

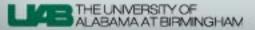
Championing Biosecurity

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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:

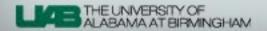
- Quality in all aspects of university activities
- Individuals to be treated with respect
- Compliance with applicable laws, regulations, and policies
- Confidential information to be used responsibly
- University resources to be safeguarded
- A safe environment

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

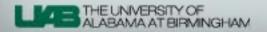
 Provide individuals with the tools and information needed to make the right decisions

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

