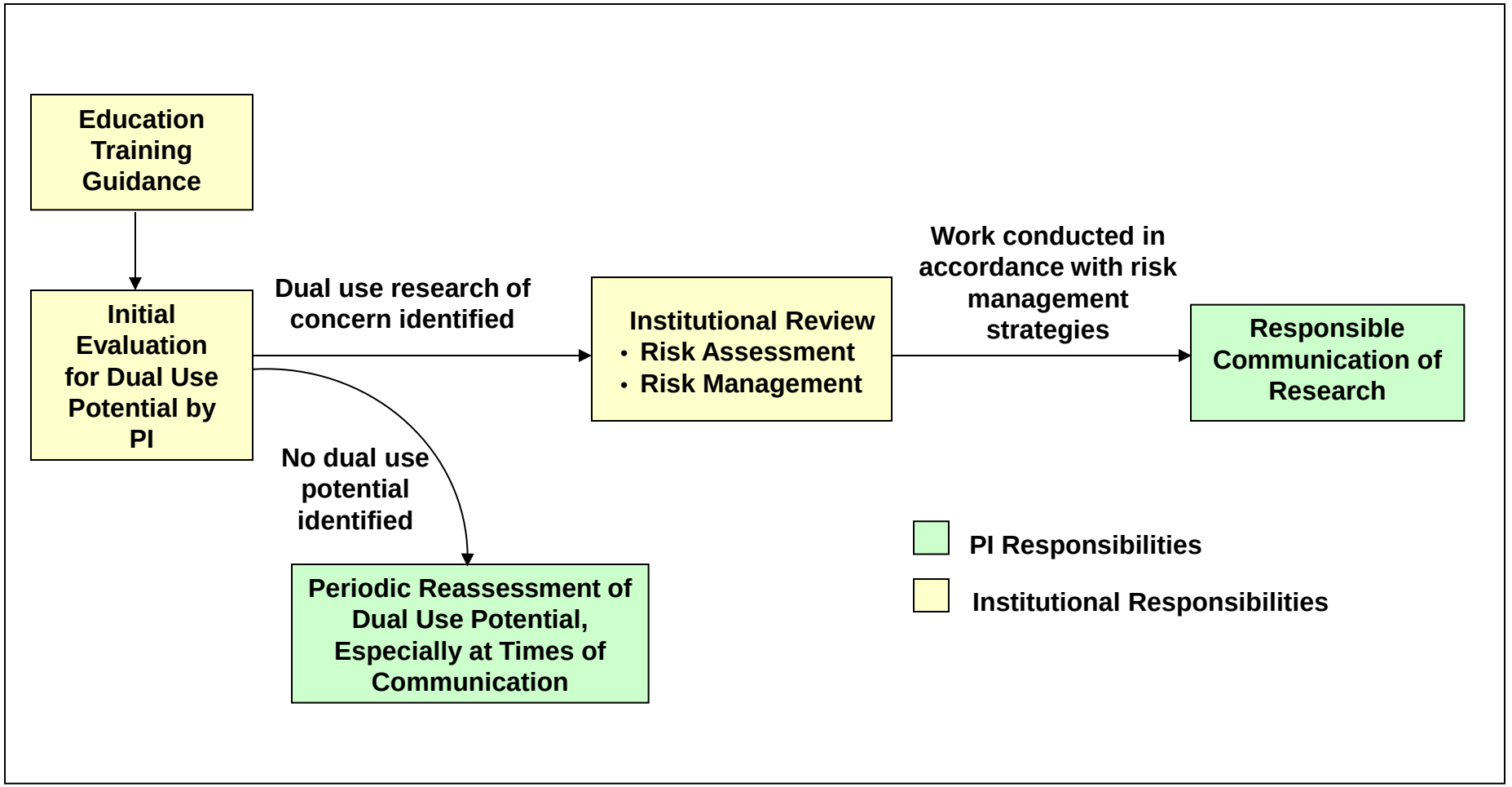
Roles and Responsibilities: NSABB

- 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**