



Championing Biosecurity

Richard B. Marchase, Vice President for Research and Economic Development
The University of Alabama at Birmingham

The Challenges So Critical to Biosecurity Also Characterize Other University Activities

- Responsible Conduct of Research
 - Heavily dependent on peer observation and reporting
 - Inquiries often triggered by students or subordinate staff
- Security surrounding animal programs
 - Terrorism by animal rights extremists
 - Infiltration by “moles” a common strategy
- Prevention of workplace violence and abuse
- Protection of intellectual property

**Visible and vigorous support from University
leadership is critical**

Culture of Trust, Integrity, and Responsibility

Tone at the top and follow-through in the middle of the organization reflect a culture that expects:

- Quality in all aspects of university activities
- Individuals to be treated with respect
- Compliance with applicable laws, regulations, and policies
- Confidential information to be used responsibly
- University resources to be safeguarded
- A safe environment

AND also expects:

- Individuals to understand and acknowledge their responsibility to report activities that are inconsistent or troubling

AND includes:

- Leadership's acknowledgement of its responsibility to act on information provided and prevent retaliation stemming from an individual's responsibility to report

Culture of Trust, Integrity, and Responsibility

Information

- Raise awareness, educate, and clarify expectations

Empowerment

- Provide individuals with the tools and information needed to make the right decisions

Accountability

- Expect individuals to be accountable for their decisions

Visible Champions Among Upper Leadership

- Speaking publicly of pride in performing biosecurity research and the confidence the institution has in its processes
- Ensuring Emergency Response Plan includes consideration of biosecurity breach
- Providing resources for and attending seminars that stress need for biosecurity
- Providing funding for security enhancements and training

Reporting Mechanisms

Multiple avenues to encourage reporting:

- Chain of leadership up to the president
- Human Resources
- Biosafety Department
- University Compliance, Risk Management, or Legal
- Hotline or help line (to remain anonymous)

Any individual receiving a report is responsible for:

- Informing the appropriate individuals charged with validating and resolving the concern
- Following the matter to ensure appropriate resolution
- Maintaining confidentiality

Investigation and Response

Investigation:

- Respond immediately
- Notify any party informed or interviewed of Good-faith Reporting and Non-retaliation Policies
- Keep interviews confidential to the extent allowable under the law
- Substantiate or refute claim or allegation
- If valid, risk-rate the findings and inform leadership and those responsible for response
- If unsubstantiated, inform appropriate parties and produce an issue closure report

Response for substantiated findings:

- Immediate for high risk-rated matters
- Develop and implement corrective action plans to ensure non-recurrence
 - Action-oriented and time-based
 - Appropriate consequences
 - Policy development
 - Use as learning opportunity where possible
- Independent validation of effectiveness

An Important Follow-Up: Ongoing Assessment of the Biosecurity Culture

Periodic independent assessment of culture of responsibility:

- Confirm all staff received training
- Blinded interview/survey of staff regarding:
 - Confidence in appropriate bio security practices
 - Comfort with reporting responsibility
 - Faith in non-retaliation for reporting
 - Observe violations of security (if violation occurs, was it reported? if not, what was the reason?)
 - Suggestions, if any, to improve security
 - Any concerns to report

Assessment results provided via management line up to VP

- Areas of concern immediately addressed
- Results from follow-up effectiveness review included in performance review of local manager and direct supervisor

Balance Must Be Maintained To Optimize Our Security

- We must protect the public now
- We must protect the public in the future
 - Long-range goals such as vaccines and treatments require research, but performing this research must not be so burdensome that talented investigators leave the field
 - Psychological evaluations would only contribute to complexity with little evidence of effectiveness
 - Several institutions chose to destroy valuable inventories rather than maintaining or transferring stocks
 - Research is already very expensive, both for the investigator and for the institution
 - Costs need to be appreciated by funding agencies