











# Select Agent Program Workshop November 2011

Agricultural Select Agent Program (USDA/APHIS)

CDC Select Agent Program (HHS/CDC)

Bioterrorism Risk Assessment Group (FBI/CJIS)







Eli W. Warnock III, M.D.

Medical Director

CDC

Office of Health, Safety, and Environment













Start with open communication between medical, biosafety, research, operations, support, and facility personnel.

Keep these lines of communication open through regularly scheduled interactions and more frequent informal contacts











Risk/hazard assessment should be performed for all work spaces and all activities to be performed within those spaces.

This should be updated periodically by schedule, and each time the conditions change.











Pre-hire (or pre-transfer) "fitness for duty" criteria.

May consist only of ability/willingness to take certain immunizations, or may have more specific fitness parameters. Be mindful of ADA/EEO considerations, and work with HR and Legal to avoid miss-steps.











Pre-hire (or pre-transfer) "fitness for duty" criteria.

Establish objective and well-documented process for performing any pre-hire fitness for duty examinations.













Pre-hire (or pre-transfer) "fitness for duty" criteria.

Certain immunizations or proof of prior immunity (documented history of immunization or confirmatory titers) may be set as requirements for performing the essential duties of the position.

This must be clearly communicated during the recruitment and hiring process. It is MUCH more difficult to impose requirements after the fact, especially if the workforce is unionized.













#### **Immunizations**

Certain immunizations may be for worker protection (and by extension, protection of the organization from injury claims), while others may be for the protection of the research animal colonies. Immunization may also have public health considerations.











#### **Immunizations**

Other immunizations may be strongly recommended but not required.

Required immunizations and/or titers for work-related pathogens should ideally be offered free of charge to workers through the occupational health program.

May also consider other general ACIP recommended adult immunizations as part of a general wellness program.













## **Periodic Health Screening**

To assess any interval changes in fitness.

To identify any medical conditions that would place the worker at increased risk (may need to modify work practices, alter PPE or engineering controls, or even restrict access.)













#### **Periodic Health Screening**

High-containment lab work: may consider screening for cardiac arrhythmias/CAD, seizures, other conditions that might result in sudden loss of consciousness. Extraction of unconscious or immobile personnel from contaminated high containment area may be problematic.













#### **Periodic Health Screening**

To identify any work-related conditions. Examples would include development of research animal allergies...may consider a separate mechanism for this specific item for those at risk.













## **Periodic Health Screening**

Develop a mechanism for reporting and addressing pregnancy and other immunocompromising personal medical conditions that may occur at intervals between scheduled screenings. Be mindful of privacy and ADA/EEO issues.











## **Periodic Health Screening**

Mandated screenings such as respirator medical clearance updates.

(Must be specific to the types of respirators that may be used.)













#### Surveillance

Serological surveillance for certain potential exposures such as brucella or Q-fever.













#### Surveillance

Disease surveillance for animal colony protection.

(e.g. periodic Tb skin testing or blood testing using interferon gamma assays.)













#### **Exposure Response**

Reporting mechanism must be streamlined and clear.

MUST encourage reporting of all exposures and near-misses by making process simple and non-judgmental.

Exposure follow-up should be educational and not punitive.













#### **Exposure Response**

Mechanism should be established to clearly communicate specific biohazard exposure risk to safety and medical staff.

Security staff should also be notified if access to the immediate area should be limited.

There may also be statutory/regulatory reporting requirements, but the burden for this should not interfere with the immediate medical response.













#### **Exposure Response**

What was the agent involved? (live/viable, attenuated, "natural" vs. experimental/lab-created)

What was the (potential) route of exposure? (Splash, bite, puncture/sharps injury, inhalation, ingestion)

What was the concentration/volume?
What was the status of PPE/engineering controls?













#### **Exposure Response**

What was the concentration/volume?

What was the status of PPE/engineering controls. (Single or double gloves? Were gloves intact? Were they leak-tested? Biosafety hood in use and functioning normally?)













#### **Exposure Response**

Updated protocol lists, room-specific hazard cards, contact info for PI/SME, etc.

Any concomitant organisms/diseases that the source could potentially have (Herpes B, rabies, Hepatitis, HIV).

Any recombinants involved?













#### **Exposure Response**

Immediate post-exposure actions: local decontamination (eye-wash, wound irrigation/scrubbing, skin decontamination, clothing removal/decontamination/disposal, notification trees.











#### **Exposure Response**

Evaluation and treatment protocols.

Immediate PEP indicated? Readily available?

After hours access mechanism. Any immediate lab studies needed for baseline serology, CBC, chem. Panels, urine? Immediate "baseline" serum for storage? Unique or specific lab studies...where/how are they sent?













#### **Exposure Response**

Any immediate baseline lab studies needed for baseline serology, CBC, chem. panels, urine?

Immediate "baseline" serum for storage?

Unique or specific lab studies...where/how are they sent?













## **Exposure Response**

Follow-up schedule for re-examination?

Interval for lab draws.

Referral mechanism.













#### **Exposure Response**

Mechanism to report symptoms.

Isolation considerations.













#### **Exposure Response**

Work restrictions.

Workers Comp issues.

























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For more information, please contact the Select Agent Program

Telephone: 301-734-5960 (APHIS) or 404-718-2000 (CDC)

E-mail: <u>Agricultural.Select.Agent.Program@aphis.usda.gov</u> (APHIS) or <u>Irsat@cdc.gov</u> (CDC)

Web: www.selectagents.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.





