Federal Select Agent Program Training

Agriculture Select Agent Services (USDA/APHIS)
Division of Select Agents and Toxins (HHS/CDC)
Bioterrorism Risk Assessment Group (FBI/CJIS)
eFSAP Information System Training
OUTLINE

- Contact Information
- APHIS/CDC Form 1 Verification
- APHIS/CDC Form 1 Amendments
- APHIS/CDC Form 3 Submission
AGENCY POINTS OF CONTACT

Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services
Cassie Armiger
cassie.c.armiger@aphis.usda.gov
301.851.2052
Chuck Divan
charles.l.divan@aphis.usda.gov
301.851.2219

Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins
Cara Jacob
CJacob@cdc.gov
404.718.2028

Von McClee
VMcClee@cdc.gov
404.718.2065
ADDITIONAL CONTACT INFORMATION

- For assistance with Secure Asset Management System (SAMS), entities should use DSATSAMSHAELP@cdc.gov

- Entities should submit amendments and inspection-related documents directly into eFSAP once the system is released to the entity.
APHIS/CDC Form 1 Verification
eFSAP APHIS/CDC Form 1 Verification

- Review APHIS/CDC Form 1 information for each section
- Verify eFSAP APHIS/CDC Form 1 contains complete, accurate and current information compared to your records on file
- Provide confirmation of successful APHIS/CDC Form 1 data transition to FSAP:
  - Responsible Official must email your FSAP POC once your entity has verified the Form 1
eFSAP Landing Page

Federal Select Agent Program Portal

Entity: University of Select Agents

LEAD AGENCY: CDC
REGISTRATION STATUS: Approved

Facility Address: 100 University Ave, Gainesville, FL 303411928

Responsible Official Name: Allen Alton
Responsible Official Title: President

Registration #: Application #: 0000000000000000

Type Status: Government - Federal

Notifications

- This is Section 1 8/29/2017 2:21:39 PM
- Testing General Discussion Functionality 8/29/2017 1:24:29 PM
- Amendment was modified (State: Submitted Amendment) by responsible official on 8/29/2017 1:01:54 PM with Cover Letter: Testing Amendment function...
- Hello world 8/28/2017 5:28:00 PM
- The only way to get to the discussion window for F3s is to create a new F3 or open a current F3. Entering this as an agency user. 8/28/2017 3:12:45 PM
eFSAP Landing Page

General Discussion

Notes between Agency and the Entity.
eFSAP Landing Page

Federal Select Agent Program Portal

Entity: University of Select Agents

LEAD AGENCY: CDC

Facility Address: 108 University Ave, Gainesville, FL 32611

Responsible Official Name: Allen Atkins
Responsible Official Title: President

Registration #: 606c2e7d-929-e71f-f00c-f0036e2
Application #: 606c2e7d-929-e71f-f00c-f0036e2

Responsible Official Address: 1000 University Ave, Gainesville, FL 32629

Type Status: Government - Federal

Summary of Amendments and their status:

<table>
<thead>
<tr>
<th>Entity Name</th>
<th>Cover Letter</th>
<th>Date Submitted</th>
<th>Status</th>
<th>RO Submitter</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>University of Select Agents</td>
<td>Add PI Williams: See document upload, file name: Section7_PI_Williams.pdf</td>
<td>08/01/2017</td>
<td>Draft</td>
<td>responsible official</td>
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<td>Remove ARO Due from the registration. Reason for removal: job duties no longer require access to select agents</td>
<td>07/26/2017</td>
<td>Posting</td>
<td>responsible official</td>
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<td>Update PI Crick work objectives to add ferret animal model. See document upload, file name: Section7_AttachC_PI_Crick.pdf</td>
<td>08/03/2017</td>
<td>Posting</td>
<td>responsible official</td>
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<tr>
<td>University of Select Agents</td>
<td>Update abstract</td>
<td>07/25/2017</td>
<td>07/26/2017</td>
<td>Approve</td>
<td>responsible official</td>
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## Supporting Documentation

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<th>Created</th>
<th>Updated by</th>
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<td>devcdcipsas\aigrant</td>
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<tr>
<td>LicenseTerms.docx</td>
<td>5/2/2017 10:04:35 PM</td>
<td><a href="mailto:aagrant@dev.cdcipsas.com">aagrant@dev.cdcipsas.com</a></td>
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<tr>
<td>Other Redistributable.txt</td>
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<td><a href="mailto:aagrant@dev.cdcipsas.com">aagrant@dev.cdcipsas.com</a></td>
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<td>EntityMetadata.xlsx</td>
<td>5/25/2017 3:48:50 AM</td>
<td><a href="mailto:aagrant@dev.cdcipsas.com">aagrant@dev.cdcipsas.com</a></td>
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<td>CheckSSC.ps1</td>
<td>6/14/2017 6:41:23 PM</td>
<td><a href="mailto:aagrant@dev.cdcipsas.com">aagrant@dev.cdcipsas.com</a></td>
</tr>
</tbody>
</table>
Select View

Select an Action

Select an action for the APHIS/CDC FORM 1 APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS.

An entity will complete APHIS/CDC Form 1 to apply to possess, use, or transfer select agents and toxins (as described in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73). The APHIS/CDC Form 1 is also used to amend an approved registration.

[View] [Amend] [Amendment History]

[Exit]
# Section 1 - Form 1 Data Completion

## Entity Information

**Entity Application Number**
600c2ea7-929-e711-80cf-001dd8603e2

**Current Registration Number**

**Entity Name**
University of Select Agents

73 of 160 characters left

**Physical Address**
100 University Ave

82 of 160 characters left

**City**
Gainesville

39 of 50 characters left

**State**
Florida

**Zip Code**
30341-1928

## Additional Physical Address(es)

## Type of Entity | Government - Federal

**Government - Federal**

## Entity Abstract

Provide a summary of the overall institution mission, functions, and size. This information can include a general estimated number of employees, square footage of entire campus or facility, number of laboratories, overall scope of research, and any international collaborations. Specialized areas of research, education, or expertise can be highlighted. Include a brief description of the management structure of the institution related to oversight of the select agent facility/facilities. Provide a brief summary of the select agent and toxin work at the entity including mission, function, and size. Note: Information specific to select agents and toxins will be required in later sections of this application.
### Section 1 - Form 1 Data Completion

| Entity Information | | |
|--------------------|------------------|
| **Entity Application Number** | **Current Registration Number** |
| 600c2ea7-d929-e711-80cf-001dd8003fe2 | |
| **Entity Name** | **Physical Address** | **City** | **State** | **Zip Code** |
| University of Select Agents | | | Florida | 30341-1928 |
| 73 of 100 characters left | 100 University Ave | | |
| 82 of 100 characters left | | | |
| **Additional Physical Address(es)** | | | | |
Entity Abstract

Entity Abstract - Provide a summary of overall institution mission, functions and size. This information can include a general estimated number of employees, square footage of entire campus or facility, number of laboratories, overall scope of research, and any instructional collaborations. Specialized areas of research, education, or expertise can be highlighted. Include a brief description of the management structure of the institution related to oversight of the select agent facility/facilities. Information specific to the select agents and toxins will be required in later sections of the application.

19389 of 20000 characters left
APHIS/CDC Form 1 Section 2 - Responsible Official Certification of Personnel and Facility Activities

Responsible Official Duties & APHIS/CDC Program Notification

The Responsible Official will:

Ensure annual inspections are conducted for each registered space where select agents and/or toxins are stored or used in order to assess compliance with the requirements of the select agent regulations.

Submit an amendment for any change in circumstances to the certificate of registration, including but not limited to: adding or removing individuals, addition of a suite/room prior to use or storage of select agent and/or toxin and any changes to Responsible or Alternate Responsible Official contact information.

Submit an amendment requesting approval to conduct a restricted experiment as defined in 7 CFR § 331.13, 9 CFR § 121.13 or 42 CFR § 73.13.

Ensure inventory audits are conducted as defined in 7 CFR Part 331.11, 9 CFR Part 121.11 or 42 CFR Part 73.11.

Request authorization from the Federal Select Agent Program using APHIS/CDC Form 2 prior to inter-entity transfer of a select agent and/or toxin, as put forth within Section 16 of the Select Agent regulations.

Upon discovery of a theft or loss, immediately notify the Federal Select Agent Program and appropriate Federal, State, or local law enforcement agencies. Immediate notification is also required upon discovery of a release of a select agent or toxin causing occupational exposure or a release of a select agent and/or toxin outside the primary barriers of the containment area. An APHIS/CDC Form 3 must be submitted to the Federal Select Agent Program within seven calendar days upon discovery of a theft, loss, or release.

Immediately report the identification of any APHIS select agent as defined in 9 CFR § 121.5, or the identification of any Tier 1 select agent and/or toxin, to the Federal Select Agent Program and other appropriate authorities when required by Federal, State, or local law. Submit APHIS/CDC Form 4 for the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification within seven calendar days of identification and/or in a specimen presented for proficiency testing within 90 calendar days of receipt of the sample.

Responsible Official Name: ____________________________ Date: 08/17/2017
### Section 3 - Select Agents and Toxins

<table>
<thead>
<tr>
<th>Agent/Toxin Name</th>
<th>Status</th>
<th>Agency</th>
<th>Tier 1</th>
<th>Possessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian influenza virus</td>
<td>Unassigned</td>
<td>USDA</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Bacillus anthracis</td>
<td>Unassigned</td>
<td>Overlap</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Bacillus cereus Biovar anthracis</td>
<td>Unassigned</td>
<td>HHS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Botulinum neurotoxin producing species of Clostridium</td>
<td>Unassigned</td>
<td>HHS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Botulinum neurotoxins</td>
<td>Unassigned</td>
<td>HHS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Brucella abortus</td>
<td>Unassigned</td>
<td>Overlap</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Brucella melitensis</td>
<td>Unassigned</td>
<td>Overlap</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Brucella suis</td>
<td>Unassigned</td>
<td>Overlap</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Conotoxins (Short, paralytic alpha)</td>
<td>Unassigned</td>
<td>HHS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Coxiella burnetii</td>
<td>Unassigned</td>
<td>HHS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Eastern Equine Encephalitis virus</td>
<td>Unassigned</td>
<td>HHS</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Ebola virus</td>
<td>Unassigned</td>
<td>HHS</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Foot-and-mouth disease virus</td>
<td>Unassigned</td>
<td>USDA</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Francisella tularensis</td>
<td>Unassigned</td>
<td>HHS</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
Security risk assessment (SRA) information is also displayed in Section 4
- Individuals must have “Unrestricted” SRA status to access select agents and toxins

eFSAP will display upcoming SRA expiration dates for an individual at 90 days and 45 days as a reminder to the entity

Additional Notes:
- The DOJ Unique Identifier Number format was updated to remove the dashes and agency prefix (A for APHIS, C for CDC). The new format is the individual’s initials (first name, last name) and 6-digit number.
- The DOJ Unique Identifier Number for an individual registered at multiple entities may have been modified from the information you have on file.
# APHIS/CDC Form 1 Section 4 Verify Personnel and SRA Information

## Section 4 - Entity Personnel

- **All**  
- RO/ARO Personnel  
- Science Personnel  
- Support Personnel

### Options
- Show Active Users  
- Show Other Users

#### Search Users:

<table>
<thead>
<tr>
<th>Tier 1 Access</th>
<th>Last Name</th>
<th>First Name</th>
<th>DCU Unique Identifier Number</th>
<th>Date of Birth (mm/dd/yyyy)</th>
<th>Supervising Principal Investigator</th>
<th>Roles:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>Adams</td>
<td>Michael</td>
<td>SA0700006</td>
<td>10/10/1980</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atlass</td>
<td>Alex</td>
<td>A-CW-123456</td>
<td>01/20/1950</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Crick</td>
<td>Francis</td>
<td>C-CW-123458</td>
<td>07/11/1973</td>
<td>Latest</td>
<td></td>
</tr>
</tbody>
</table>

**SRA Status:** Unrestricted  

**SRA Initial Date:** 07/26/2017  
**SRA Approved Date:** 08/03/2017  
**SRA Expiration Date:** 08/03/2020

**SRA Status:** Unrestricted  

**SRA Initial Date:** 10/01/2004  
**SRA Approved Date:** 10/05/2014  
**SRA Expiration Date:** 10/05/2017

**SRA Status:** Unrestricted  

**SRA Initial Date:** 07/11/2017  
**SRA Approved Date:** 07/11/2017  
**SRA Expiration Date:** 07/11/2017

**Roles:**  
- Laboratory  
- Responsible Officer  
- Latest
### Example of New DOJ# Format and SRA Expiration Dates

<table>
<thead>
<tr>
<th>Tier 1 Access</th>
<th>Last Name</th>
<th>First Name</th>
<th>DOJ Unique Identifier Number</th>
<th>Date of Birth</th>
<th>Supervising Principal</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adams</td>
<td>Michael</td>
<td>SA070066</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atkins</td>
<td>Allen</td>
<td>A-CW-123456</td>
<td>01/20/1950</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Crick</td>
<td>Francis</td>
<td>C-CW-123458</td>
<td>07/11/1973</td>
<td>Louis Pasteur, Marie Curie, Robert Koch</td>
<td>Laboratory</td>
</tr>
<tr>
<td></td>
<td>Fleming</td>
<td>Alexander</td>
<td>C-CW-202020</td>
<td>06/15/1989</td>
<td>Louis Pasteur</td>
<td>Laboratory</td>
</tr>
<tr>
<td></td>
<td>Gates</td>
<td>Bill</td>
<td>C-CW-111111</td>
<td>09/09/1956</td>
<td></td>
<td>IT</td>
</tr>
</tbody>
</table>

**New DOJ Number format**

- **Orange:** 90 days
- **Red:** 45 days
1. This facility is: (check all that apply)
   - ☑ Government owned
   - ☐ Entity owned
   - ☐ Rented/leased
   - ☐ Shared with another entity or program
   - ☐ Other

2. Does the entity have a security officer or other individual(s) identified to assist the RO in security matters?
   - ☑ Yes  ☐ No
   If yes, does the security plan contain procedures for coordination between the RO and the entity’s security professionals?
   - ☑ Yes  ☐ No

3. A threat assessment has been conducted:
   - ☑ Yes  ☐ No
     a. Were local law enforcement or federal agencies consulted in developing the threat assessment?
        - ☑ Yes  ☐ No
     b. Has there been a break-in at the entity in the last three years?
        - ☑ Yes  ☐ No
     c. Have there been any direct threats against the entity or its scientists in the last three years?
        - ☑ Yes  ☐ No
     d. Have there been protests at the entity in the last three years?
        - ☑ Yes  ☐ No

If yes to any of the above, describe below.

A bomb threat was called in to the building.
Section 5B - Entity-Wide Biosafety/Biocontainment

1. Describe the program or expertise used to develop and implement the biosafety and biocontainment procedures described in the site-specific biosafety or biocontainment plan.

- Limited/Restricted access when work is in progress
- Decontaminate work surfaces before and after use with effective disinfectant.

2. Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins.
   - Yes □ No □

3. Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required.
   - Yes □ No □

4. Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program.
   - Yes □ No □

5. Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate.
   - Yes □ No □

6. There are policies for the safe handling of sharps.
   - Yes □ No □

7. There is a spill protocol in place appropriate to the select agent and/or toxin risk.
   - Yes □ No □

8. There is an effective, integrated pest management program in place.
   - Yes □ No □
Section 5C - Entry Requirements for Federal Select Agent Program Inspectors

1. Describe procedures for entry to the facility, such as gate location, visitor reception area, and parking for inspectors performing a site visit.

The inspectors will make entrance through the security gate on South Street. They will be directed to sign in at the visitor reception area. Parking for the inspectors will be at the South parking lot.

2. Identification requirements:
   - [ ] Government ID
   - [ ] Other ID

3. Are there security clearance requirements?
   - [ ] Yes
   - [ ] No

4. Is respiratory protection required?
   - [ ] Yes
   - [ ] No

5. List other PPE required (indicate what will be provided by the entity).

6. Medical documentation required:
   - [ ] Yes
   - [ ] No

7. Is entity specific training required?
   - [ ] Yes
   - [ ] No

8. Describe any additional entry requirements for inspectors.
# Section 6 A/B

## Buildings, Suites/Rooms

<table>
<thead>
<tr>
<th>Building</th>
<th>Room/Suite</th>
<th>Tier 1</th>
<th>Suite</th>
<th>Number of Rooms</th>
<th>Storage</th>
<th>Biosafety Levels</th>
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<tbody>
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<td>100</td>
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<td>✔️</td>
<td>2</td>
<td></td>
<td>BSL3</td>
</tr>
<tr>
<td>3Ag</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>1</td>
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<td>BSL3Ag, BSL4</td>
</tr>
<tr>
<td>50</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>1</td>
<td>✔️</td>
<td>No BSLs Assigned</td>
</tr>
<tr>
<td>blue</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td>1</td>
<td></td>
<td>BSL2</td>
</tr>
<tr>
<td>BT Lab</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>6</td>
<td></td>
<td>ABSL3, ACL3, BSL3, NIHBL3</td>
</tr>
<tr>
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<td>✔️</td>
<td>✔️</td>
<td></td>
<td>1</td>
<td></td>
<td>ABSL3, BSL3, NIHBL3</td>
</tr>
<tr>
<td>20</td>
<td>blue</td>
<td>✔️</td>
<td>✔️</td>
<td>1</td>
<td></td>
<td>BSL3</td>
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<td>✔️</td>
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<td>1</td>
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<td>BSL3</td>
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<td>✔️</td>
<td></td>
<td>1</td>
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<td>BSL3</td>
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<tr>
<td>30</td>
<td>1001</td>
<td>✔️</td>
<td>✔️</td>
<td>1</td>
<td></td>
<td>No BSLs Assigned</td>
</tr>
</tbody>
</table>
APHIS/CDC Form 1 Section 7A & 7C Principal Investigator (PI) Information and Select Agent and Toxin Locations
## Section 7B – Strain or Serotype Designation Information

### Saved Agents / Strain or Serotypes

<table>
<thead>
<tr>
<th>#</th>
<th>Agent/Toxin</th>
<th>Strain Or Serotype</th>
<th>Assigned PI</th>
<th>Entity Wide..</th>
<th>Edit</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Bacillus anthracis</td>
<td>Ames</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Brucella suis</td>
<td>1330</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Brucella abortus</td>
<td>2308</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Bacillus anthracis</td>
<td>Vo1um</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Bacillus anthracis</td>
<td>Pakistan-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Avian influenza virus</td>
<td>A/Goose/Guangdong/</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Francisella tularensis</td>
<td>Schu S4</td>
<td></td>
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</tr>
<tr>
<td>7</td>
<td>Eastern Equine Encephalitis virus</td>
<td>FL93</td>
<td></td>
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<tr>
<td>8</td>
<td>Yersinia pestis</td>
<td>CO02</td>
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<tr>
<td>9</td>
<td>Bacillus anthracis</td>
<td>Vo1um</td>
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<td></td>
</tr>
</tbody>
</table>

**General Discussion**
Contact FSAP if you identify inaccuracies in Form 1 data transition

Email agency POC with specific details including:
- Entity Name
- Section or Attachment name
- Brief description of the concern
- Amendment numbers (where applicable)

Agency POC will work with you to resolve the concerns and update eFSAP

Once eFSAP is corrected, RO must provide email confirmation of successful APHIS/CDC Form 1 data transition to FSAP
APHIS/CDC Form 1 Amendments
<table>
<thead>
<tr>
<th>Entity Name</th>
<th>Cover Letter</th>
<th>Date Submitted</th>
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<th>Status</th>
<th>RO Submitter</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Select Agents</td>
<td>Add PI Williams. See document upload, file name Section7_PI Williams.pdf</td>
<td>06/01/2017</td>
<td></td>
<td>Draft</td>
<td>responsible official</td>
<td>Edit</td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Remove ARO Dee from the registration. Reason for removal - job duties no longer require access to select agents</td>
<td>07/25/2017</td>
<td></td>
<td>Pending</td>
<td>responsible official</td>
<td>Edit</td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7/AttachC_PI_Crick.pdf</td>
<td>08/03/2017</td>
<td></td>
<td>Pending</td>
<td>responsible official</td>
<td>Edit</td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Update abstract</td>
<td>07/25/2017</td>
<td>07/26/2017</td>
<td>Approved</td>
<td>responsible official</td>
<td>Edit</td>
</tr>
</tbody>
</table>
eFSAP APHIS/CDC Form 1 Amendments

- Hybrid amendment process - digital cover letter and upload of Form 1 (fillable pdf)

- Future eFSAP release will have both digital cover letter and ability for RO/ARO to edit APHIS/CDC Form 1 information

- Communication log for correspondence between FSAP and entity RO/ARO
Step 1: Upload Supporting Document for Amendment

- Scroll to Supporting Documentation on landing page
- Click Browse and select “Form 1” pdf file
- Click Upload

- Note: Entity will not have option to view the uploaded document until a future release
Step 2: Create Amendment Request

- Click “Form 1” on landing page
- Then select “Amend”
Step 3: Cover Letter

- **Select “Amendment” from drop down menu**
  - These options will change once release full Form 1 digital editing features

- **Enter cover letter text**
  - Brief description of change
  - Keywords to start request: ADD, REMOVE, UPDATE
  - For personnel removals, state reason for removal

- **Then, click ok – this creates the amendment request (draft)**
Examples of Cover Letter Text

Amendment Selection

Welcome to the Form 1 Amendment page. Before we get started we need a little information. Below are the types of Amendments available for this form and actions specific to the Amendment.

Select the type of Amendment you would like to perform

Amendment

Complete your cover letter for this amendment:

Enter a brief description of the requested change:
Add James Doe
Remove John Smith, reason for removal: retirement from university on August 1, 2017
Update entity abstract
Step 4: Withdraw, Save or Submit

Amendment

Note: No delete button! Amendment request has been recorded into system
Communication Log

- Two way communication between entity and FSAP
- FSAP will use this log to request additional information related to the amendment (replaces email)
- Entity can reply to FSAP request for information, or ask questions about the amendment
  - RO/ARO enters message, then click “SEND”
- Messages will post to the communication log with user name, date/time stamp
Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf.
Example of Request For Information in Communication Log

University of Select Agents

Amendment

AMENDMENT COVER LETTER

Update PI Crick work objectives to add ferret animal model. See document upload, file name Section?AttachC_PI_Crick.pdf

19880 of 20000 characters left

COMMUNICATION LOG

Agency User, 08/03/2017 11:08 +00:00:
Please provide an update to Attachment C to describe the animal housing that will be used for ferrets.

Agency User, 08/03/2017 11:08 +00:00:
Changed state from Pending to Request For Information

Enter Message SEND
APHIS/CDC Form 1 Amendment – Status

- **Pending** – RO/ARO has clicked “submit” and sent amendment to FSAP
- **Request For Information** – FSAP has returned amendment to entity for additional information (review Communication log for details)
- **Draft** – RO/ARO has created a draft amendment by clicking “save” but has not yet submitted amendment to FSAP

<table>
<thead>
<tr>
<th>Entity Name</th>
<th>Cover Letter</th>
<th>Date Submitted</th>
<th>Date Approved</th>
<th>Status</th>
<th>RO Submitter</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Select Agents</td>
<td>Remove ARO Doe from the registration. Reason for removal - job duties no longer require access to select agents</td>
<td>07/25/2017</td>
<td></td>
<td>Pending</td>
<td>responsible official</td>
<td></td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf</td>
<td>08/03/2017</td>
<td></td>
<td>RequestForInformation</td>
<td>responsible official</td>
<td></td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Add PI Williams. See document upload, file name Section7_PI_Williams.pdf</td>
<td>08/01/2017</td>
<td></td>
<td>Draft</td>
<td>responsible official</td>
<td></td>
</tr>
</tbody>
</table>
### APHIS/CDC Form 1 Amendment – Status Continued

- **Approved** – FSAP has approved the amendment request
- **Rejected** – FSAP has denied the amendment request
- **Deactivated** – RO/ARO has “withdrawn” the amendment

<table>
<thead>
<tr>
<th>University of Select Agents</th>
<th>Action Description</th>
<th>Date</th>
<th>Date</th>
<th>Status</th>
<th>Responsible Official</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Select Agents</td>
<td>Please add laboratorian C. Jacob see uploaded document</td>
<td>07/26/2017</td>
<td>07/26/2017</td>
<td>Approved</td>
<td>responsible official</td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>We would like to remove an RO, ARO, PI. Basically we fired everyone and need to hire new staff.</td>
<td>07/26/2017</td>
<td></td>
<td>Rejected</td>
<td>responsible official</td>
</tr>
<tr>
<td>University of Select Agents</td>
<td>Add strain for Bacillus anthracis</td>
<td>07/25/2017</td>
<td></td>
<td>Deactivated</td>
<td>responsible official</td>
</tr>
</tbody>
</table>
APHIS/CDC Form 3 Submission
Select Form 3
Select an Action

Select an action for the APHIS/CDC FORM 3 TO REPORT A THEFT, LOSS, OR RELEASE OF A SELECT AGENT OR TOXIN.

The discovery of a theft, loss, or a release of a select agent or toxin is required to be immediately reported (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73).

Create View All

Location Incident Date
### Section A - ENTITY INFORMATION

**1. Name of Entity:**
Charlotte's Entity
236 of 255 characters left

**3. Physical Address:**
123 Preston Street
237 of 255 characters left

**4. City:**
Atlanta
43 of 50 characters left

**5. Name of Responsible Official or Laboratory Supervisor:**
Janie Coleman
242 of 255 characters left

**6. Zip Code:**
30001

**7. Telephone Number:**
(770)425-1633ext.

**8. Fax Number:**
(770)425-1696ext.

**9. E-mail address:**
Colman.Janie@ocustlabs.com

### Section B - INCIDENT INFORMATION
### APHIS/CDC Form 3  Report of a Theft, Loss or Release of Select Agent or Toxin

#### Section B - INCIDENT INFORMATION

1. **Date and Time of Incident:**
   - **Date:** 07/19/2017
   - **Time:** 06:15:AM

2. **Date of Immediate Notification:** 07/20/2017

3. **Type of Immediate Notification:**
   - Email
   - Fax
   - Telephone
   - eFSAP

4. **Location of Incident:**
   - Carruthers - 123
   - Carruthers - 123
   - 239 of 255 characters left

5. **Name of Select Agent or Toxin:** Abrin

6. **Strain Designation:**
   - Powder
   - 249 of 256 characters left

7. **Quantity:**
   - 25 mg
   - 95 of 100 characters left
APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

<table>
<thead>
<tr>
<th>Name of Select Agent or Toxin</th>
<th>Strain Designation</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>Powder</td>
<td>25 mg</td>
</tr>
</tbody>
</table>

8. Type of Incident:
- Theft
- Loss
- Release/ Potential Exposure

Note:
Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.
**APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin**

**Section E - REPORT OF RELEASE**

1. **Type of Potential Exposure/Release** (choose all that apply):
   - Animal bite/scratch
   - PPE failure
   - Spill
   - Needle stick/Sharps
   - Decontamination failure
   - Inactivation failure
   - Equipment/mechanical failure
   - Package damaged in transit (fill out Appendix B)
   - Unintended Animal Infection
   - Unintended Plant Pathogen Release
   - Work performed on an open bench
   - Other

2. **Was there a release outside containment barriers?** (choose all that apply)
   - Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)
   - Release beyond secondary containment (e.g., laboratory)
   - Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat)

3. **What PPE was worn at the time of the incident?** (choose all that apply)
   - Hand Protection (e.g., gloves)
   - Head Protectors/Covers
   - Body Protection
   - Foot Protection (e.g., booties, shoe covers)
   - Eye/Face Protection (e.g., goggles, face shield)
   - Respiratory Protection
   - Other

4. **Did the release result in potential exposure(s)?**
   - Yes
   - No

5. **Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?**
   - Yes
   - No
   - Not currently known
APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

<table>
<thead>
<tr>
<th>6. Has medical surveillance been initiated?</th>
<th>7. Has prophylaxis or treatment been provided?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
<td>☐ No</td>
</tr>
</tbody>
</table>

8. Has an internal review of laboratory procedures and policies been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?

☐ Yes (If yes, please provide additional details.)
☐ No

**Details:**

> A mandatory retraining initiative was indicated and undertaken.

1937 of 2000 characters left
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?</td>
<td>None</td>
</tr>
<tr>
<td>10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.</td>
<td>Work surfaces were decontaminated with Clorox solution.</td>
</tr>
<tr>
<td>11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).</td>
<td>Follow-up medical appointments made at 3 and 6 months post exposure.</td>
</tr>
</tbody>
</table>
Provide a detailed summary of events, including a timeline of what occurred.
APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

Sign Document

Certification: I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of the select agent regulations may result in civil or criminal penalties, including imprisonment. 7 CFR 331, 9 CFR 121, 42 CFR 73.

Signature of Respondent: ____________________________
Title: ____________________________
Date: ____________________________

This is an official document.

Please type name as above.

Public reporting burden:

The estimated amount of time for this collection of information is 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).
AGENCY POINTS OF CONTACT

Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services
Cassie Armiger
cassie.c.armiger@aphis.usda.gov
301.851.2052
Chuck Divan
charles.l.divan@aphis.usda.gov
301.851.2219

Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins
Cara Jacob
CJacob@cdc.gov
404.718.2028

Von McClee
VMcClee@cdc.gov
404.718.2065
ADDITIONAL CONTACT INFORMATION

- For assistance with Secure Asset Management System (SAMS), entities should use DSATSAMSHELP@cdc.gov

- Entities should submit amendments and inspection-related documents into eFSAP once the system is released to the entity.
Federal Select Agent Program Training

For more information, please contact the Federal Select Agent Program

Telephone: 301-851-3300 Option 3 (USDA) or 404-718-2000 (CDC)
E-mail: AgSAS@aphis.usda.gov (USDA) or lrsat@cdc.gov (CDC)
Web: http://www.selectagents.gov