

Conceptualizing an Oversight Framework for Dual Use Research

NSABB Working Group on
Oversight Framework Development
October 25, 2006



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

- **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**

Shared Principles and Features of Extant Oversight Systems

- **Stewardship role of USG**
- **Distributive (and sometimes overlapping) responsibility**
 - Institution
 - Investigator
 - Federal agency
- **Public trust, accountability and transparency**
 - Public members on review entities
 - Public access to meetings and meeting summaries

Shared Principles and Features

- **Expert scientific review**
- **Ethical review**
- **Consideration of social consequences**
- **Employ principles of risk assessment and risk management**
 - **Risks to individuals**
 - **Risks to community/environment**
 - **Degree of oversight titrated to risk**

Federal Oversight:

- Policy development
- Policy interpretation
- Adjudication
- Education
- Compliance
- Expert Consultation

Institutional Oversight:

- Education
- Compliance

Risk Assessment

Risk Management

**PI identification of research projects
subject to guidelines/regulations**

Guidelines and Regulations

- Fiduciary responsibility
- Stewardship
- Public input
- Revision as science advances
- Degree of oversight titrated to risk

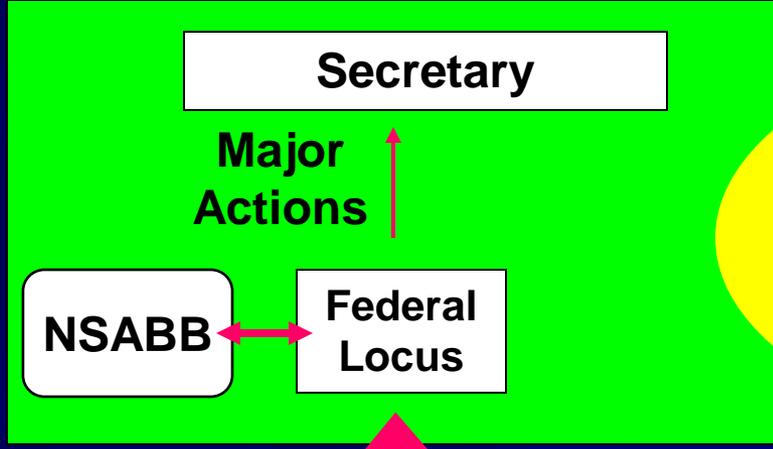
- Fiduciary responsibility
- Stewardship
- Compliance a condition of funding
- Register with federal entity
- Establish local expert review body
- Provision of resources

- Expert review
- Authority within institution
- Degree of oversight titrated to risk
 - Levels of review
 - Local monitoring
- Public input

- Researcher responsibility and accountability

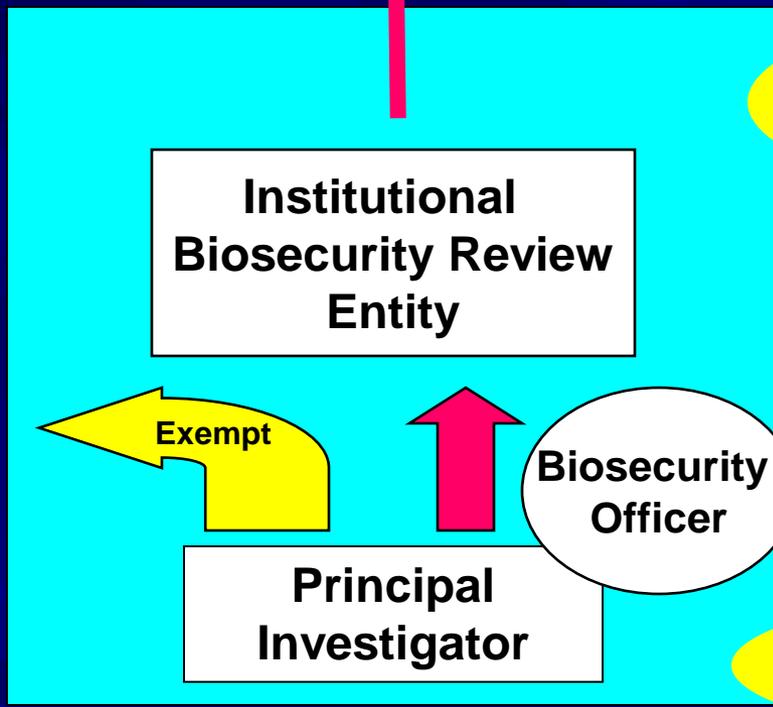
- Public input
- Revision as science advances

FEDERAL OVERSIGHT



- Federal Oversight:
 - Policy development
 - Policy interpretation
 - Adjudication
 - Education
 - Compliance
 - Expert Consultation

LOCAL OVERSIGHT



- Institutional Oversight:
 - Education
 - Compliance

- Risk Assessment
- Risk Management

GUIDELINES

Federal Guidelines for Evaluation and Review of Dual Use Research

PI identification of research projects subject to guidelines/regulations

Guidelines and Regulations

Draft Principles for Oversight of Dual Use Research

- 1. Life sciences research is essential for improvements in health and safety**
 - Potential for producing information with dual use potential**
 - Therefore appropriate to have framework and tools for oversight, conduct, communication**
 - Oversight must address needs for both security and research progress**
 - Scientific community awareness of dual use potential key to effective oversight**

Draft Principles for Oversight of Dual Use Research

2. Effective oversight will help maintain public trust

- Demonstrates that scientific community recognizes implications of dual use research
- Demonstrates that scientists acting responsibly to protect public welfare and security
- Responsibility shared by Federal funding agencies, recipient institutions, researchers

Draft Principles for Oversight of Dual Use Research

- 3. Ongoing dialogues among scientific communities, government agencies, and public are essential for effective oversight**

Draft Principles for Oversight of Dual Use Research

4. Foundation of oversight of dual use research:

- Investigator awareness
- Peer review
- Local institutional responsibility

This facilitates:

- Direct input from investigators
- Timely review
- Personal responsibility on part of scientists

Draft Principles for Oversight of Dual Use Research

- 5. Because research is dynamic and can yield unanticipated results, it should be periodically evaluated for dual use potential**
- 6. Oversight process should be evaluated periodically**
 - Effectiveness
 - Impact on research enterprise

Draft Principles for Oversight of Dual Use Research

- 7. Responsible communication of dual use research of concern is essential to maintain public confidence in the scientific community**

Dual Use Research Oversight: Possible Key Features

- Institutional review of research with dual use potential
- Risk assessment & risk management
 - Oversight titrated to degree of risk of misuse
- Compliance with dual use research policies
 - Mandatory for federally funded institutions
 - Voluntary for other institutions

Dual Use Research Oversight: Possible Key Features

- **Investigator awareness of dual use concerns and policies**
- **Training**
- **Appeals process(es)**
- **Evaluation of oversight system**

Oversight Framework: Possible Elements

- **Federal government**
- **National review body**
- **Dual use research biosecurity guidelines**
- **Institutions receiving federal support for life sciences research**

Oversight Framework: Possible Elements

- Institutional dual use research biosecurity review entity
- Institutional dual use research biosecurity officer
- Research staff

Oversight Framework: Possible Tools

Criteria	√
Guidance on code of conduct	√
Communication tools	√
Risk assessment tools	TBD
Risk management tools	TBD
Evaluation tools	TBD

Next Steps

- **Continue refining key features of oversight**
- **Continue fleshing out specific elements of oversight framework**
 - **Purpose**
 - **Roles and responsibilities**
 - **Attributes**
- **Identify array of tools needed for oversight**
 - **As necessary, develop needed tools**