



**Managing  
Personnel Reliability  
at the  
Galveston National  
Laboratory  
University of Texas  
Medical Branch**

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# Select Agent Research Program at UTMB

## Secure Select Agent Facility

BSL-2 52,634 net ft<sup>2</sup>

BSL-3 29,713 net ft<sup>2</sup>

BSL-4 14,330 net ft<sup>2</sup>

*>4 years of safe and secure BSL-4 operations*

**~380 SRA-approved Employees**

**FY10 Security Costs: > \$4,000,000**

**Focus: Basic pathogenesis and discovery research  
GLP validation of vaccines and therapies**

**A deeply engrained culture of safety  
stems from a strong team spirit**

**Two multi-disciplinary committees  
advise the RO and multiple AROs**

**Active support and engagement of  
the highest levels of university  
administration**

**Extensive community outreach**

**Web-based posting of potential  
research-related exposures to any infectious agent**

**<http://www.utmb.edu/GNL/safety/report.shtml>**

# **Notable Similarities and Differences in UTMB's Current BSAT Personnel Policies and Federal PRP Programs**

**Shared requirement for DOJ SRA and CDC registration q5 yrs**

**No consolidated, formal PRP exists at UTMB**

**Rules, regulations reside within multiple distinct UTMB policies**

**State institution, not a federal agency, subject to state laws**

**UTMB 'Level 2' Security Check on employment (Acxiom)**

**Pre-employment drug screen (and q3 yrs for BSL-4 staff)**

**No two-person rule for accessing BSAT stocks**

**Live and taped video of BSAT stocks only at BSL-4**

**Use of deadly force is authorized to prevent unauthorized access**

## **Other Current UTMB Policies**

**Mandatory annual training for all BSAT users**

**Formal annual attestation by BSAT users of non-restricted status**

**Full medical examination with mini-mental for BSL-4 staff q3 yrs**

**Institutional promotion of a culture of “self-reporting”**

**Emphasis on PI responsibility**

**Containment Lab Scientific Directors**

**Biosafety and biosecurity staff recognized as part of the “team”**

**Active RO Advisory Committee**

**Multi-disciplinary Biocontainment & Risk Assessment Committee**

# Considerations for a More Formal PRP at UTMB

## Why?

- Imperative to continuously assess and improve operations.
- Need to assure local and national stake-holders that all possible measures are being taken to ensure the safety and security of BSAT operations.
- Recognition that the ability to conduct research at high containment and with BSATs is a privilege, not a right.

# Considerations for a More Formal PRP at UTMB

## How?

- Need to respect the privacy of individuals.
- Need to ensure that a culture of “self-reporting” is not replaced by a culture of “big brother is watching”, and that individuals are not punished for temporary suspension of access.
- Need to conform to state laws and employment policies.
- Need to accommodate foreign students and postdocs

## **Considerations for a More Formal PRP at UTMB**

### **How?**

- Need to ensure that research essential to public health and the security of our society is not unnecessarily impeded.**
- Strong belief that an effective PRP is an institutional responsibility that cannot be managed by the federal government.**



## Essential Elements of a Draft UTMB PRP

Focus on BSL-4 staff given complexities and stress of BSL-4 research, pathogenicity of BSL-4 agents, and numbers of involved staff (~28 persons).

Sequential, compartmentalized reviews by HR, Employee Health Service, and Biosafety Officer/ARO to protect confidentiality and ensure expert evaluation at each step:

 HR: Employee consents, background checks, drug screen

Employee Health: “Fit for duty” determination

Biosafety Officer: Safety training, SRA

Certifying Official (RO)

Certifying Official approves access only with positive determinations from each preceding level of review.

## Sequential Steps in Draft UTMB PRP

- ❑ **HR**: Consents: Prior employment and medical records  
Background checks: local and national databases  
Drug screen, Employment offer letter with stipulations



- ❑ **Employee Health**: “Fit for duty” determination  
BSL-specific health and medical examination  
BSL-4: Complete physical examination  
Mental health: MMPI-2 and R-BANS  
Expert panel review as needed



- ❑ **Biosafety Officer**: BSL-specific training  
DOJ Security Risk Assessment, CDC registration



- ❑ **Certifying Official** (Responsible Official)

## Other Considerations

- “Yes-No-Deferred” determination at each step of the process; to protect privacy, details of the review do not flow to the next review level.**
- Once granted, access can be terminated immediately by Laboratory Director, Biosafety Officer, or RO/ARO.**
- Limited appeal process for loss of access due to biosafety concerns (Institutional Biosafety Committee).**
- Laboratory staff encouraged to “opt out” without penalty if inter-current illness, medications, etc.**

## Other Considerations

- Concerns about utility of formal mental health assessments (MMPI-2, R-BANS) and their applicability to foreign-born students, post-docs, and staff.
- Use of credit checks considered, but thought to be unhelpful in assessing reliability, difficult to standardize assessment across employee groups, and possibly constrained by state law.
- All staff recognize that institutional e-mail traffic is not private and always subject to review.

## Concluding Thoughts

- ❑ The scale of UTMB's BSAT research program increases the feasibility of a formal PRP. Such programs may not be feasible at academic centers with smaller BSAT research programs.
- ❑ Close personal working relationships in a team environment are likely to be much more effective than any formal PRP in early recognition and management of potential reliability issues.
- ❑ There is a need for better training for supervisors regarding early recognition of potential reliability concerns.



Thank You