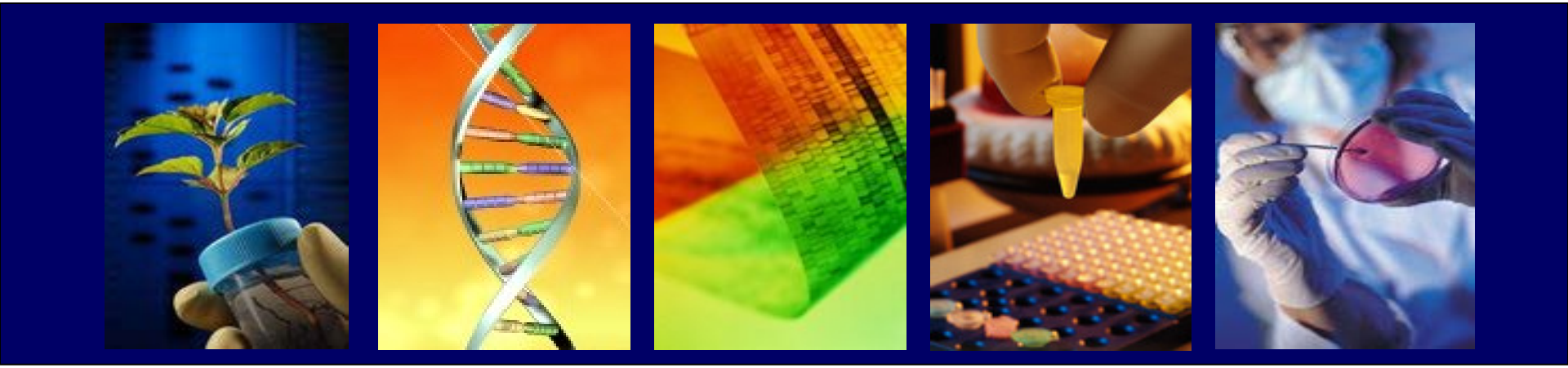
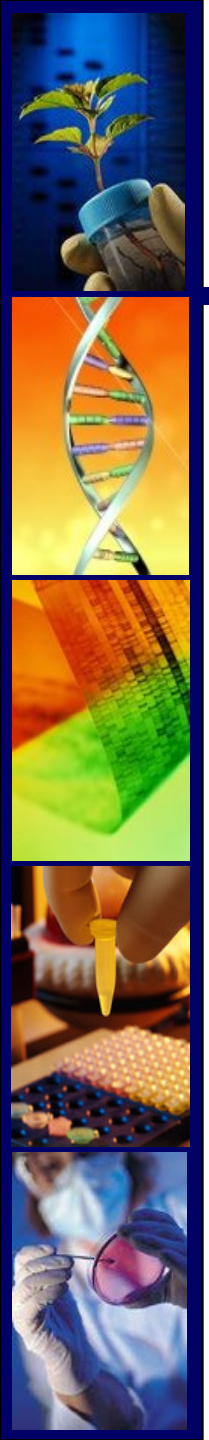
Report of the NSABB Working Group on Culture of Responsibility

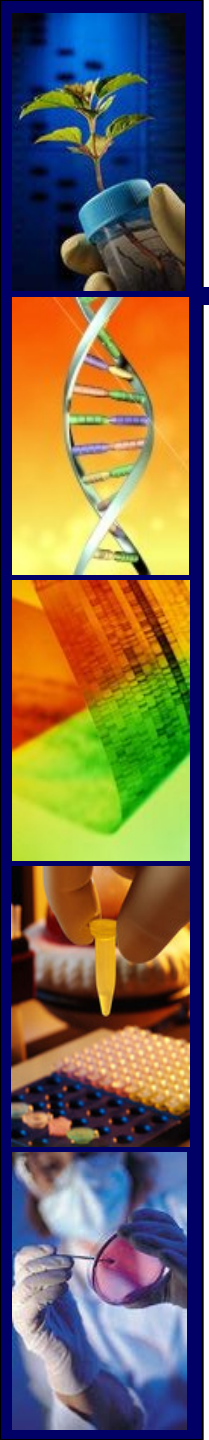


October 19, 2010



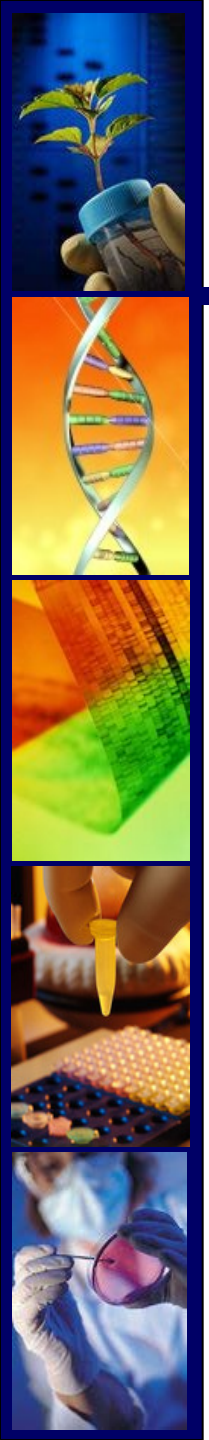
WG Roster

- Paul Keim (co-chair)
- Stan Lemon (co-chair)
- Arturo Casadevall
- Murray Cohen
- Susan Ehrlich
- Pat Fitch
- Mike Imperiale
- Joe Kanabrocki
- Randy Murch
- Andrew Sorenson
- Dennis Dixon (NIH/NIAID)
- Anne Kinsinger (DOI)
- Jane Knisely (NIH/NIAID)
- Laura Kwinn (HHS/OS)
- Jan Nicholson (CDC)
- Jessica Petrillo (State Dept.)
- Rob Weyant (CDC SAP)
- Ed You (DOJ/FBI)



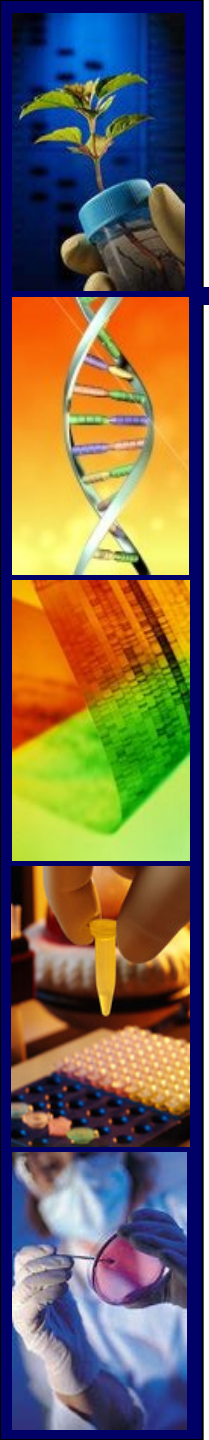
CRWG Aims

- **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**



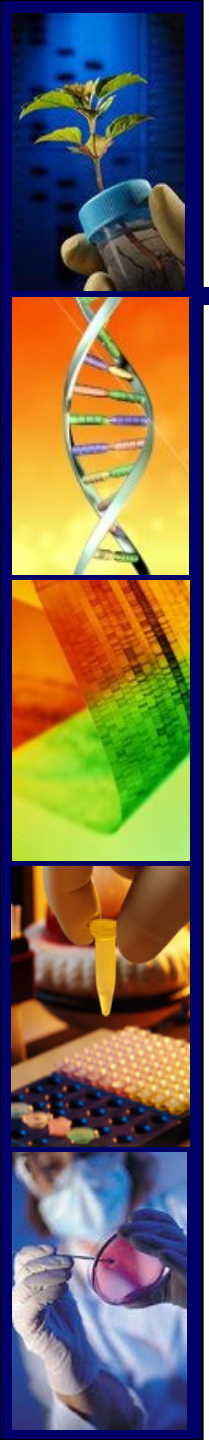
Approach

- **Review and elaborate on recommendations in the NSABB report on personnel reliability**
- **Identify additional practices for promoting CR**
- **Consult with the scientific community**
  - **July 15: Building Personnel Reliability at the Local Level: A Roundtable on Enhancing CR**
  - **Sept 2: Roundtable on Practices for Enhancing Personnel Reliability and the Culture of Responsibility in High Containment Labs**
  - **Scheduling: Panel on legal considerations for hiring practices**
  - **Planning: Public consultation on ways to enhance CR and PR**



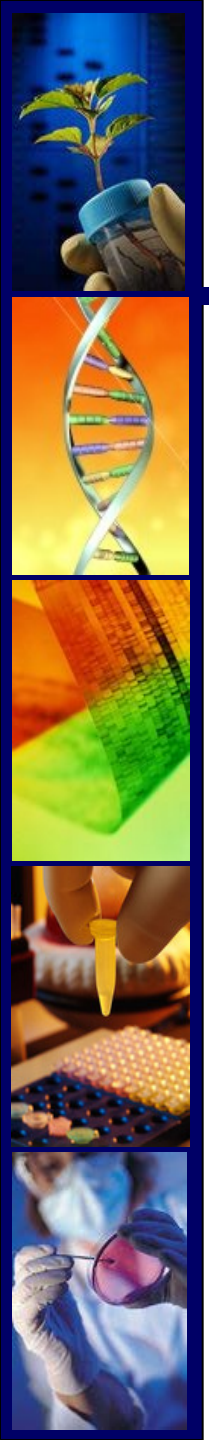
Proposed Introductory Concepts

- **Premise: Personnel reliability is the responsibility of local institutions**
  - **A strong culture of responsibility with respect to biosecurity and biosafety is probably the most effective tool for enhancing biosecurity and personnel reliability**
- **Discussion of what is meant by "culture of responsibility"**
- **With a few exceptions, the proposed strategies are applicable to all life sciences research, not just BSAT research, and in many cases could apply to all sciences**
- **For all proposed practices for enhancing CR, training will be essential!**



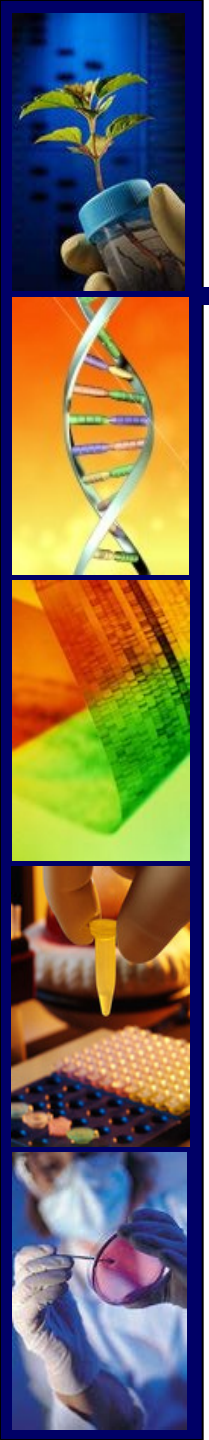
Categories of Practices for Enhancing PR and CR

- **"Best practices"**
  - Widely agreed upon, broadly applicable
- **"Potentially useful practices"**
  - Less broadly applicable; use should be based on risk assessment at local level
- **"Other practices that have been considered"**
  - More controversial, may be subject to local laws
  - Articulate pros & cons



Proposed "Best Practices" to be Elaborated

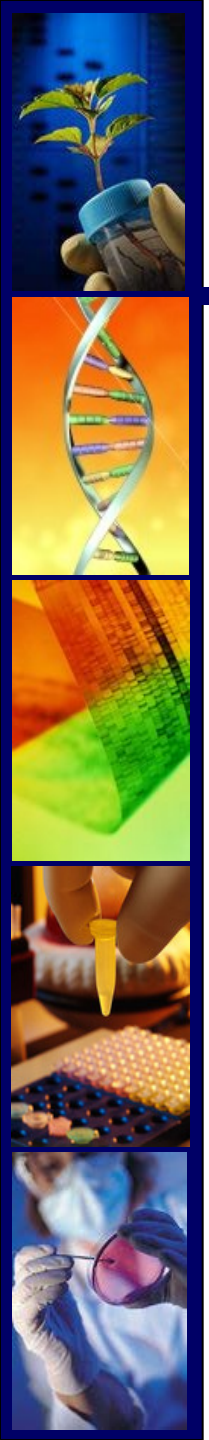
1. **Good hiring and employment practices**
   - **Go beyond verifying scientific bona fides and competence; explore reliability and biosecurity dimensions with current and previous employers**
   - **How to address liability concerns about sharing derogatory information or negative perceptions about a current or former employee**



Proposed "Best Practices" to be Elaborated

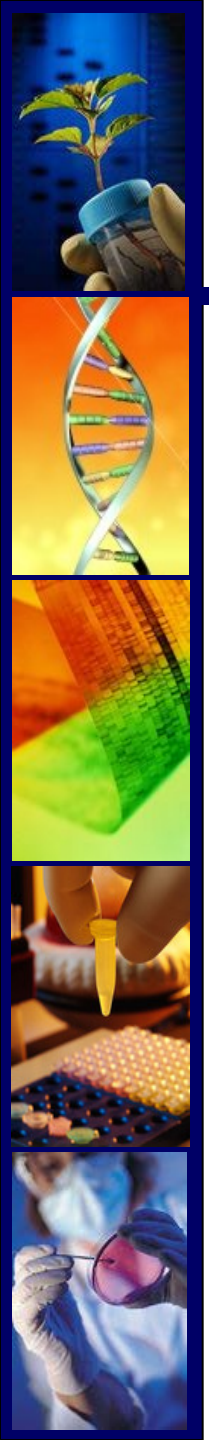
2. **Encourage biosecurity awareness and promote responsible conduct**
   - **At the level of institutional leadership**
   - **At the laboratory level**

3. **Explicitly articulate the institution's expectations of employees**
   - **Expectations should be in writing, signed by employee, and become part of employee record**



Proposed "Best Practices" to be Elaborated

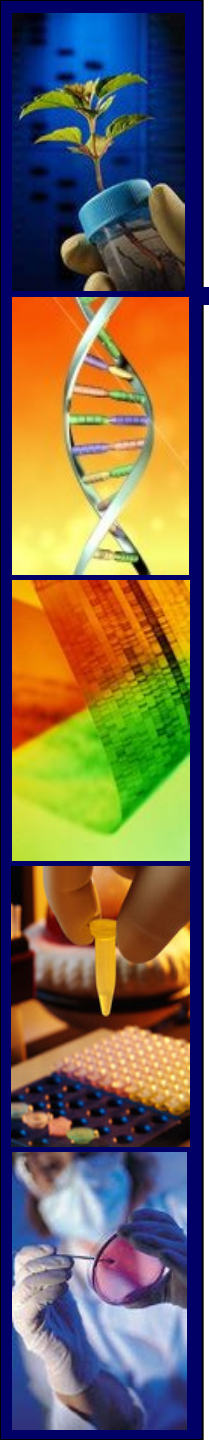
4. **Peer reporting of concerning behavior**
   - **Explain purpose and importance of awareness and vigilance**
   - **Provide guidance on:**
     - **The types of behaviors and behavior changes that might be of concern**
     - **To whom concerns should be reported**
     - **Protections in place for reporter and subject of report**
     - **Extent to which privacy and confidentiality can be maintained**



Proposed "Best Practices" to be Elaborated

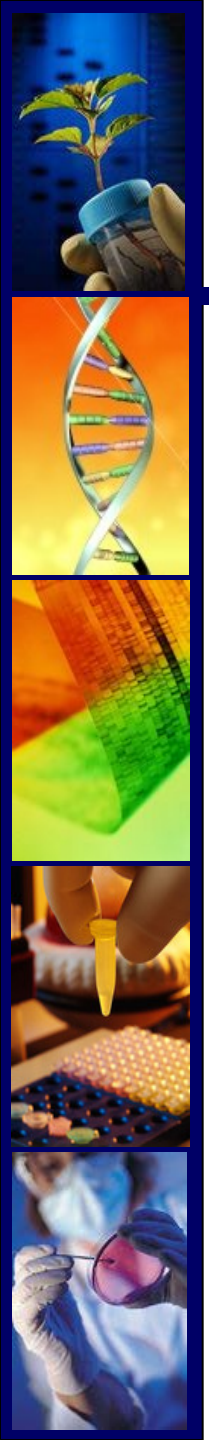
5. Opting out of research with BSATs

- Provide guidance on:
  - When this might be necessary
  - When and to whom such decisions should be reported
  - Under what conditions should restricted access be lifted
  - Minimizing potential for professional stigmatization



Proposed "Best Practices" to be Elaborated

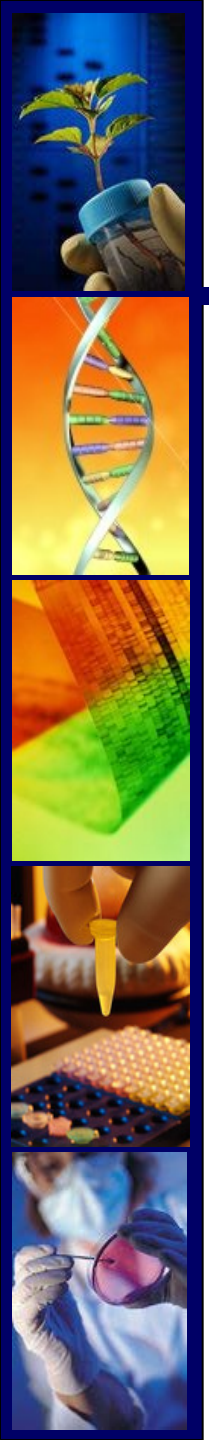
6. **Local review (risk assessment) of all BSAT research**
   - **Not just research involving recombinant DNA or requiring high containment**
   - **Consider reliability of all staff associated with the research and whether they have been appropriately trained re biosecurity and DUR issues**
   - **Include public representation**



Proposed "Potentially Useful Practices" for Consideration by Local Institutions

1. Video monitoring of BSAT labs

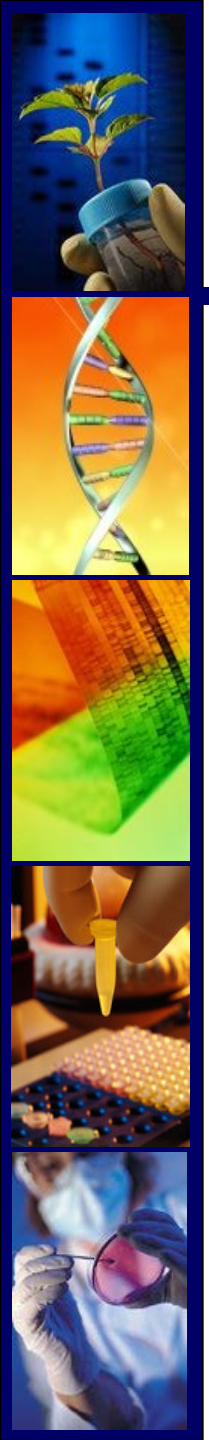
- Can be utilized for biosafety and biosecurity purposes
- Can be resource intensive
- Use should be based on a risk assessment conducted by local institution and should not be a federal requirement



Proposed "Potentially Useful Practices" for Consideration by Local Institutions

2. "Two Person" rule

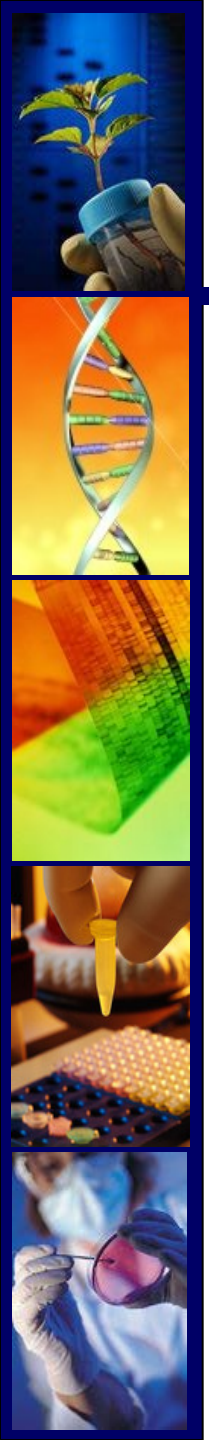
- Can be implemented for biosafety and biosecurity purposes
- Can be resource intensive and in some situations may have negative impact on safety
- Use should be based on a risk assessment conducted by local institution and should not be a federal requirement



Proposed "Other Practices That Have Been Considered"

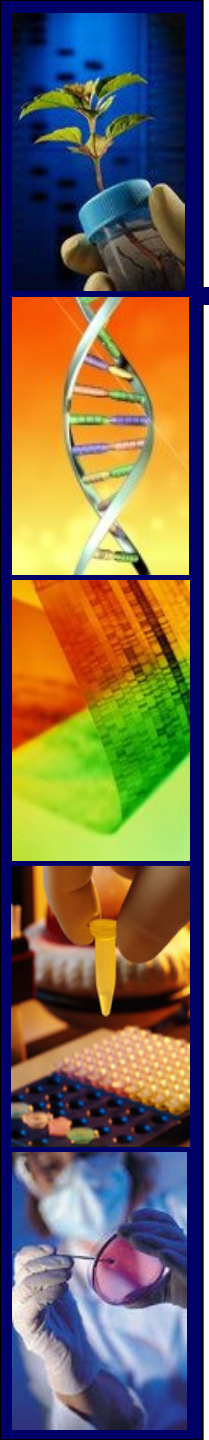
Examples:

1. **Drug and alcohol testing**
   - **State laws may prohibit testing**
2. **Credit checks**
   - **Many reasons for debt**
   - **Problematic in an academic setting**
3. **Search social networks (e.g., Facebook)**
   - **May not be accurate/legitimate**



Additional Topic to Address?

- **Metrics and methods for evaluating the effectiveness and impacts of practices aimed at enhancing personnel reliability and CR**
  - **Always a challenge!**



Discussion

- Did we miss anything?
- Any concerns, suggestions?