



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

Federal Select Agent
Program 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

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Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins

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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 directly into eFSAP once the system is released to the entity.

APHIS/CDC Form 1 Verification

Federal Select Agent
Program Training





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

Home Notifications

Forms Form 1 Form 2 Form 3 Form 4 Form 5 IPP

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 Atkins	Responsible Official Title: President	Responsible Official Address: 1000 University Ave, Gainesville, FL 300291009
Registration #:	Application #: 600c2ea7-d929-e711-80cf-001dd8003fe2	Type Status: Government - Federal

Notifications [View All Notifications](#)

- This is Section 1 8/29/2017 2:21:39 PM
- Testomg General Discussion Functionality 8/29/2017 1:24:29 PM
- Amendment was modified (State: SubmittedAmendment) by responsible official on 8/29/2017 1:01:55 PM with Cover Letter: Testing Amendment functio... 8/29/2017 1:01:54 PM
- 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

List of Notifications



eFSAP Landing Page

General Discussion Notes between Agency and the Entity.

General Discussion

AU Testing the general discussion as an agency user. Can see both "General Discussion" and "FTE Discussion" on the main page. - jw

responsible official 8/29/2017 1:02:51 PM **RO**
Testing Communication Functionality.

responsible official 8/29/2017 2:18:57 PM **RO**
We are considering renaming to "Stark Industries". what is required of us for a rename?

CA 8/29/2017 2:20:11 PM **CRM Admin**
That is just a section 1 of form 1 submittal.

Type your message here... Send



eFSAP Landing Page

responsible.official@dev.cdcpas.com
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Forms

Form 1
Form 2
Form 3
Form 4
Form 5
IPP

Summary

Filter:

Entity Name	Cover Letter	Date Submitted	Date Approved	Status	RO Submitter	Details
University of Select Agents	Add PI Williams. See document upload, file name Section7_PI_Williams.pdf	08/01/2017		Draft	responsible official	Edit
University of Select Agents	Remove ARO Doe from the registration. Reason for removal - job duties no longer require access to select agents	07/25/2017		Pending	responsible official	Edit
University of Select Agents	Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf	08/03/2017		Pending	responsible official	Edit
University of Select Agents	Update abstract	07/25/2017	07/26/2017	Approved	responsible official	Edit

Summary of Amendments and their status



eFSAP Landing Page

Supporting Documentation

Supporting Documentation


Browse...

Upload

Name	Created	Updated by
sampleweb.config	4/25/2017 8:01:17 PM	devcdcipsas\aa grant
LicenseTerms.docx	5/2/2017 10:04:35 PM	aa grant@dev.cdcipsas.com
Other Redistributable.txt	5/2/2017 9:07:56 PM	aa grant@dev.cdcipsas.com
EntityMetadata.xlsx	5/25/2017 3:48:50 AM	aa grant@dev.cdcipsas.com
CheckSSO.ps1	6/14/2017 6:41:23 PM	aa grant@dev.cdcipsas.com



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@dev.cdcpas.com
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Home
Notifications ▾

Forms
Form 1
Form 2
Form 3
Form 4
Form 5
IPP

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University of Select Agents	Update abstract	07/25/2017	07/26/2017	Approved	responsible official	Edit



eFSAP Landing Page

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 for registration 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](#)



eFSAP APHIS/CDC Form 1 View

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SECTION 1

Section 1 - Form 1 Data Completion

SECTION 2

SECTION 3

SECTION 4

SECTION 5A

SECTION 5B

SECTION 5C

SECTION 6

SECTION 7A & 7C

SECTION 7B

Entity Information

Entity Application Number

Current Registration Number

Entity Name

73 of 100 characters left

Physical Address

82 of 100 characters left

City

39 of 50 characters left

State

Zip Code

Additional Physical Address(es)

Type of Entity | *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.



APHIS/CDC Form 1 Section 1 Entity Information

Section 1 - Form 1 Data Completion

Entity Information

Entity Application Number

600c2ea7-d929-e711-80cf-001dd8003fe2

Current Registration Number

Entity Name

University of Select Agents

73 of 100 characters left

Verify the full legal name of the Entity

Physical Address

100 University Ave

82 of 100 characters left

Verify the address

City

State

Florida



Zip Code

30341-1928

Additional Physical Address(es)



APHIS/CDC Form 1 Section 1 Entity Abstract

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:



APHIS/CDC Form 1 Section 3 – Verifying Select Agents and Toxins

Section 3 - Select Agents and Toxins

Type of Agents

All Current Historical Unassigned

Agent Toxin Name	Status	Agency	Tier 1	Possessed
Avian influenza virus	Unassigned	USDA	No	<input checked="" type="checkbox"/>
Bacillus anthracis	Unassigned	Overlap	Yes	<input checked="" type="checkbox"/>
Bacillus cereus Biovar anthracis	Unassigned	HHS	Yes	<input type="checkbox"/>
Botulinum neurotoxin producing species of Clostridium	Unassigned	HHS	Yes	<input type="checkbox"/>
Botulinum neurotoxins	Unassigned	HHS	Yes	<input checked="" type="checkbox"/>
Brucella abortus	Unassigned	Overlap	No	<input checked="" type="checkbox"/>
Brucella melitensis	Unassigned	Overlap	No	<input checked="" type="checkbox"/>
Brucella suis	Unassigned	Overlap	No	<input type="checkbox"/>
Conotoxins (Short, paralytic alpha)	Unassigned	HHS	No	<input checked="" type="checkbox"/>
Coxiella burnetii	Unassigned	HHS	No	<input type="checkbox"/>
Eastern Equine Encephalitis virus	Unassigned	HHS	No	<input checked="" type="checkbox"/>
Ebola virus	Unassigned	HHS	Yes	<input type="checkbox"/>
Foot-and-mouth disease virus	Unassigned	USDA	No	<input type="checkbox"/>
Francisella tularensis	Unassigned	HHS	Yes	<input checked="" type="checkbox"/>



APHIS/CDC Form 1 Section 4 Personnel and SRA Information

- ❑ ***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

All

Options

Show Active Users Show Other Users

Search Users:

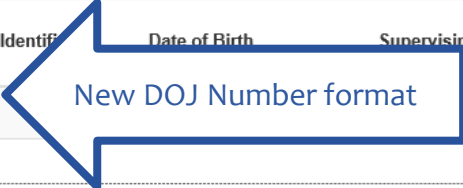
Text

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Supervising Principal Investigator	
<input checked="" type="checkbox"/>	Adams	Michael	SA070006	10/10/1980		View
Roles: Laboratorian PI						
SRA Status:Unrestricted SRA Initial Date 07/25/2017 SRA Approved Date 08/03/2017 SRA Expiration Date 08/03/2020						
<input checked="" type="checkbox"/>	Atkins	Allen	A-CW-123456	01/20/1950		View
Roles: Responsible Official						
SRA Status:Unrestricted SRA Initial Date 10/01/2004 SRA Approved Date 10/05/2014 SRA Expiration Date 10/05/2017						
<input checked="" type="checkbox"/>	Crick	Francis	C-CW-123458	07/11/1973	Louis Pasteur Marie Curie Robert Koch	View
Roles: Laboratorian						



Example of New DOJ# Format and SRA Expiration Dates

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth	Supervising Principal	
<input checked="" type="checkbox"/>	Adams	Michael	SA070006			Edit
Roles: Laboratorian PI						
SRA Status:Unrestricted SRA Initial Date 07/25/2017 SRA Approved Date 08/03/2017 SRA Expiration Date 08/03/2020						
<input checked="" type="checkbox"/>	Atkins	Allen	A-CW-123456	01/20/1950		Edit
Roles: Responsible Official						
SRA Status:Unrestricted SRA Initial Date 10/01/2004 SRA Approved Date 10/05/2014 SRA Expiration Date 10/05/2017						
<input checked="" type="checkbox"/>	Crick	Francis	C-CW-123458	07/11/1973	Louis Pasteur Marie Curie Robert Koch	Edit
Roles: Laboratorian						
SRA Status:Unrestricted SRA Initial Date 08/19/2008 SRA Approved Date 08/30/2015 SRA Expiration Date 08/30/2018						
<input type="checkbox"/>	Fleming	Alexander	C-CW-202020	06/15/1989	Louis Pasteur	Edit
Roles: Laboratorian						
SRA Status:Unrestricted SRA Initial Date 09/03/2003 SRA Approved Date 09/15/2014 SRA Expiration Date 09/15/2017						
<input type="checkbox"/>	Gates	Bill	C-CW-111111	09/09/1956		Edit
Roles: IT						
SRA Status:Unrestricted SRA Initial Date 11/12/2009 SRA Approved Date 11/22/2015 SRA Expiration Date 11/22/2018						





APHIS/CDC Form 1 Section 5A - Entity-Wide Security Assessment and Incident Response

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.



APHIS/CDC Form 1 Section 5B - Entity-Wide Biosafety/Biocontainment

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.

1371 of 1500 characters left

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



APHIS/CDC Form 1 Section 5C - Entry Requirements for Federal Select Agent Program Inspectors

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.

1297 of 1500 characters left

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.



APHIS/CDC Form 1 Section 6 A/B Viewing Building

Section 6 A/B

Buildings, Suites/Rooms

Building	Room/Suite	Tier 1	Suite	Number of Rooms	Storage	Biosafety Levels
10	100	<input checked="" type="checkbox"/> Tier 1	<input checked="" type="checkbox"/> Suite	2	<input type="checkbox"/> Storage	BSL3
	3Ag	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	BSL3Ag; BSL4
	50	<input type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input checked="" type="checkbox"/> Storage	No BSLs Assigned
	blue	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	BSL2
	BT Lab	<input checked="" type="checkbox"/> Tier 1	<input checked="" type="checkbox"/> Suite	6	<input type="checkbox"/> Storage	ABSL3; ACL3; BSL3; NIHBL3
	orange	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	ABSL3; BSL3; NIHBL3
20	blue	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	BSL3
	red	<input type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	BSL3
	white	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	BSL3
30	1001	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input type="checkbox"/> Storage	No BSLs Assigned



APHIS/CDC Form 1 Section 7A & 7C Principal Investigator (PI) Information and Select Agent and Toxin Locations

Section 7A & 7C - Principal Investigator (PI) Information and Select Agent and Toxin Locations

Show Work Objectives Show Buildings with Room/Suites

Saved Agents / Toxins

Assigned PI

Work Objectives & Associated BSLs

Viral pathogenesis and virulence determinants to develop universal vaccine candidates.

BSL3

Select Agent / Toxin / Regulated Nucleic Acid:

Avian influenza virus Eastern Equine Encephalitis virus Genomic Material - Eastern Equine Encephalitis Virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus SARS-associated coronavirus (SARS-CoV)

Required Attachments: **B** Work Details

Small scale production and characterization of novel botulinum neurotoxin constructs for therapeutic potential

BSL2

Select Agent / Toxin / Regulated Nucleic Acid:

Botulinum neurotoxin producing species of Clostridium Botulinum neurotoxins Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin

Required Attachments: **A** **B** Work Details

Select Work
Details



APHIS/CDC Form 1 Section 7B Strain or Serotype Designation Information

Section 7B – Strain or Serotype Designation Information

Saved Agents / Strain or Serotypes

Toggle Filtering

#	Agent/Toxin	Strain Or Serotype	Assigned P I	Entity Wide	Edit
0	Bacillus anthracis	Ames		<input type="checkbox"/>	Edit
1	Brucella suis	1330		<input type="checkbox"/>	Edit
2	Brucella abortus	2308		<input type="checkbox"/>	Edit
3	Bacillus anthracis	Volum		<input type="checkbox"/>	Edit
4	Bacillus anthracis	Pakistan-1	Louis Pasteur	<input type="checkbox"/>	Edit
5	Avian influenza virus	A/Goose/Guangdong/...		<input type="checkbox"/>	Edit
6	Francisella tularensis	Schu S4		<input type="checkbox"/>	Edit
7	Eastern Equine Encephalitis virus	FL93		<input type="checkbox"/>	Edit
8	Yersinia pestis	CO92		<input type="checkbox"/>	Edit
9	Bacillus anthracis	Vollum		<input type="checkbox"/>	Edit
10	Brucella abortus	test		<input type="checkbox"/>	Edit

/ 2

 items per page
 1 - 25 of 31 items

General Discussion



eFSAP APHIS/CDC Form 1 Verification - Edits Needed

- ❑ *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

Federal Select Agent
Program Training





eFSAP APHIS/CDC Form 1 Amendments



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Forms **Form 1** Form 2 Form 3 Form 4 Form 5 IPP

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Summary

Filter:

Entity Name	Cover Letter	Date Submitted	Date Approved	Status	RO Submitter	Details
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University of Select Agents	Remove ARO Doe from the registration. Reason for removal - job duties no longer require access to select agents	07/25/2017		Pending	responsible official	Edit
University of Select Agents	Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf	08/03/2017		Pending	responsible official	Edit
University of Select Agents	Update abstract	07/25/2017	07/26/2017	Approved	responsible official	Edit



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*

Supporting Documentation

Browse...

Name	Created	Updated by
sampleweb.config	4/25/2017 8:01:17 PM	devcdcipsas\laagrnt

- ❑ *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”

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.

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View Amend Amendment History

Exit



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

Ok

Responsible Official Name: Allen Atkins Responsible Official Title: President Responsible Official Address: 1000 University
Gainesville, FL 300291009

Application #: 600c2ea7-d929-e711-80cf-001dd8003fe2 Type Status: Government - Federal



Step 4: Withdraw, Save or Submit

Amendment

AMENDMENT COVER LETTER

Update RO Atkins email address

19970 of 20000 characters left

COMMUNICATION LOG

Enter Message

SEND

 Withdraw Amendment

Save Submit

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*



eFSAP APHIS/CDC Form 1 Communication Log



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Amendment

AMENDMENT COVER LETTER

Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf

19880 of 20000 characters left

COMMUNICATION LOG

[Withdraw Amendment](#)



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 Section7AttachC_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

Entity Name	Cover Letter	Date Submitted	Date Approved	Status	RO Submitter	Details
University of Select Agents	Remove ARO Doe from the registration. Reason for removal - job duties no longer require access to select agents	07/25/2017		Pending	responsible official	Edit
University of Select Agents	Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf	08/03/2017		RequestForInformation	responsible official	Edit
University of Select Agents	Add PI Williams. See document upload, file name Section7_PI_Williams.pdf	08/01/2017		Draft	responsible official	Edit



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*

University of Select Agents	Please add laboratorian C. Jacob see uploaded document	07/26/2017	07/26/2017	Approved	responsible official	Edit
University of Select Agents	We would like to remove an RO, ARO, PI. Basically we fired everyone and need to hire new staff.	07/26/2017		Rejected	responsible official	View
University of Select Agents	Add strain for Bacillus anthracis	07/25/2017		Deactivated	responsible official	Edit


APHIS/CDC Form 3 Submission

Federal Select Agent
Program Training





eFSAP Landing Page



Select Form 3

Home
ACCOUNTS

Federal Select Agent Program Portal

Entity: University of Select Agents

LEAD AGENCY: CDC

Facility Address: 100 University Ave, Gainesville, FL, FL 303411928

Responsible Official Name: Allen Atkins **Responsible Official Title:** President **Responsible Official Address:** 1000 University Ave, Gainesville, FL 300291009

Registration #: **Application #:** 600c2ea7-d929-e711-80cf-001dd8003fe2 **Type Status:** Government - Federal

Forms

Form 1
Form 2
Form 3
Form 4
Form 5
IPP

Summary

Filter:

Entity Name	Cover Letter	Date Submitted	Date Approved	Status	RO Submitter	Details
University of Select Agents	Add PI Williams. See document upload, file name Section7_PI_Williams.pdf	08/01/2017		Draft	responsible official	Edit
University of Select Agents	Remove ARO Doe from the registration. Reason for removal - job duties no longer require access to select agents	07/25/2017		Pending	responsible official	Edit
University of Select Agents	Update PI Crick work objectives to add ferret animal model. See document upload, file name Section7AttachC_PI_Crick.pdf	08/03/2017		Pending	responsible official	Edit
University of Select Agents	Update abstract	07/25/2017	07/26/2017	Approved	responsible official	Edit



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

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).

Select Create

[Create](#) [View All](#)

Location	Incident Date
----------	---------------

[Exit](#)



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

SECTION A

SECTION B

APPENDIX A

Section A - ENTITY INFORMATION

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

2. Entity Registration Number:

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

4. City:
Atlanta
43 of 50 characters left

5. State:
Select PI

6. Zip Code:
30001-____

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

8. Name of Responsible Official or Laboratory Supervisor:
Tier 1
James Jones
Michael Jones
Slade Sade
Carlie Sanders
Dawn Smith
Slade Sade
245 of 255 characters left

9. Telephone Number:
(770)425-1633ext. ____

10. Fax Number:
(770)425-1696ext. ____

11. E-mail address:
Coleman.Janie@locuslabs.com
23 of 50 characters left

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 255 characters left

7. Quantity

25 mg

95 of 100 characters left

+ Add Row



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

+ Add Row

Name of Select Agent or Toxin

Strain Designation

Quantity

Abrin

Powder

25 mg

Delete

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):

- | | |
|--|---|
| <input type="checkbox"/> Animal bite/scratch | <input type="checkbox"/> Equipment/mechanical failure |
| <input type="checkbox"/> PPE failure | <input type="checkbox"/> Package damaged in transit (fill out Appendix B) |
| <input checked="" type="checkbox"/> Spill | <input type="checkbox"/> Unintended Animal Infection |
| <input type="checkbox"/> Needle stick/Sharps | <input type="checkbox"/> Unintended Plant Pathogen Release |
| <input type="checkbox"/> Decontamination failure | <input type="checkbox"/> Work performed on an open bench |
| <input type="checkbox"/> Inactivation failure | <input type="checkbox"/> 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)

- | | |
|--|---|
| <input checked="" type="checkbox"/> Hand Protection (e.g., gloves) | <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) |
| <input type="checkbox"/> Head Protectors/Covers | <input type="checkbox"/> Eye/Face Protection (e.g., goggles, face shield) |
| <input type="checkbox"/> Body Protection | <input type="checkbox"/> Respiratory Protection: |
| | <input type="checkbox"/> 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

6. Has medical surveillance been initiated?

- Yes
- No

7. Has prophylaxis or treatment been provided?

- Yes
- No

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



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

None

1996 of 2000 characters left

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

Work surfaces were decontaminated with Clorox solution.

1945 of 2000 characters left

11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

Follow-up medical appointments made at 3 and 6 months post exposure.

1932 of 2000 characters left



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

Appendix A - EVENTS TIMELINE

Provide a detailed summary of events, including a timeline of what occurred.

 Save Draft

 Immediate Notification

 Initiate Submit



APHIS/CDC Form 3 Report of a Theft, Loss or Release of Select Agent or Toxin

Sign Document ✕

Signature

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:
<input type="text"/>	<input type="text"/>	<input type="text" value="08/22/2017"/>

responsible official

Please type name as above.

Public reporting burden

Public reporting burden of providing this information is estimated to average 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 Irsat@cdc.gov (CDC)

Web: <http://www.selectagents.gov>

