

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

APHIS/CDC Form 1 Registration Renewal





From your entity's landing page, select Form 1.

Home	Form 1 Form	2 Form 3 Form 4 Inspections	Admin Center		
University of Select Ag	ents				
LEAD AGENCY: CDC	REGISTRATION STATUS: Approved	REGISTRATION EXPIRES: 01/30/202	2 🗶		
Facility Address: Contracting and Contracting F		Registration #: 20200130-091620			
Responsible Official Name:	Responsible Official Business #:	Responsible Official Emergency #:			
Primary FSAP POC:	Primary POC Office #: 123-456-7890	Primary POC Mobile #: 999-124-7891	Primary POC Mobile #: 999-124-7891		
Secondary FSAP POC:	Secondary POC Office #: 225-222-2222	Secondary POC Mobile #: 333-333-3333			
A Notifications			Select an Action		
Archive Selected		Current Archived 	Select an action for the APH		
Select All From Y Type Y	Date And Time Y Notification	v	An entity will complete APHI CFR part 121, and 42 CFR p		

Select Amend.



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Amendment Selection

Select "Renewal" from the drop down list.

Walcome 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
equest Change of Lead Agency
Request Registration Renewal

Amendment Selection	х О.	
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		webapp.ipsastest.com says Proceeding will create the amendment in a draft state. The draft may be withdrawn later from the Amendment Review and Discussion page. OK Cancel
	20 Ok	A dialog box will appear. Click OK .

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

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 drils 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 escoried 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 commensue as so in a specime presented for proticiency testing within 90 Calendar days of receipt of the sample.

> Date: 11/08/2017

responsible official4 Please type name as above.

Responsible Official Name

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

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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.



Click **Navigate to Amendment** to continue.

Amendment Review and Discussion	
Amendment Cover Letter	Ceneral Discussion
	Type your message here
▲ Withdraw Amendment	Send Review or Make Changes Save Draft Submit

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

Archive Selected						
Select All	From ~	Туре ~	Date And Time ~	Notification ~	~	
	responsible o	Amendment View	12/6/2019 12:39:28 PM	Amendment #330949 - Request Registration Renewal amendment was modified (State: Pending) by responsible official	🍽 Flag	

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The notification center will show that an amendment was submitted.

Additional Assistance

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

