



# Electronic Federal Select Agent Program (eFSAP) Information System - Updates

APHIS/CDC Form 1  
Registration Renewal





# Registration Renewals

Select  
“Renewal”  
from the  
drop down  
list.

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

Request Registration Renewal

Section 2 - Sign Section 2

Section 3 - Add Select Agent or Toxin

Section 3 - Reactivate Select Agent or Toxin

Section 4 - Add/Remove/Modify/Reapply Personnel

Section 4 - Change Responsible Official

Section 5A - Modify Entity-Wide Security Assessment and Incident Response

Section 5B - Modify Entity-Wide Biosafety/Biocontainment

Section 5C - Modify Entry Requirements for Federal Select Agent Programs Inspectors

Section 6 - Add New Building

Section 6 - Add New Room or Suite

Section 6 - Modify Building

Section 6 - Modify Room or Suite

Section 6 - Remove Building

Section 7AC - Add New Work Objective

Section 7AC - Modify Work Objective and/or Attachment(s)

Section 7AC - Remove Approved Work Objective

Section 7B - Add/Remove/Modify Strains and Serotypes

Replace Principal Investigator

Request Change of Lead Agency

Request Registration Renewal

# Registration Renewals

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

Renewal

Complete your cover letter for this amendment:

We would like to request a 3 year renewal for our entity

Ok

Responsible Official Name: Stevenson Steve Responsible Official Title: Director of Science Responsible Official Address: 1020 Va

Type your cover letter and click **OK**.

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Proceeding will create the amendment in a draft state. The draft may be withdrawn later from the Amendment Review and Discussion page.

OK Cancel

A dialog box will appear. Click **OK**.

# Registration Renewals

## Section 2 - Responsible Official Certification of Personnel and Facility Activities

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations (7 CFR 331, 9 CFR 121, and 42 CFR 73):

### Security, Biosafety and Incident Response

There is a written, site-specific security plan designed according to a site-specific risk assessment that provides graded protection in accordance with the risk of the select agent and/or toxin.

There is a written, agent-specific, and site-specific biosafety plan commensurate with the risk of the select agent and/or toxin that contains sufficient information and documentation to describe the biosafety and containment procedures.

There is a written, site-specific incident response plan commensurate with the hazards of the select agent and/or toxin that fully describe the entity's response procedures to include the theft, loss or release of a select agent and/or toxin, inventory discrepancies, security breaches, natural disasters and emergencies.

The security, biosafety and incident response plans are reviewed annually and revised as necessary, including after any drill or exercise and after any incident.

Laboratory specific drills or exercises are conducted at least annually to validate or test the effectiveness of the security, biosafety and incident response plans.

### Training

Individuals with access approval, authorized visitors, and escorted personnel are provided training on safety, security, and incident response for select agents and/or toxins, as appropriate for their role, as defined in 7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15.

### Records

Complete records are maintained for at least 3 years that include but are not limited to: an accurate, current inventory for each select agent and/or toxin possessed, information about all entries into areas containing select agent and/or toxin, and a current list of all individuals that have been granted access approval.

### Responsible Official Duties & APHIS/CDC Program Notification

The Responsible Official will:

Ensure annual inspections are conducted for each registered space where select agent 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 or identification and/or final disposition of any select agent or toxin presented for proficiency testing within 90 calendar days of receipt of the sample.

**Responsible Official Name:**

**responsible official4**

Please type name as above.

**Date:**

Read and agree  
to the  
certification  
statement by  
signing in the  
lower left  
corner.

# Registration Renewals

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Responsible Official Name:

responsible official4 x

1. Sign

Date:

11/08/2017

responsible official4

✓ Signature confirmed, please click **SAVE** to sign this document.

✓ Previously signed by **responsible official4** on **11/08/2017**

Navigate to Amendment

3. Navigate to Amendment

2. Save

SAVE

After signing, click **Save**. A dialog box will appear stating the signature was accepted. Click **OK**.

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Signature accepted and noted in log. Click 'Navigate to Amendment' to submit this renewal request.

OK

Click **Navigate to Amendment** to continue.

# Registration Renewals

Amendment Review and Discussion

Amendment Cover Letter

General Discussion

Type your message here...

Send

[Withdraw Amendment](#) [Review or Make Changes](#) [Save Draft](#) [Submit](#)

Save as a Draft, Withdraw, or Submit the renewal amendment.

# Registration Renewals

 **Notifications**

Archive Selected Current  Archived  Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>					
<input type="checkbox"/>	responsible o...	Amendment <a href="#">View</a>	12/6/2019 12:39:28 PM	Amendment #330949 - Request Registration Renewal amendment was modified (State: Pending) by responsible official	<input type="button" value="Flag"/>

The notification center will show that an amendment was submitted.

## Additional Assistance

- ❑ The eFSAP Resource Center has resources to assist with the use of eFSAP.
- ❑ For technical assistance with eFSAP, or for assistance with the Secure Asset Management System (SAMS), please submit a help request ticket at eFSAP Customer Support Request Form, email [eFSAPSupport@cdc.gov](mailto:eFSAPSupport@cdc.gov), or call 1 (877) 232-3322.
- ❑ For all other inquiries regarding your entity's registration, please contact your designated FSAP point of contact (POC).

