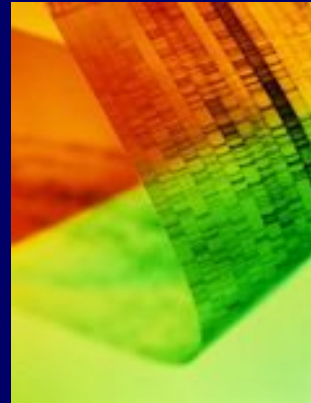
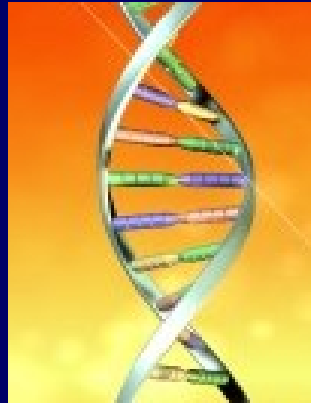


NSABB Working Group on Culture of Responsibility



**NSABB Meeting
June 23, 2011
Susan Ehrlich, J.D., LL.M.**

WG Roster

Voting Members

- Paul Keim (co-chair)
- Stan Lemon (co-chair)
- Arturo Casadevall
- Murray Cohen
- Susan Ehrlich
- Pat Fitch
- Mike Imperiale
- Joe Kanabrocki
- Randy Murch
- Andrew Sorenson (deceased)

Federal Representatives

- Dennis Dixon (NIH/NIAID)
- Denise Gangadharan (CDC SAP)
- Jane Knisely (NIH/NIAID)
- Laura Kwinn (HHS/OS)
- Theresa Lawrence (HHS)
- Don Malinowski (ODNI)
- Jan Nicholson (CDC)
- Jessica Petrillo (Dept. of State)
- Rob Weyant (CDC SAP)
- Ed You (DOJ/FBI)

CRWG Aims

- **Identify strategies and develop specific guidance for enhancing the culture of responsibility (CR) among individuals with access to BSATs**
 - **Implementation should be at the local level**
 - **Assist institutional and laboratory leadership in developing and implementing practices that promote a culture of responsibility**
 - **Broadly engage the scientific community**
 - **Promote a sense of trust in the public**





Impetus for Current Report: Selected NSABB Recommendations on Personnel Reliability (2009)

- **It is appropriate to enhance personnel reliability measures for individuals with access to select agents**

But promulgation of a formal, national Personnel Reliability Program (PRP) is unnecessary at this time

- **The select agent rules have already been significantly strengthened**
- **A PRP would be likely to have unintended detrimental consequences**
- **There is insufficient evidence of the effectiveness of PR measures to warrant the additional burden on research institutions**



Selected NSABB Recommendations on Personnel Reliability (2009)

- **The culture of responsibility and accountability should be enhanced at institutions that conduct select agent research**

This was noted by many whom the NSABB consulted as the best defense against the insider threat and can be accomplished without any significant expenditure of resources or disrupting research progress



Selected NSABB Recommendations on Personnel Reliability (2009)

- **Briefly mentioned ways to enhance the culture of responsibility:**
 - Rigorous hiring practices
 - Raise level of awareness about importance of biosecurity, risk of insider threat, need for vigilance
 - All must understand responsibility to report concerning behaviors
 - Build strong sense of team in select agent labs
 - Allow temporary opt-out of select agent research



This Will Help Build Public Trust

- Building and maintaining public trust is the responsibility of the entire scientific community
- Measures to ensure the reliability of individuals working with select agents will help to allay public concerns about such research
- Demonstrating that the scientific community is acting responsibly and proactively to protect public welfare and security will help strengthen public trust



Current NSABB Task: Expand on Recommendation regarding CR

- Recommend specific strategies and guidance for **enhancing the culture of responsibility** among individuals with access to select agents
 - Develop specific guidance on how best to implement practices such as self- and peer-reporting, including how to “de-stigmatize” such reporting
 - Delineate the good hiring practices that will help to optimize personnel reliability
 - Recommend ways for local institutional leadership to communicate that security and personnel reliability is valued and a priority

Approach

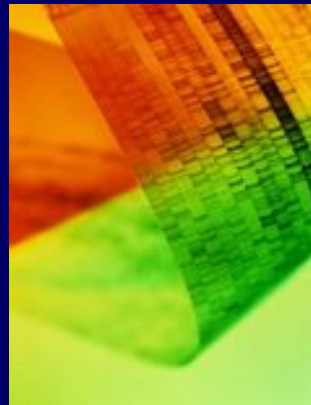
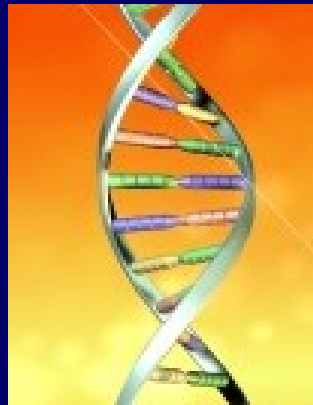
- Review and elaborate on recommendations in the NSABB report on personnel reliability
- Identify additional practices for promoting CR
- Consult broadly with scientists in their capacities as institutional leaders and with experts in relevant fields such as Human Resources and law



WG Consultations

- **Building Personnel Reliability at the Local Level: A Roundtable on Enhancing a Culture of Responsibility**
- **Roundtable on Practices for Enhancing Personnel Reliability and the Culture of Responsibility in High Containment Labs**
- **Panel on legal considerations for hiring practices**
- **Public consultation on ways to enhance CR and PR**
- **Panel to discuss the scope of activities of IBC review**
- **Briefing on updates to the Security Risk Assessment process**
- **Briefing on the final report of the Amerithrax Expert Behavioral Analysis Panel**

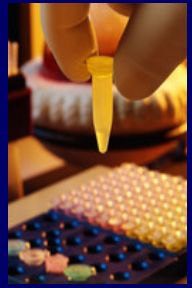
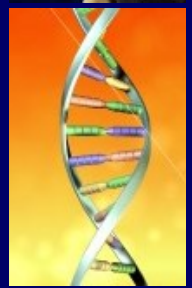
Public Consultation on Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility at the Local Level



January 5, 2011
Hyatt Regency Bethesda

Public Consultation Topics

- **Engaged institutional leadership: Promoting biosecurity, personnel reliability, and a CR**
- **Encouraging biosecurity awareness and promoting responsible conduct in the laboratory through communication, lab rapport, and a strong sense of team**
- **Peer reporting of concerning behaviors**
- **Addressing impediments to disclosure of negative information about job candidates**
- **Assessment of effectiveness and impact of practices for strengthening personnel reliability and CR**





200 attendees

- **Academia**
- **Professional societies**
- **Non-government organizations**
- **Local government**
- **Federal government**

Take-home Messages

■ CR starts at the top

- Communicate biosecurity expectations on an ongoing basis
- Empower individuals with tools to make right decisions
- Demand accountability for decisions
- Have visible champions among upper leadership
- Trust is essential



Take-home Messages

- **References are a critical tool in creating a CR and building reliable staff**
 - Need to be able to trust colleagues to provide relevant information so that hiring decisions are informed decisions
 - Withholding relevant information can be problematic if it means that “bad apples” are passed along
 - “Just the facts.” Can relay incidents without making judgments and drawing conclusions; those can be left up to the hiring institution



Take-home Messages

■ Lead by example

- Continually seek improvement in methods
- Keep people informed
- Consider the input of others
- Be open to a range of opinions
- Acknowledge contributions of others

■ Foster strong working relationships

- Train newcomers personally
- Build lab rapport
- Respect is the foundation



Take-home Messages

- **Reporting of concerning behavior of peers, supervisors and staff**
 - Have multiple avenues for reporting
 - Transparency is critical
 - Have procedures in place ahead of time for reporting
 - Keep an open mind when investigating reports



Take-home Messages

- **Rigorous education programs on CR**
 - For new hires, IBC members, all lab personnel
 - Education by faculty is advantageous
 - Could be incorporated into extant programs, e.g. ethics





Take-home Messages

- **Consider the burden**
 - Investigators already have to comply with numerous requirements that infringe significantly on research time
 - Make it easy to comply
- **Biosecurity is multi-dimensional**
 - An institutional biosecurity taskforce could serve as a resource to RO on full range of biosecurity issues
 - Would provide, as needed, input from the BSO, campus security, occupational health, IBC, public affairs, general counsel

Take-home Messages

- **IBCs are a key component of CR**
 - Service should be seen as an honor, not a burden
 - Should have adequate and appropriate expertise
 - Need to be empowered by institutional leadership
- **Institutional biosecurity champions are key components of CR**
 - 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 constituency

