

## STANDARD OPERATING PROCEDURES CDC Reporting of Select Agent

<b>Title:</b> CDC Reporting of Select Agent	<b>SOP:</b> Version 4
<b>Updated:</b> March 2019	

### **PURPOSE:**

Select agents and toxins are those biological agents and toxins which the Federal government has determined to have the potential to pose a severe threat to public health and safety to animal health, or to animal products. The purpose of this standard operating procedure (SOP) is to describe the policy and procedures associated with the identification and reporting of select agents at the VMTH.

VMTH is a Non-Registered Entity (NRE): **#NRE071350**. Please use this number when submitting Form 3 or 4.

### **REPORTING THE THEFT, LOSS, OR RELEASE OF SELECT AGENTS AND TOXINS – [CDC FORM 3](#)**

The APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins, is used by entities to report a theft, loss, or release of a select agent or toxin (See Appendix 1 for a list of Select Agents and Toxins). An entity is required by regulations (7 CFR 331, 9 CFR 121, and 42 CFR 73) to contact the Federal Select Agent Program immediately upon the discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin. APHIS/CDC Form 3 must be sent to APHIS or CDC within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. Form 3 is available on the CDC and APHIS website (<https://www.selectagents.gov/form3.html>).

- Report theft, loss, or release of Select Agents immediately to the VMTH Reporting Official, who in turn will complete APHIS/CDC Form 3. All involved parties must submit a detailed summary of events including a timeline of what occurred.

**Shirley Liu**  
VMTH Select Agent Reporting Official  
Telephone: (530)219-0632  
Email: [sleung@ucdavis.edu](mailto:sleung@ucdavis.edu)

Answers to the following questions will help in the reporting process:

- What was the date of the incident?
- What type of incident was this? Theft, Loss, Release, or Lab Acquired Infection?
- Did the release result in a potential exposure? Has medical surveillance been initiated? Were personnel exposed provided information concerning the select agent, symptoms, etc.?
- What time did the incident occur?

- Where did this incident occur?
  - How did the exposure or release occur?
  - Biosafety level?
  - What is the name of the select agent or toxin being reported? Characterization of the agent (e.g. strain, ATCC #, type of tissue)? What is the quantity?
  - What is the timeline of exposure?
  - Was any risk assessment of the event conducted to determine the root cause of the incident?
  - What was the specific personal protective equipment worn by personnel in the area?
  - What were the hazards posed to humans by the extent of the release or occupational exposure?
  - What is the estimated extent of the release or exposure in relation to the proximity of susceptible humans, animals, and plants?
  - What was done to the material that contained the select agent (it needs to be disposed within seven days, unless it is saved as a formalin-fixed paraffin-embedded block of tissue using a method that is published for that specific select agent – the facility needs to have an SOP that matches the published method and references that article)?
  - How was the laboratory or work surfaces decontaminated after the incident?
  - For investigative purposes, provide the names of the exposed personnel. These names will not be used to report to the CDC.
- Upon completion, VMTH Reporting Official will have the following Biosecurity officers sign off on APHIS/CDC Form 3. The completed forms will then be submitted to the CDC.

**Dr. Steven Epstein**

VMTH Small Animal Biosecurity Officer

Telephone: (530)400-2539

Email: [seepstein@ucdavis.edu](mailto:seepstein@ucdavis.edu)

**Dr. K. Gary Magdesian**

VMTH Large Animal Biosecurity Officer

Telephone: (530)752-4255

Email: [kgmagdesian@vmth.ucdavis.edu](mailto:kgmagdesian@vmth.ucdavis.edu)

- ❖ If a Biosecurity officer is not available to sign off on the Form3, a Laboratory Supervisor will sign off on the document.
- Once Form 3 is completed and signed by the IDC Officers, the VMTH Select Agent Reporting Official will send all necessary documents to the CDC. He/She will be the point of contact for the VMTH.

Centers for Disease Control and Prevention

Division of Select Agents and Toxins

1600 Clifton Road NE, Mailstop A-46

Atlanta, GA 30333

Fax: (404)471-8375

Email: [form3@cdc.gov](mailto:form3@cdc.gov)

## **REPORTING THE DIAGNOSIS/VERIFICATION/IDENTIFICATION OF A SELECT AGENT OR TOXIN FROM A CLINICAL/DIAGNOSTIC SPECIMEN – CDC FORM 4A**

“Identification” occurs at that point and time that a definitive test confirms the presence of a select agent in or from a specimen. Regardless of the amount identified, clinical and diagnostic laboratories that identify a select agent contained in a sample presented for diagnosis or verification must report the identification of the agent. Regulatory obligations begin on the day of confirmatory identification.

The APHIS/CDC Form 4A, Report of the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

Clinical or diagnostic laboratories and other entities that have identified select agents or toxins (See Appendix 1 for a list of Select Agents and Toxins) contained in a specimen presented for diagnosis or verification are required by regulation (7 CFR 331, 9 CFR 121, and 42 CFR 73) to report the identification within 7 calendar days to the Federal Select Agent Program. Form 4A is available on the CDC and APHIS website (<https://www.selectagents.gov/form4.html>).

- Upon confirmatory identification of a select agent or toxin, clinical or diagnostic laboratories must notify the VMTH Select Agent Reporting Official immediately (e.g., via telephone, or email). In addition, the **completed** and **signed** APHIS/CDC Form 4A must be sent immediately to the reporting official.

**Shirley Liu**

VMTH Select Agent Reporting Official

Telephone: (530)219-0632

Email: [sleung@ucdavis.edu](mailto:sleung@ucdavis.edu)

- In addition to reporting the identification of a select agent or toxin contained in a specimen presented for diagnosis or verification using the APHIS/CDC Form 4A, the following select agents and toxins are required to be immediately (i.e. within 24 hours) reported to Federal Select Agent Program (e.g., via telephone, fax, or email):
  - *Bacillus anthracis*
  - *Bacillus cereus*
  - Biovar *anthracis*
  - Botulinum neurotoxins
  - Botulinum neurotoxin producing species of Clostridium
  - *Burkholderia mallei*
  - *Burkholderia pseudomallei*
  - Ebola virus
  - Foot-and-mouth disease virus
  - *Francisella tularensis*
  - Marburg virus
  - Rinderpest virus
  - Variola major virus (Smallpox virus)
  - Variola minor virus (Alastrim)
  - *Yersinia pestis*

- Once received, the VMTH Select Agent Reporting Official will send all necessary documents to the CDC. He/She will be the point of contact for the VMTH.

Centers for Disease Control and Prevention  
Division of Select Agents and Toxins  
1600 Clifton Road NE, Mailstop A-46  
Atlanta, GA 30333  
Fax: (404)471-8469  
Email: CDCForm4@cdc.gov

Upon confirmatory identification of a select agent or toxin and potential for exposure, VMTH Select Agent Reporting Official must also notify EH&S immediately. Reporting to EH&S can be accomplished by emailing:

**Philip Barruel**

UC Davis Select Agent Program Responsible Official  
Telephone: (530)752-1777  
Fax: (530)752-4527  
Email: [prbarruel@ucdavis.edu](mailto:prbarruel@ucdavis.edu)

**Chelsea Schiano**

UC Davis Select Agent Program Responsible Official – Alternate  
Telephone: (530)752-8589  
Fax: (530)752-4527  
Email: [caschiano@ucdavis.edu](mailto:caschiano@ucdavis.edu)

- ❖ If there was a potential for theft or loss, notify campus Police
  - Non-emergency: (530)752-1727 or <https://police.ucdavis.edu/>
- ❖ If there was a potential for exposure, complete [CDC Form 3](#)

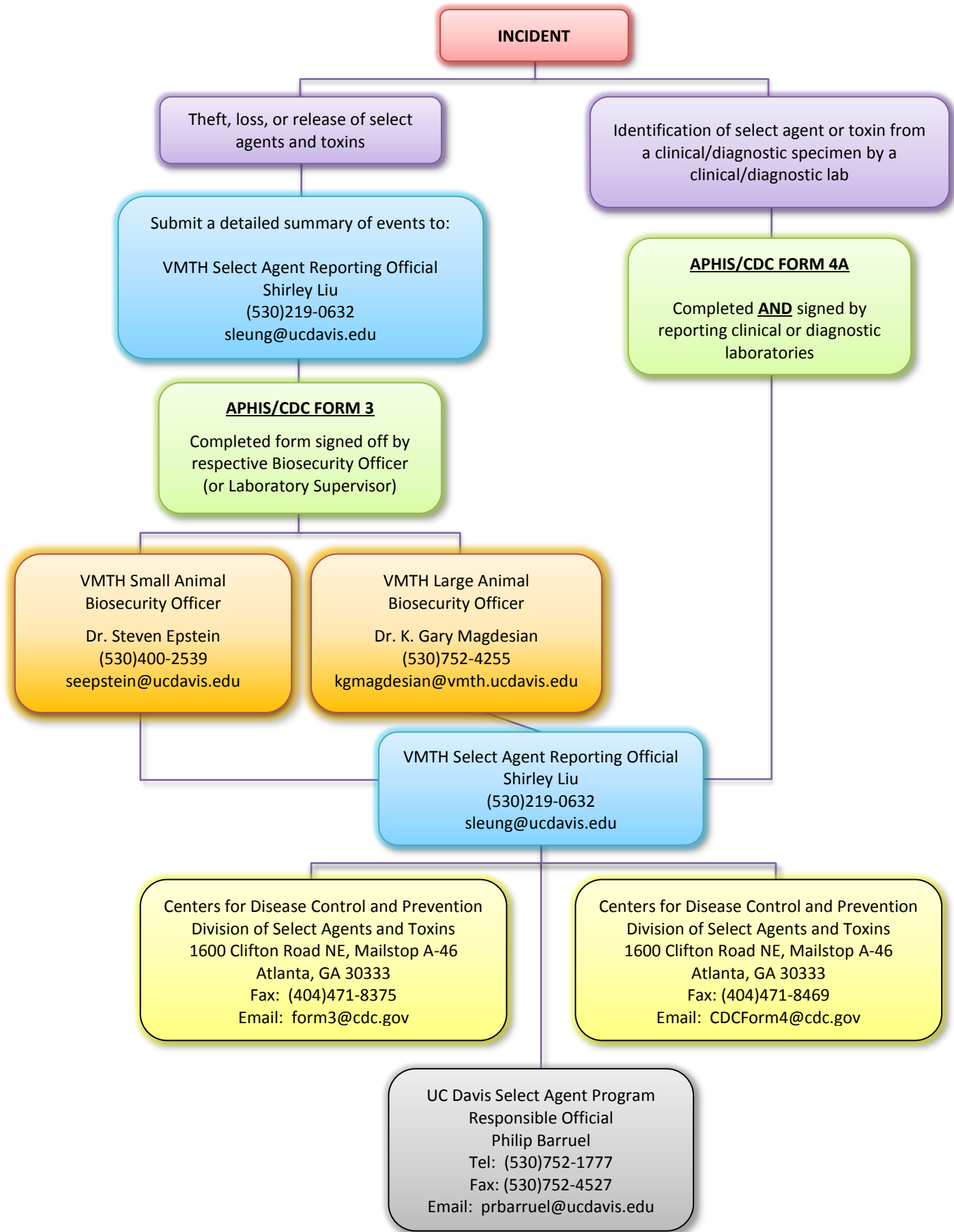
## **DESTRUCTION**

All specimens, samples, and isolates (including regulated genetic elements, recombinant organisms, etc.) must be destroyed, and inactivated/rendered incapable of replication. Below are the approved recognized methods that can be used:

- Autoclave
- Irradiation
- Incineration
- Chemical
- Commercial medical waste disposal company (any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company)

## **SUSPECTED OR KNOWN EXPOSURES**

Suspected or known occupational exposures to a select agent may be considered a “release” and therefore reportable to APHIS/CDC. All such situations must be reported to EH&S and Occupational Health Services immediately.



## **CONTACTS:**

### **CENTER FOR DISEASE CONTROL (CDC)**

**Kurtis W. Straub** - Microbiologist/Form 3 Coordinator  
Division of Select Agents and Toxins (DSAT) Center for Preparedness and Response Centers for  
Disease Control and Prevention (CDC)  
1600 Clifton Road, NE MS A-46  
Atlanta, GA 30329  
Tel: (404) 718-2027; Mob: (404) 904-1016; Fax: (404) 471-8333  
Email: [wul1@cdc.gov](mailto:wul1@cdc.gov)  
Website: [www.selectagents.gov](http://www.selectagents.gov)

### **CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE (CDFA)**

**Kent Fowler** - Branch Chief  
1220 N Street  
Sacramento, CA 95814  
Tel: (916) 900-5002  
Fax: (916) 900-5333  
Email: [KFowler@cdfa.ca.gov](mailto:KFowler@cdfa.ca.gov)

### **VMTH: ANATOMIC PATHOLOGY NECROPSY SERVICE**

**UC Davis School of Veterinary Medicine - VMTH**  
**Becky Griffey** - Anatomic Pathology Service Manager  
One Shields Avenue; VM3A #1345  
Davis, CA 95616  
Tel: (530)752-1369  
Fax: (530)754-1400  
Email: [mggriffey@ucdavis.edu](mailto:mggriffey@ucdavis.edu)

### **NAPA-SOLANO-YOLO-MARIN COUNTY PUBLIC HEALTH LABORATORY**

Katya Ledin – Director  
2201 Courage Drive, MS9-200  
Fairfield, CA 94533  
Tel: (707)784-4410  
Fax: (707)423-1979

The following laboratories are used for PCR testing. If something is reported positive that is a select agent, they would need to fill out CDC/APHIS Form 4A.

### **COMPARATIVE PATHOLOGY LABORATORY (CPL)**

**UC Davis School of Veterinary Medicine**  
**Dr. Denise M. Imai-Leonard** - Director  
1000 Old Davis Road  
Main Laboratory R-1  
Davis, CA 95616  
Tel: (530)754-4937/(530)752-2832  
Fax: (530)754-9159  
Email: [dmimai@ucdavis.edu](mailto:dmimai@ucdavis.edu)

**TACMAN LAB**

**UC Davis School of Veterinary Medicine** Real-time PCR Research and Diagnostics Core Facility

**Samantha Barnum** - Laboratory Manager

3110 Tupper Hall, UC Davis

Davis, CA 95616

Tel: (530)752-7991

Fax: (530)754-6862

Email: [smmapes@ucdavis.edu](mailto:smmapes@ucdavis.edu)

**WASHINGTON ANIMAL DISEASE DIAGNOSTIC LAB (WADDL)**

**College of Veterinary Medicine, Washington State University**

Bustad Hal, Room 155-N

Pullman, WA 99164-7034

Tel: (509)335-9696

Fax: (509)335-7424

Email: [waddle@vetmed.wsu.edu](mailto:waddle@vetmed.wsu.edu)

Website: <https://waddl.vetmed.wsu.edu/>

The following laboratory is used for Microbiology, Toxicology, and Immunohistochemistry testing. If something is reported positive that is a select agent, they would need to fill out CDC/APHIS Form 4A.

**CALIFORNIA HEALTH AND FOOD SAFETY LAB (CAHFS)**

**Elizabeth Reay** - Responsible Official at CAHFS for 'Select Agents'

1125 Thurman

UC Davis

Davis, CA 95616

Tel: (530)752-7508

Fax: (530)752-8299

Email: [ereay@ucdavis.edu](mailto:ereay@ucdavis.edu)

The following laboratory is used for Microbiology testing. If something is reported positive that is a select agent, they would need to fill out CDC/APHIS Form 4A.

**VMTH MICROBIOLOGY LABORATORY**

**Dr. Barbara Byrne**

UC Davis

Davis, CA 95616

Tel: (530)754-6286

Fax: (530)752-3349

Email: [bbyrne@ucdavis.edu](mailto:bbyrne@ucdavis.edu)