

# Managing Personnel Reliability at the University of Texas Medical Branch



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# Select Agent Research Program at UTMB

## Secure Select Agent Facilities

BSL-2 5,200 net ft<sup>2</sup>

BSL-3 & ABSL3 29,713 net ft<sup>2</sup>

BSL-4 & ABSL4 14,330 net ft<sup>2</sup>

*>6 years of BSL-4 operations*

~350 SRA-approved Employees

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

Focus: Basic pathogenesis and discovery research

Product development and evaluation

GLP validation of vaccines and therapies

## UTMB's Approach to PRP

- ❑ Accept the responsibility and challenge of ensuring responsible research
- ❑ Protecting personal information from public disclosure
- ❑ Look for innovative ways to address PRP
- ❑ Conform to state laws and employment policies
- ❑ Improve and stream line existing reliability measures already in place
- ❑ Strong belief that an effective PRP is an institutional responsibility

## Process of the UTMB PRP

- ❑ Focus on BSL-4 staff, not BSAT, given complexities and stress of BSL-4 research, pathogenicity of BSL-4 agents, and numbers of involved staff (~35 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, initial background checks, drug screen

Employee Health: “Fit for duty” determination

Biosafety Officer: Safety training, SRA

- ❑ Access is granted only with positive determinations from each preceding level of review.

## Human Resources

- Informed consent:
  - Informs applicant of program requirements
  - Reviews restricted persons criteria
  - Previous employer and reference check release
- Previous employment records
- Education verification
- Drug screen
- Level 2 Background check:
  - Suspected terrorist list
  - FBI alleged suspects
  - Designated foreign terrorist organization list
  - FBI's most wanted
  - OSFI-Individual Terrorist
  - OSFI-Entities of concern to the business community
  - Bank of England
  - European Union list
  - Sanctioned countries
  - Denied person list
  - Unverified list
  - List of debarred parties
  - Selective service verification
  - EPLS: Excluded party screening
  - Sex offender registry
  - National Criminal Access Search (7 years)

# Employee Health Services

## Biosafety level specific health assessment

### Routine medical questionnaire:

Completed annually

Required for BSL-2 – BSL-4

Current medications

Allergies

Vision

Bronchitis

Asthma

Pneumonia

Tuberculosis

Abnormal breathing tests

Hepatitis

Diabetes

Thyroid

Immunological disease

Skin issues

Unexplained fever

Bleeding problems

Previous exposures

Immunizations

### Respiratory fit test

Completed annually

Required for BSL-3 - BSL-4

### Review of relevant medical records as need

# Employee Health Services

## Biosafety level specific health assessment

### BSL-4 ONLY:

#### Complete medical assessment (q 3 years)

Full physical

Audiogram

PPD

Vision testing

Chest X-ray

Spirometry

EKG

Drug screen

Breath alcohol test

CBC

Required immunizations

Baseline serum collection

Hepatitis panel

HIV

Urine dip

Comprehensive  
metabolic panel

## Mental health assessment (q 3 years)

Clinical interview

Depression, anxiety, and substance abuse

Referral for clinical assessment as needed

Quality assurance review



## Employee Health Services Summary

	<b>Medical Questionnaire (q 1 year)</b>	<b>Respiratory Fit Test (q 1 year)</b>	<b>Complete Physical Assessment (q 3 years)</b>	<b>Drug and Alcohol screen (q 3 years)</b>	<b>Mental Health Assessment (q 3 years)</b>
BSL-2	X	X			
BSL-3	X	X			
BSL-4	X	X	X	X	X



## Biosafety and Security

- Biosafety theoretical and hands on classes
  - Pre and post assessments
- SRA approval process
- Security Training
- Facility safety and security orientation
- Biosafety Officer check off and review
  - Ensures appropriate training & documentation is complete
- Mentorship
  - Must be mentored for specific number of hours
- Annual training
  - Biosafety and incident response
  - Biosecurity
  - Restricted persons self declaration

# Estimated Cost of PRP

<b>PR Elements</b>	<b>ESTIMATED Cost/Person</b>
Background Check(UTMB Level 2	35
Complete Physical	500
Drug screen	50
Mental Health Assessment	270
Training	2,000-5,000
Quality Assurance	200
Review process	1,000-?
<b>Cost for 1 New Hire BSL-4 Person</b>	<b>~ 4 - 7,000</b>

# Ongoing Evaluation

- Self reporting
  - Opt- out of containment work
  - Communicate with
    - Biosafety Officers
    - Supervisors
    - Employee Health
- Peer reporting
  - Additional training under development
- Supervisor reporting and communication
  - Additional training under development

# PRP Risks

- Overly prescriptive rules could hinder local implementation
- Federal rules don't provide information protection
- Specific metrics exclude various populations (*i.e.* students)
- Financial burden over whelms smaller institutions
- Lawsuits
- Abuse of system via false reports, retaliation, access to information
- Poor decisions are made for the wrong reasons
- Peer reporting fails

# Culture of Responsibility

It is the responsibility of the administration to support the processes that are in place.

It is the responsibility of each person to be aware of their surroundings and their co-workers.

It is the responsibility of each person to seek information and help when necessary.

It is the responsibility of the entity as a whole to make the process work.



**Thank You**