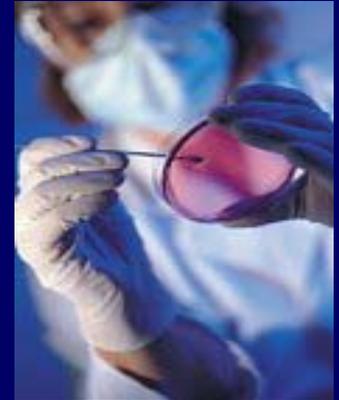
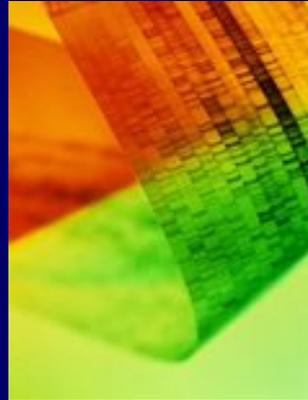


Draft Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility



**NSABB Meeting
June 23, 2011
Paul Keim, PhD**

Outline of Report

1. Executive Summary
2. Introduction & Background
3. Recommended Practices
 - Good Hiring & Employment Practices
 - Encouraging biosecurity awareness and promoting responsible conduct
4. Potentially Useful Practices for Enhancing PR and a Culture of Responsibility



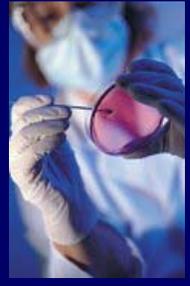
Outline of Report (cont.)

5. PR Practices That Are Not Recommended for Broad Implementation
6. Assessing the effectiveness of practices aimed at enhancing PR and the culture of responsibility
7. Summary of NSABB Recommendations



What is a “culture of responsibility”?

- All scientists—especially life scientists—are called to cultivate a culture of responsibility:
 - Goal remains the advancement of knowledge.
 - Beliefs, attitudes, and values reflect a heightened consciousness of the implications of their research, including any potential for the deliberate misuse of their research.
 - Demonstrate these beliefs, attitudes, and values through day-to-day practices of research.
 - Recognize the continuous, reciprocal process of promoting and bearing mutual responsibility for the research.



CRWG Scope

- CRWG's charge focused on members of the life sciences community who work with BSAT.
- All individuals at institutions engaged in life sciences research must be aware of surrounding activities and understand that it is an individual and collective responsibility to report concerning behaviors.



CRWG Scope (cont.)

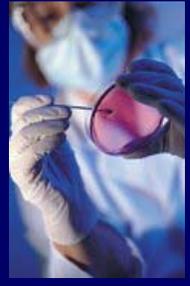
- Most of the recommended practices should be applied to all life sciences research
 - Reliable, responsible personnel are essential to all life sciences scientific research;
 - All research personnel are in a position to notice & report concerning behaviors;
 - DUR/DURC in the life sciences is not limited to research on BSAT; and
 - An insider threat could involve someone who does not have direct access to BSAT.



Recommendations

Good Hiring & Employment Practices

- Good Hiring & Employment Practices
 - References
 - Reviewing credentials and professional status of prospective employees
 - Criminal background checks
 - Articulating the institution's expectations of its employees
 - Performance Evaluations



Recommendations

Good Hiring & Employment Practices

1. The NSABB strongly urges the provision of accurate and candid references for individuals with access to BSAT and recommends that institutions have policies in place for all levels of staff on the topic of providing references.



Recommendations

Good Hiring & Employment Practices (cont.)

2. When considering a candidate for employment, potential employers should attempt to seek one or more employment references from the prospective employee's current employer, including the current supervisor.



Recommendations

Good Hiring & Employment Practices (cont.)

3. When feasible, and to the extent possible, potential employers should conduct personal follow-up inquiries with individuals familiar with the candidate's skills, abilities, and past performance rather than relying on a written statement of the qualifications, skills, and attributes of the employment candidate (i.e., letters of recommendation).



Recommendations

Good Hiring & Employment Practices (cont.)

4. When considering a candidate for a position with access to BSAT, potential employers should explore aspects of the individual's prior work performance that directly relate to issues of reliability.



Recommendations

Good Hiring & Employment Practices (cont.)

5. When seriously considering a candidate for a position that involves access to BSAT, employers should go beyond verifying a candidate's education and/or degrees, licensure, previous positions, and/or a positive SRA if available.



Recommendations

Good Hiring & Employment Practices (cont.)

6. Local institutions should conduct their own criminal background checks for employment candidates and employees who are granted access to BSAT in their facilities.



Recommendations

Good Hiring & Employment Practices (cont.)

7. Institutions conducting research on BSAT should communicate to incoming personnel the particular risks and responsibilities involved in undertaking BSAT research and implement an attestation by personnel that each individual fully understands these risks and responsibilities.



Recommendations

Good Hiring & Employment Practices (cont.)

8. Institutions conducting life sciences research should implement an achievement- or goal-focused, documented, and periodic performance review process for all laboratory personnel.



Recommendations

Good Hiring & Employment Practices (cont.)

9. When considering a candidate for a position that involves access to BSAT, laboratory leadership should consider requesting copies of the employment candidate's performance evaluations with prior employers.

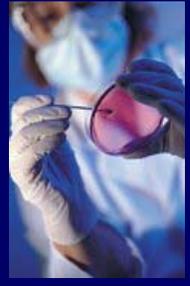
Likewise, institutions undertaking BSAT research should develop policies that allow the performance evaluations of current or prior employees who have had access to BSAT to be shared with prospective employers.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct

- Encouraging biosecurity awareness and promoting responsible conduct
 - Leadership
 - Education & Training
 - Codes of conduct
 - Reporting of Concerning Behaviors
 - Opting out of research involving biological select agents and toxins
 - Institutional & Local peer review of research involving biological select agents and toxins



Recommendations

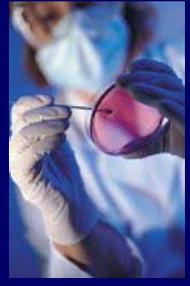
Encouraging Biosecurity Awareness & Promoting Responsible Conduct

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10. Institutional leadership should endeavor to communicate the institution's expectations that all individuals, including researchers in the life sciences and specifically those working with BSAT, will be:
- Treated with respect;
 - Comply with laws, regulations, and institutional policies;
 - Understand and acknowledge their responsibility to report activities that are inconsistent with these laws, regulations, or policies; and
 - Handle confidential information appropriately.

Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

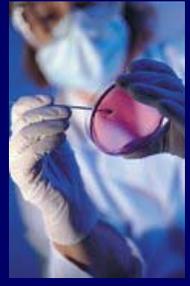
11. Institutional leadership should communicate a commitment to provide individuals with the and tools needed to meet these expectations, marshal resources to support such activities, and act upon information provided and prevent retaliation stemming from an individual's responsible report of a biosecurity concern.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

12. Leadership at institutions conducting research with BSAT should actively identify or recruit institutional leaders and champions whose position within the institution enables them to give credibility and strategic support to the strengthening of biosecurity and a culture of responsibility.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

13. All courses in research ethics and the responsible conduct of research should incorporate topics or modules addressing the issues of biosecurity and the dual use implications of life sciences research.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

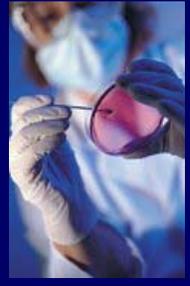
14. Discussion of codes of conduct should be included in any educational program that includes the topics of the responsible conduct of research, biosecurity, and dual use research.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

15. Institutions conducting BSAT research should implement programs or mechanisms that enable reporting of concerning behaviors in a respectful and responsible manner.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

16. The provision of an employee-initiated, temporary opt-out mechanism for personnel working with BSAT is a responsible practice that should be implemented by all institutions undertaking BSAT research.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

17. Research institutions should take steps to ensure that an employee's decision to opt-out is not stigmatizing and that any actions taken in response to an opt-out request are not punitive.



Recommendations

Encouraging Biosecurity Awareness & Promoting Responsible Conduct (cont.)

18. All institutions conducting BSAT research should perform a thorough risk assessment of all laboratory protocols involving BSAT prior to the initiation of the protocol or planned research and on an ongoing basis throughout the lifespan of the research project, as appropriate.



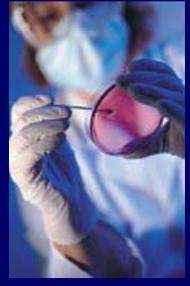


Potentially Useful Practices

- Should not be mandated federally
 - Use/implementation should be based upon a risk assessment by the local institution.
1. Video monitoring
 - High costs, variable benefits
 - Use of video cameras should not be mandated by federal regulation.
 2. Two-person rule
 - Can be useful in situations that carry higher risk to the safety of personnel
 - Can have significant impacts on workflow and unintended consequence of increasing the safety risks

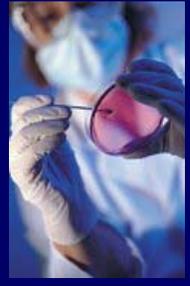
Practices that are Not Recommended

- Not Recommended for Broad Implementation
 - Some have privacy implications and may not be permitted by law or institutional policies.
 - Some are also resource-intensive and of unproven or unsubstantiated value.
- Mental health assessment
- Drug and alcohol testing
- Credit Checks
- Polygraph tests



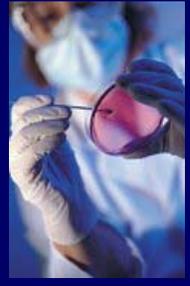
Assessing PR Practices & the Culture of Responsibility

- Goal of PR practices & Culture of Responsibility:
 - Safeguarding of the public's trust, safety, and security through the management of the risks associated with BSAT research
- Recommended practices:
 - Reflect the successful strategies employed by institutions and researchers as they go about the important work of conducting and supporting BSAT research
 - Implementation impacts the day-to-day conduct, cost of research



Assessing PR Practices & the Culture of Responsibility

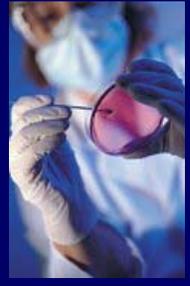
- The Challenge of Assessing PR Practices and a Culture of Responsibility
 - “Success” is not directly measurable
 - Assessing an institution’s or community’s culture of responsibility can be a “moving target”
- Despite challenges, existing strategies and methods offer insight
 - Assessments and evaluations of prevention efforts
 - Assessment of an institution’s ethical climate & its impact on the responsible conduct of research



Assessing PR Practices & the Culture of Responsibility

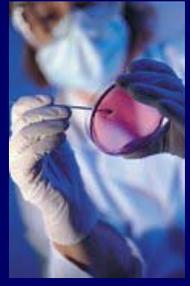
■ Strategies & Methods

- Assessments should be designed with the desired "end state" in mind
 - Ex: strong culture of responsibility that strengthens personnel reliability within the BSAT and life science research communities
- Identify intermediate outcomes
- Assess effectiveness (as well as performance)
- Capture unintended consequences



Assessing PR Practices & the Culture of Responsibility

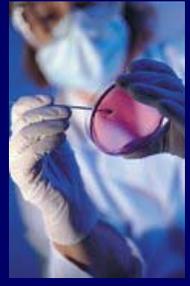
- Assessments of a culture of responsibility
 - Fields such as business ethics, management, organizational development, adult learning, offer valuable and informative parallels
 - Methods exist to assess the attitudes, perceptions, and practices of the members of the institution/organization towards the institution's policies and procedures.



Assessing PR Practices & the Culture of Responsibility

- The Role of Leadership
- Leadership must continually communicate and assess progress towards the desired “end state”
 - Revise this goal (as needed)
 - Stay in tune with research environment
 - Adapt to changes in skills, knowledge, and experience of research community

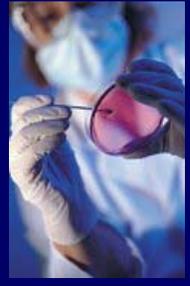




Recommendation

Assessing PR Practices & the Culture of Responsibility

19. Responsible practice dictates that the effectiveness, potential impacts, and unintended consequences of any measures being implemented be considered in light of the costs and burdens that they impose.



Thank you!

Any questions?