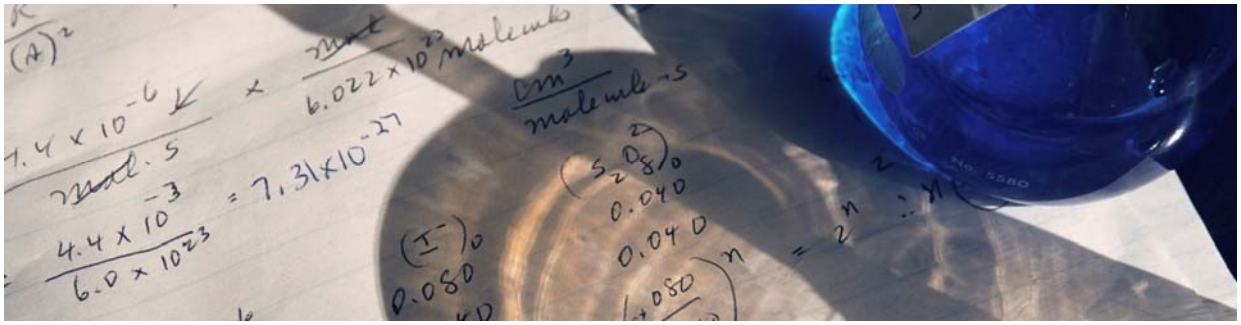
National
Science
Advisory
Board for
Biosecurity



Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility

A Report of the National Science Advisory Board for Biosecurity

September 2011

Table of Contents

ABBREVIATIONS iii

1. EXECUTIVE SUMMARY 1
- **SUMMARY OF RECOMMENDATIONS** 3

2. INTRODUCTION AND BACKGROUND 7
- **2.1 PREMISE AND PURPOSE OF THIS REPORT** 7
- **2.2 BACKGROUND** 7
  - *2.2.1 DEFINING A "CULTURE OF RESPONSIBILITY"* 7
- **2.3 NSABB APPROACH** 9
- **2.4 SCOPE OF NSABB RECOMMENDATIONS** 11

3. RECOMMENDED PRACTICES FOR ENHANCING PERSONNEL RELIABILITY AND CULTURE OF RESPONSIBILITY 13
- **3.1 GOOD HIRING AND EMPLOYMENT PRACTICES** 13
  - *3.1.1 REFERENCES* 14
  - *3.1.2 REVIEWING CREDENTIALS AND PROFESSIONAL STATUS OF PROSPECTIVE EMPLOYEES* 16
  - *3.1.3 CRIMINAL BACKGROUND CHECKS* 17
  - *3.1.4 ARTICULATING THE INSTITUTION'S EXPECTATIONS OF ITS EMPLOYEES* 19
  - *3.1.5 PERFORMANCE EVALUATIONS* 19
- **3.2 ENCOURAGING BIOSECURITY AWARENESS AND PROMOTING RESPONSIBLE CONDUCT** 20
  - *3.2.1 LEADERSHIP* 20
  - *3.2.2 EDUCATION AND TRAINING* 21
  - *3.2.3 CODES OF CONDUCT* 22
  - *3.2.4 REPORTING OF CONCERNING BEHAVIORS* 23
  - *3.2.5 OPTING OUT OF RESEARCH INVOLVING BIOLOGICAL SELECT AGENTS AND TOXINS* 25
  - *3.2.6 INSTITUTIONAL AND LOCAL PEER REVIEW OF RESEARCH INVOLVING BIOLOGICAL SELECT AGENTS AND TOXINS* 26

4. POTENTIALLY USEFUL PRACTICES FOR ENHANCING PERSONNEL RELIABILITY AND CULTURE OF RESPONSIBILITY 31
- **4.1 VIDEO MONITORING** 31
- **4.2 TWO-PERSON RULE** 32

5. PERSONNEL RELIABILITY PRACTICES THAT ARE NOT RECOMMENDED FOR BROAD IMPLEMENTATION 33
- **5.1 MENTAL HEALTH ASSESSMENT** 33
- **5.2 DRUG AND ALCOHOL TESTING** 34
- **5.3 CREDIT CHECKS** 34
- **5.4 POLYGRAPH TESTS** 35

6. ASSESSING THE EFFECTIVENESS OF PRACTICES AIMED AT ENHANCING PERSONNEL RELIABILITY AND THE CULTURE OF RESPONSIBILITY 37
- **6.1 THE CHALLENGE OF ASSESSING PERSONNEL RELIABILITY PRACTICES AND A CULTURE OF RESPONSIBILITY** 37
- **6.2 STRATEGIES AND METHODS FOR ASSESSING PERSONNEL RELIABILITY PRACTICES AND A CULTURE OF RESPONSIBILITY** 37
  - *6.2.1 ASSESSING OUTCOMES AND EFFECTIVENESS* 38
  - *6.2.2 ASSESSING THE CULTURE OF RESPONSIBILITY* 39
  - *6.2.3 THE ROLE OF LEADERSHIP* 40

7. SUMMARY OF NSABB FINDINGS AND RECOMMENDATIONS 41

APPENDICES **45**

APPENDIX A - NSABB ROSTER **47**
APPENDIX B - PANEL DISCUSSIONS ON EMPLOYMENT LAW AND HUMAN RESOURCE PRACTICES **51**
APPENDIX C - PANEL DISCUSSION ON INSTITUTIONAL BIOSAFETY COMMITTEES **55**
DISCUSSION QUESTIONS, FEBRUARY 1, 2011 55
APPENDIX D - BUILDING PERSONNEL RELIABILITY AT THE LOCAL LEVEL: A ROUNDTABLE ON ENHANCING THE CULTURE OF RESPONSIBILITY **57**
AGENDA, JULY 15, 2010 57
INVITED PARTICIPANTS 58
APPENDIX E – ROUNDTABLE ON PRACTICES FOR ENHANCING PERSONNEL RELIABILITY AND THE CULTURE OF RESPONSIBILITY IN HIGH CONTAINMENT LABS **59**
AGENDA WITH DISCUSSION QUESTIONS, SEPTEMBER 2, 2010 59
INVITED PARTICIPANTS 61
APPENDIX F – NSABB-CHINESE ACADEMY OF SCIENCES VIDEO TELECONFERENCE **63**
AGENDA WITH DISCUSSION QUESTIONS 63
APPENDIX G – NSABB PUBLIC CONSULTATION ON GUIDANCE FOR ENHANCING PERSONNEL RELIABILITY AND STRENGTHENING THE CULTURE OF RESPONSIBILITY AT THE LOCAL LEVEL **65**
AGENDA 65
SUMMARY HIGHLIGHTS 72
APPENDIX H - CONSIDERATIONS IN DEVELOPING A CODE OF CONDUCT FOR DUAL USE RESEARCH IN THE LIFE SCIENCES **83**

Abbreviations

ARO	Alternate Responsible Official (Select Agent Program)
BSAT	Biological Select Agents and Toxins
BSO	Biosafety Officer
CDC	Centers for Disease Control and Prevention (HHS)
CJIS	Criminal Justice Information Services (FBI)
CRWG	Culture of Responsibility Working Group (NSABB)
DOD	Department of Defense
DOE	Department of Energy
DNA	Deoxyribonucleic acid
DUR	Dual Use Research
DURC	Dual Use Research of Concern
EAP	Employee Assistance Program
FBI	Federal Bureau of Investigation (Department of Justice)
HHS	Department of Health and Human Services
IBC	Institutional Biosafety Committee
NIH	National Institutes of Health (HHS)
NRC	National Research Council (National Academies)
NSABB	National Science Advisory Board for Biosecurity
PI	Principal Investigator
PRP	Personnel Reliability Program
RCR	Responsible Conduct of Research
RO	Responsible Official (Select Agent Program)
SAP	Select Agent Program
SAR	Select Agent Rules
SOP	Standard Operating Procedures
SRA	Security Risk Assessment (Select Agent Program)
USG	United States Government
USDA	United States Department of Agriculture

1. Executive Summary

As a follow-up to the National Science Advisory Board for Biosecurity's (NSABB or "Board") May 2009 report on personnel reliability,[1] this report was undertaken in response to the U.S. government's request for specific strategies and guidance for assisting the scientific community in establishing and implementing practices that promote a culture of responsibility with respect to biosecurity.

As part of its charge, the Board was asked to engage the scientific community and members of the public during its deliberations in order to ensure that the guidance reflects broad input from stakeholders. In order to provide a foundation for its guidance, the NSABB engaged the broader scientific community, as well as experts in other relevant fields and members of the public, at several points during its deliberations. For example, the Board held panel discussions with experts in employment law and human-resources practices, representatives of Institutional Biosafety Committees, an authority on the Select Agent Program's Security Risk Assessment process, and a representative from the Amerithrax Expert Behavioral Analysis Panel. The Board also held two roundtables which engaged different perspectives from the scientific research community (e.g., principal investigators, university administrators, university counsel, laboratory managers) in a discussion of practices that could be administered at the institutional level to promote the culture of responsibility. Finally, the NSABB hosted a public consultation on issues of personnel reliability and a culture of responsibility in order to obtain input from the broader scientific community and general public regarding strategies for enhancing personnel reliability and strengthening the culture of responsibility at facilities that conduct research with dangerous pathogens.[2]

In this report, the NSABB recommends a number of practices for enhancing personnel reliability and a culture of responsibility. Above all, good management practices are the foundation that underpins the development of a culture of responsibility, integrity, trust, and effective biosecurity. In addition, strong institutional and laboratory leadership, clear articulation of priorities and expectations, and an institutional framework that provides relevant education, training, performance review, and employee support will facilitate responsible practices, personnel reliability, safety, and security, while allowing research on biological select agents and toxins (BSAT) to flourish.

Responsible hiring and employee management practices include:

- Willingness on the part of current and former employers to provide candid references;
- Thorough checking of references for prospective employees (via dialogue rather than only letters of recommendation), including from the current supervisor, as well as review of available past performance evaluations;
- Rigorous, biosecurity-minded review of credentials and professional status of prospective employees as well as a check of any possible criminal history;

[1] NSABB, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.
[2] NIH (HHS), "Public Consultation on Personnel Reliability and Culture of Responsibility Issues," *Federal Register* 75, no. 237 (December 10, 2010): 76997; edocket.access.gpo.gov/2010/pdf/2010-31056.pdf.

- Periodic performance review for all laboratory personnel that addresses, among other topics, the responsible conduct of research, adherence to biosecurity policies and practices, and practices that contribute to a culture of responsibility; and
- Clear articulation and documentation of conditions of employment and expectations regarding trust, integrity, and reliability, and notice that all information regarding the employee's reliability or suitability with respect to biosafety and biosecurity can be shared with potential employers during a reference check and with the Select Agent Program, if applicable.

Leadership, both at the institution and laboratory levels, is a key element in enhancing a culture of trust, integrity, and responsibility, and in fostering biosecurity. Leaders must convey the importance of biosecurity and a strong culture of responsibility and provide individuals with the information and tools needed to address these issues through formal and informal training and education. A code of conduct is one possible tool for strengthening the culture of responsibility. Leadership of institutions housing research on BSAT should also ensure that all employees are educated about their responsibility to report behaviors or activities that present biosecurity concerns, the type of behaviors and activities that should be reported, the institutional process for reporting concerns, and the institutional process for responding to such reports, including protections in place for those reporting and those who are the subjects of reports.

Another practice for enhancing the responsible conduct of BSAT research is to allow employees to voluntarily opt-out of such work in response to a temporary condition or situation that affects the individual's ability to perform BSAT research safely and securely. Institutions should 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 in nature.

One of the ways institutions conducting BSAT research demonstrate their commitment to a culture of responsibility is through the oversight of BSAT research. 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. Such risk assessments must be performed by an appropriately constituted review body and should address biosafety and biosecurity as well as the potential for dual use.

The NSABB also briefly discusses two potentially useful practices for enhancing personnel reliability and a culture of responsibility at the local level—video monitoring and the "two person rule." These practices were not recommended for broad implementation, however, because they can be difficult to implement effectively, may have negative and unintended consequences, and may be cost-prohibitive. Consequently, the decision to implement these practices should be based on a risk and impact assessment conducted by the institution.

The NSABB also briefly discusses some of the other practices that may be utilized in formal Personnel Reliability Programs—mental health assessments, drug and alcohol testing, credit checks, and polygraph testing. The NSABB does <u>not</u> recommend these practices for widespread implementation by institutions, particularly academic institutions. In some cases, these practices

are redundant to the Security Risk Assessment process. Other practices have adverse privacy implications and may not be allowed under federal and state laws or institutional policies. Still others are resource-intensive and of unproven or unsubstantiated value. Institutions considering the adoption of these practices should carefully consider the costs and benefits of each, any evidence for their effectiveness, and the likelihood of any unintended or detrimental consequences for the scientific enterprise.

While the practices recommended in this report aim to address the very real challenges posed by research on BSAT, it should not be forgotten that their implementation impacts the day-to-day conduct, cost, and burden associated with scientific research. Therefore, responsible practice dictates that the effectiveness, potential impact, and unintended consequences of any measures being implemented be considered in light of the costs and administrative burdens that they impose. While assessing the effectiveness and direct impact of personnel reliability measures is challenging because their "success," i.e., a decrease in the incidence of an insider threat, is not directly measurable, an evaluation of an institution's or community's culture of responsibility and the impact of personnel reliability measure or efforts to enhance a culture of responsibility can be assessed.

Recommendations

NSABB Recommendations Related to Hiring and 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 regarding the topic of providing references.

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

3. The NSABB recommends that 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).

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

5. When seriously considering a candidate for a position that involves access to BSAT, the NSABB recommends that employers go beyond verifying a candidate's education, degrees, licensure, previous positions, and a positive Security Risk Assessment, if applicable. For example, when verifying credentials or checking public records, prospective employers should specifically probe whether there have been any instances of concerning behaviors in a candidate's work

history, any legitimate concerns about reliability of the candidate, or any biosecurity issues related to the candidate.

6. The NSABB recommends that institutions conduct their own criminal background checks for employment candidates and employees who are granted access to BSAT in their facilities.

7. It is incumbent upon institutions conducting research on BSAT to communicate to incoming personnel the particular risks and responsibilities involved in undertaking BSAT research and to implement a process of attestation by personnel that each individual fully understands these risks and responsibilities.

8. The NSABB recommends that institutions conducting life sciences research implement an achievement- or goal-focused, documented, and periodic performance review process for all laboratory personnel.

9. When considering a candidate for a position that involves access to BSAT, the NSABB recommends that laboratory leadership consider requesting copies of the candidate's performance evaluations with prior employers. Likewise, it is recommended that institutions undertaking BSAT research 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 for Encouraging Biosecurity Awareness and Promoting Responsible Conduct

10. The NSABB recommends that institutional leadership 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.

11. Institutional leadership is recommended to communicate a commitment to provide individuals with the information 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.

12. Institutional leadership at institutions conducting research with BSAT is recommended to 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.

13. It is recommended that all courses in research ethics and the responsible conduct of research incorporate topics or modules addressing the issues of biosecurity and the dual use implications of life sciences research.

14. The NSABB recommends that 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.

15. Institutions conducting BSAT research are recommended to implement programs or processes that enable the reporting of concerning behaviors in a respectful and responsible manner.

16. The provision of an employee-initiated, temporary opt-out process for personnel working with BSAT is a responsible practice recommended for implementation by all institutions undertaking BSAT research.

17. The NSABB recommends that research institutions 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.

18. All institutions conducting BSAT research are recommended to 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.

Recommendation for Assessing the Effectiveness of Practices Aimed at Enhancing Personnel Reliability and the Culture of Responsibility

19. The effectiveness, potential impact, and unintended consequences of any measures being implemented should be considered in light of the costs and burdens that they impose.

2. Introduction and Background

2.1 Premise and Purpose of This Report

In its May 2009 report, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents*,[3] the NSABB noted that strengthening personnel reliability in high-containment laboratories can be achieved through enhancing the culture of responsibility and accountability among individuals with access to biological select agents and toxins (BSAT). Finding no persuasive evidence that many extant personnel reliability measures (e.g., psychological testing, credit checks, national security clearances, polygraph tests, and medical monitoring) were effective means for identifying a real or potential "insider threat," the NSABB recommended that enhancing the culture of responsibility and accountability, particularly at the local level, would be an appropriate approach to strengthening personnel reliability.

The NSABB's findings and recommendations on personnel reliability have informed a number of federal activities to strengthen biosecurity in the U.S. In follow-up to the NSABB's report on personnel reliability, the U.S. government tasked the NSABB with identifying specific strategies and developing guidance for assisting the scientific community in establishing and implementing practices that promote a culture of responsibility with respect to biosecurity. The Board was asked to engage the scientific community and members of the public during its deliberations in order to ensure that the guidance reflects broad input from stakeholders.

In this report, the NSABB describes its findings and recommendations for enhancing a culture of responsibility and reliability within the life sciences community. Detailed are practices that can be administered at the local level to promote reliability and responsibility as well as specific guidance on how to implement these recommendations. Although the NSABB was tasked with recommendations for the life sciences community, many of the principles of a culture of responsibility that underlie these recommendations can be applied to all scientific endeavors.

2.2 Background

2.2.1 Defining a "Culture of Responsibility"

What is a "culture"? In modern usage, the word "culture" has many meanings, depending, of course, on the context. For the purpose of this report, the most relevant of the meanings is this: A culture is a set of shared beliefs, attitudes, values, goals, and practices that characterizes, and in some way defines, the identity of an institution or group of individuals.

What is "responsibility"? "Responsibility" is an indispensable concept for thinking about the ethics of individuals, groups, and institutions. We praise people and organizations for being responsible, i.e., for acting with the sort of care, diligence, and concern that we deem appropriate or fundamental to their roles and for being accountable for their actions. In the broader context of science, scientists exemplify the virtue of responsibility when their actions are well-aligned with the pursuit of knowledge and truth, when they are willing to

[3] NSABB, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.

acknowledge consequences for both their successes and their failures in that pursuit, and when their behaviors invite and earn the trust of their peers.

What is a "culture of responsibility" in the context of biosecurity? Knowledge is rarely, if ever, neutral. That knowledge can be used for good as well as for evil is one of the recurrent, indeed dominant, themes in the history of humankind. And it is a theme that has been underscored by recent events that have highlighted the potential for misuse of the fruits of scientific progress. Thus today, in the pursuit of knowledge and truth, all scientists—especially those working in the life sciences—are called to cultivate among themselves a culture of responsibility with regard to the conduct and the achievements of their research:

- Their goal remains that of the generation and advancement of knowledge, but, in some cases, such knowledge may be applied for both beneficial and harmful purposes.
- Their beliefs, attitudes, and values must reflect a heightened consciousness of the implications of their research, especially of any potential for the deliberate misuse of the information, products, and technologies generated from their research.
- They must consciously live and demonstrate these beliefs, attitudes, and values through day-to-day practices of mindful research. With transparency, they must examine their own research with consideration of its potential for misuse, and they must conduct and communicate their research in ways that mitigate any risks of misuse.
- Finally, in cultivating and sustaining a culture of responsibility, scientists who conduct research must recognize that they engage in a continuous, reciprocal process of promoting and bearing mutual responsibility for their work: They must hold themselves and their peers accountable—collegially and with a shared commitment to advancing science and maintaining public trust.

Other Perspectives on a "Culture of Responsibility"

In 2006, the National Research Council (NRC) Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats highlighted the role of a "common culture of awareness and shared sense of responsibility" in its report, *Globalization, Biosecurity, and the Future of the Life Sciences*.[4] The Committee recommended the adoption and promotion of a shared culture of awareness and responsibility that takes into account the history of openness within the life sciences community as well as the international scope of scientific research and the global dimensions of biosecurity issues. Foreign scientific exchanges, codes of ethics or conduct, and education programs were described as reinforcing a "lived culture" of awareness and responsibility within the life sciences.

In its 2009 report, *Responsible Research with Biological Select Agents and Toxins*, the NRC Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins described a "culture of trust and responsibility" as involving the engagement of all members of a

[4] Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, National Research Council, *Globalization, Biosecurity, and the Future of the Life Sciences* (Washington, D.C.: The National Academies Press, 2006), www.nap.edu/catalog.php?record_id=11567.

laboratory to "watch out for each other and take responsibility for both their own performance and that of others." While this committee specifically considered a culture of responsibility in relation to personnel reliability issues encountered in BSAT facilities, the Committee also noted the responsibilities of the broader scientific community to promote a culture that establishes and promotes normative standards (e.g., "misuse of biological materials remains taboo") and partakes in education and training to "create and maintain a culture of trust and responsibility that is central to sustaining good scientific conduct."[5, 6]

The National Security Council, in its 2009 report, *National Strategy for Countering Biological Threats,* also highlighted "supporting the 'culture of responsibility' in the life sciences" as one in a series of steps to protect against the misuse of the life sciences to develop or use biological agents to cause harm. The *Strategy* addressed life scientists' role in establishing and promoting "norms regarding the beneficial intent of their contribution to the global community as well as those activities that are fundamentally intolerable."[7]

Others have conceptualized a culture of responsibility as an engagement of life scientists in the wider socio-political context of their work to include the creation of standards and normative principles to guide the life sciences community in regarding science not simply as a value-neutral endeavor but as a body of work for which scientists must assume responsibility.[8] Furthermore, it has been argued that the continued engagement of greater numbers of life scientists and groupings of life scientists in the responsible conduct and use of research will serve to strengthen biosecurity to a measure equal to that of any new risks posed by life sciences research.[9]

2.3 NSABB Approach

In response to its charge from the U.S. government to specifically delineate ways to enhance the culture of responsibility, the NSABB formed the Culture of Responsibility Working Group (CRWG) in early 2010. See Appendix A for a roster of the NSABB and this Working Group. The CRWG was asked to identify strategies and develop specific guidance for enhancing the already well-established culture of responsibility among individuals with access to BSAT, to elaborate on hiring practices that will help to optimize personnel reliability, and to recommend ways for

---

[5] Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins; National Research Council, *Responsible Research with Biological Select Agents and Toxins* (Washington, D.C.: The National Academies Press, 2009), www.nap.edu/catalog.php?record_id=12774.

[6] During the course of the NSABB's work on the issue of a culture of responsibility, it learned of other entities' efforts regarding personnel reliability and the cultural impacts upon it. For more information, see the works of the Defense Personnel Security research Center (PERSEREC) including *Insider Risk Evaluation and Audit* (August 2009, www.dhra.mil/perserec/reports/tr09-02.pdf;), *Ten Tales of Betrayal: The Threat to Corporate Infrastructures by Information Technology Insiders* (September 2005, www.dhra.mil/perserec/reports/tr05-13.pdf), and *Improving Supervisor and Coworker Reporting of Information of Security Concern* (January 2003, www.dhra.mil/perserec/reports/tr02-03.pdf). See also the Federal Experts Security Advisory Panel, *Recommendations Concerning the Select Agent Program* (November 2010, www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf).

[7] National Security Council, *National Strategy for Countering Biological Threats* (November 2009), www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf.

[8] James Revill and Malcolm Dando, "Life Scientists and the Need for a Culture of Responsibility: After Education ... What?," *Science and Public Policy* 35, no. 1 (February 2008): 29-35, media.web.britannica.com/ebsco/pdf/499/31156499.pdf.

[9] Benjamin Wittes, *Innovation's Darker Future: Biosecurity, Technologies of Mass Empowerment, and the Constitution*, The Future of the Constitution (Washington, D.C.: Brookings Institution, Dec 8, 2010), www.brookings.edu/papers/2010/1208_biosecurity_wittes.aspx.

institutional leadership to communicate that security and personnel reliability is valued and a priority.

The CRWG convened regular teleconferences from April 2010 through June 2011 to identify objectives for addressing its charge and to conceptualize and develop its report. In order to provide a foundation for its guidance, the CRWG engaged the broader scientific community as well as experts in other relevant fields and members of the public, at several stages:

- During the course of its regular teleconferences, the CRWG convened panel discussions with experts in employment law and human-resources practices in order to gain more insight into issues related to hiring and employment. See Appendix B for the agenda and questions for these panel discussions.
- The CRWG also convened a panel of representatives of Institutional Biosafety Committees (IBCs) in order to better understand the process of IBC reviews, the diversity of IBCs in terms of scope and staffing levels, and the institutional responsibilities and burdens associated with an IBC. See Appendix C for the agenda and questions for this panel discussion.
- In order to gain broad input from the scientific community, the CRWG held the first of two roundtables on July 15, 2010. This event, entitled *Building Personnel Reliability at the Local Level: A Roundtable on Enhancing the Culture of Responsibility*, engaged different perspectives from the scientific research community (e.g., principal investigators, university administrators, university counsel, laboratory managers) in a discussion of practices that could be administered at the institutional level to promote the culture of responsibility. See Appendix D for the agenda and participant list of this roundtable.
- The CRWG convened a second roundtable, *Practices for Enhancing Personnel Reliability and the Culture of Responsibility in High Containment Labs,* on September 2, 2010, and brought together a group of investigators to discuss practices for, and the challenges of, achieving and maintaining personnel reliability and a culture of responsibility in high- and maximum-containment facilities. See Appendix E for the agenda and participant list of this roundtable.
- With the aim of gaining a global perspective on the issue, in November 2010, the NSABB co-sponsored with the Chinese Academy of Sciences a video-teleconference entitled *Strengthening the Culture of Responsibility with Respect to Dual Use Research and Biosecurity* that engaged participants of an international workshop on trends in science and technology relevant to the Biological and Toxins Weapons Convention.[10, 11] See Appendix F for the agenda of this video-teleconference.
- Finally, the NSABB hosted a public consultation on issues of personnel reliability and a culture of responsibility on January 5, 2011, in order to obtain input from the scientific community and general public regarding strategies for enhancing personnel reliability and strengthening the culture of responsibility at facilities that conduct research with

[10] NSABB, *Strengthening the Culture of Responsibility with Respect to Dual Use Research and Biosecurity* (Bethesda, MD & Beijing, China; November 1, 2010), oba.od.nih.gov/biosecurity/bio_video_teleconference_Nov2010.html.
[11] Chinese Academy of Sciences, *International Workshop on Trends in Science and Technology Relevant to BWC* (Institute of Biophysics Chinese Academy of Sciences, October 31-November 3 2010), english.ibp.cas.cn/ns/es/201011/t20101115_61377.html.

dangerous pathogens.[12] Panels considered strategies for engaging institutional leadership in the promotion of biosecurity, personnel reliability, and a culture of responsibility; encouraging biosecurity awareness and promoting responsible conduct in the laboratory through communication, laboratory rapport, and a strong sense of team; addressing impediments to the disclosure of negative information about employment candidates; and assessing the effectiveness and impact of practices aimed at strengthening personnel reliability and a culture of responsibility. See Appendix G for the agenda, speakers list, and summary of this public consultation.

2.4 Scope of NSABB Recommendations

While many of the principles of a culture of responsibility can be applied to all areas of science, the NSABB's current charge to identify strategies and develop specific guidance for enhancing the already well-established culture of responsibility is focused on members of the life sciences community who work with BSAT. However, 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 behaviors of a colleague that are inappropriate for assigned duties. Therefore, the NSABB strongly recommends that the practices described herein, with the noted BSAT-only exceptions, be applied to all life sciences research for the following reasons:

- Reliable, responsible personnel are essential to all life sciences research;
- All research personnel are in a position to notice concerning behaviors, and all share the responsibility to report such observations;
- Dual use research (DUR) and dual use research of concern (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.

[12] NIH (HHS), "Public Consultation on Personnel Reliability and Culture of Responsibility Issues," *Federal Register* 75, no. 237 (December 10, 2010): 76997; edocket.access.gpo.gov/2010/pdf/2010-31056.pdf.

3. Recommended Practices for Enhancing Personnel Reliability and the Culture of Responsibility

As the NSABB engaged members of the life sciences community on the topic of personnel reliability and the culture of responsibility, a number of common concerns faced by institutions conducting research on BSAT emerged as well as some effective practices directed at addressing some important issues. Many of these practices are in some way reflected in the NSABB's recommendations that follow. Above all, the NSABB recognizes that the rigorous use of good management practices, including the use of biosecurity-related goals and metrics in the performance evaluations of laboratory personnel, is the foundation that underpins the development of a culture of responsibility, integrity, and trust. Good management practices regarding biosecurity and a culture of responsibility do not emerge from a vacuum, however. They are enabled by strong institutional and laboratory leadership that articulates the institution's and laboratory's priorities and expectations as well as an institutional framework that provides relevant education, training, review, and support to BSAT researchers. It is these practices of sound management and strong leadership within a relevant and responsive framework of institutional policies that provide an environment that strengthens responsible practice, personnel reliability, safety, and security while allowing research on BSAT to flourish.

3.1 Good Hiring and Employment Practices

Hiring and employment practices provide an important foundation for the development of a sense of mutual responsibility and support among members of a laboratory and an institution, and in setting a tone of trust, integrity, and reliability. A shared culture of responsibility requires the rigorous implementation of sound management practices that ensure communication between leadership and staff, provide a mechanism for assessing work performance, and enable the hiring and retention of reliable personnel. Practices of employee management such as the regular assessment of employee performance and communication of expectations can, when implemented effectively, strengthen the culture of responsibility by providing opportunities to reiterate biosecurity and biosafety priorities, encourage responsible practices, discuss issues or concerns, and document performance-related subjects that may impact biosecurity and biosafety. Likewise, examining the employment and performance history of a potential employee is an indispensible step in assessing a candidate's suitability for work in any research environment.

Issues related to hiring and employment can be difficult to address and may involve legal considerations. For example, many employers are reluctant to give detailed professional or personal references for current and past employees and instead have policies to provide only minimal, objective information such as the dates of employment and eligibility for rehire. Such a failure by institutions, employers, supervisors, and peers to candidly disclose information about a person's reliability and suitability in response to a reference inquiry is irresponsible and does not demonstrate a full commitment to the life sciences community's culture of responsibility and the public's trust.

3.1.1 References

An accurate portrayal of both the positive and negative aspects of an individual's work history is invaluable to a prospective employer in the assessment of an individual's suitability for working with BSAT. Therefore, providing employment references (i.e., detailed accounts of the skills, qualifications, and other attributes of an individual by someone who is familiar with his or her work history or performance) for a current or former employee or subordinate is the responsibility of any employer or supervisor and a critical component of a culture of integrity and responsibility.

Providing References for Current or Former Employees

The NSABB strongly urges the provision of accurate and candid references and recommends that institutions have policies in place for all levels of staff on the topic of providing references. This guidance should include information for reference providers on ascertaining the purpose of the reference request, documenting the information provided about the candidate, and acquiring consent to share information about a potential employee's work history.

The provision of employment references for a current or former employee presents legitimate legal concerns (e.g., issues of possible discrimination and defamation) for institutions and persons communicating details about an individual's past work performance. Applicable federal statutes include Title VII of the Civil Rights Act (prohibiting discrimination by employers on the basis of race, color, religion, sex, or national origin),[13] the American With Disabilities Act (ADA) (protecting individuals from discrimination based on disability),[14] the Age Discrimination in Employment Act (ADEA),[15] and the Rehabilitation Act of 1973.[16] Many states also have laws addressing employment discrimination, and defamation law varies widely. Potential employers and reference providers should consult with their institution's human-resources department and general counsel for advice about these issues in the context of providing references.

Checking Employment References for Prospective Employees

Employment references can provide important information on an employment candidate's job performance as well as valuable information regarding the candidate's skills, characteristics, and whether the individual would be considered for re-hire, including information about the candidate's reliability, appropriate concern with biosecurity and biosafety matters, and willingness to follow laboratory and institutional procedures. Such efforts should help to avoid facilitating the hiring or "passing on" of employees who may be unsuitable to work with BSAT.

---

[13] 42 USC §2000d et seq. See also U.S. Equal Employment Commission, "Title VII of the Civil Rights Act of 1964," www.eeoc.gov/laws/statutes/titlevii.cfm.

[14] 42 USC §12101 et seq. See also Department of Justice, "Americans with Disabilities Act of 1990, As Amended," www.ada.gov/pubs/ada.htm.

[15] 29 USC §621 et seq. See also U.S. Equal Employment Commission, "The Age Discrimination in Employment Act of 1967," www.eeoc.gov/laws/statutes/adea.cfm.

[16] 29 USC §791 et seq. See also U.S. Equal Employment Commission, "The Rehabilitation Act of 1973," www.eeoc.gov/laws/statutes/rehab.cfm.

Accordingly, the NSABB recommends that potential employers should attempt to seek one or more employment references from the prospective employee's current employer, including the current supervisor. Many candidates are understandably reluctant to give a current employer as a reference for fear that the current supervisor might react negatively to the candidate's desire to work elsewhere or might provide an uncomplimentary report of his or her past performance. However, a candidate's recent history is an essential factor in assessing his or her reliability and suitability to work with BSAT. In cases in which the candidate prefers to keep the job search confidential, the final employment offer could be contingent upon a conversation with or reference from the candidate's current employer or supervisor.

Some individuals, such as early-career researchers and trainees, may not have a history of employment that can be drawn upon to provide a reference but should nonetheless be encouraged and enabled to pursue a career that involves BSAT work. In these cases, prospective employers should request references who are currently or have recently been engaged with the candidate on a regular or ongoing basis and can speak to the candidate's skills, character, and reliability.

The NSABB recommends that 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). For example, employment references from previous supervisors, peers, individuals who have reported directly to or been supervised by the candidate, other relevant institutional personnel (such as the candidate's biosafety officer and the institute's Responsible Official), and known professional associates or collaborators (e.g., co-authors) may be valuable sources of information about the candidate's past performance and current skills and abilities. The use of secondary or "referred" references (i.e., references from an individual identified by one or more of the candidate's primary reference providers) may also be very helpful in considering a potential employee's reliability and suitability. Conversations with reference providers should be conducted even when the candidate is an internal one (e.g., when an individual is being hired into a different laboratory within the same university).

When checking references, potential employers should clearly express the purpose of the information request, including the need to ascertain the prospective employee's reliability and suitability for the position. **In cases in which an individual would be hired for a position with access to BSAT, the NSABB recommends that the potential employer should explore aspects of the individual's prior work performance that directly relate to issues of reliability, including:**

- Adherence to standard operating procedures (SOPs), including biosafety and biosecurity procedures.
- Ability to work well in a group; ability to interact well with peers and other institutional personnel.
- Adherence to institutional, departmental, and laboratory procedures.

- History of unapproved or unaccountable absenteeism.
- History of exhibiting any concerning behaviors. Please see Box 4 (page 24) for more information on concerning behaviors.
- A request of information about the employment candidate's previous registration with the Select Agent Program (SAP), the status of this registration, and the date of termination, if the applicant previously worked with BSAT.

Suggestions for more specific questions can be found in Box 1 (below).

Institutions should also consider requesting employment candidates to sign a form giving the prospective employer permission to obtain information on the candidate's employment history, including copies of the candidate's performance reviews, and to contact the candidate's professional references. A signed release may relieve concerns and make a reference provider more willing to provide candid information regarding a candidate's suitability for work in a research environment. Again, the institution's human-resources department and general counsel should be consulted.

Box 1. Sample Questions for Checking References of Prospective Employees

- Can you describe this person's skills and knowledge? If so, please explain.
  - If applicable: Can you describe this person's skills and knowledge regarding biosafety-related practices and regulations? If so, please explain.
  - If applicable: Can you describe this person's skills and knowledge regarding biosecurity-related practices and regulations? If so, please explain.
- Describe the applicant's character.
- Can you describe this individual's experience working as a member of a team? If so, please explain.
  - If applicable*:* Can you describe this individual's experience working as a member of a team in a secure or high-containment setting? If so, please explain.
- Summarize what you see as this individual's strengths and weaknesses.
- What distinguishes this applicant from other employees with whom you have worked?
- Do you have any reason to question this person's honesty or trustworthiness? If so, please explain.
- Do you have any adverse information about this person's employment or other activities concerning violations of the law? If so, please explain.
  - If applicable: Do you have any adverse information about this person's employment or other activities concerning violations of biosafety guidelines or regulations? If so, please explain.
  - If applicable: Do you have any adverse information about this person's employment or other activities concerning violations of the Select Agent rules/regulations? If so, please explain.
- Do you know of any other conduct relating to an assessment of potential untrustworthiness and/or unreliability? If so, please explain.
- Describe the individual's professional reputation.
- Is there anything you would want a prospective employer to know about this applicant?
- Would you rehire this individual for the same or a different position? If not, please explain.

3.1.2 Reviewing Credentials and Professional Status of Prospective Employees

Misrepresentations about work histories, education, and credentials are, unfortunately, not uncommon in the employment process. Since an honest representation of an individual's background and experience speaks to trustworthiness, integrity, and reliability, fact-checking

is essential. **When seriously considering a candidate for a position that involves access to BSAT, the NSABB recommends that employers go beyond verifying a candidate's education and/or degrees, licensure, previous positions, and/or a positive Security Risk Assessment (SRA) if available.** For example, when verifying credentials or checking public records, prospective employers should specifically probe whether there have been any instances of concerning behaviors in a candidate's work history, any legitimate concerns about reliability of the candidate, or any biosecurity issues related to the candidate. Potential employers should also check publicly available records, including the Excluded Parties List System (EPLS),[17] and the resources made available by the Department of Health and Human Services Office of Research Integrity[18] that report findings of scientific misconduct or debarment.

3.1.3 Criminal Background Checks

The practice of checking criminal databases is included as part of the Select Agent Program's (SAP) Security Risk Assessment (SRA) process. The SRA is initiated once an applicant provides fingerprints and a completed SRA Assessment Form (FD-961) to the Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation (FBI). The FD-961 collects personal identifying information that subsequently assists in making determinations about the applicant based on any history of criminal behavior, illicit use of drugs or controlled substances, mental health issues, and dishonorable discharge from the Armed Services. Information is collected from naturalized citizens and permanent residents regarding immigration status and country of birth.[19] Once CJIS receives the FD-961, the applicant is screened through a number of biographical and biometric databases in order to determine if the applicant meets any of the criteria of a restricted or prohibited category as proscribed by the 2001 USA PATRIOT Act[20] and the 2002 Bioterrorism Response Act.[21] See Box 2 for list of categories. The FBI then sends the SRA results to the SAP officials who in turn notify the institution's Responsible Official (RO). SAP officials and ROs are authorized to deny, limit, or grant the applicant access to BSAT. They may also subsequently deny, limit, or revoke an individual's access to BSAT at any time if the individual's actions place him or her in a prohibited category or if deemed appropriate by the institution's RO or Alternate Responsible Official (ARO). SRAs are currently renewed every five years and, in the interim, individuals with favorable SRAs are periodically cross-checked against the most current federal databases.

A favorable SRA does not negate the need for local personnel reliability measures and does not eliminate the need to vet applicants at the local level. While thorough, it is important to note that the SRA process is not a "silver bullet" for identifying individuals who should not be granted access to BSAT. A number of misdemeanor charges may not be detected by the SRA

[17] EPLS, available at www.epls.gov.
[18] HHS, Office of Research Integrity, ori.hhs.gov.
[19] FBI, Bioterrorism Security Risk Assessment Form (FD-961), www.fbi.gov/about-us/cjis/bioterrorism-security-risk-assessment-form/bioterrorfd961.
[20] *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001*, Public Law 107-56, 107th Cong., 2nd Sess. (October 26, 2001) www.gpo.gov/fdsys/pkg/PLAW-107publ56/pdf/PLAW-107publ56.pdf.
[21] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Public Law 107-188, 107th Congress, 2nd Sess. (June 12, 2002), www.selectagents.gov/resources/PL107-188.pdf.

process but are nonetheless very important for consideration of suitability for access to BSAT. For example, charges of assault, driving under the influence of alcohol or drugs, theft, unlawful possession of a weapon, and possession of a controlled substance may not be pursued by charging officials, may be dismissed by courts, or may result in misdemeanor charges. Because a misdemeanor conviction does not result in a term of imprisonment exceeding one year, the individual would not be flagged by CJIS as a restricted person. **The NSABB recommends that institutions conduct their own criminal background checks for employment candidates and employees who are granted access to BSAT in their facilities.** In addition, the institution's RO and ARO should consider reviewing the information provided by an applicant on his or her signed FD-961. Institutions should understand, however, the legal rights of the employment applicant, including whether the access to information, including that of past arrests, is restricted or if employers are prohibited from using certain information when determining eligibility for employment. Institutions must also carefully consider the nature and gravity of any crime(s), the amount of time that has passed since the arrest and/or conviction, and how the offense(s) relate to work with BSAT.[22] These factors are best assessed at the local level as they require input from institutional leadership, principal investigators, research managers, human-resources departments, and general counsel.

Box 2. Restricted and Prohibited Categories for Individuals with Access to BSAT

Restricted categories under the USA PATRIOT Act (18 U.S.C. §175b):

- Individual is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
- Individual has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
- Individual is a fugitive from justice;
- Individual is an unlawful user of any controlled substance as defined in section 102 of the Controlled Substances Act (21 U.S.C. §802);
- Individual is an alien illegally or unlawfully in the United States;
- Individual has been adjudicated as a mental defective or committed to any mental institution;
- Individual is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism; or
- Individual has been discharged from the Armed Services of the United States under dishonorable conditions.

The Bioterrorism Response Act prohibits individuals reasonably suspected of:

- Committing a crime specified in 18 U.S.C. §2332b(g)(5);
- Having a knowing involvement with an organization that engages in domestic or international terrorism as defined in 18 U.S.C. §2331 or with any other organization that engages in intentional crimes of violence; or
- Being an agent of a foreign power as defined in 50 U.S.C. §1801.

[22] See EEOC, *Policy Guidance of the Consideration of Arrest Records in Employment Decisions Under Title VII of the Civil Rights Act of 1964, as* Amended, www.eeoc.gov/policy/docs/arrest_records.html, for more information on the potential applicability of conviction records in employment decisions.

3.1.4 Articulating the Institution's Expectations of its Employees

An integral aspect of a culture of responsibility is an understanding by laboratory personnel and researchers of the risks to which they are subject and the responsibilities they hold in order to maintain laboratory safety and biosecurity, strengthen the institution's culture of trust, integrity, and responsibility, and help ensure the public's confidence in the scientific enterprise.

The general conditions of employment and specific conditions for holding a particular position should be communicated to all life sciences research personnel at the time of hire and thereafter on a regular basis (e.g., during a performance review or evaluation), and signed attestations should be included in the employee's file. These terms and conditions of employment should make explicit mention of the institution's expectations regarding trust, integrity, and reliability. Conditions of employment should also provide notice that all information regarding the employee's reliability or suitability with respect to biosafety and biosecurity can be shared with potential employers during a reference check and with the SAP, if applicable.

It is incumbent upon institutions conducting research on BSAT to communicate to incoming personnel the particular risks and responsibilities involved in undertaking BSAT research and to implement a process of attestation by personnel that each individual fully understands these risks and responsibilities. As personnel accessing BSAT must undergo and maintain a positive SRA, the initial and annual attestation should include the exclusion categories covered in the SRA.

3.1.5 Performance Evaluations

Regular performance evaluations are a widespread management tool that can, when implemented effectively, serve as one source of information regarding an individual's performance of duties as they relate to responsibly and reliably conducting research involving BSAT. More importantly, performance evaluations provide a regular, consistent venue to communicate expectations regarding security and safety in the conduct of research on BSAT and to convey an institutional and laboratory commitment to biosecurity and personnel reliability.

In its previous report on personnel reliability, the NSABB noted the "value in assessing prior work history and performance as a predictor of future conduct."[23] In addition to the assessment of an employee's effectiveness, performance evaluations provide an opportunity for laboratory personnel and leadership to communicate the importance of biosecurity, discuss concerns, and address any potential problems that may have an impact on work performance.

The NSABB recommends that institutions conducting life sciences research should implement an achievement- or goal-focused, documented, and periodic performance review process for all laboratory personnel. Such a performance review process should also

[23] NSABB, *Enhancing Personnel Reliability among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), pg. 14, oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.

address the responsible conduct of research, including adherence to biosecurity policies and practices, and practices that contribute to a culture of responsibility. Performance evaluations of personnel working with BSAT should include, but not be limited to, a review of the individual's ability to work well in a team, follow instructions, adhere to standard operating procedures, take responsibility for work quality and safety, and respond appropriately to identified work-related weaknesses. The performance evaluations of personnel working with BSAT should also provide a forum for personnel to discuss biosecurity and personnel reliability issues.

In addition to their role as a tool for effective management and focused communication, performance evaluations can serve as a resource for assessing the prior work history of an individual under consideration for employment. While the practice of evaluating employee performance varies by institution, written achievement- or goal-focused performance evaluations, if available, can be a valuable source of information on a potential employee's strengths and challenges and may also reflect the individual's history of addressing or responding to identified weaknesses.[24] **When considering a candidate for a position that involves access to BSAT, the NSABB recommends that laboratory leadership consider requesting copies of the employment candidate's performance evaluations with prior employers. Likewise, it is recommended that institutions undertaking BSAT research develop policies that allow the performance evaluations of current or prior employees who have had access to BSAT to be shared with prospective employers.**

3.2 Encouraging Biosecurity Awareness and Promoting Responsible Conduct

3.2.1 Leadership

The leadership of a research institution has an inestimable effect on the organization's culture and is a key element in both enhancing a culture of trust, integrity, and responsibility and fostering biosecurity as an institutional goal. Leadership can support an institution's culture of responsibility by many means, including efforts to strengthen laboratory cohesiveness (or sense of team), trust, reliability, personal responsibility, worker safety and health, and scientific integrity.

At the institutional level, senior leadership (e.g., President, CEO, COO, Dean, Vice President for Research) play an important role in setting the tone concerning both biosecurity and a culture of trust, integrity, and responsibility. **The NSABB recommends that institutional leadership 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. Institutional leaders must also recognize their responsibilities and are recommended to communicate a commitment to provide individuals with the information and tools needed to meet these expectations, marshal resources to support such activities, and act upon information**

[24] Sharon Armstrong, *The Essential Performance Review Handbook: A Quick and Handy Resource For Any Manager or HR Professional*, 1st ed. (Career Press, 2010).

provided and prevent retaliation stemming from an individual's responsible report of a biosecurity concern.

In addition to senior leadership, other institutional officials, such as a biosafety officer or Responsible Official, are critical institutional champions for biosecurity and a culture of responsibility. **The NSABB recommends that leadership at institutions conducting research with BSAT actively identify or recruit such 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.** Such strategic support can take many forms but should be iterative and responsive to the institution's BSAT researchers by, for example, communicating the institution's pride in performing BSAT research and its confidence in both its researchers and security processes; marshaling funds for any needed security enhancements or education and training; and assessing, on an ongoing basis, the institution's culture of responsibility and communicating the results of such an assessment to senior leadership.

At the laboratory level, the leadership of principal investigators, laboratory managers, and other supervisors also plays a crucial role in establishing a tone of mutual trust and open communication that strengthens morale, communication, and laboratory cohesiveness. These attributes can, in turn, strengthen biosecurity and enhance the institution's culture of responsibility. Communication is the most effective tool at the disposal of laboratory leadership to make consideration of biosecurity and responsible conduct of research a part of daily life in the laboratory. Opportunities for communicating about biosecurity are many - from initiating informal conversations about biosecurity-related events to routinely raising biosecurity considerations during meetings such as journal clubs or staff meetings, or including discussions of biosecurity and responsible conduct during the planning or execution of research proposals, experiments, and manuscripts, as well as inviting group participation in planning and preparing for biosecurity-related laboratory inspections. In addition, laboratory leadership can convey the importance of biosecurity and personnel reliability to their students, trainees, and staff through communicating their own personal commitment to these goals (e.g., demonstrating knowledge of guidelines and standard operating procedures concerning biosecurity and reliability, taking an active role in institutional-, regional-, or federal-level activities relating to biosecurity, and encouraging and supporting training and education on biosecurity-related topics).

3.2.2 Education and Training

Formal training in biosecurity and personnel reliability practices and the dual use implications of life sciences research is critical for all persons engaged in the life sciences. Many research institutions, as well as some funding organizations,[25, 26] require research personnel to participate in courses on research ethics, the responsible conduct of research, or both. **The NSABB recommends that all such courses in research ethics and the responsible conduct of research incorporate topics or modules addressing the issues of**

[25] National Science Foundation, "Chapter II - Proposal Preparation Instructions," *Grant Proposal Guide*, January 2010, www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/gpg_2.jsp#IIC1e.
[26] Office of Research Integrity, ori.dhhs.gov/policies/RCR_Policy.shtml.

biosecurity and the dual use implications of life sciences research. Instruction on biosecurity and dual use research in undergraduate and graduate ethics courses should include discussion of the relationship between laboratory biosafety and biosecurity, the extant biosecurity regulations (e.g., the Select Agent Rules), the concept of dual use research and its application to the life sciences, the role of personal responsibility in maintaining a culture of trust and responsibility within the life sciences research endeavor, and potential resources to utilize for further understanding of dual use research or biosecurity. (See example course topic list, Box 3.) In addition, because courses on the responsible conduct of research (RCR) and research ethics are often only required for students and trainees, it is necessary to additionally ensure that more established researchers and other laboratory personnel are also educated or provided a refresher course. One way in which this can be accomplished is by incorporating a module on biosecurity and reliability into an extant annual training program.

Box 3. Topics in Biomedical Ethics Lecture for Graduate Students

- Where safety and security meet
  - Relationship between safety and security
  - Who are the interested parties?
- Select Agent Rules
  - What are they and from where did they come?
  - What do they mean for us?
- Dual use research
  - Can we define it?
  - Will we know it when we see it?
- What is our responsibility?
  - Do we need a code of ethics?
  - If we do nothing, others will certainly do something.

Source: Theresa M. Koehler, PhD, University of Texas, Houston Health Science Center.

3.2.3 Codes of Conduct

Codes of conduct are implemented to strengthen the concepts of personnel reliability and a culture of responsibility within the setting of an institution or to foster a sense of heightened awareness and responsibility among members of a formal group such as a scientific society or association. Codes of conduct for scientists engaged in life sciences research serve to reflect the professional identity of life scientists and to address and prevent the unethical use of biological research. Such codes can be a tool in setting clear expectations critical to prevention of misuse and helping to clarify key aspects of the social responsibilities of scientists. In itself, a code of conduct reflects an ethic of responsibility.

If undertaken as a voluntary, grass-roots initiative, the process of incorporating or adapting a code of conduct can be an effective way to increase awareness about biosecurity and dual use dilemmas related to life sciences research. The process of debating and building consensus on the content of a code (e.g., the specific responsibilities or values that will be spelled out in its provisions) can be very empowering and can inculcate a sense of "ownership," commitment, and achievement among engaged individuals.

The educational aspects of codes of conduct are inseparable from an institution's willingness to develop and implement a code of conduct. **Thus, the NSABB recommends that 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.** Codes of conduct should also be "living" documents or, in other words, continually discussed, developed, and improved upon in response to the concerns of the institutional community and developments in science, law, regulation, and policies.

For more information on codes of conduct for dual use research, please see Appendix H, "Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences," developed as part of the NSABB's June 2007 report, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*.[27] The NSABB is also considering the issue of codes of conduct and a report entitled *Promoting Awareness and Responsibility in Dual Use Research: A Code of Conduct Tool Kit* is under development.

3.2.4 Reporting of Concerning Behaviors

The secure and responsible conduct of BSAT research is dependent, in part, on observation and reporting by peers, supervisors, and subordinates. Individuals working with BSAT must understand and acknowledge their responsibility to report activities that are inconsistent with a culture of responsibility or are otherwise troubling. Likewise, institutional and laboratory leadership must acknowledge their responsibility to respond to reports of concerning behavior and undertake actions to prevent retaliation stemming from such reports. **The NSABB recommends that institutions conducting BSAT research implement programs or mechanisms that enable reporting of concerning behaviors in a respectful and responsible manner.**

Enabling Reporting

Reporting can be made operational through the formal implementation of a program or system or can be kept as an informal institutional process. Regardless of whether an institution's reporting process is formalized, the responsibility to report concerning behavior must be communicated by leadership and shared among laboratory personnel. In addition, laboratory staff should be educated on warning signs, the reporting process, and protections in place. Above all, it is imperative to develop a laboratory culture that is conducive to the reporting of concerning behaviors of individuals with access to BSAT. Practices that aid in developing a culture conducive to the reporting of concerning behaviors include:

- Both laboratory and institutional leadership should address the purpose and importance of vigilance regarding personnel reliability and biosecurity regularly (e.g., during periodic laboratory meetings).
- Institutions should provide documentation to personnel with access to BSAT on the protections in place for both the subject and source of a report. Information on the possible actions that might be taken in response to a report should also be provided.

[27] NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*, (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

- During one-on-one meetings with staff and also during performance reviews, supervisors should routinely ask laboratory personnel if they have any reliability- or biosecurity-related concerns they would like to discuss.
- Institutions should provide multiple avenues for reporting concerning behaviors. For example, some individuals may feel most comfortable reporting concerns to a supervisor while others may prefer to speak to the institution's biosafety officer, Responsible Official, human-resources representative, or ombudsman. Anonymous reporting mechanisms may also be valuable. Despite the different avenues for reporting, all mechanisms should be coordinated and acted upon appropriately and in a timely manner.
- Institutional leadership should communicate with faculty, staff, and students regarding whom to contact with a concern about a student, trainee, colleague, or supervisor. Institutional resources such as safety procedures, employee assistance programs, counseling services, and emergency services should be highlighted for all staff and faculty.
- Institutional leadership should respond to reports immediately and appropriately.

Concerning Behaviors

The range of healthy human behavior is varied and the source of much enjoyment, bewilderment, and creativity. Scientists are not exempt from exhibiting the array of human behaviors, and humankind has benefitted immensely from the creative and intellectual output of a profession that attracts and accepts a range of personality types. However, there are some behaviors or changes in behavior (see Boxes 4 and 5 below) that may indicate unusual stress. Addressing such potentially problematic or concerning behaviors or behavioral changes early may be the best way to avoid later problems.

Box 4. Examples of Concerning Behavioral Changes

- Increasingly withdrawn
- Performance of duties declines markedly
- Increase in risk-taking behaviors
- Significant increase in terms of distraction, mistakes
- Significant and prolonged deterioration in appearance

Box 5. Examples of Concerning Behaviors

- Sending inappropriate emails
- Talking about wanting to harm self and/or others
- Physical violence (to objects or persons)
- Mention of plans to commit acts of violence to persons or property
- Acts of vandalism or property damage
- Unlawfully carrying weapons
- Criminal activity
- Unjustified anger, aggression
- Signs of alcohol/drug abuse
- Laboratory work that does not correspond to official project
- Working in "off hours" without justification or documentation
- Security breaches, accessing computer/email passwords, stealing laboratory notebooks or reagents
- Sabotaging colleagues' research
- Providing false information on applications or other formal institutional documents
- Deception
- Unexplained absences
- Inappropriate conduct toward colleagues
- Cruelty to animals

Reporting Concerns

Institutions should provide multiple routes for individuals to report concerns ranging from notifying the laboratory leadership, ombudsman, biosafety officer, human-resources officer, relevant committee (e.g., university threat assessment committee), and/or task force to, if feasible and appropriate, an anonymous reporting mechanism. Guidance should also be developed for staff regarding the process for alerting campus police or law enforcement, if needed.

Protections

Inquiries or reports of concerning behavior may be submitted by students, trainees, or subordinate staff, and it therefore is important to have a process in place to protect those individuals reporting concerns. Institutions should develop procedures, including documentation, for protecting the reporter and should have these in place *before* an incident occurs.

It is equally important to protect the subject of an unjustified, frivolous or retaliatory report. The privacy and confidentiality of the subject of a report should also be maintained to the extent permitted by law.

Training

The provision of education and training on the issue of reporting concerning behaviors is essential. Training must make individuals aware of their responsibilities, what is expected of them by the institution, what behaviors should be reported, the (preferably multiple) procedures for reporting, and the protections in place for the reporter and the subject of the report.

3.2.5 Opting Out of Research Involving Biological Select Agents and Toxins

Some institutions conducting BSAT research have implemented policies that allow employees to temporarily "opt-out" of performing research involving BSAT. Such employee-initiated "opting-out" is a voluntary decision to interrupt or stop working directly with BSAT for a short period of time, a decision that is made and implemented, in conjunction with a supervisor, in response to a temporary condition or situation that affects the individual's ability to perform BSAT research safely and securely. Temporary conditions that might affect a person's ability to perform BSAT research include temporary physical ailments that may impair mental acuity or physical performance or a temporary emotional or personal crisis that could interfere with one's ability to focus or concentrate. Examples of temporary conditions that may lead an employee to opt-out of working with BSAT temporarily include cold medications that may leave a person feeling "groggy," lack of sleep due to a child's illness, or a lessened ability to concentrate due to the death of a family member. Employee opting-out programs should not be confused with management decisions to a change an individual's employment duties and restrict an individual's access to a BSAT facility, which should be reported to the SAP. Instances of employee-initiated opting-out should be communicated to the laboratory's principal investigator and the institution's Responsible Official (RO) and biosafety officer (BSO), but such temporary, voluntary interruption of regular work duties need not be reported to the SAP.

The provision of an employee-initiated, temporary opt-out mechanism for personnel working with BSAT is a responsible practice recommended for implementation by all institutions undertaking BSAT research. An individual considering temporarily opting-out of research may want to discuss the underlying reasons with his or her supervisor or the institution's RO or biosafety officer; however, institutional resources such as an Employee Assistance Program (EAP) or office of occupational health may be useful to individuals who do not wish to disclose. In cases of a temporary opt-out of BSAT research, an institution should keep the employee's reasons behind the decision confidential to the extent permitted by institutional policies and the law. Plans and procedures, including those for maintaining confidentiality, should be put in place prior to implementing a temporary opt-out program. Likewise, procedures for resuming normal duties should be established early and communicated to all BSAT personnel.

Personnel working with BSAT may be reluctant to temporarily opt out of research due to concerns over loss of employment, disruption of research, or fears of social or professional stigmatization. **Therefore, the NSABB recommends that research institutions 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.** Education and training offer opportunities to inform BSAT researchers and their supervisors about their roles and responsibilities regarding opt-out policies and to discuss the range of possible reasons that a researcher may decide to opt-out. Laboratory and institutional leadership also play a role in setting a tone that de-stigmatizes opting-out and emphasizes it as a responsible practice.

3.2.6 Institutional and Local Peer Review of Research Involving Biological Select Agents and Toxins

One of the ways in which institutions conducting BSAT research demonstrate their commitment to a culture of responsibility is through the oversight of the BSAT research. Responsible research with BSAT involves not only addressing the scientific questions underpinning the research but also ensuring that the research is conducted in a safe manner and in a secure environment and that the work is carried out by well-trained, competent and reliable individuals. While principal investigators, biosafety officers (BSOs), and Responsible Officials (ROs) each play a significant role in establishing the tone of responsible conduct of BSAT research, considerations of BSAT research should also include other members of the institution's research community who can offer a valuable "second set of eyes" in the assessment of the biosafety and biosecurity risks posed by BSAT research as well as the consideration of the dual use potential of the research.

The NSABB recommends that all institutions conducting BSAT research 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 life of the research project, as appropriate. Such risk assessments must be performed by an appropriately constituted review body and should address biosafety and biosecurity issues as well as the potential for dual use. While the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight made a similar recommendation to "require that, at all institutions conducting high or maximum containment research, an appropriately

constituted review body performs a thorough risk assessment of all laboratory protocols potentially requiring high or maximum containment,"[28] **the NSABB recommends that it apply to all research involving BSAT and extend beyond biosafety review to include considerations of biosecurity and dual use potential.**

Scope of the Review

Research projects (i.e., the planned research of a principal investigator's or research group's line of inquiry) involving BSAT should be reviewed for biosafety, biosecurity, and dual use considerations. Institutions can address these considerations in a single review process or the institution may divide the considerations between appropriately constituted review bodies. The institution may also choose to expand the scope of these reviews to include infectious disease agents that are of concern but not regulated as BSAT.

- Biosafety and Incident Response Review Components.
  Each project involving BSAT should be reviewed in light of the institution's biosafety and incident response procedures as well as each laboratory's written, agent-specific, site-specific biosafety plan. All entities possessing, using, or transferring BSAT should base their biosafety plans and incident response procedures on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*), 29 CFR 1910.1450, or other required assessment materials.[29] Reviews of research involving BSAT should also consider whether an individual is suitable (i.e., is technically competent and properly trained) with respect to biosafety.

- Dual Use Review Components.
  Each project involving BSAT should be evaluated for its dual use potential at the inception of any research and periodically throughout the research process. The review should include an assessment of any risk(s) associated with the findings, technologies, or agents that might be generated from the research to include:
  - Identification of the ways in which the information, technologies, or agents could be misused for harmful purposes, and
  - Consideration of the potential consequences if the research information, technologies, or BSAT are misused.

  Education and training are important aspects of a review of research for dual use concerns. Thus, biosecurity reviews should also consider whether an individual has been properly trained with respect to dual use research issues. (See Box 6 below for the NSABB's criterion for identifying dual use research of concern. For more information on the review of research for its dual use potential and other steps in the local oversight of research with dual use potential, please see the NSABB's June 2007 report, *Proposed*

[28] HHS, "Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight," July 2009, www.phe.gov/Preparedness/legal/boards/biosafetytaskforce/Documents/transfedbiocontainmentrpt092009.pdf.
[29] HHS and USDA, "Guidance Document for Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)," 2009, www.selectagents.gov/resources/APHIS-CDC_Form1_Enabled_updated_05-04-10.pdf.

Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information.[30])

Box 6. NSABB Criterion for Identifying Dual Use Research of Concern (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 and safety, agricultural crops and other plants, animals, the environment, or materiel.
See NSABB, "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information," pgs. 16-17 (National Institutes of Health, June 2007),

- Biosecurity Review Components.
  Biosecurity risk assessments of BSAT research should include consideration of the physical security of the laboratory where the research is being conducted and the reliability and suitability of the individuals involved in the research.
  - Physical security. Each research project involving BSAT must be reviewed in light of the site-specific written security plan for each laboratory where the research is taking place. The laboratory's plan should be one component of the security measures put in place to ensure compliance with Section 11 of the Select Agent Regulations.[31] Other security measures include the use of procedures or mechanisms to limit or monitor access to the research laboratory, the processes in place for control of and accountability for the laboratory's infectious disease agents and/or BSAT, and the processes and procedures in place to ensure control access to the laboratory's manual- and electronic-records security.

  - Personnel reliability and suitability. The reliability of the investigators and other staff involved with each BSAT research project must be considered. As is the case for all research, education and training are important aspects of an investigator's or researcher's suitability to work with infectious disease agents and/or BSAT. Thus, biosecurity reviews must also consider whether an individual has been properly trained with respect to the procedures in place to ensure compliance with the Select Agent Regulations.[32] In addition, the review must consider whether the education of the individuals conducting the research in question addresses the needs of the individual, the work being performed, and the risks posed by the infectious disease agent(s) and/or BSAT. In addition, individuals must be required to demonstrate their technical proficiency in laboratory procedures prior to working with BSAT. Refresher training should be readily provided if any gaps or needs for reinforcement in the individual's skills or knowledge are identified by management, peers, or the individual. Individuals with insight and awareness of

[30] NSABB, "Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information" (National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.
[31] HHS and USDA, "Guidance Document for Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)," 2009, www.selectagents.gov/resources/APHIS-CDC_Form1_Enabled_updated_05-04-10.pdf.
[32] For more information on biosecurity-related training, please see HHS and USDA, "Guidance Document for Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)," pg. 10, 2009, www.selectagents.gov/resources/APHIS-CDC_Form1_Enabled_updated_05-04-10.pdf.

the proficiency, training, and reliability of the researchers involved with the research project under review, such as laboratory managers or biosafety officers, may serve as good resources when assessing the reliability and/or suitability of an individual.

Composition and Operation of the Review Body

Currently, some institutions review research with biosecurity or dual use concerns through their Institutional Biosafety Committees (IBCs). IBCs have been established at institutions that sponsor research that is subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) in order to review research with recombinant DNA for biosafety purposes.[33] Many institutions have elected to task their IBCs with review of other biohazardous research, whether it involves recombinant DNA research or not. Due to the overlapping expertise needed for biosafety and biosecurity review, some IBCs have effectively taken the additional responsibility of assessing protocols for biosecurity considerations.

Expanding the scope of IBC review to include biosecurity risks and dual use considerations of BSAT research is not the only model for effective review of protocols for biosecurity risks, personnel reliability and suitability, and dual use concerns. Not all research institutions have IBCs as they may not conduct research involving recombinant DNA molecules or may not be subject to the *NIH Guidelines*. Or, for a variety of reasons, an institution may choose not to expand the scope of IBC review. Whether the review function is performed by the IBC or another review body, the constitution of the review body should be suited to the culture and needs of the institution. In addition, the discussions of the review body should be deliberative and allow, to the extent possible, collective or consensus-driven assessments of risk. Thus, meetings of the review body should be conducted in a convened meeting rather than by e-mail correspondence, and minutes should be taken. Although transparency is an important component of a culture of responsibility and the maintenance of public trust, it must be balanced appropriately with a need for confidentiality that requires a closed meeting. For a closed meeting, properly redacted minutes detailing the title and/or role of those present and the action items identified should be made available. The review body should maintain confidentiality to the extent allowable by law and institutional polices.

Review Body Attributes

It is imperative that members of the review body possess the requisite expertise to assess risks related to biosecurity, biosafety, and dual use research. This includes:

- Expert knowledge of the biological systems and research methodologies and technologies associated with the proposed research.
- Knowledge enabling the identification of potential risks to public health, laboratory workers, and/or the environment, whether through breaches of safety, physical containment, and/or security.
- Knowledge of the biosecurity concerns related to the institution's research portfolio is also important. In many cases, it is the institution's BSO and/or RO who may be most

[33] NIH, *NIH Guidelines for Research Involving Recombinant DNA Molecules*, January 19, 2011 update, oba.od.nih.gov/rdna/nih_guidelines_oba.html.

knowledgeable about biosecurity matters related to the research being conducted at the institution. Investigators may also have biosecurity knowledge or expertise.

- As needed, this review body should include individuals with knowledge of institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment.
- If feasible, the review body should include at least one member representing the technical staff of the institution's laboratories.
- When permissible from a security perspective, this review body should include viewpoints from the local community.

4. Potentially Useful Practices for Enhancing Personnel Reliability and Culture of Responsibility

As the NSABB investigated the array of practices implemented in personnel reliability programs,[34] two practices, the use of video monitors and the two-person rule, were considered potentially useful to institutions as they strive to strengthen their reliability measures. These practices may, however, be difficult to implement effectively, may have negative, unintended consequences, and may be cost-prohibitive. Due to these inherent difficulties, the NSABB does not consider their wide-spread implementation to be a critical factor in strengthening personnel reliability and any federally mandated implementation of these practices is not in the best interest of the public, the research community, or national security. Some institutions nonetheless may find these practices valuable in strengthening their personnel reliability efforts despite their costs, implementation challenges, and possible unintended consequences. In these cases, the NSABB recommends that local institutions conduct a thorough risk assessment of these practices prior to implementation of video monitoring or the two-person rule.

4.1 Video Monitoring

Video monitoring of laboratories has been employed to enhance both the security and safety of research facilities. In terms of biosafety, surveillance cameras and video records have been used, with varying success, for biosafety training purposes and in identifying the causes of biosafety accidents or incidents. While not a requirement under the Select Agent Program, security cameras also have been utilized by some research facilities for biosecurity purposes. Surveillance cameras can be implemented as an enhancement of the laboratory's or facility's security measures, and the videos can, under some circumstances, serve as a record of who accessed materials and equipment at specific times. Such records can be helpful for investigations in follow-up to a biosecurity event and may provide protection to employees or staff if there is an event (i.e., can be used to exonerate employees).

Implementation of surveillance cameras can be resource-intensive, however. When implemented solely for biosecurity purposes, video monitoring can be unmanned, which is less costly than manned monitors used for biosafety purposes. Video storage is also resource intensive as video records must be stored for a length of time that corresponds with the laboratory's or facility's underlying reasons for implementing video monitoring (i.e., biosafety, security enhancement, or record creation). In cases in which surveillance cameras are implemented as a security enhancement, the length of time that tapes are stored should be a local decision and should take into consideration the length of time needed to investigate an event, institutional policies, and state and federal law (e.g., statutes of limitations). If video records are intended to meet the records requirement under Sections 11 and 17 of the Select Agent Regulations, the video must meet certain requirements and be stored un-edited for three years.[35] Given the costs involved in implementation and storage and the impact of laboratory design and set-up on monitoring capability, the use of video cameras should be based on a risk assessment by the local institution and should not be mandated by federal regulation.

[34] NSABB, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.
[35] National Select Agent Registry, "Security FAQs," www.selectagents.gov/FAQ_Security.html.

4.2 Two-person Rule

Laboratory policies that require two people to be physically present in the laboratory when work is taking place (the "two-person rule") have been employed as a means of enhancing both biosecurity and biosafety at some high-containment laboratories. While implementation of the two-person rule can also be costly, particularly for smaller laboratories with fewer numbers of SRA-cleared personnel, video-monitoring can be implemented to meet a requirement for a "second set of eyes." The two-person rule can be useful in situations that carry higher risk to the safety of personnel (e.g., conducting inventory or transfers, performing invasive procedures, working with animals, moving heavy laboratory equipment, training new personnel). However, the implementation of the two-person rule can have significant impacts on workflow changes and time requirements needed to satisfy the rule, which may have the unintended consequence of increasing the safety risks faced by laboratory personnel.[36] For example, personnel may perceive that they are inconveniencing the second person, which may lead to increased stress or time pressure. For these reasons, the two-person rule should not be mandated federally and its use should be based upon a risk assessment by the local institution.

[36] LeDuc JW, Anderson K, Bloom ME, Carrion R Jr, Feldmann H, Fitch JP, et al. "Potential impact of a 2-person security rule on BioSafety Level 4 laboratory workers," *Emerging Infectious Diseases*, 15, no. 7 (July 2009), www.cdc.gov/EID/content/15/7/e1.htm.

5. Personnel Reliability Practices That Are Not Recommended for Broad Implementation

As discussed in the NSABB's report on personnel reliability, formal Personnel Reliability Programs (PRPs) have been instituted at some research facilities (notably federal) that work with BSAT. These PRPs require that individuals with access to select agents meet standards of reliability in addition to the SAR. Current PRPs are modeled after those within the traditional surety programs and may include extensive background investigations, security clearances, medical evaluations involving the release and review of complete medical records, psychological testing, drug and alcohol testing, polygraph examinations, credit checks, and a comprehensive review of service and employment records. PRPs usually involve ongoing monitoring mechanisms (e.g., self-reporting, peer-reporting, ongoing monitoring by supervisors); periodic reassessments such as annual physical examinations, random drug tests, re-evaluation of medical records and medications, recurring psychological evaluations, and renewal of security clearances; and certification of the reliability and suitability of all personnel by a designated official.[37] While the promulgation of formal PRPs on a national scale has been deemed unnecessary by the NSABB, certain practices such as a review of employment records, the implementation of reporting mechanisms, and the use of employee-initiated, temporary opt-out programs are recommended for consideration by institutions. (See Section 3 of this document.)[38]

This section addresses some of the practices used in formal PRPs that the NSABB does *not* recommend for widespread implementation by institutions, particularly academic institutions. In some cases, these practices have privacy implications and may not be permitted by law or institutional policies. Some of these practices are also resource-intensive and of unproven or unsubstantiated value. While not recommended by the NSABB for broad implementation, the practices described below have been implemented by some institutions or recommended by other entities and hence deserve discussion. Institutions considering the adoption of these practices should carefully consider the costs and benefits of each, any evidence for their effectiveness, and the likelihood of any unintended or detrimental consequences for the scientific enterprise.

5.1 Mental Health Assessment

The NSABB has previously debated the value of psychological assessments for determining the reliability of individuals granted access to BSAT, as an individual's mental and emotional status impacts his or her ability to focus, perform job-related duties, and make sound decisions.[39] While these types of assessments may have value under certain circumstances,[40, 41, 42] they are resource-intensive and neither their effectiveness nor their predictive value in identifying an insider threat is proven. In addition, some institutions, particularly academic ones, may lack the appropriate infrastructure to effectively implement these features or to address their associated legal

[37] Department of the Army, *Nuclear and Chemical Weapons and Materiel - Biological Surety (Army Regulation 50-1)* (Washington, D.C.: Department of the Army, July 28, 2008), www.fas.org/irp/doddir/army/ar50-1.pdf.
[38] NSABB, *Enhancing Personnel Reliability among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.
[39] Ibid.
[40] Morgan CA, "Psychological Assessment in the Selection of Personnel for specialized roles in Government: Where does it fit in? What role might it play?" (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, MD, April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Morgan.pdf.
[41] Baker, J, "Psychological Assessment" (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, MD, April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Baker.pdf.
[42] Skvorc, C and Wilson, DE, "Developing a Behavioral Health Screening Program for BSL-4 Laboratory Workers at the National Institutes of Health," *Biosecurity and Bioterrorism,* www.liebertonline.com/doi/full/10.1089/bsp.2010.0048.

concerns. The establishment of a psychological baseline for an individual would require access to complete medical records, which may present privacy concerns, and the professional administration and interpretation of psychological assessments. As the NSABB has also noted, in order to identify variations from this baseline, these assessments would need to be conducted periodically, perhaps annually, which would incur significant costs.[43]

The NSABB does not recommend the implementation of mental health or psychological assessments due to their resource-intensive nature and unproven predictive value. Institutions performing BSAT research should recognize that an individual's ability to make decisions can fluctuate based on social and emotional factors. When implemented effectively, reporting mechanisms and voluntary, temporary, and employee-initiated opt-out programs for individuals with access to BSAT (as described in Section 3 of this document) provide ample opportunities for individuals to address emotional or mental stress in a responsible manner. In addition, codes of conduct, educational and training opportunities, and sound leadership and management practices can help communicate an individual's responsibility to report or respond to concerning behaviors or behavioral changes in the individual or in others.

5.2 Drug and Alcohol Testing

Drug and alcohol use can affect a person's emotional stability and capacity for sound judgment and impact his or her ability to focus, perform job-related duties, and make sound decisions. Current SRA regulations prohibit the unlawful use of a controlled substance by individuals granted access to BSAT, but it is important to acknowledge that past problems with alcohol or drug use do not necessarily mean that an individual is presently unsuitable for work with BSAT. In addition, the protections of various laws are implicated (e.g., individuals seeking or undergoing treatment for addiction may be protected from discrimination). Accordingly, the legality and practicality of drug- and alcohol-testing is best determined at the local level and requires input from institutional leadership, principal investigators, research managers, legal counsel, and human-resources departments. In light of these factors, the NSABB does not recommend the use of drug or alcohol testing and instead emphasizes the implementation of reporting and temporary opt-out processes to identify any problems related to alcohol or drug use and suggests that institutional leadership encourage the utilization of employee assistance programs and other institutional resources in addressing these problems.

5.3 Credit Checks

Credit checks are one source of information used in the national security clearance process to assess an individual's vulnerability to coercion. Indeed, an individual with significant debt may be willing to sell access to BSAT. Nonetheless, while credit checks are commonly employed and may already be conducted by some employment offices, the NSABB could determine no objective way to translate the information gathered from a credit check into any meaningful measure of reliability. Furthermore, the types of individuals who conduct BSAT research range from graduate students to postdoctoral fellows to laboratory technicians to tenured professors, all of whom are at different stages in their professional and personal lives and may have varying levels and types of debt for a variety of reasons. The variability in the financial histories of BSAT researchers suggests that credit checks as an assessment of vulnerability to coercion may not be a useful predictive tool

[43] NSABB, *Enhancing Personnel Reliability among Individuals with Access to Select Agents* (Bethesda, MD: National Institutes of Health, May 2009), oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf.

for determining reliability, and they are not recommended by the NSABB as a measure to strengthen the reliability of personnel with access to BSAT.

5.4 Polygraph Tests

The NSABB also considered polygraph examinations and does not recommend their implementation. While a polygraph requirement may serve as a deterrent for individuals who may be seeking access to BSAT for nefarious purposes, the examination's lack of scientific reliability in detecting false or misleading statements does not warrant its inclusion in a personnel reliability program.[44]

[44] See Faigman DL, Saks MJ, Sanders J, and Cheng EK, "Polygraph Tests," in *Modern Scientific Evidence: The Law and Science of Expert Testimony*, vol. 5, 2010-2011 ed. (Eagan, MN: West, 2010).

6. Assessing the Effectiveness of Practices Aimed at Enhancing Personnel Reliability and the Culture of Responsibility

The ultimate goal of efforts to strengthen personnel reliability and enhance the culture of responsibility within the life sciences research community is the safeguarding of the public's trust, safety, and security, while furthering the scientific enterprise, all through the management of the risks associated with BSAT research. As discussed in Sections 3 and 4, most of the practices discussed in this report reflect the successful strategies employed by institutions and researchers as they go about the important work of conducting and supporting BSAT research. While the practices described in Sections 3 and 4 aim to address the very real challenges posed by researching BSAT, it should not be forgotten that their implementation impacts the day-to-day conduct, cost, and burden of research. **Therefore, responsible practice dictates that the effectiveness, potential impact, and unintended consequences of any measures being implemented be considered in light of the costs and burdens that they impose, particularly the burdens of unnecessary or duplicative policies that stifle scientific research.**

6.1 The Challenge of Assessing Personnel Reliability Practices and a Culture of Responsibility

Although critical, assessing the effectiveness and direct impact of personnel reliability measures is challenging because their "success," i.e. a decrease in the incidence of an insider threat, is not directly measurable. Likewise, assessing an institution's or community's culture of responsibility can be a "moving target" as attitudes and perceptions change in reaction to leadership, education, experience, and the state of national and international security. Despite the challenges in assessing personnel reliability measures and a culture of responsibility, there are existing strategies and methods that offer insight and understanding of their effectiveness and their unintended consequences. Assessments and evaluations of prevention efforts, such as systems implemented to reduce accidents or deter deliberate acts of sabotage or terrorism, have arisen in other research environments and can be used as analogies for the BSAT research community.[45] Likewise, the assessment of a culture of responsibility can draw upon the fields of organizational development, business ethics, management, and organizational behavior. These research fields offer insight into an institution's ethical climate and its impact on the responsible conduct of research.[46]

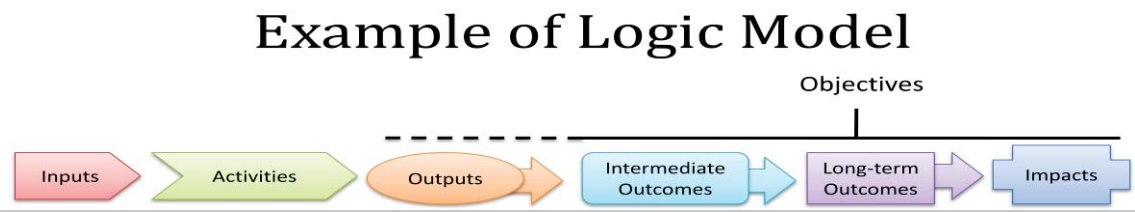
6.2 Strategies and Methods for Assessing Personnel Reliability Practices and a Culture of Responsibility

Assessments of the impact of personnel reliability measures and efforts to strengthen a culture of responsibility should be designed with the desired "end state" in mind. In this case, the desired end state may simply be a strong culture of responsibility that strengthens personnel reliability within the BSAT and life sciences research communities but could be more specific for different organizations. While an organization's desired end state may be difficult or impossible to measure, standard evaluation techniques such as the identification of intermediate outcomes and the development of logic models, are helpful in identifying factors that can be measured or assessed. See Box 7 below for an example of a logic model that incorporates intermediate outcomes. While logic models may be limited by their linearity, they provide a useful description

[45] Susan E. Cozzens, "Evaluating the Unobservable: The Power of Logic Models and Intermediate Outcomes," presented at the NSABB Public Consultation, Bethesda, MD, January 5, 2011, oba.od.nih.gov/biosecurity/meetings/Jan2011/Susan_Cozzens_Panel5.pdf.
[46] Mark S. Frankel, "Assessment, Personal Reliability & Culture of Responsibility," presented at the NSABB Public Consultation, Bethesda, MD, January 5, 2011, oba.od.nih.gov/biosecurity/meetings/Jan2011/Mark_Frankel_Panel5.pdf.

of the major features of a plan or approach, help make assumptions explicit, and generally provide a framework for deliberation about the progression towards the intended outcomes.

Box 7.



Adapted from Susan E. Cozzens, "Evaluating the Unobservable: The Power of Logic Models and Intermediate Outcomes," presented at the NSABB Public Consultation, Bethesda, MD, January 5, 2011.

6.2.1 Assessing Outcomes and Effectiveness

Great care should be taken in selecting the indicators, metrics, and/or instruments used to assess, evaluate, or otherwise understand the outcome(s) and impact of personnel reliability measures and efforts to enhance a culture of responsibility. For example, focusing an assessment of personnel reliability measures on the ability of the measures, as implemented, to achieve the desired end state orients the evaluation on the *effectiveness* of the effort or plan in positively impacting personnel reliability. (See Box 8 for examples of effectiveness and performance metrics.) Because impacts are long term and multi-factorial, the evaluation of more directly-attributable outcomes becomes an important tool for assessing effectiveness. Many outcomes are obviously also long-term. Therefore, when possible, intermediate outcomes (i.e., shorter-term outcomes that lead to the final outcome or desired state) should be identified and assessed. Unintended consequences can also be used as an outcome measure that can be easier to evaluate than the planned outcomes.

Box 8. Examples of Effectiveness and Performance Metrics

Measures of performance indicate how swiftly or how thoroughly a measure or set of measures was implemented.

- Was a reporting system implemented? What population is reporting most often, and was this the target population? How quickly are the reported problems or issues resolved?
- Have opting-out programs been implemented and utilized? Has utilization increased or decreased?
- Has a code of conduct been implemented at the institution?
- Are performance evaluations conducted for all BSAT employees? What has been the change in these evaluations over time?

Measures of effectiveness indicate how well a measure contributed to realizing a desired end state.

- Are cases of reporting indicative of actual or real problems, or could they be characterized as retaliatory or frivolous in nature? Is the root cause of reporting incidents stemming from a lack of communication or training? (i.e., could they have been avoided through better leadership, management, or training?)
- If utilization of opting-out has decreased, why is this happening? Is stigma a reported concern in utilizing opting-out programs?
- Has the code of conduct change the community's thinking about a culture of responsibility?

Intermediate and long-term outcomes will often represent a mix of indicators and metrics that assess both effectiveness (i.e., the ability for the outcome to contribute to the achievement of

the desired end state) and/or performance metrics, which often simply reveal information about how well the implementation of a plan has been executed towards its own ends. Implementing personnel reliability measures and subsequently assessing performance in order to indicate that they have indeed been put into place has some limited utility; however, performance measures are not a surrogate for the effectiveness of personnel reliability measures in the attainment or achievement of the desired end state.

6.2.2 Assessing the Culture of Responsibility

In 2002 the Institute of Medicine's Committee on Assessing Integrity in Research Environments was tasked with identifying ways to enhance the culture of scientific integrity as well as determining ways to evaluate scientific integrity in the research community. The Committee concluded that, while no established measures for evaluating integrity in the research community existed at that time, other fields such as business ethics, management, organizational development, and adult learning, offered valuable and informative parallels from which to draw. These fields give insight on the ways in which a research culture is implemented and measurable by assessing the attitudes, perceptions, and practices of the members of the institution/organization towards the institution's policies and procedures.[47] Specifically, these fields provide insight on the identification of the elements of a research environment that promote research integrity, how these elements might be measured, the determination of appropriate outcome measures, and how to best encourage or enable adoption of measures meant to promote research integrity.[48] (See Box 9 for examples of metrics for assessing an institution's culture of responsibility.) Assessing the change in a research culture prior to or early in the process of implementing personnel reliability measures or efforts to enhance a culture of responsibility and then re-assessing the culture periodically will give insight into the effectiveness of the measures and may help uncover any unintended consequences.

Notable resources and instruments for the assessment of the research culture include the following:

- *Ethical Climate Index*. This instrument empirically measures an organization's climate or culture against certain ethical standards and has been validated in the business literature.[49]
- *National Business Ethics Surveys*. These surveys are conducted every two years by the Ethics Resource Center and include metrics that address both the creation and degradation of an ethical climate in an organization.[50]
- *The Center for Academic Integrity Assessment Guide*. This guide assesses the climate of academic integrity at an institution, using a number of indices, and has been validated in university environments.[51]
- *Survey of Responsible Research Practices*. This instrument assesses the climate for research integrity and is in the process of being validated.[52]

---

[47] Mark S. Frankel, "Assessment, Personal Reliability & Culture of Responsibility," presented at the NSABB Public Consultation, Bethesda, MD, January 5, 2011, oba.od.nih.gov/biosecurity/meetings/Jan2011/Mark_Frankel_Panel5.pdf.

[48] Committee on Assessing Integrity in Research Environments, National Research Council, Institute of Medicine, *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct* (Washington, D.C.: The National Academies Press, 2002), www.nap.edu/catalog.php?record_id=10430.

[49] Anke Arnaud, "Conceptualizing and Measuring Ethical Work Climate: Development and Validation of the Ethical Climate Index," *Business & Society*, June 2010, Vol 49, No 2 345-358, bas.sagepub.com/content/early/2010/03/04/0007650310362865.

[50] Ethics Resource Center, "National Business Ethics Survey (NBES)," www.ethics.org/topic/national-surveys (Arlington, VA).

[51] Clemson University, Rutland Institute for Ethics, "Assessment Guide," *The Center for Academic Integrity*, 2010, www.academicintegrity.org/assessment_guide/index.php.

Box 9. Examples of Metrics for Assessing an Institution's Culture of Responsibility

- Reporting, including self-reporting, of violations or concerning behaviors.
- The community's response to a report of violation.
  - The collective opinion of the community as to whether the reporting system is fair, timely, efficient, etc.
- Options for understanding professional responsibilities and seeking ethics guidance.
  - Is the organization open to encourage people to raise issues? Is the reporting process clear?
- Performance of a risk assessment.
  - Does the benefit posed by the new practices or policies outweigh their burden?
- Resource allocation for fulfilling professional responsibilities.
  - Does the budget support the objectives or requirements of the program?
- Leadership support for "doing the right thing."
  - How does leadership behave when issue arise that affecting a culture of responsibility?

6.2.3 The Role of Leadership

In addition, satisfaction or comfort with the personnel reliability measures or culture-enhancing efforts as implemented should not be confused with their effectiveness. For example, if investigators or institutional leadership are very comfortable with a current set of measures, yet staff perceives a hostile work environment or that reports of concerning behavior are not taken seriously, then the status quo is not working, and responsible practice dictates that these issues be addressed. Likewise, there is a responsibility to show that more burdensome personnel reliability measures will be, or have been, more effective than previous prevention efforts or the lack thereof.

Leadership must continually communicate and assess progress towards the desired "end state" for personnel reliability and a culture of responsibility. As with the implementation of personnel reliability measures or efforts to enhance the culture of responsibility, the evaluation of these same measures or efforts, and the use of that evaluation data to improve the institution's processes or culture, is greatly enhanced by laboratory and institutional leadership. The practice of (re)turning to the concept of the desired "end state" and revising this goal through an iterative process, if needed, also enables leadership to stay in tune with the research environment and adapt to changes in the skill, knowledge, and experiences of members of the research community.

[52] Carol R. Thrush, Jim Vander Putten, Carla Gene Rapp, L. Carolyn Pearson, Katherine Simms Berry, and Patricia S. O'Sullivan, "Content Validation of the Organizational Climate for Research Integrity (OCRI) Survey," *Journal of Empirical Research on Human Research Ethics*, pp 35-52, www.jstor.org/stable/10.1525/jer.2007.2.4.35.

7. Summary of NSABB Findings and Recommendations

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.**
   This guidance should include information for reference providers on ascertaining the purpose of the reference request, documenting the information provided about the candidate, and acquiring consent to share information about an employee's work history. Employers and reference providers should consult with their institution's human-resources department and general counsel for more advice about these issues in the context of providing references.

2. **When considering a candidate for employment, the NSABB recommends that potential employers should attempt to seek one or more employment references from the prospective employee's current employer, including the current supervisor.**
   Such conversations with reference providers should be conducted even when the candidate is an internal one (i.e., when an individual is being hired into a different laboratory within the same university).

3. **The NSABB recommends that 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 only on a written statement of the qualifications, skills, and attributes of the employment candidate (i.e., letters of recommendation).**

4. **When considering a candidate for a position with access to BSAT, the NSABB recommends that potential employers explore aspects of the individual's prior work performance that directly relate to issues of reliability.**
   Such aspects include the individual's adherence to standard operating procedures, including biosafety and biosecurity procedures; his or her ability to work well in a group; the candidate's ability to interact well with peers and other institutional personnel; his or her adherence to institutional, departmental, and laboratory policies and procedures; any history of unapproved or unaccountable absenteeism; incidences or a history of exhibiting any concerning behaviors; and information about the employment candidate's previous registration, if any, with the Select Agent Program.

5. **When seriously considering a candidate for a position that involves access to BSAT, the NSABB recommends that employers go beyond verifying a candidate's education and/or degrees, licensure, previous positions and/or a positive SRA if available.**
   For example, when verifying credentials or checking public records, prospective employers should specifically probe whether there have been any instances of concerning behaviors in a candidate's work history, any legitimate concerns about reliability of the candidate, or any biosecurity issues related to the candidate.

6. **The NSABB recommends that local institutions conduct their own criminal background checks for employment candidates and employees who are granted access to BSAT in their facilities.**
   FBI approval of an SRA applicant does not negate the need for local personnel reliability measures and does not eliminate the need to vet applicants at the local level. For example, misdemeanor charges and convictions may not be detected by the SRA process but may be nonetheless very important for consideration.

7. **It is incumbent upon institutions conducting research on BSAT to communicate to incoming personnel the particular risks and responsibilities involved in undertaking BSAT research and to implement a process of attestation by personnel that each individual fully understands these risks and responsibilities.**
   The general conditions of employment and specific conditions for holding a particular position should make explicit mention of the institution's expectations regarding trust, integrity, and reliability, and should be communicated to all life sciences research personnel at the time of hire and thereafter on a regular basis (e.g., during a performance review or evaluation), and signed attestations should be included in the employee's file. As personnel accessing BSAT must undergo and maintain a positive SRA, the initial and annual attestation should include the exclusion categories covered in the SRA. In addition, the conditions of employment for personnel with access to BSAT should also provide notice that all information regarding the employee's reliability or suitability with respect to biosafety and biosecurity can be shared with potential employers during a reference check and with the SAP, if applicable.

8. **The NSABB recommends that institutions conducting life sciences research should implement an achievement- or goal-focused, documented, and periodic performance review process for all laboratory personnel.**
   Such a performance review process should also address the responsible conduct of research, including adherence to biosecurity policies and practices, and practices that contribute to a culture of responsibility. Performance evaluations of personnel working with BSAT should include, but not be limited to, a review of the individual's ability to work well in a team, follow instructions, adhere to standard operating procedures, take responsibility for work quality and safety, and respond appropriately to identified work-related weaknesses. The performance evaluations of personnel working with BSAT should also provide a forum for personnel to discuss biosecurity and personnel reliability issues.

9. **When considering a candidate for a position that involves access to BSAT, the NSABB recommends that laboratory leadership consider requesting copies of the employment candidate's performance evaluations with prior employers. Likewise, it is recommended that 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.**

10. **The NSABB recommends that institutional leadership 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.**

11. **Institutional leadership is recommended to communicate a commitment to provide individuals with the information 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.**

12. **The NSABB recommends that leadership at institutions conducting research with BSAT 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.**

13. **The NSABB recommends that all courses in research ethics and the responsible conduct of research incorporate topics or modules addressing the issues of biosecurity and the dual use implications of life sciences research.**
    Instruction on biosecurity and dual use research in undergraduate and graduate ethics courses should include discussion of the relationship between laboratory biosafety and biosecurity, the extant biosecurity regulations (e.g., the Select Agent Rules), the concept of dual use research and its application to the life sciences, the role of personal responsibility in maintaining a culture of trust and responsibility within the life sciences research endeavor, and potential resources to utilize for a further understanding of dual use research or biosecurity.

14. **The NSABB recommends that 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.**
    An institution's code of conduct should also be a "living" document or, in other words, continually discussed, developed, and improved upon in response to the concerns of the institutional community and developments in science, law, regulation and policies.

15. **The NSABB recommends that institutions conducting BSAT research implement programs or processes that enable the reporting of concerning behaviors in a respectful and responsible manner.**
    Reporting by peers, supervisors, or subordinates is enabled through the regular communication of an individual's responsibility to report concerning behavior; education and guidance on warning signs, the reporting process, and protections in place, etc.; and the provision of multiple routes to report concerns.

16. **The provision of an employee-initiated, temporary opt-out mechanism for personnel working with BSAT is a responsible practice recommended for implementation by all institutions undertaking BSAT research.**
    Plans and procedures, including those for maintaining confidentiality, should be put in place prior to implementing an employee-initiated, temporary opt-out program. Likewise, procedures for

resuming normal duties should be established early and communicated to all BSAT personnel. Instances of employee-initiated opting-out should be kept confidential to the extent permitted by institutional policies and the law.

17. **The NSABB recommends that research institutions 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.**
    Education and training offer opportunities to inform BSAT researchers and their supervisors about their roles and responsibilities regarding opt-out policies and to discuss the range of possible reasons that a researcher may decide to opt-out. Laboratory and institutional leadership also play a role in setting a tone that de-stigmatizes opting-out and emphasizes it as a responsible practice.

18. **The NSABB recommends that all institutions conducting BSAT research 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.**
    This assessment should be performed by an appropriately constituted review body and should include a biosafety review, a biosecurity review, and a consideration of the project's dual use potential.

NSABB Recommendations for Assessing the effectiveness of practices aimed at enhancing personnel reliability and the culture of responsibility

19. **The effectiveness, potential impact, and unintended consequences of any measures being implemented must be considered in light of the costs and burdens that they impose, particularly the burdens of unnecessary or duplicative policies that stifle scientific research.**

Summary of Findings Regarding Potentially Useful Practices

- Given the costs involved in implementation and storage and the impact of laboratory design and set-up on monitoring capability, the use of video cameras should not be mandated by federal regulation. Any implementation of video cameras in BSAT facilities should be based on a risk assessment by the local institution.

- While the two-person rule can be useful in situations that carry higher risk to the safety of personnel, the implementation of the practice can have significant impacts on workflow changes and time requirements needed to satisfy the rule, which may have the unintended consequence of increasing the safety risks of laboratory personnel. Therefore, the two-person rule should not be mandated federally and its use should be based upon a risk assessment by the local institution.

Appendices

APPENDIX A – NSABB ROSTER **47**
APPENDIX B - PANEL DISCUSSIONS ON EMPLOYMENT LAW AND HUMAN RESOURCE PRACTICES **51**
APPENDIX C - PANEL DISCUSSION ON INSTITUTIONAL BIOSAFETY COMMITTEES **55**
DISCUSSION QUESTIONS, FEBRUARY 1, 2011 55
APPENDIX D - BUILDING PERSONNEL RELIABILITY AT THE LOCAL LEVEL: A ROUNDTABLE ON ENHANCING THE CULTURE OF RESPONSIBILITY **57**
AGENDA, JULY 15, 2010 57
INVITED PARTICIPANTS 58
APPENDIX E – ROUNDTABLE ON PRACTICES FOR ENHANCING PERSONNEL RELIABILITY AND THE CULTURE OF RESPONSIBILITY IN HIGH CONTAINMENT LABS **59**
AGENDA WITH DISCUSSION QUESTIONS, SEPTEMBER 2, 2010 59
INVITED PARTICIPANTS 61
APPENDIX F – NSABB-CHINESE ACADEMY OF SCIENCES VIDEO TELECONFERENCE **63**
AGENDA WITH DISCUSSION QUESTIONS 63
APPENDIX G – NSABB PUBLIC CONSULTATION ON GUIDANCE FOR ENHANCING PERSONNEL RELIABILITY AND STRENGTHENING THE CULTURE OF RESPONSIBILITY AT THE LOCAL LEVEL **65**
AGENDA 65
SUMMARY HIGHLIGHTS 72
APPENDIX H - CONSIDERATIONS IN DEVELOPING A CODE OF CONDUCT FOR DUAL USE RESEARCH IN THE LIFE SCIENCES **81**

Appendix A – NSABB Roster

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

ROSTER

Acting Chair

Paul S. Keim, PhD[†]
Division Director, Pathogen Genomics
The Translational Genomics Research Institute
Cowden Endowed Chair in Microbiology
Northern Arizona University
Flagstaff, AZ

Other Voting Members

Kenneth I. Berns, MD, PhD
Director of Genetics Institute
University of Florida
Genetics Institute
Gainesville, FL

Arturo Casadevall, MD, PhD[‡]
Professor and Chairman
Dept. of Microbiology & Immunology
Division of Infectious Diseases
Albert Einstein College of Medicine
Bronx, NY

Murray L. Cohen, PhD, MPH, CIH[‡]
President and Chairman
Frontline Healthcare Worker's Safety Foundation, Ltd.
Atlanta, GA

Susan A. Ehrlich, JD, LLM (biotechnology & genomics)[‡]
Judge (ret.), Arizona Court of Appeals
Adjunct Professor, Department of Microbiology & Immunology, University of Texas Medical Branch – Galveston, Galveston National Laboratory

Lynn W. Enquist, PhD
Professor and Chair
Dept. of Molecular Biology
Princeton University;
Editor and Chief, Journal of Virology
Princeton, NJ

J. Patrick Fitch, PhD[‡]
Laboratory Director
National Biodefense Analysis and Countermeasures Center
President, Battelle National Biodefense Institute, LLC
Frederick, MD

David R. Franz, DVM, PhD
Vice President and Chief Biological Scientist
Midwest Research Institute;
Director, National Agricultural Biosecurity Center
Kansas State University
Frederick, MD

Claire M. Fraser-Liggett, PhD
Director, Institute of Genome Sciences
University of Maryland School of Medicine
Baltimore, MD

General John A. Gordon
General, USAF (Retired)
Alexandria, VA

Christine M. Grant, JD
CEO/Founder
InfecDetect Rapid Diagnostic Tests, LLC
Princeton, NJ

Michael J. Imperiale, PhD[‡]
Professor
Dept. of Microbiology and Immunology
University of Michigan Medical School
Ann Arbor, MI

[†] Co-Chair, Culture of Responsibility Working Group
[‡] Member, Culture of Responsibility Working Group

Joseph Kanabrocki, PhD, CBSP[‡]
Assistant Dean for Biosafety
Associate Professor of Microbiology
Biological Sciences Division
University of Chicago
Chicago, IL

Stanley M. Lemon, MD[†]
Professor of Medicine and Microbiology & Immunology
Division of Infectious Diseases, Department of Medicine
The University of North Carolina at Chapel Hill
Chapel Hill, NC

Stuart B. Levy, MD
Director
Center for Adaptation Genetics and Drug Resistance;
Professor of Medicine and Molecular Biology and Microbiology
Tufts University School of Medicine
Boston, MA

John R. Lumpkin, MD, MPH
Senior Vice President and Director of the Health Care Group
Robert Wood Johnson Foundation
Princeton, NJ

Jeffery F. Miller, PhD
Professor and Chair
Department of Microbiology, Immunology and Molecular Genetics
David Geffen School of Medicine
University of California – Los Angeles
Los Angeles, CA

Randall Murch, PhD[‡]
Associate Director
Research Program Development
Virginia Tech – Northern University
Alexandria, VA

Mark E. Nance, JD
General Counsel
Medical Diagnostics
GE Healthcare
Princeton, NJ

Michael T. Osterholm, PhD, MPH
Director, Center for Infectious Disease Research and Policy;
Associate Director, Dept. of Homeland Security National Center for Food Protection and Disease;
Professor, School of Public Health
University of Minnesota
Minneapolis, MN

David A. Relman, MD
Professor of Microbiology & Immunology and of Medicine
Stanford University School of Medicine
Stanford, CA

James A. Roth, D.V.M., Ph.D., D.A.C.V.M.
Director, Center for Food Security and Public Health
Executive Director, Institute for International Cooperation in Animal Biologics
College of Veterinary Medicine
Iowa State University
Ames, IA

Andrew Sorensen, PhD[‡, *]
Senior Vice President for Development
Special Assistant to the President for Advancement
President, The Ohio State University Foundation
The Ohio State University
Columbus, OH

Anne K. Vidaver, PhD
Professor Emeritus
Department of Plant Pathology
University of Nebraska-Lincoln
Lincoln, NE

[*] Deceased.

Federal Representatives

Jason Boehm, PhD[§]
Office of the Director
National Institute of Standards and Technology
Department of Commerce

Parag R. Chitnis, PhD[§]
Deputy Director
Division of Molecular and Cellular Biosciences
National Science Foundation

Susan Coller-Monarez, PhD[§]
Deputy Chief Medical and Science Officer
Science and Technology Directorate
Department of Homeland Security

Brenda A. Cuccherini, PhD, MPH[§]
Special Assistant to the Chief R&D Officer
Office of Research and Development
Veterans Health Administration
Department of Veterans Affairs

Amanda Dion-Schultz, PhD
Office of the Chief Scientist

Dennis M. Dixon, PhD[‡]
Branch Chief, Bacteriology and Mycology
Division of Microbiology and Infectious Disease
DHHS/NIH/NIAID

Anthony S. Fauci, MD[§]
Director
National Institute of Allergy and Infectious Disease
National Institutes of Health
Department of Health and Human Services

Denise Gangadharan, PhD[‡]
Acting Associate Director for Science
Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Atlanta, GA

Tom Hopkins, PhD[§]
Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Programs (Acting)
Department of Defense

Franca R. Jones, PhD[§]
LCDR, MS, USN
Senior Policy Analyst
Office of Science and Technology Policy
Executive Office of the President

Peter R. Jutro, PhD[§]
Deputy Director
National Homeland Security Research Center
Environmental Protection Agency

Lisa Kaplowitz, MD, MSHA[§]
Director, Office of Policy and Planning
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

Anne E. Kinsinger[§]
Associate Director for Biology
U.S. Geological Survey
Department of the Interior

Jane Knisely, PhD[‡]
Scientific Program Analyst
Bacteriology and Mycology Branch
Division of Microbiology and Infectious Disease
DHHS/NIH/NIAID

Laura Kwinn, PhD[‡]
Science Policy Advisor
Office of the Assistant Secretary for Preparedness and Response
DHHS/OPP/ASPR

Theresa Lawrence, PhD[‡]
Senior Science Officer
Office of the Assistant Secretary for Preparedness and Response
Office of Research and Development Coordination
DHHS/OPP/ASPR

David R. Liskowsky, PhD[§]
Director, Medical Policy & Ethics
Office of the Chief Health and Medical Officer
National Aeronautics & Space Administration

[§] NSABB Ex Officio Member

CDR Carmen Maher[§]
Acting Deputy Director
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
Department of Health and Human Services

Donald Malinowski, MS[‡]
Biological Specialist
Office of the Director of National Intelligence
National Counterproliferation Center
Global Biological Threats Directorate

Janet K. A. Nicholson, PhD[‡ §]
Associate Director for Laboratory Science
National Center for Infectious Diseases
Center for Disease Control and Prevention
Atlanta, GA

Chris Park, PhD[§]
Bureau of International Security and Nonproliferation
Office of Chemical and Biological Weapons Threat Reduction
U.S. Department of State

Jessica Petrillo, PhD[‡]
Scientific Advisor
Biological Policy Staff
Bureau of International Security and Nonproliferation
U.S. Department of State

Caird E. Rexroad, Jr., PhD[§]
Associate Administrator
Agricultural Research Service
U.S. Department of Agriculture

David G. Thomassen, PhD
Chief Scientist
Office of Biological & Environmental Research
Office of Science
Department of Energy

Edward H. You[‡§]
Supervisory Special Agent
FBI Weapons of Mass Destruction Directorate
Countermeasures Unit
Bioterrorism Team
Federal Bureau of Investigation

NSABB Executive Director

Paul Lewis, PhD
Office of Biotechnology Activities
Office of Science Policy
Office of the Director

Culture of Responsibility Working Group Staff

Allison Hodges Mistry, MS, MA
Health Science Policy Analyst
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health

Erin Luetkemeier, PhD
AAAS Science and Technology Policy Fellow
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health

Mary Groesch, PhD
Senior Policy Analyst
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health

F. Daniel (Dan) Davis, PhD
Senior Advisor for Bioethics and Policy
Office of Biotechnology Activities
Office of Science Policy, Office of the Director
National Institutes of Health

NSABB Working Group on the Culture of Responsibility

November 12, 2010 Teleconference on legal and HR considerations for strengthening hiring and employment practices.

Invited Panelists:

Paige Carness, Regulatory Specialist, Galveston National Laboratory, University of Texas Medical Branch, Galveston, TX

Marc Coleman, JD, Law Offices of Marc Coleman, Long Beach, CA.

Leslie Platt, JD, Leslie Platt & Associates, LLC, Washington, DC

Stephanie Quincy, JD, Steptoe & Johnson LLC, Phoenix, AZ

Discussion Questions,

Main Issue	Related questions
1. Fear of liability resulting from passing on derogatory information to a potential employer	a. Is the fear of administrative proceedings, e.g., Equal Employment Opportunity Commission (EEOC), or/and a lawsuit for passing on derogatory information to a potential employer well-founded?
	b. What are the potential liabilities of passing on accurate and derogatory information?
	c. What are the potential liabilities of passing on false information? Does it matter if the information, although false, had a good-faith basis?
	d. What types of derogatory or negative information can and cannot be passed on to a potential employer? Are there exceptions to certain types of information?
	e. What options or resources should be available to an employer who has questions or concerns about providing a referral to a potential employer?
	f. What are the potential consequences and liabilities of not providing a full and accurate account or otherwise misrepresenting an employee's past performance? Is there an affirmative duty to disclose information about an employee's past performance?
	g. What roles should an institution's human resources office and general counsel play?
	h. What alternatives exist for providing truthful and accurate accounts of an employee's past performance to a potential employer?

2. Employer's rights and responsibilities with regard to an employee opting-out of SA research	a. What legal implications should an employer consider in implementing a program for an employee to "opt-out" of Select Agent research?
	b. What options and/or resources should be available to an employer who has questions or concerns about the enacted or perceived stigma that an opting-out employee may experience?
	c. What roles should an institution's human resources office and general counsel play in implementing an opt-out program?
	d. Do the legal implications change based on whether the "opt-out" is temporary or permanent?
3. Employee's rights and responsibilities with regard to opting-out of SA research	a. What kind of information should an employee have when considering whether to "opt-out" of research? For example, should he or she be entitled to an expectation that the reasons for opting out will be kept confidential? Under what circumstances?
	b. What options and/or resources should be available to an employee who has questions or concerns about any stigma that the employee may experience?
4. Employer's rights and responsibilities in peer-reporting systems	a. What legal implications should an employer consider in implementing a peer-reporting program?
	b. What options and/or resources should be available to an employer who has questions or concerns about a report of concerning behavior?
	c. What are the best ways to prevent abuse of a peer-reporting system?
	d. What role should an institution's human resources office and/or general counsel play in implementing a peer-reporting program?
5. Employee's rights and responsibilities in peer-reporting systems	a. What kind of information and education should employees have when the employer implements a peer-reporting system?
	b. What options and/or resources should be available to an employee who has questions or concerns about concerning behavior (short of officially reporting it)?
	c. What are the best ways to protect the rights of a person who is reporting the concerning behavior of a colleague?
	d. What are the best ways to protect the rights of the subject of a report?
6. Employer's and employee's rights and responsibilities in systems for reporting concerns about supervisors and other superiors.	a. What kind of information and education should employees have when the employer implements a system for reporting concerns about supervisors or other superiors?
	b. What options and/or resources should be available to an employee who has questions or concerns about concerning behavior (short of officially reporting it)?
	c. What are the best ways to protect the rights of a person who is reporting the concerning behavior of a supervisor or other superior?
	d. What are the best ways to protect the rights of the subject of a report?

December 13, 2010 Teleconference on legal and HR considerations for strengthening hiring and employment practices.

Invited Panelists:

David P. Fidler, JD, James Louis Calamaras Professor of Law, Indiana University Maurer School of Law

Donald L. Letizia, JD, Associate General Counsel, Batelle Memorial Institute

James C. Manuel, JD, Associate General Counsel, Batelle Memorial Institute

Katherine A. Rojo Del Busto, JD, Executive Vice President for Administration and Legal Affairs/Chief of Staff, Division of Research and Graduate Studies, Texas A&M University

Daniel P. Westman, JD, Morrison & Foerster LLP

Discussion Questions,

Main Issue	Related questions
1. Fear of liability resulting from passing on derogatory information to a potential employer.	a. Is the fear of administrative proceedings, e.g., Equal Employment Opportunity Commission (EEOC), or/and a lawsuit for passing on derogatory information to a potential employer well-founded?
	b. What are the potential liabilities of passing on accurate and derogatory information?
	c. What are the potential liabilities of passing on false information? Does it matter if the information, although false, had a good-faith basis?
	d. What types of derogatory or negative information can and cannot be passed on to a potential employer? Are there exceptions to certain types of information?
	e. What options or resources should be available to an employer who has questions or concerns about providing a referral to a potential employer?
	f. What are the potential consequences and liabilities of not providing a full and accurate account or otherwise misrepresenting an employee's past performance? Is there an affirmative duty to disclose information about an employee's past performance?
	g. What roles should an institution's human resources office and general counsel play?
	h. What alternatives exist for providing truthful and accurate accounts of an employee's past performance to a potential employer?
	i. What are some potential solutions (e.g., regulatory tools or legislative actions) that could alleviate concerns about providing information about an employee's performance?

2. Employer's rights and responsibilities with regard to an employee opting-out of Select Agent (SA) research.	a. What legal implications should an employer consider in implementing a program for an employee to "opt-out" of Select Agent research?
	b. What options and/or resources should be available to an employer who has questions or concerns about the enacted or perceived stigma that an opting-out employee may experience?
	c. What roles should an institution's human resources office and general counsel play in implementing an opt-out program?
	d. Do the legal implications change based on whether the "opt-out" is temporary or permanent?
3. Employee's rights and responsibilities with regard to opting-out of SA research.	a. What kind of information should an employee have when considering whether to "opt-out" of research? For example, should he or she be entitled to an expectation that the reasons for opting out will be kept confidential? Under what circumstances?
	b. What options and/or resources should be available to an employee who has questions or concerns about any stigma that the employee may experience?
4. Employer's rights and responsibilities in peer-reporting systems.	a. What legal implications should an employer consider in implementing a peer-reporting program?
	b. What options and/or resources should be available to an employer who has questions or concerns about a report of concerning behavior?
	c. What are the best ways to prevent abuse of a peer-reporting system?
	d. What role should an institution's human resources office and/or general counsel play in implementing a peer-reporting program?
5. Employee's rights and responsibilities in peer-reporting systems.	a. What kind of information and education should employees have when the employer implements a peer-reporting system?
	b. What options and/or resources should be available to an employee who has questions or concerns about concerning behavior (short of officially reporting it)?
	c. What are the best ways to protect the rights of a person who is reporting the concerning behavior of a colleague?
	d. What are the best ways to protect the rights of the subject of a report?
6. Employer's and employee's rights and responsibilities in systems for reporting concerns about supervisors and other superiors.	a. What kind of information and education should employees have when the employer implements a system for reporting concerns about supervisors or other superiors?
	b. What options and/or resources should be available to an employee who has questions or concerns about concerning behavior (short of officially reporting it)?
	c. What are the best ways to protect the rights of a person who is reporting the concerning behavior of a supervisor or other superior?
	d. What are the best ways to protect the rights of the subject of a report?

Appendix C - Panel discussion on Institutional Biosafety Committees

Discussion Questions, February 1, 2011

NSABB WORKING GROUP ON THE CULTURE OF RESPONSIBILITY

February 1, 2011 TELECONFERENCE

Invited Discussants

Scott Weaver, PhD, John Sealy Distinguished University Chair in Human Infections and Immunity, Director, Institute for Human Infections and Immunity, UniversityUniversity of Texas Medical Branch -- Galveston

Stanley Maloy, PhD, Professor and Dean of the College of Sciences, San Diego State University

Brenda Wong, Biosafety Manager, Department of Environment Health and Safety, University of California, San Diego

Sue Gotta, Vice Chair, IBC, Biological Safety Officer, Environmental Health & Safety, Thomas Jefferson University

Discussion Questions

- Does your institution have an IBC and if so, what types of research does it review (e.g., recombinant DNA, select agent, all pathogens) and for what purpose (e.g. biosafety, biosecurity, dual use research)?
- If your IBC does not review all research involving infectious agents, what additional burden would it impose on the committee to do so?
- Do you utilize any non-IBC committees (besides IRBs and IACUCs) to review biomedical research, and if so, for what purpose and is there public representation on these committees?

Appendix D - Building Personnel Reliability at the Local Level: A Roundtable on Enhancing the Culture of Responsibility

Agenda, July 15, 2010

NSABB Culture of Responsibility Working Group

Building Personnel Reliability at the Local Level: A Roundtable on Enhancing the Culture of Responsibility

National Institutes of Health
Bethesda, MD
Building 1, Wilson Hall

Thursday, July 15, 2010
8:30 am - 3:00 pm

Agenda

8:30 am **Opening Remarks and Introductions**
Stanley Lemon, CRWG Co-Chair
NSABB Member and Professor, School of Medicine, University of North Carolina, Chapel Hill

8:45 am **Overview of findings and recommendations relevant to enhancing the culture of responsibility**
Mary Groesch, NIH Office of Biotechnology Activities

- NSABB, *Enhancing Personnel Reliability among Individuals with Access to Select Agents (May 2009)*
- Executive Order 13486 WG, *Report of the Working Group on Strengthening the Biosecurity of the United States* (January 2010)
- NRC, *Responsible Research with Biological Select Agents and Toxins* (2009)
- AAAS, AAU, and APLU, *Competing Responsibilities?: Addressing the Security Risks of Biological Research in Academia* (January 2010)

9:05 am **Discussion**
Stanley Lemon
Discussion Questions:

- Is what the NSABB proposed in terms of ways to enhance the culture of responsibility among individuals with access to select agents on the right track?
- What other practices could be administered at the local level to help promote the culture of responsibility?
- In what ways does your institution (or other institutions you are familiar with) promote a culture of responsibility? Any “lessons learned” that you can share?
- How can institutional leadership convey a commitment to biosecurity? Who should be the leaders in this regard?
- How can we promote strong leadership (in terms of culture of responsibility) at the laboratory level?
- Does your institution require self- and/or peer-reporting (i.e., reporting concerning

behavior in others or indicating a need to temporarily opt-out of sensitive work) What are the major challenges that you foresee in instituting a policy of peer- and self-reporting?

- How to foster acceptance for what may be new responsibility in many sectors of the life sciences research community?
- Is it possible to develop metrics that could be used to evaluate the effectiveness and impacts of practices aimed at enhancing the culture or responsibility?

10:00 am Break

10:20 am Continued Discussion

12:15 pm Lunch with invited guests or working lunch with CRWG members

1:15 pm Invited guests depart

Invited Participants

Nathan Andersen, JD, LLM
Attorney & Interim Public Information Officer
Department of Legal Affairs
The University of Texas Medical Branch -- Galveston

Cynthia Baldwin, PhD
Jefferson Science Fellow
Senior Advisor for Int'l Res Cooperation
USAID
Washington, DC

Heinz Feldmann, MD, PhD
Chief, Laboratory of Virology
Rocky Mountain Laboratories
Hamilton, MT

Leah Gillis, MS, PhD, HCLD (ABB)
Laboratory Director - Miami
Florida Department of Health, Bureau of Laboratories
Miami, FL

Todd Harrington, JD
General Counsel and Secretary
Battelle National Biodefense Institute

Julie Lovchik, PhD
Research Assistant Professor
University of New Mexico
Health Sciences Center
Albuquerque, NM

Steven Luperchio, PhD
Senior Manager, Corporate Development
Cubist Pharmaceuticals
Lexington, MA

Susan S. Straley, PhD
Professor, Microbiology, Immunology & Molecular Genetics
University of Kentucky College of Medicine
Lexington, KY

Appendix E – Roundtable on Practices for Enhancing Personnel Reliability and the Culture of Responsibility in High Containment Labs

Agenda with Discussion Questions, September 2, 2010

Practices for Enhancing Personnel Reliability and Culture of Responsibility in High Containment Labs

Bethesda North Conference Center
Bethesda, MD

September 2, 2010

Agenda

8:00 am **Welcome and Remarks**
WG Co-chairs

8:10 am **Roundtable Discussion Session I**
Moderators: *Susan Ehrlich, JD, LL.M.*
Andrew Sorenson, MPH, PhD

Discussion Questions:

Hiring Practices

- What are your hiring practices for individuals with access to biological select agents and toxins (BSAT)?
  - Do you rely on letters of reference or are you also able to personally follow-up with previous employers and other relevant institutional personnel (e.g., institutional biosafety committee staff)?
  - Do you check publically-available records on scientific misconduct, debarment, state licensure, etc.?
  - Do your hiring practices differ if select agent access is not involved?
- How do you determine if someone is sufficiently reliable to have access to BSAT?

Self Reporting

- Does your institution require those with access to BSATs to report any problem or condition that could affect their ability to work with BSATs safely and securely? If so, what has been your experience with this practice? What have been the challenges, lessons learned?
  - How do you train or instruct new hires and current employees on issues that should be reported (e.g., stress, illness, use of medications), the responsibilities to report, and what protections are in place?
  - Does there seem to be any stigma regarding such self-reporting?
  - How are confidentiality and privacy maintained by supervisors in instances of self-reporting and possible opting-out of BSAT work?

10:10 am **Break**

10:30 am **Panel Discussion Session II**

Moderators: *Joseph Kanabrocki, PhD*
J. Patrick Fitch, PhD

Discussion Questions:

Peer Reporting of Concerning Behavior

- Does your institution require those with access to select agents to report concerning behaviors? If so, what has been your institution's experience with this practice? What have been the challenges, lessons learned?
  - How do you train or instruct new hires and current employees on issues that should be reported (e.g., unusual behavior or actions), the responsibilities to report, and what protections are in place for the reporter and the subject of the report?
  - How do you address the issue of reporting concerning behavior by an individual more senior than the observer/reporter?
  - How do you guard against frivolous or retaliatory reporting?
  - To what extent and by what procedures id confidentiality and privacy maintained? How do you make the limits of privacy and confidentiality?
  - How do you dispel the notion that peer-reporting is "snitching" about one's colleagues or constitutes an otherwise inappropriate or negative activity?

Monitoring of Individuals with Access to BSATs

- Does your institution in any way monitor individuals with access to BSATs? This includes physical monitoring (e.g., video monitoring, the 'two person rule') as well as personal monitoring or screening (e.g., physical health, mental health, drug/alcohol testing, financial status, criminal status).
  - What has been your experience with any of these monitoring techniques? What have been the challenges, lessons learned?

Management and Leadership

- Do you consider or address issues related to security or personnel reliability in performance evaluations of individuals with access to BSATs?
- Does your institution have a process in place for temporarily or permanently rescinding an individual's access to select agents? If so, what is reported and to whom? What have been the challenges and lessons learned?
- What practices do you have in place to build and maintain a strong sense of team and strong working relationships within your laboratory? What is the best way for PIs and ROs to engage with and stay attuned to lab personnel?
- What do you think are the most effective ways to instill or enhance a culture of responsibility with respect to biosecurity?

National Toolbox

- What should be the components of a "national toolbox" for enhancing personnel reliability and the culture of responsibility with respect to biosecurity?

12:15 pm **Lunch with invited guests and CRWG members**

John Belisle, PhD
Director, Rocky Mountain Regional Center of Excellence

Gerald Byrne, PhD
Director, Regional Biocontainment Laboratory, University of Tennessee Health Science Center

Samuel C. Cartner, DVM, PhD
Director, Animal Resources Program, University of Alabama at Birmingham

Kelly Stefano Cole, PhD
Associate Director, Pittsburgh Regional Biocontainment Lab, University of Pittsburg Center for Vaccine Research

Deborah Kochvar, DVM, PhD
Dean and Henry and Lois Foster Professor, Cummings School of Veterinary Medicine, Tufts University

Olaf Schneewind, MD, PhD
Director, Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, University of Chicago

Fred Sparling, MD
Director, Southeast Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, University of North Carolina, Chapel Hill

Laura Via, PhD
Staff Scientist, Tuberculosis Research Section NIH/NIAID

Appendix F – NSABB-Chinese Academy of Sciences Video Teleconference

Agenda with Discussion Questions

Strengthening the culture of responsibility with respect to dual use research and biosecurity[†]

November 1st 2010

Agenda

7:30 PM **Welcome and introductions**
NIH: Dr. Amy Patterson and CAS (Chinese Academy of Sciences): Dr. Li Huang

7:40 PM **Principal features or attributes of a culture of responsibility and strategies for promoting, creating, and sustaining a culture of responsibility**
Remarks to stimulate responses to questions and discussion:
Dr. Paul Keim

7:50 PM **Questions for conference participants**[‡]
Co-moderators: NSABB: Dr. David Franz, CAS: Dr. Li Huang

1. The NSABB has been tasked with developing guidance on how to enhance the culture of responsibility with regard to biosecurity concerns in general and in high containment laboratories. What are the attributes of a strong culture of responsibility in this regard?
2. What are some of the ways that principal investigators/laboratory leaders can strengthen a culture of responsibility regarding biosecurity?
3. How can the senior leaders of research institutions help foster a culture of responsibility regarding biosecurity?
4. What are effective ways to educate scientists about the importance of biosecurity? For example, should it be tied in with education about biosafety?
5. Do you think codes of conduct are a useful tool for strengthening the culture of responsibility and raising awareness about dual use research and biosecurity issues? What is the best way to encourage acceptance of and adherence to a code of conduct in a research organization?

8:25 PM **Closing remarks**
NIH: Dr. Amy Patterson and CAS: Dr. Li Huang

8:30 PM **Adjourn**

[†] Satellite session of the workshop entitled Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention held in Beijing, China, October 31-November 3, 2010, in cooperation with the InterAcademy Panel, the Global Network of Science Academies, the International Union of Microbiological Societies, the International Union of Biochemistry and Molecular Biology, the Chinese Academy of Sciences , and the National Research Council of the U.S. National Academy of Sciences.
[‡] Moderators: David Franz, DVM, PhD. (NSABB) and Li Huang, PhD (CAS). Panelists: Amy Patterson, MD (NIH) and NSABB members Susan A. Ehrlich, JD, LL.M., Paul Keim, PhD, and Stuart Levy, MD.

Appendix G – NSABB Public Consultation on Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility at the Local Level

Agenda

NSABB Public Consultation on Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility at the Local Level

January 5, 2011
8:30 am-6:00 pm

Hyatt Regency Bethesda
Bethesda, Maryland

8:30 am **Welcome and opening remarks**

Stanley Lemon, M.D.
NSABB Member and Professor, Department of Medicine, University of North Carolina at Chapel Hill

8:45 am **Panel I – Engaged institutional leadership: Promoting biosecurity, personnel reliability, and a culture of responsibility**

Moderators:
Joseph Kanabrocki, Ph.D., C.B.S.P.
NSABB Member and Assistant Dean for Biosafety and Associate Professor of Microbiology, University of Chicago

Stanley Lemon, M.D.

Background: During the NSABB's deliberations and consultations, the concept of engaged institutional leadership was noted repeatedly as being critically important to ensuring personnel reliability. The concept of leadership that values security; fosters a sense of vigilance and responsibility among personnel; and encourages teamwork, camaraderie, and close personal working relationships was mentioned consistently as one of the most effective and feasible ways to enhance personnel reliability. Indeed, it was suggested that engaged leadership and teamwork may be more effective than the formal assessments conducted under some comprehensive personnel reliability programs. One suggestion has been that there should be "institutional champions" for promoting biosecurity, personnel reliability, and a culture of responsibility. This panel will explore best practices in these regards.

Discussion Questions: (for panelists and then plenary discussion)
- What are specific ways that institutional leaders can convey their commitment to these concepts and foster "buy-in" by all employees at all levels?

- Who should be the institutional champions of biosecurity, personnel reliability, and culture of responsibility?
- Are there specific ways to incentivize laboratory leadership to promote a culture of responsibility among lab personnel?
- Are there any lessons to be learned from other arenas? For example, does your institution have "institutional champions" in other areas? What role do they play and what strategies do they utilize?

Panelists

- Institutional leadership perspective
  Richard Marchase, Ph.D.
  Vice President for Research and Economic Development
  University of Alabama at Birmingham

  Stanley Maloy, Ph.D.
  Professor and Dean, College of Sciences
  San Diego State University

- Investigator perspective
  Ronald Atlas, Ph.D.
  Professor of Art and Sciences Biology
  University of Louisville

- Biosafety professional perspective
  Bruce Whitney, Ph.D.
  Associate Vice President for Research Compliance, Responsible Official, and Biological Safety Officer, Texas A&M University

9:15 am **Discussion of Panel I questions (open to all attendees)**

10:15 am **Break**

10:30 am **Panel II - Encouraging biosecurity awareness and promoting responsible conduct in the laboratory through communication, lab rapport, and a strong**

Moderators:
Murray Cohen, Ph.D., M.P.H., C.I.H.
NSABB Member and President & Chair, Frontline Healthcare Workers® Safety Foundation, Ltd.

Janet Nicholson, Ph.D.
NSABB Member ex officio and Senior Advisor for Laboratory Science, Office of Infectious Diseases, Centers for Disease Control and Prevention

Background: The NSABB has heard previously from the scientific community that one way to enhance the culture of responsibility is by building a strong sense of team within laboratories that work with select agents and toxins. Responsible Officials (ROs) and principal investigators (PIs) play a critically important role in setting an appropriate tone regarding biosecurity and personnel reliability and in creating an environment that is conducive to communication. These leaders should work to build and foster strong working relationships with lab staff. This will not only help to build a sense of

trust and responsibility that will foster peer-reporting, but it will also help the RO and PI in being able to recognize concerning behavioral changes that may presage a reliability or biosecurity problem. The importance of ROs and PIs being engaged in the work that is conducted and attuned to personnel was a recurring theme in NSABB discussions as being one of the most effective personnel reliability measures. This panel will focus on strategies for encouraging biosecurity awareness and promoting responsible conduct among laboratory personnel by enhancing communication and building strong lab rapport and sense of team.

Discussion questions: (for panelists and then plenary discussion)

- What practices will help lab leaders to foster: vigilance regarding personnel reliability and biosecurity among their lab staff; understanding that such vigilance is the responsibility of all personnel; and an environment in which personnel are comfortable in reporting concerns?
- How can lab leaders build and foster strong working relationships with and among lab personnel?
- How can lab leaders convey the importance of and their commitment to biosecurity and personnel reliability?
- What are strategies for making the consideration of biosecurity, dual use research, and responsible conduct of research a routine part of daily life in the lab?

Panelists

- Investigator perspective
  Jean Patterson, Ph.D.
  Chair, Department of Virology and Immunology
  Southwest Foundation for Biomedical Research

  Theresa Koehler, Ph.D.
  Microbiology and Molecular Genetics, Herbert L. and Margaret W. DuPont Professorship in Biomedical Science
  University of Texas Health Science Center at Houston

  Kelly Stefano Cole, Ph.D.
  Associate Director, Regional Biocontainment Laboratory
  Associate Professor, Department of Immunology
  University of Pittsburgh

- Postdoctoral research perspective
  Jenni Weeks, Ph.D.
  St. Jude Children's Research Hospital

- Biosafety Professional/Responsible Official perspective
  William Mellon, Ph.D.
  Professor of Pharmaceutical Sciences and Associate Dean for Research Policy
  University of Wisconsin

  Deborah Wilson, Dr.P.H, C.B.S.P.
  Director, Division of Occupational Health and Safety
  National Institutes of Health

11:00 am **Discussion of Panel II topics (open to all attendees)**

12:00 am **Lunch**

1:00 pm **Panel III - Peer reporting of concerning behaviors**

Moderators:
Michael Imperiale, Ph.D.
NSABB Member and Professor, Department of Microbiology and Immunology
University of Michigan Medical School

Dennis Dixon, Ph.D.
NSABB ex officio designee and Chief, Bacteriology and Mycology Branch
National Institute of Allergy and Infectious Disease, National Institutes of Health

Background: All individuals in a research environment that includes pathogens should be aware of surrounding activities and understand that it is their individual and collective responsibility to report if a colleague appears to be behaving in ways that are inappropriate for work with pathogens. This awareness and understanding is important to maintaining a culture of research responsibility and should be used to encourage peer-reporting in good faith. It will be important to dispel any notion that peer-reporting is "snitching" about one's colleagues or constitutes an otherwise inappropriate or negative activity. This can and should be addressed through training of personnel about their responsibilities in this regard, what should be reported and to whom, and what protections are in place for the reporter and the subject of the report. There should be procedures and policies in place that protect against frivolous or retaliatory reporting, maintain confidentiality and privacy to the extent possible, protect against retaliation, and address reporting on more senior scientists or supervisors. This panel will discuss relevant concerning behaviors and practices for reporting and addressing them.

Discussion questions: (for panelists and then plenary discussion)

- What types of behaviors or behavioral changes should raise red flags in terms of reliability or biosecurity?
- To whom should concerns be reported?
- What protections should be in place for the reporter? For the subject of the report?
- How can frivolous or retaliatory reporting be discouraged?
- How and to what extent can privacy and confidentiality be maintained?
- How can institutions dispel any stigma associated with reporting concerning behaviors?
- What legal implications should an employer consider in implementing a peer-reporting program?
- What are the best ways to protect the rights of a person who is reporting the concerning behavior of a supervisor or other superior?

Panelists:

- Biosafety professional/ Responsible Official perspective
  William Gaylord, III
  Director, R&D Environmental Health and Safety and Responsible Official
  Allergan Sales, LLC

  Paul Kimsey, Ph.D.
  Deputy Director and Responsible Official
  California State Public Health Laboratory

- Investigator perspective
  Theodora Ross, M.D., Ph.D.
  Comprehensive Cancer Center Hematology
  University of Michigan

  Thomas Pistole, Ph.D.
  Professor of Microbiology
  University of New Hampshire

- Postdoctoral researcher perspective
  Jenni Weeks, Ph.D.
  St. Jude Children's Research Hospital

- Legal perspective
  Stephanie Quincy, J.D.
  Steptoe & Johnson LLC, Phoenix, AZ

1:30 pm **Discussion of Panel III questions (open to all attendees)**

2:30 pm **Break**

2:45 pm **Panel IV – Addressing impediments to disclosure of negative information about job candidates**

Moderators:
J. Patrick Fitch, Ph.D.
NSABB Member and Director, National Biodefense Analysis and Countermeasures Center
President, Battelle National Biodefense Institute, LLC

Susan Ehrlich, J.D., LL.M.
NSABB Member and Judge (Retired), Arizona Court of Appeals

Background: In previous discussions regarding personnel reliability, the NSABB heard anecdotes indicating that the fear of being sued is a barrier to providing potential employers with a full and candid review of an employee's past performance. This panel will discuss this issue and strategies for addressing it.

Discussion questions: (for panelists and then plenary discussion)

- What are the potential liabilities of passing on accurate but derogatory information?
- What types of derogatory or negative information can and cannot be passed on to a potential employer? Are there exceptions to certain types of information?
- What are the potential consequences and liabilities of not providing a full and accurate account of an employee's past performance? Is there an affirmative duty to disclose information about an employee's past performance?
- What are some strategies to alleviate the general reluctance to provide candid references due to fear of a lawsuit?

Panelists:

- Human Resources perspective
  Karen Silverberg
  Assoc. Dean, Appointments, Promotions and Tenure
  Duke University School of Medicine

- Legal perspective
  Stephanie Quincy, J.D.
  Steptoe & Johnson LLC, Phoenix, AZ

- Investigator perspective
  Samuel Miller, M.D.
  Professor of Medicine and Microbiology
  Principle Investigator, Northwest Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research, University of Washington

  Olaf Schneewind, M.D., Ph.D.
  Director, Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Diseases, University of Chicago

3:30 pm **Discussion of Panel IV topics (open to all attendees)**

4:30 pm

Panel V- Assessment of effectiveness and impact of practices for strengthening personnel reliability and a culture of responsibility

Moderators:
Randall Murch, Ph.D.
NSABB Member and Associate Director, Research Program Development
Virginia Tech – Northern University

Laura Kwinn, Ph.D.
NSABB ex officio designee and Science Policy Advisor, Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services

Background: The goal of implementing personnel reliability measures is to enhance security and safeguard public trust. Because of the impact these measures can have on day-to-day research, it is important to assess the effectiveness and impact of any

measure being implemented. Although important, assessing the effectiveness and impact of these measures is challenging because gauging "success," e.g., prevention of an insider threat, may be impossible. This panel aims to identify strategies, methods, and possible metrics for determining the effectiveness of measures aimed at enhancing personnel reliability at the local level.

Discussion questions: (for panelists and then plenary discussion)

- How can we evaluate the effectiveness and impacts of practices aimed at enhancing personnel reliability and the culture of responsibility?
- Are there lessons learned from other arenas that have had similar challenges?

Panelists:

- Evaluation expert perspective
  Susan Cozzens, Ph.D.
  Associate Dean for Research Ivan Allen College
  Georgia Tech

- Scientific Community Perspective
  Mark Frankel, Ph.D.
  Director, Scientific Freedom, Responsibility and Law Program
  American Association for the Advancement of Science

- Biosafety professional perspective
  Janet Peterson, RBP, CBSP
  Biosafety Officer and Assistant Director, Department of Environmental Safety
  University of Maryland

5:15 pm **Discussion of Panel V topics (open to all attendees)**

6:00 pm **Concluding remarks, meeting adjournment**

Summary Highlights

Public Consultation Meeting on Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility at the Local Level

Overview

In light of heightened concerns about insider threats at facilities that conduct research with highly pathogenic agents, the NSABB was tasked with advising on ways to enhance personnel reliability among individuals with access to select agents. In its 2009 report, the NSABB recommended a number of ways to strengthen personnel reliability, including by enhancing the culture of responsibility that currently exists within the scientific community, particularly with respect to biosecurity and dual use research. The US Government subsequently asked the NSABB to expand on its general recommendations in this regard and to develop specific guidance that reflects broad input from the scientific community. Toward this end, the NSABB convened a public consultation on practices for enhancing personnel reliability and strengthening the culture of responsibility at the local level on January 5th 2011 in Bethesda, Maryland.

Approximately 200 individuals attended the public consultation, bringing perspectives of academia, professional societies, non-governmental organizations, and federal and local government. The meeting was structured around five discussion panels: 1) Engaged institutional leadership for promoting biosecurity, personnel reliability, and a culture of responsibility; 2) Encouraging biosecurity awareness and promoting responsible conduct in the laboratory through communication, lab rapport, and a strong sense of team; 3) Peer reporting of concerning behaviors; 4) Addressing impediments to disclosure of negative information about job candidates; and 5) Assessment of effectiveness and impact of practices for strengthening personnel reliability and culture of responsibility. Each session included ample time for input from meeting attendees.

More information, including slides of panelist presentations and a link to the videocast of the meeting can be found at oba.od.nih.gov/biosecurity/nsabb_past_meetings.html#jan2011.

The following sections are organized by panel and discussion questions with both panelist and audience comments displayed without attribution. Comments displayed are those that summarized the general discussion.

Panel I – Engaged institutional leadership: Promoting biosecurity, personnel reliability, and a culture of responsibility

- **What are specific ways that institutional leaders can convey their commitment to these concepts and foster "buy-in" by all employees at all levels?**
  - Culture of trust starts at the top. Need to clarify expectations, empower individuals with tools to make the right decisions, demand accountability for decisions, have visible champions among upper leadership that foster pride in performing biosecurity research, and provide resources for attending seminars and security enhancement training.
  - PIs already feel burdened by biosecurity requirements; to ensure that the need for biosecurity requirements are not so burdensome that they cause talented investigators to leave the field. If there are too many requirements, PIs are likely to lose the sense of urgency about them.

- IBCs need to be empowered, be more visible. If IBC service were seen as an honor--that those selected are among the best-- it would send a commendable message and raise the profile of IBCs. IBC members also need to be appropriately trained. Who will provide the resources (funding) for this when institutional resources are already limited? The best way to show commitment is to provide money – this shows seriousness.
- Incorporate compliance issues into responsible conduct of research/ethics programs and thereby reach every graduate student in the institution. This instills a culture of responsibility, which will be passed on as these students move on to different labs/institutions.
- Be committed to communicating expectations on an ongoing basis, not only because no one wants to get in trouble, but also because good science and good safety is the right thing to do. First requirement for the culture of responsibility is trust across the board. Must also have a just culture – that is handling things appropriately. If you have "trust and just," then you can have a reporting culture which is seen not as something bad but rather as something that improves the system.
- Lead by example, continually seek improvement in methods, keep people informed, consider the input of others because this builds teamwork, be open to a range of opinions (there is not necessarily just one right way) and acknowledge others' contributions.

- **Who should be the institutional champions of biosecurity, personnel reliability, and culture of responsibility?**
  - Institutional biosecurity champions are key components of a culture of responsibility.
    - They need credibility and visibility to be effective.
    - Scientific expertise can be a source of "common ground."
    - Need to be able to influence others.
    - Need to be known and visible to their constituency.
  - Institutional champions should include the CEO, the PI because they are a peer leader for the culture of responsibility in the lab, and the RO and Biosafety Officer. They should collaborate closely with IBC members.

- **Are there specific ways to incentivize laboratory leadership to promote a culture of responsibility among lab personnel?**
  - Formally recognize the role of the lab leader in biosecurity awareness among lab personnel and either make them part of the job description or propose for a separate individual to maintain these tasks.
  - The challenge is to maintain a culture of responsibility after the lab is built and research ensues.

- **Are there any lessons to be learned from other arenas? For example, does your institution have "institutional champions" in other areas? What role do they play and what strategies do they utilize?**
  - Challenges that are critical to biosecurity parallel other university activities such as with:
    - Responsible conduct of research, which is heavily dependent on peer observation and reporting and inquiries are often triggered by students or subordinate staff as is seen with biosecurity issues;
    - Security surrounding the use of research animals;
    - Prevention of workplace violence and abuse, which requires vigilance by university staff.

- Tap into professional societies to reinforce investigator responsibility. Build a network of organizations and individuals that reinforces this culture of responsibility.

Panel II - Encouraging biosecurity awareness and promoting responsible conduct in the laboratory through communication, lab rapport, and a strong sense of team

- **What practices will help lab leaders to foster: vigilance regarding personnel reliability and biosecurity among their lab staff; understanding that such vigilance is the responsibility of all personnel; and an environment in which personnel are comfortable in reporting concerns?**
  - Human Resources play a major role in verifying basic information of lab personnel to assist in fostering a safe environment within the lab.
  - The Environmental Health and Safety office within an Institution plays a significant role regarding immunization programs, medical evaluations, screening, and to assist in maintaining a safe working environment.
  - Maintain rigorous training programs on culture of responsibility for incoming candidates.
    - Since safety is no longer an element of the Responsible Conduct of Research mandate from NIH or NSF, preexisting safety training should be sure to include responsible conduct of research content to ensure that the widest possible array of people are receiving responsible conduct of research training.
  - Have high visibility of safety personnel – this makes clear the importance of safety and fosters team effort.
  - Instill a system of zero tolerance for not complying with lab rules or requirements.

- **How can lab leaders build and foster strong working relationships with and among lab personnel?**
  - Discuss biosecurity and responsible conduct with lab personnel when planning research proposals, experiments and manuscripts. Involve lab staff in preparing for inspections, since they are stakeholders.
  - Foster strong working relationships. Train newcomers personally.
  - Respect needs to be the foundation of trust within a laboratory.
  - Ethical issues of biosecurity can be incorporated into preexisting ethics courses. This trains graduate students, even those students who are not dealing with pathogens, in an area that they seldom think about.
  - Build lab rapport by getting to know each other and building relationships. Familiarity within a working environment helps individuals recognize uncharacteristic, troubling behaviors.
  - PI must lead by example and be a strong mentor – not just with science but also with Select Agent regulations.
  - Build the relationship based on earned trust – PIs understand this from a scientific point of view – it is the same for regulatory environments.
  - Encourage feedback from personnel. Have the ability to reward lab managers in the regulatory areas (this needs to be addressed nationally).

- **How can lab leaders convey the importance of and their commitment to biosecurity and personnel reliability?**
  - Be knowledgeable about guidelines and Standard Operating Procedures; take an active role in university environmental health safety activities; participate in deliberations at local, regional and federal levels; convey information and solicit ideas from lab personnel.

- Have regular meetings with staff for ongoing dissemination of biosecurity information.
- PIs should have as high an expectation for compliance with biosecurity rules as for scientific research itself.
- PIs should lead by example, actively participate in biosecurity training, promote and endorse these training programs; continually seek improvement in training methods; show interest and stay informed of biosecurity updates; and make suggestions for training program improvement.

- **What are strategies for making the consideration of biosecurity, dual use research, and responsible conduct of research a routine part of daily life in the lab?**
  - Everyone should be required to participate in the Select Agent refresher training annually but the concepts addressed in this training could be reinforced throughout the year informally in the laboratory. Make AROs available to assist in this area.
  - Respect and transparency are the foundation within a work environment. Treat everyone alike; integrate biosecurity into the scientific training system with which scientists are already familiar, use varying and continuous non-intrusive approaches in an attempt to reach a multitude of personnel in many different environments.
  - Biosafety officials must emphasize to investigators that we "have your back; we're here to ensure you can do your research in a safe, responsible manner and we are not here to impinge on that."
  - Consider the use of the two-person rule, or a modified version of the two-person rule that could be instituted on a case-by-case basis when necessary since an across-the-board mandate might be impractical or unnecessarily burdensome.

<u>Panel III - Peer reporting of concerning behaviors</u>

- **General comments:**
  - The institution should have a credible policy for reporting suspicious behavior showing that it does what it should be doing. What gets a program shut down is when regulators don't have faith in the institution.
  - Do the right thing, regardless of what the consequences might be. Address the problems proactively and as early as possible.
  - Should be able to point to cases where people did the right things, especially in national security cases. Need a body of evidence showing that people are acting responsibly.

- **What types of behaviors or behavioral changes should raise red flags in terms of reliability or biosecurity?**
  - All deceptive, illegal, destructive, and suspicious behaviors in addition to performing non-approved research. This is a safety and Select Agent issue.
  - Keep an open mind. The most seemingly trusted employee could be the culprit of a biosecurity issue, therefore the culprit can be very difficult to categorize.
  - Be cautious about profiling; keep an open mind when investigating reports – diversity in academia must be honored.
  - PI should be attentive to their personnel. Many small complaints about one person could be an indicator of a larger underlying problem. Have an action plan in place in advance for how to deal with complaints when they come in; lack of corrective measures may discourage reporting.

- **To whom should concerns be reported?**
  - Provide multiple avenues for reporting concerns and respond to reports immediately and appropriately. Ensure confidentiality to the extent possible.
  - Supervisor, HR Ethics hotline or Chief Compliance Office
  - Consider a person/office/ombudsman independent of the university who can provide a context and respond to questions.
    - The National Academies of Science has suggested that having an ombudsman with the expertise to deal with a wide variety of problems is effective.
  - Provide a clear system of reporting to people who know how to: a) handle specific issues, b) help the individuals involved, and c) move things forward while ensuring security and safety. Knowing where to turn to get help is critical. People turn a blind eye when they don't know what to do.
  - If formally reporting a concerning behavior, strive to engage the appropriate person closest to the situation, e.g., find the lowest level that makes sense.
  - Be familiar in advance with institutional policy on reporting (every institution has some kind of policy and know it before an issue comes up. Recognize that once a formal report is made, the reporting individual may no longer have a say in the ensuing process and they must realize that at some point, there is no turning back).
  - Responsible Officials must have the authority to make things happen and cause change (e.g. remove someone from the Select Agent program) if that is what is required.

- **What protections should be in place for the reporter? For the subject of the report?**
  - Extreme confidentiality for both the reporter and the subject of the report; very limited distribution of information regarding the report. Human Resources should manage the procedural aspects.
  - Need a strong screening process of the report before moving ahead with a complaint, as this protects both the reporter and the subject of the report.
  - Recognize that whistle blowing is often associated with undesirable consequences for the reporter (no one comes out unscathed). Find alternative approaches, whenever possible.
  - Do not be punitive to the reporter, stress anonymity and confidentiality and that education is the reason for reporting. Keep an open mind when investigating reports.

- **How can frivolous or retaliatory reporting be discouraged?**
  - Encourage all reporting. Management process would sort through elements. Better to have more information than less. The set point must be low enough not to miss significant issues.
  - Establish a good culture of responsibility of which peer reporting is just one part, promote an encouraging environment, and bring the Select Agent program into the institutional culture.
  - Establish mandatory instruction for graduate students, and highly recommend instruction for others on the basic concepts of research integrity, whistle blowing and related issues (faculty should be encouraged to participate; training by faculty has proven to be advantageous).
  - Consider developing an honor code that fosters reporting as protective of the team. Have a reward system for reporting – not monetary but recognition that the person did the right thing.

- **How and to what extent can privacy and confidentiality be maintained?**
  - Confidentiality can be assured though not guaranteed, but never promise anonymity because at some stage the reporter must be questioned.

- **How can institutions dispel any stigma associated with reporting concerning behaviors?**
  - Encourage a team atmosphere and ask all employees to find the rogue person who does not pull as part of the team.
  - Difficult to achieve – once a concerning behavior has been reported it lives on. Thus, it is important to have safeguards in place to screen complaints and proceed only if there is a true issue.
  - Do not be afraid or reluctant to publicize the issue or a report. This shows the benefit of doing the right thing (e.g. Sabotage article in *Nature*).

- **What legal implications should an employer consider in implementing a peer-reporting program?**
  - Privacy rights- deal with workplace issues when they first come up but realize that a workplace investigation must be reasonable in its inception and reasonable in its scope and must abide by privacy rights of all individuals.
  - Americans with Disabilities Act – should be considered in a peer reporting system. Keep in mind that some mental impairments are covered by ADA. Complaints should be thoroughly investigated.
  - Revoking access to Select Agents is the default position while the investigation is going on.
  - Put policies and practices in place to assure that there is appropriate follow-up to reports of concerning behaviors:
    a. Reporting system and writing policy.
    b. Assurance (but not a guarantee) of confidentially and no retaliation.
    c. Trained and experienced investigators.
    d. Thorough and impartial investigations.
    e. Balanced and fair decision-making by more than one person, with legal issues analyzed during the investigation and decision-making. Make sure that you are not hasty and that you keep proper lines of communication open.

- **What are the best ways to protect the rights of a person who is reporting the concerning behavior of a supervisor or other superior?**
  - Before a problem occurs have procedures in place to follow-up on reports against supervisors or superiors before they arise.
  - Have a strong informational/advisory system in place for the potential reporter to determine the appropriate person and procedure to report.
  - Have a mechanism for relocating affected students or postdoctoral fellows into different work environments, if necessary.
  - Restrict the role of the subject of the report in decisions affecting reporter, if allegations are confirmed.

Panel IV – Addressing impediments to disclosure of negative information about job candidates

- **General Comments:**
  - References are a critical tool in creating a culture of responsibility and building reliable staff.
  - Need to be able to trust colleagues to provide relevant information so that hiring decisions are informed decisions.

- **What are the potential liabilities of passing on accurate but derogatory information?**
  - Defamation, invasion of privacy, misrepresentation.
  - Not much legal protection for employers who provide candid references.
  - Some state laws are addressing this problem and providing immunity for accurate information.

- **What types of derogatory or negative information can and cannot be passed on to a potential employer? Are there exceptions to certain types of information?**
  - Never disclose medical information.

- **What are the potential consequences and liabilities of not providing a full and accurate account of an employee's past performance? Is there an affirmative duty to disclose information about an employee's past performance?**
  - Withholding relevant information can be problematic if it means that "bad apples" are passed along.

- **What are some strategies to alleviate the general reluctance to provide candid references due to fear of a lawsuit?**
  - Stick to the facts, act in good faith, and keep excellent documentation.
  - Require consents and waivers from employees authorizing release of information.
  - Have a policy for references re what information to give and limit who can give it. Document everything that is sent out. Respond only to written requests and only give written references.
  - Be accurate about performance evaluations – they should not be overly flowery or congratulatory if the employee has not performed to that level. Don't say "exceeded expectations" if all the employee did was meet expectations.
  - Do not volunteer information – especially if it is hearsay.
  - When seeking references, you can ask key questions such as "would you hire X again and in what capacity?" Why did X leave?"
  - Limit references to confirming factual information (date of employment, position held, and salary). Realize that fact verification by trained personnel can reveal much information because a surprisingly large percentage of candidates lie about their work history.
  - Realize that as a prospective employer you can ask anything you want. As a former employer, you may wish to be more circumspect about how you respond.
    - Can relay incidents without making judgments and drawing conclusions; those can be left up to the hiring institution.
  - It is permissible to terminate a candidate's employment if it turns out after he/she is hired that he/she does not meet the conditions of the job, such as finding that the candidate failed the SRA.

- Legislation by Congress in this area is doable but would be complicated by how to define standards and transgressions. This may be a good area for preemptive federal regulation.
- Information in national databases is one way to ensure that certain information about undesirable employees is available, but such databases might impair reporting.

Panel V- Assessment of effectiveness and impact of practices for strengthening personnel reliability and culture of responsibility

- **How can we evaluate the effectiveness and impacts of practices aimed at enhancing personnel reliability and the culture of responsibility?**
  - It is difficult to measure the effectiveness of personnel reliability programs and additional personnel reliability measures are not needed for the Select Agent program. Enhancing the culture of responsibility will do more to decrease the insider threat than implementing additional personnel reliability measures.
  - It is possible to establish evaluative practices using intermediate outcomes to evaluate whether progress has been made toward the long-term goals. The task at hand is not only to look at whether things that are required are happening, but also to determine whether there are unintended consequences, which is easier than trying to measure whether events have been prevented.
  - Don't substitute the comfort of investigators for the effectiveness of the measures of a culture of responsibility.
  - Need a beta test of personnel reliability programs at different institutions to measure the true cost of compliance.

- **Are there lessons learned from other arenas that have had similar challenges?**
  - Analogous research does exist – see especially a) the ethical climate index, a validated index to measure whether a culture is behaving according to ethical standards, b) Center for Academic Integrity Assessment Guide, which assesses the climate of academic integrity at an institution using a number of indices, c) National Business Ethics Surveys, which use metrics to answer questions about what creates an ethical climate in an organization and what detracts from it and d) the Survey of Responsible Research Practices which has measures that are still being validated to assess the climate for research integrity.
  - Metrics that could be used include:
    - Reporting - including self-reporting of violations.
    - Response to report of violation (perceptions – what do people think about the reporting system – fair, timely, unfair?).
    - Options for understanding professional responsibilities and seeking ethics guidance (the literature asks is the organization open to encouraging people to raise issues; is it clear who to go to; how does the organization respond).
    - Risk assessment (one size does not fit all, but should have a risk assessment to prevent unnecessary measures from being put in place).
    - Resource allocations for fulfilling professional responsibilities (do the budgets support what institutions say investigators should do).
    - Leadership support for "doing the right thing" (look at how leadership is speaking).

Appendix H - Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences[53]

INTRODUCTION

Important benefits to society have been achieved in no small measure by scientists who have strived to conduct their work conscientiously and with integrity. This commitment forms the basis of a culture of responsibility in which scientists consider the risks and implications of their research and take appropriate measures to ensure that they carry out their work safely, ethically, and in a manner that warrants continued public trust and support. To achieve this aim, scientists should consider the relevant standards and guideposts for ethical and responsible research conduct as well as the potential impact their research may have on society. The importance of thoughtful consideration of ethics and research is amplified when scientists engaged in well-intended research are confronted with its potential for misuse.
In recent years, increased attention has been directed to the possibility that the knowledge, products, or technologies derived from some life sciences research may be misapplied to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern." All those involved in life sciences research have a responsibility to avoid or minimize the foreseeable risks and harm that could result from malevolent use of research outcomes.

The National Science Advisory Board for Biosecurity (NSABB) has given extensive consideration to the characteristics that define dual use research of concern. Following its charge, the NSABB is proposing a series of recommendations and tools to help the scientific community identify and manage the risks associated with this type of research. The NSABB has observed that there is a need not only to raise life scientists' awareness of the dual use potential of their research but also to provide and promote principles of research conduct that will sustain a culture of responsibility within the scientific community.

One useful tool for raising awareness of the potential for dual use research and promoting responsible research behavior is a code of conduct. Typically developed by societies, associations, and institutions, a code of conduct articulates shared values and standards of conduct. Codes also can be used to educate people regarding their ethical responsibilities. The value of a code is reinforced when it is discussed in training sessions, at meetings, and during the course of routine activities.

USING THIS DOCUMENT

The following document lays a foundation for a code of conduct that explicitly addresses dual use research of concern by:

- Describing the general utility and potential applications of such a code
- Articulating a core set of responsibilities related to dual use research that can serve as a foundation for a code

[53] Excerpted from: NSABB, *Proposed Framework for the Oversight of Dual Use Life Sciences Research*, pp.43-50 (Bethesda, MD: National Institutes of Health, June 2007), oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf.

- Delineating additional responsibilities related to specific phases of the research process and research-related activities

The core set of responsibilities and the additional specific responsibilities outlined below provide a template that users of this document can adopt verbatim, modify, or use as the basis for developing more specific guidance on ethical behavior. This document is intended to be used in tandem with other elements of the framework of policy and guidance pertinent to this issue that are now under development.

AUDIENCES FOR THIS DOCUMENT

Every individual associated with the life sciences should be aware of the potential dual use of scientific knowledge, products, or technology and be knowledgeable of the ethical obligations that ensue in regard to research that can be considered "dual use of concern." Specifically, the considerations in this document are intended to apply to the following audiences:

Life sciences societies and associations. Life sciences societies and associations are important sources of guidance for scientists on the ethical standards that apply to their disciplines. These organizations are encouraged to enhance their bylaws or codes of conduct to address the considerations within this document. They may choose to adopt any portion of this document into an existing code or to modify its contents in order to adapt them to a specific discipline and context. Alternatively, organizations may choose to adopt or create a stand-alone document to give it particular salience. In either case, organizations generally adopt or modify their codes through a governance process involving broad discussion with the membership; therefore, the process of considering the ethical standards applicable to dual use research of concern is a valuable exercise in its own right. Whatever the manner in which a society chooses to develop and adopt a code on dual use research of concern, the code should be widely disseminated to members (for example, by publishing it in society newsletters and journals). It should be revisited frequently at annual membership meetings and other events in order to refresh and reinforce its impact and to address evolving issues.

Research institutions. Whether public or private, academic or industrial, research institutions are responsible for the integrity of their research programs. Institutions that oversee a body of research typically have rules, guidelines, and standard operating procedures to guide staff on how to conduct research in an ethical and legal manner, as well how to conform to institution-specific policies and requirements. Institutions should consider the adoption and dissemination of specific guidance on dual use research in faculty handbooks, procedures manuals, institutional Web sites, training and education of students and staff, and other appropriate venues. Many such institutions also offer formalized employee orientation programs and courses of instruction in the responsible conduct of research. It would be appropriate and helpful to incorporate the topic of dual use research, along with related guidance on ethical and legal responsibilities, in such courses and programs.

Industry. Life scientists who are engaged in research for commercial purposes share the same responsibilities for safeguarding the public welfare as their colleagues in the academic or public sectors. Each commercial organization will have its own mechanisms for raising

awareness of dual use research of concern and for developing policies to address related issues.

Research leadership. Scientists who have risen to leadership positions (for example, society presidents, medical school deans, and department chairs in universities) serve as role models for other scientists. In particular, those who are responsible for oversight of research programs should consider how their institutions are addressing the responsibilities outlined in this document. For example, it is important to ensure that issues related to dual use research of concern are well understood by life scientists, that dual use research of concern is reported in accordance with institutional policies, and that life scientists are aware of and compliant with other applicable requirements. All those who have gained the respect of other scientists through their work can play a critical role in assuring that the issues associated with dual use research of concern are thoughtfully addressed.

Individual life scientists. Scientists bear the primary responsibility for the integrity of their own research. By their actions and explicit guidance, they can foster a sense of ethical responsibility in the research team and an awareness of applicable laws and guidelines. This document may aid in increasing their awareness of their responsibilities in the area of dual use research of concern and help them mentor students, trainees, and technical staff. Mentors are encouraged to involve these individuals in laboratory discussions of dual use research of concern, the ethical responsibilities that are outlined in this document, and the relevance of these responsibilities to their work.

Technicians, trainees, and others involved in the research process. Technical staff, postdoctoral fellows, students, and others who contribute to research activities bear their own measure of responsibility for the integrity of these projects. These individuals are also encouraged to review this document carefully, consider how it may apply to current work, and engage their instructors and mentors in addressing any questions they may have regarding its relevance.

Funding agencies/institutions. Institutions and agencies that fund research establish the framework for decisions about the research considered eligible for funding and provide oversight to ensure responsible stewardship of funds. In order to avoid endangering public health, agriculture, plants, animals, the environment, or materiel, they are responsible for ensuring that projects that could be considered dual use research of concern are identified prior to funding. When a project meets the criteria for this type of research, the funders should ensure that a process is in place to manage risks through a thoughtful and informed consideration of options that could mitigate or manage them.

Journal editors, reviewers, and publishers. Those who play decisionmaking roles in the process of communicating scientific information have an ethical responsibility to consider whether the information being considered for publication could be used to endanger public health, agriculture, plants, animals, the environment, or materiel. Depending on their analysis of the risks and benefits of communications regarding information or technology that meet criteria for dual use research of concern, they may choose to proceed in a way that mitigates

or manages the risks associated with communication, for example, by adding contextual information not found in the original article or delaying communication until a time at which the risks would be reduced.

CORE RESPONSIBILITIES OF LIFE SCIENTISTS IN REGARD TO DUAL USE RESEARCH OF CONCERN

The text box below identifies the fundamental responsibilities of all life scientists with regard to dual use research of concern. These obligations flow from the underlying principle of concern for the public good and should lie at the heart of any code of conduct that addresses this topic.

LIFE SCIENTISTS: CORE RESPONSIBILITIES REGARDING DUAL USE RESEARCH OF CONCERN

Life sciences research is a critically important endeavor that has benefited society by advancing our understanding of living systems. Critical to the future of scientific progress and freedom is the preservation of public trust and support, which scientists have earned through their attention to responsible research practice. Despite a scientist's conscientious approach to research conduct, the knowledge, products, or technologies derived from some life sciences research may be misused by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel. Research with this potential is known as "dual use research of concern."

Individuals involved in any stage of life sciences research have anethical obligation to avoid or minimize the risks and harm that could result from malevolent use of research outcomes.

Toward that end, scientists should:

- Assess their own research efforts for dual use potential and report as appropriate
- Seek to stay informed of literature, guidance, and requirements related to dual use research
- Train others to identify dual use research of concern, manage it appropriately, and communicate it responsibly
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for dual use research of concern
- Be alert to potential misuse of research

RESPONSIBILITIES IN THE RESEARCH PROCESS

Research is a complex, iterative process, and the potential for dual use may be recognized at many junctures and through different activities. Consequently, while it is valuable to be mindful of the core responsibilities articulated above, those involved in life sciences research may also benefit from a more specific review of their responsibilities in regard to dual use research of concern.

Proposing Research

When designing and proposing research, the ethical responsibilities of life scientists include:

1. Considering whether the knowledge, products, or technology resulting from the research could be deliberately misused to endanger public health, agriculture, plants, animals, the environment, or materiel
2. Striving to design research that promotes beneficial scientific advances, while avoiding or minimizing elements of study design that raise concerns about dual use
3. Weighing carefully the benefits of study elements presenting dual use concerns that cannot be completely eliminated against the harm that could occur through their deliberate misuse
4. Considering ways to modify the research design to manage and mitigate potential misuse when it is clear that the benefits of the research with dual use potential outweigh the potential harm

Managing Research

The ethical responsibilities of persons who manage research programs, whether within the public or private sector, include the following:

1. Promoting awareness of dual use research of concern and the ethical responsibilities it entails
2. Developing and maintaining systems, policies, and training to ensure that dual use research of concern is identified and managed appropriately
3. Implementing federal, state, and other appropriate guidelines specific to dual use research of concern

Reviewing Research

The ethical responsibilities of those responsible for establishing and managing the review process (e.g., funding agencies) include the following:

1. Ensuring that when research proposals are reviewed, appropriate systems are in place to identify the possibility of dual use of concern and to address related issues. Examples of common means of reviewing research proposals include Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), and peer review groups.
2. Ensuring that both researchers and reviewers are knowledgeable of, and adhere to, all ethical, institutional, and legal requirements that apply to the review of possible dual use research of concern.
3. Reconsidering institutional review systems periodically to ensure that they reflect current criteria defining dual use research of concern and are consistent with applicable federal and state guidelines.

The ethical responsibilities of individuals serving on peer review groups or otherwise engaged in research review include the following:

1. Becoming well educated about dual use research of concern and related ethical, legal, and institutional requirements, as well as applicable federal and state guidelines
2. Being mindful during the review process of whether the research could meet the criteria for dual use of concern
3. Using methods in keeping with the reviewer's charge and context to make appropriate people aware that the research being reviewed meets the criteria for dual use research of concern

Conducting Research

The ethical responsibilities of life scientists engaged in research include the following:

1. Observing safe practices[53] and ethical behaviors in the laboratory, clinic, field, and classroom and ensuring that subordinate personnel do so as well
2. Using appropriate security measures and continually reassessing their adequacy as concerns about potential misuse evolve
3. Observing applicable guidelines for the responsible conduct of dual use research of concern
4. Being attentive to the dual use potential of the knowledge, products, or technology resulting from research activities as they emerge
5. Alerting responsible institutional officials when dual use research of concern is identified and when decisions must be made to manage associated risks

Collaborating on Research

Research endeavors frequently involve the participation and cooperation of multiple laboratories and disciplines, which can be subject to different management, codes of conduct, cultural values, or operating procedures. Besides the ethical responsibilities associated with conducting research, scientists involved in such collaborations have the additional obligations of:

1. Engaging in open dialog regarding whether knowledge, products, or technology resulting from the research could be considered dual use research of concern; when such research is pursued, ensuring that all parties are aware of their ethical responsibilities
2. Agreeing on specifically assigned responsibilities to ensure ethical oversight of all aspects of research with dual research potential, including its outcomes.
3. Considering and respecting expressions of concern regarding the possible dual use of knowledge, products, or technology resulting from the research and ensuring that these concerns are raised with those charged with responsibility for research oversight
4. Considering appropriate measures to reduce or eliminate risks to public health, agriculture, plants, animals, the environment, or materiel resulting from the research project
5. Maintaining a current awareness of national and international standards and policies regarding dual use research of concern

Communicating the Results of Dual Use Research of Concern

Regardless of the stage of the research process and the form of the communication, those involved in communications regarding knowledge, products, or technology that can be considered dual use research of concern have the following ethical responsibilities:

1. Being aware of ethical and legal considerations relevant to communications regarding knowledge, products, or technology that can be considered dual use research of concern.
2. Analyzing potential risks to public health, agriculture, plants, animals, the environment, or materiel that could result from research-related communications, balancing them against the potential benefits.

---

[53] Safe laboratory practices are embodied in such documents as *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* (www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm), *NIH Guidelines for Research Involving Recombinant DNA Molecules* (www4.od.nih.gov/oba/rac/guidelines/guidelines.html), and *Biological Safety: Principles and Practices* (ASM Press, www.asm.org/), and applicable occupational and safety regulations and standards.

3. Considering options for communication that may reduce or eliminate risks when communicating information with dual use potential is clearly warranted by its benefits. Examples of mitigating strategies may include a delay in releasing the information, the addition of appropriate contextual information, or communicating the information to a more limited audience.

Scientific Education and Mentorship

Practicing scientists who serve as role models to developing scientists (e.g., their trainees, students, and staff) have the following ethical responsibilities:

1. Raising developing scientists' awareness of what constitutes dual use research of concern and why it matters
2. Informing developing scientists of their ethical, legal, and institutional responsibilities when engaged in dual use research of concern, as well as applicable federal and state guidelines
    - Encouraging open and respectful discussion of issues related to dual use research of concern, including whether or not a particular project could be considered dual use research of concern