Managing Personnel Reliability at the University of Texas Medical Branch



Dee Zimmerman Biosafety Officer Alternate Responsible Official Environmental Health and Safety

Select Agent Research Program at UTMB

Secure Select Agent Facilities
BSL-2 5,200 net ft²
BSL-3 & ABSL3 29,713 net ft²
BSL-4 & ABSL4 14,330 net ft²
>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

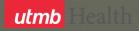
- ☐ Focus on BSL-4 staff, not BSAT, given complexities and stress of BSL-4 research, pathogenicity of BSL-4 agents, and numbers of involved staff (~35 persons).
- ☐ Sequential, compartmentalized reviews by HR, Employee Health Service, and Biosafety Officer/ARO to protect confidentiality and ensure expert 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				
□ <u>Drug screen</u>				
☐ Level 2 Background check:				
□Suspected terrorist list □FBI alleged suspects	☐Sanctioned countries ☐Denied person list			
□ Designated foreign terrorist organization	·			
	□List of debarred parties			
□FBI's most wanted	☐Selective service verification			
□OSFI-Individual Terrorist	□EPLS: Excluded party screening			
□OSFI-Entities of concern to the business	Sex offender registry			

□National Criminal Axcess Search (7 years)

community

□Bank of England

□European Union list

Employee Health Services

☐ Biosafety level specific health assessment □ Routine medical questionnaire: ☐ Completed annually ☐ Required for BSL-2 – BSL-4 □Current medications □ Abnormal breathing tests □Bleeding problems □ Allergies □ Hepatitis □ Previous exposures □Vision □ Diabetes □ Immunizations □ Bronchitis □ Thyroid □ Asthma □Immunological disease □Skin issues □ Pneumonia □ Tuberculosis □Unexplained fever □ Respiratory fit test □ Completed annually ☐ Required for BSL-3 - BSL-4 ☐ Review of relevant medical records as need



Employee Health Services

Biosafety leve	el specific hea	alth assessment		
□ BSL-4 ON	ILY:			
☐ Comp	olete medical	assessment (q 3 yea	ars)	
□Audiog □PPD □Vision t □Chest >	ram esting <-ray	□Drug screen □Breath alcohol test □CBC □Required immunizations □Baseline serum collection □Hepatitis panel □HIV	□Urine dip □Comprehensive metabolic panel	
☐ Mental he	alth assessm	nent (q 3 years)		
☐ Clinical interview				
Depression, anxiety, and substance abuse				
☐ Referral for clinical assessment as needed				
Quality assurance review				
	BSL-4 ON Comp Full phy Audiogn PPD Vision to Chest > Spirom EKG Mental he Clinic Depre	□ BSL-4 ONLY: □ Complete medical □ Full physical □ Audiogram □ PPD □ Vision testing □ Chest X-ray □ Spirometry □ EKG □ Mental health assessm □ Clinical interview □ Depression, anxiet □ Referral for clinical	□ Complete medical assessment (q 3 years) □ Full physical □ Drug screen □ Audiogram □ Breath alcohol test □ PPD □ CBC □ Vision testing □ Required immunizations □ Chest X-ray □ Baseline serum collection □ Spirometry □ Hepatitis panel □ EKG □ HIV □ Mental health assessment (q 3 years) □ Clinical interview □ Depression, anxiety, and substance about the Referral for clinical assessment as need.	

Employee Health Services Summary

	Medical Questionnai re (q l year)	Respirator y Fit Test (q 1 year)	Complete Physical Assessmen t (q 3 years)	Drug and Alcohol screen (q 3 years)	Mental Health Assessme nt (q 3 years)
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

PR Elements	ESTIMATED Cost/Person
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-?
Cost for 1 New Hire BSL-4 Person	~ 4 - 7,000

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.

