



# Electronic Federal Select Agent Program (eFSAP) Information System September 2019 Release Updates

Federal Select Agent  
Program Training



# New User Role: Entity “Super-Admin”

Responsible Officials (ROs) can request one or multiple SAMS account holders to be assigned as “super-admins”

- Super-admins are able to:
  - Draft (but not submit) the following:
    - All Form 1 technical amendments
    - Form 2s
    - Form 3s
    - Form 4s
    - Responses to inspection findings
  - Enter general correspondence
  - Upload, download, and archive supporting files
  - Print inspection findings and Forms 2-4
  - Export Form 1 Section 4 and Section 7B data

The screenshot displays a user interface for responding to a request. At the top, a message from a 'Branch Chief' dated 08/20/2019 asks for documentation regarding a biosafety cabinet. Below this, an 'Entity Response' section contains a text box with the text: 'We have uploaded the certification documents. Please let us know if any additional information is needed'. At the bottom right of the response area, there are two buttons: 'Save Draft' and 'Send'. An upward-pointing arrow is positioned below the 'Save Draft' button, and another upward-pointing arrow with a red 'X' over it is positioned below the 'Send' button, indicating that super-admins can save drafts but cannot submit them.

Super-admins can save information as a draft, but can not submit information in eFSAP. When an RO or ARO logs in, they can review the draft and submit it.

# Work Objective Histories

- Changes to work objectives over time are able to be tracked in Form 1 Section 7A/C

**Work Objective:** WO001475.001.001      **Status:** Approved      **Date Approved:** 07/22/2019      Amendment Pending

**Principal Investigators:** Erica Erickson      **Storage Only**      [View](#)

**Agents/Toxins:** Ricin


**Required Attachments:** A B C D E F G

**Buildings/Rooms:**  
*Building 2*  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab  
*Building 20*  
- storage room

**Biosafety Levels:** Storage Only

Work objectives with historical versions have a folder icon next to the "view" button

**Work Objective:** WO001295.015.003      **Status:** Approved      **Date Approved:** 07/22/2019      Active Work

**Principal Investigators:** Erica Erickson      **Work and Storage**       [View](#)

**Agents/Toxins:** Botulinum neurotoxins

**Required Attachments:** A B C D E F G

**Buildings/Rooms:**  
*Building 2*  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab

**Biosafety Levels:** BSL3  
NIHBL3

# Work Objective Histories - continued

Changes to work objectives over time are able to be tracked in Form 1 Section 7A/C

**After clicking “view”, previous versions of the work objective are available for review.**

Work Objective Number	Approved	Approved By	
WO001295.015.003	07/22/2019	William Wang	<a href="#">View</a>
WO001295.015.001	07/22/2019	Branch Chief	<a href="#">View</a>
WO001295.014.002	07/18/2019	Chad Hernandez	<a href="#">View</a>
WO001295.014.001	07/18/2019	fte advanced	<a href="#">View</a>
WO001295.012.001	06/21/2019	William Wang	<a href="#">View</a>
WO001295.011.001	06/21/2019	Chad Hernandez	<a href="#">View</a>
WO001295.008.001	05/24/2019	William Wang	<a href="#">View</a>
WO001295.007.001	05/24/2019	Lisa Smith	<a href="#">View</a>
WO001295.004.001	04/17/2019	Lisa Smith	<a href="#">View</a>
WO001295.002.001	01/22/2019	Chad Hernandez	<a href="#">View</a>
WO001295.001.001	01/22/2019	William Wang	<a href="#">View</a>

Close

Work Objective: WO001475.001.001 Status: Approved

Principal Investigators: Erica Erickson Storage Only

Agents/Toxins: Ricin

Work Objective: WO001295.015.003 Status: Approved

Principal Investigators: Erica Erickson Work and Storage

Agents/Toxins: Botulinum neurotoxins

Biosafety Levels: Storage Only

Active Work

View Modify

Biosafety Levels: BSL3 NIHBL3

# APHIS/CDC Form 1 Section 4 updates

- Form 1 Section 4 defaults to show an entity's unrestricted personnel when the page is initially loaded or upon page refresh
- The section also displays the "BRAG-received" date (the date that FBI/CJIS began the individual's background check)

## Section 4 - Entity Personnel

All  Pending  Unrestricted  Withdrawn  Expired  Restricted  Denied

All  RO/ARO Personnel  Principal Investigator  Science Personnel  Support Personnel



Last Name	First Name	DOJ#	Status	Roles	Tier 1	Supervising Pls	SRA Initial	BRAG Received Date	SRA Approval	SRA Expiration	SRA withdrawn		
							Start Date End Date	Start Date End Date	Start Date End Date	Start Date End Date	Start Date End Date		
Beck	Britney	BB070202	Unrestricted	Principal Investigator	Yes		06/02/2016	06/03/2016	08/16/2016	11/18/2019		Edit	History
Edwin	Sam	SS070062	Unrestricted	Responsible Official, ...	Yes		07/20/2017	07/22/2017	07/30/2017	07/30/2020		Edit	History
Erickson	Erica	EE070193	Unrestricted	Principal Investigator	Yes		10/24/2017	10/25/2017	10/25/2017	10/25/2020		Edit	History
Jarvis	Jerry	JJ070200	Unrestricted	Owner/Controller	No		10/25/2017	10/26/2017	10/28/2017	10/28/2020		Edit	History
Lancaster	Luke	LL070201	Unrestricted	Laboratorian	Yes	David Howard	10/25/2017	10/30/2017	11/01/2017	11/01/2020		Edit	History
Lopez	Killian	KL070225	Unrestricted	Principal Investigator	Yes		11/02/2017	11/02/2017	11/02/2017	11/02/2020		Edit	History
Alexander	David	DA070203	Unrestricted	Laboratorian	Yes	Erica Erickson	10/25/2017	11/01/2017	11/05/2017	11/05/2020		Edit	History

# Amendment Numbers

Unique amendment numbers are assigned to each technical amendment for easier reference, search, and retrieval

## Amendments



Cover Letter	Number	Date Submitted	Date Approved	Status	Last Modified By	
<input type="text"/>	<input type="text"/>	Start Date End Date	Start Date End Date	<input type="text"/>	<input type="text"/>	
Cover letter for demo	00330120	07/25/2019		Pending	responsible official4	<a href="#">Edit</a>
We need to add BoN...	00330091	07/23/2019	07/23/2019	Approved	Branch Chief	<a href="#">Edit</a>
We'd like to add new...	00330092	07/23/2019	07/25/2019	Approved	Branch Chief	<a href="#">Edit</a>
We need to remove ...	00330093	07/23/2019	07/23/2019	Approved	Branch Chief	<a href="#">Edit</a>
We need to add a Ti...	00330101	07/23/2019		Pending	responsible official4	<a href="#">Edit</a>
We would like to rem...	00330086	07/22/2019	07/22/2019	Approved	Branch Chief	<a href="#">Edit</a>

# APHIS/CDC Form 3 Case Identifiers and Agents/Toxins

- Unique Case IDs are assigned to new APHIS/CDC Form 3s for easier reference, search, and retrieval
- Form 3 data tables show the agent or toxin involved

## Form 3 - VIEW ALL

<u>Case ID</u> ▾	<u>Agent Or Toxin</u> ▾	TLR ▾	Status ▾	Incident Date ▾	Immediate Notification Date ▾	Incident Type ▾
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Start Date <input type="text"/> End Date <input type="text"/>	Start Date <input type="text"/> End Date <input type="text"/>	<input type="text"/>
TLR-F3-000002	Abrin		Submitted	11/11/2018	11/11/2018	Theft
TLR-F3-000003	Conotoxins (Short, paralytic alpha)		Submitted	08/09/2018	08/09/2018	Loss
TLR-F3-000004	Ebola virus	false	Draft	08/19/2019	08/19/2019	

# Simple Principal Investigator (PI) Replacement

New APHIS/CDC administrative amendment

- If a PI needs to be removed, eFSAP is able to automatically assign the following to another unrestricted PI:
  - all of their approved work objectives
  - all of their personnel
  - all of their strains and serotypes
- This new feature negates the need to submit Form 1 Section 7A/C technical amendments, as well as Section 4 and 7B administrative changes, if the removed PI's work objectives, personnel, and strains/serotypes need to be retained



# Simple Principal Investigator (PI) Replacement- continued

## Section 4 - Entity Personnel

All  Pending  Unrestricted  Withdrawn  Expired  Restricted  Denied

All  RO/ARO Personnel  Principal Investigator  Science Personnel  Support Personnel

Last Name	First Name	DOJ#	Status	Roles	Tier 1
Beck	Britney	BB070202	Unrestricted	Principal Investigator	Yes
→ Erickson	Erica	EE070193	Unrestricted	Principal Investigator	Yes
Lopez	Killian	KL070225	Unrestricted	Principal Investigator	Yes
Johnson	James	JJ000001	Unrestricted	Principal Investigator	Yes
Howard	David	DH070290	Unrestricted	Principal Investigator	Yes
→ Rubio	Ruben	RR070526	Unrestricted	Principal Investigator	Yes

**In the following example, PI Erickson is retiring. Your entity would like to transfer her personnel, work objectives, and strains/serotypes to another unrestricted principal investigator, PI Rubio.**

**This can now be accomplished without submitting numerous technical amendments and administrative changes.**

# Simple Principal Investigator (PI) Replacement- continued

## Section 7A & 7C - Principal Investigator, Select Agent and Toxin Locations

OMB: 0920-0576

All  Current  Historical  Pending

erickson|

Work Objective: WO001477.001.002	Status: Approved	Date Approved: 07/23/2019	<a href="#">View</a>
Principal Investigators: Erica Erickson	Storage Only		

Agents/Toxins:  
Botulinum neurotoxins

Required Attachments: **A B C D E F G**

Buildings/Rooms:  
Building 20  
- storage room

Biosafety Levels:  
**Storage Only**

Work Objective: WO001475.002	Status: Approved	Date Approved: 08/26/2019	<a href="#">View</a>
Principal Investigators: Erica Erickson	Storage Only		

Agents/Toxins:  
Ricin

Required Attachments: **A B C D E F G**

Buildings/Rooms:  
Building 2  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab  
Building 20  
- storage room

Biosafety Levels:  
**Storage Only**

Work Objective: WO001295.015.003	Status: Approved	Date Approved: 07/22/2019	<a href="#">Active Work</a> <input checked="" type="checkbox"/>	<a href="#">View</a>
Principal Investigators: Erica Erickson	Work and Storage			

Primary human and murine mast cells are pretreated with onabotulinum toxin A or B or control. Mast cell degranulation is evaluated by  $\beta$ -hexosaminidase activity. Expression of botulinum toxin receptor Sv2 is measured by qPCR. The presence of SNAP-25 and VAMP2 is established by immunofluorescence. In vivo rosacea model is established by intradermally injecting LL-37 with or without onabotulinum toxin A pretreatment. Mast cell degranulation is assessed in vivo by histologic counts. Rosacea biomarkers are analyzed by qPCR of mouse skin sections.

Agents/Toxins:  
Botulinum neurotoxins

Required Attachments: **A B C D E F G**

Buildings/Rooms:  
Building 2  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab

Biosafety Levels:  
BSL3  
NIHBL3

**Before the replacement, note that PI Erickson has 3 approved work objectives that your entity would like to keep on its registration.**

# Simple Principal Investigator (PI) Replacement- continued

## Section 7B - Strain or Serotype Designation Information

Saved Agents / Strain or Serotypes

All  Current  Historical

Agent/Toxin	Strain Or Serotype	Assigned PI
<input type="text"/>	<input type="text"/>	erickson <input type="text"/>
Botulinum neurotoxins	Type A	<a href="#">Erica Erickson</a>
Ricin	Serotype A	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type B	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type E	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type F	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type G	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type C	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type D	<a href="#">Erica Erickson</a>
Botulinum neurotoxins	Type H	<a href="#">Erica Erickson</a>

**PI Erickson also has several toxin serotypes in her inventory that your entity would like to retain after she retires.**

# Simple Principal Investigator (PI) Replacement- continued

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

- Section 2 - Sign Section 2
- Section 3 - Add Select Agent or Toxin
- Section 3 - Reactivate Select Agent or Toxin
- Section 4 - Add/Remove/Modify/Reactivate 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

Select All	From				
<input type="checkbox"/>	respo				
<input type="checkbox"/>	respo				
<input type="checkbox"/>	David				
<input type="checkbox"/>	Branch				
<input type="checkbox"/>	CRM Admin	Form1 View	8/20/2019 4:01:01 AM	SRA status will expire in 90 days on 11/18/2019 for Britney Beck (BB070202)	Flag
<input type="checkbox"/>	CRM Admin	Form1 View	8/19/2019 1:48:10 PM	SRA status will expire in 90 days on 11/18/2019 for Britney Beck (BB070202)	Flag

To conduct the PI replacement, first navigate to the amendment selection screen from your entity home page.

Select “Replace Principal Investigator” from the drop-down menu.

# Simple Principal Investigator (PI) Replacement- continued

Replace Principal Investigator

Select Principal Investigator    Supervised Personnel    Work Objectives    Strains    Confirmation

Select Principal Investigator you would like to replace    Select replacement Principal Investigator(s)

Britney Beck- Tier 1  
David Howard- Tier 1  
**Erica Erickson- Tier 1**  
James Johnson- Tier 1  
Killian Lopez- Tier 1  
Ruben Rubio- Tier 1

Back    Next    Close

REGISTRATION EXPIRES: 01/20/2020

Responsible Official Address: 100 Peachtree Street  
Atlanta, GA 30316

Type Status: Government - State/Local

You will then select the PI you wish to replace, Erica Erickson.

# Simple Principal Investigator (PI) Replacement- continued

Application name

## Replace Principal Investigator

Select Principal Investigator    Supervised Personnel    Work Objectives    Strains    Confirmation

Home

Select Principal Investigator you would like to replace    Select replacement Principal Investigator(s)

Erica Erickson- Tier 1

- Britney Beck - Tier 1
- Killian Lopez - Tier 1
- David Howard - Tier 1
- Ruben Rubio - Tier 1

Back    Next    Close

Inspections

Entity: eFSAP T

LEAD AGENCY: A

Facility Address: 1020 Valley Drive, Atlanta, GA 30333-1234

**Indicate one or more replacement PIs. In this case, PI Rubio.**

# Simple Principal Investigator (PI) Replacement- continued

Application name

## Replace Principal Investigator

Select Principal Investigator [Supervised Personnel](#) Work Objectives Strains Confirmation

Personnel under Erica Erickson	Current List of Supervising Principal Investigator(s)	Revised List of Supervising Principal Investigator(s)
Yoshi Ortiz	Erica Erickson	Ruben Rubio
Henry Henderson	Erica Erickson Britney Beck Killian Lopez David Howard	Britney Beck Killian Lopez David Howard Ruben Rubio
David Alexander	Erica Erickson	Ruben Rubio
William Smith	Erica Erickson	Ruben Rubio
Sam Smith	Erica Erickson	Ruben Rubio
David Worth	Erica Erickson Britney Beck Killian Lopez David Howard	Britney Beck Killian Lopez David Howard Ruben Rubio

Back Next Close

After selecting the PI who is leaving and the PI you wish to replace him or her with, eFSAP will provide a few confirmation pages to review.

The first page will show the personnel that are supervised by PI Erickson, and the resulting PI(s) supervising them after the replacement.

# Simple Principal Investigator (PI) Replacement- continued

Application name

## Replace Principal Investigator

Select Principal Investigator    Supervised Personnel    **Work Objectives**    Strains    Confirmation

Work Objectives Under Erica Erickson	Current List of Principal Investigator(s)	Revised List of Principal Investigator(s)
WO001295.015.003 - Approved	Erica Erickson	Ruben Rubio
WO001477.001.002 - Approved	Erica Erickson	Ruben Rubio
WO001475.002 - Approved	Erica Erickson	Ruben Rubio

Back    Next    Close

Home    Inspections

Federal Select    Entity: eFSAP T    LEAD AGENCY:    020

Facility Address: 1    Responsible Official Name: Sam Edwin    Responsible Official Title: Lab Director    Responsible Official Address: 100 Peachtree Street, Atlanta, GA 30316

Registration #: 20190822-150427    Application #: c0c7e336-f01e-e711-80cf-001dd8003fe2    Type Status: Government - State/Local

**The next screen will show the work objectives that eFSAP will automatically transfer from PI Erickson to PI Rubio.**



# Simple Principal Investigator (PI) Replacement- continued

Replace Principal Investigator

Select Principal Investigator    Supervised Personnel    Work Objectives    **Strains**    Confirmation

Strain(s) and/or Serotype(s) assigned to Principal Investigator Erica Erickson	Current List of Principal Investigator(s)	Revised List of Principal Investigator(s)
<b>Botulinum neurotoxins will have 8 Strains Updated</b>		
Type A	Erica Erickson	Ruben Rubio
Type B	Erica Erickson	Ruben Rubio
Type E	Erica Erickson	Ruben Rubio
Type F	Erica Erickson	Ruben Rubio
Type G	Erica Erickson	Ruben Rubio
Type C	Erica Erickson	Ruben Rubio
Type D	Erica Erickson	Ruben Rubio
Type H	Erica Erickson	Ruben Rubio
<b>Ricin will have 1 Strains Updated</b>		
Serotype A	Erica Erickson	Ruben Rubio

Back    Next    Close

**The final review screen will show the strains/serotypes that eFSAP will automatically transfer to PI Rubio.**

# Simple Principal Investigator (PI) Replacement- continued

**Replace Principal Investigator**

Select Principal Investigator    Supervised Personnel    Work Objectives    Strains    **Confirmation**

You will be replacing Principal Investigator Erica Erickson with Principal Investigator(s) Ruben Rubio. All personnel, work objectives, and strains/serotypes previously assigned to Principal Investigator Erica Erickson, will be assigned to Principal Investigator(s) Ruben Rubio. These changes will take effect immediately. Press "Commit Changes" to proceed.

Back    Next    **Commit Changes**    Close

Branch Chief    Root View    8/22/2019 3:04:29 PM    - Entity registration status has been updated to 1/20/2020 5:00:00 AM by

**After reviewing the changes that will be applied, click "Commit Changes" to have eFSAP automatically process the PI replacement.**

# Simple Principal Investigator (PI) Replacement- continued

## Notifications

Archive Selected

Current  Archived  Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/>	responsible o...	Form1 <a href="#">View</a>	8/26/2019 3:50:28 PM	Principal Investigator Erica Erickson has been replaced by Principal Investigator Ruben Rubio. Erica Erickson is no longer assigned to any work objectives, personnel, or strains/serotypes. Please update Erica Erickson's role or status.	<a href="#">Flag</a>
<input type="checkbox"/>	fte advanced	Amendment <a href="#">View</a>	8/26/2019 10:27:38 AM	Section 7a/c - Amendment for work objective WO001475 002 was modified	<a href="#">Flag</a>

# Simple Principal Investigator (PI) Replacement- continued

Work Objective: WO001477.001.003      Status: Approved      Date Approved: 07/23/2019

Principal Investigators: Ruben Rubio      Storage Only      [View](#)

Agents/Toxins: Botulinum neurotoxins

Required Attachments: **A B C D E F G**

Buildings/Rooms: Building 20  
- storage room

Biosafety Levels: Storage Only

Work Objective: WO001475.002.002      Status: Approved      Date Approved: 08/26/2019

Principal Investigators: Ruben Rubio      Storage Only      [View](#)

Agents/Toxins: Ricin

Required Attachments: **A B C D E F G**

Buildings/Rooms: Building 2  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab  
Building 20  
- storage room

Biosafety Levels: Storage Only

Work Objective: WO001295.015.004      Status: Approved      Date Approved: 07/22/2019      **Active Work**

Principal Investigators: Ruben Rubio      Work and Storage      [View](#)

Primary human and murine mast cells are pretreated with onabotulinum toxin A or B or control. Mast cell degranulation is evaluated by  $\beta$ -hexosaminidase activity. Expression of botulinum toxin receptor Sv2 is measured by qPCR. The presence of SNAP-25 and VAMP2 is established by immunofluorescence. In vivo rosacea model is established by intradermally injecting LL-37 with or without onabotulinum toxin A pretreatment. Mast cell degranulation is assessed in vivo by histologic counts. Rosacea biomarkers are analyzed by qPCR of mouse skin sections.

Agents/Toxins: Botulinum neurotoxins

Required Attachments: **A B C D E F G**

Buildings/Rooms: Building 2  
- Room 1 - Tier 1 Lab and Storage Suite \ BSL3 Lab

Biosafety Levels: BSL3  
NIHBL3

**Section 7A/C will now show PI Rubio overseeing the three work objectives previously assigned to PI Erickson.**

# Simple Principal Investigator (PI) Replacement- continued

## Section 7B - Strain or Serotype Designation Information

### Saved Agents / Strain or Serotypes

All  Current  Historical

Agent/Toxin <input type="text"/>	Strain Or Serotype <input type="text"/>	Assigned PI <input type="text" value="rubio"/>
Botulinum neurotoxins	Type A	Ruben Rubio
Ricin	Serotype A	Ruben Rubio
Botulinum neurotoxins	Type B	Ruben Rubio
Botulinum neurotoxins	Type E	Ruben Rubio
Botulinum neurotoxins	Type F	Ruben Rubio
Botulinum neurotoxins	Type G	Ruben Rubio
Botulinum neurotoxins	Type C	Ruben Rubio
Botulinum neurotoxins	Type D	Ruben Rubio
Botulinum neurotoxins	Type H	Ruben Rubio

# Simple Principal Investigator (PI) Replacement- continued

## Section 4 - Entity Personnel

All  Pending  Unrestricted  Withdrawn  Expired  Restricted  Denied

All  RO/ARO Personnel  Principal Investigator  Science Personnel  Support Personnel

Last Name	First Name	DOJ#	Status	Roles	Tier 1
<input type="text" value="erickson"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Erickson	Erica	EE070193	Unrestricted		Yes

**The PI who was replaced will no longer show as a PI on Section 4.**

**You will need to conduct an administrative Section 4 change to either withdraw the former PI or change his/her role.**



## 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).