

eFSAP - Did You Know?

2021 RO Webinar Series

August 18, 2021



Objectives

- Did You Know?
- Form 1 Amendments
- Uploading Documents
- eFSAP Resource Center



Did You Know?



Did You Know?

- It is the responsibility of the Responsible Official (RO) to ensure that information in the electronic Federal Select Agent Program Portal (eFSAP) information system is current and accurate
- Information in eFSAP is the official program record
- For help and support, contact the eFSAP helpdesk at eFSAPsupport@cdc.gov



Did You Know?

- **Section 3 and Section 7B are tied together**
 - Section 3 lists the agents and/or toxins the entity is registered to use or possess
 - Section 7B lists the strains of the agents and/or toxins that the entity possesses
- **The possession status listed on the Section 3 is correlated with the information entered on the Section 7B**



Did You Know?

Section 3

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 SECTION 6 SECTION 7

UMBRELLA CORPORATION

Section 3 - Select Agents and Toxins

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

All Current Historical

Agent Toxin Name	Status	Agency	Tier 1	Possessed	Approved	Withdrawn	
Abn	Approved	HHS	No	<input checked="" type="checkbox"/>	02/04/2021		History
African horse sickness virus	Pending	USDA	No	<input type="checkbox"/>			History
Avian influenza virus	Unassigned	USDA	No	<input type="checkbox"/>	01/25/2019		History
Bacillus cereus Biovar anthracis	Unassigned	HHS	Yes	<input type="checkbox"/>			History
Botulinum neurotoxins	Unassigned	HHS	Yes	<input type="checkbox"/>	01/28/2019		History
Brucella abortus	Unassigned	Overlap	No	<input type="checkbox"/>			History
Brucella melitensis	Approved	Overlap	No	<input type="checkbox"/>	09/02/2020		History
Brucella suis	Approved	Overlap	No	<input checked="" type="checkbox"/>	08/13/2020		History

Section 7B

SECTION 1 SECTION 2 SECTION 3 SECTION 4 SECTION 5 SECTION 6 SECTION 7

UMBRELLA CORPORATION

Section 7B Strain or Serotype Designation Information

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

All Current Historical

Agent/Toxin	Strain/Serotype	Additional Info	Count	Assigned PIs	Recombinant
					<input type="checkbox"/>
Abrin	Other	2021	1	Travis Trench, Gerald Gallant	✗
+ Abrin	Unknown		2	Travis Trench	✗
- Brucella suis	Other		2	rita hoover, Jill Next	✓
Brucella suis	Other	type1		rita hoover	✓
Brucella suis	Other	ffispiarew		Jill Next	✗



APHIS/CDC Form 1 Amendments



Amendment Status



Amendment Status

- Draft
- Pending
- Request for Information



Adding a Principal Investigator (PI)



Adding a Principal Investigator (PI)

- Section 4 - submit "Add/Remove/Modify/Reapply Personnel" amendment
- Section 7AC - submit "Add New Work Objective" or "Modify Work Objective and/or Attachments" amendment



Adding a Principal Investigator (PI)

Add Work **Add Work and Storage** **Add Storage Only**

Designate BioSafetyLevel !
BSL3

Designate Additional Biosafety Levels (if applicable)
NIHBL3
NIHBL3-LS

Designate Select Agent(s) and Toxin(s)
Non Tier 1
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella suis
Tier 1
Bacillus cereus Biovar anthracis
Burkholderia mallei
Burkholderia pseudomallei
Francisella tularensis

Designate Principal Investigator
Non Tier 1
Britney Beck
David Howard
Tier 1
James Johnson
Killian Lopez
Sam Samuelson

Designate Building and Room
1414
Building 1
Building 2

Tier 1
Lab and Storage Suite / BSL3/NIHBL3 Lab and Storage
Lab and Storage Suite / BSL3/NIHBL3 Lab Only
Lab and Storage Suite / BSL3/NIHBL3 Lab only (2)
Tier 1 Lab and Storage Room, ABSL3, BSL3

Cancel Reset **Proceed**

Amendment Cover Letter

Add additional work for PI Beck.

19968 of 20000 characters left

Required Attachments: A B C D E F G

General Discussion

Type your message here...

Send

View amended data

Withdraw Amendment

Review or Make Changes Save Submit

Add New Work Objective



Adding a Principal Investigator (PI)

Biosafety Levels: BSL3 NIHBL3 [Add/Remove](#)

Agents/Toxins: Brucella abortus [Add/Remove](#)

Principal Investigators: Britney Beck
David Howard [Add/Remove](#)

Buildings/Rooms: Building 1
- Lab and Storage Suite \ BSL3/NIHBL3 Lab and Storage [Add/Remove](#)

Biosafety Levels: BSL3 NIHBL3 [Add/Remove](#)

Agents/Toxins: Brucella abortus [Add/Remove](#)

Principal Investigators: Britney Beck
David Howard
James Johnson [Add/Remove](#)

Buildings/Rooms: Building 1
- Lab and Storage Suite \ BSL3/NIHBL3 Lab and Storage [Add/Remove](#)

Amendment Review and Discussion

Mostly Work Objective - WO001475.015

Amendment Cover Letter

19998 of 20000 characters left

Required Attachments: A B C D E F G

General Discussion

General Discussion

Type your message here...

Send

Save Draft Submit

Notifications

Current Archived

From	Type	Date And Time	Notification
the advanced	Amendment View	12/6/2019 11:50:38 AM	Amendment #330947 - Section 7a/c - Amendment for work objective (WO001475.015) was modified (State: Pending) to add work to PI: Britney Beck, Killian Lopez, Ruben Rubio, for Agent Toxins: Brucella suis, Burkholderia mallei, Burkholderia pseudomallei

Modify Work Objective



Replacing a PI



Replacing a PI

- Select amendment “Replace Principal Investigator” and click “OK”
- Select the PI to be replaced from drop-down menu
- Replace the PI who is leaving with the new PI (one or more PIs can be named as replacements)



Replacing a PI

- Review screen displays
- Select "Commit Changes" to have eFSAP process the PI replacement
- Add a role to the replaced PI or remove the PI from the registration



Removing a PI



Removing a PI

- The removal of a PI must be completed in the following order:
 - Remove the PI from Section 7B strains and serotypes, if necessary
 - Remove the PI from any Section 7AC work objectives
 - Remove the PI from Section 4



Removing a PI

- Section 7B - submit "Add/Remove/Modify Strains or Serotypes" amendment to remove all strains associated with the PI being removed
- Section 7AC - submit "Modify Work Objective and/or Attachments" amendment if removing PI from a shared work objective or "Remove Approved Work Objective" if on an independent work objective; PI must be removed from all associated work objectives before being removed from Section 4
- Section 4 - submit "Add/Remove/Modify/Reapply Personnel" amendment; can either update role of individual if remaining on registration or remove from registration



Removing a PI

Section 7B- Remove Strains

Burkholderia mallei	NCTC 120		1			X	X	✓	06/10/2020
Burkholderia pseudomallei	1106a	K36 243	1			X	✓	X	02/20/2019
Ebola virus	Reston		1			X	X	✓	06/10/2020
Synchytrium endobioticum	Race 2 NFLD		1			X	X	✓	06/10/2020

Page Size: 100 | First | Prev | 1 | Next | Last | 29 Total Strains | [Go](#) | [Delete](#)

1	Bruceella melitensis	biovar 2	3			X	✓	✓	11/15/2019
1	Bruceella melitensis	biovar 2	12			X	✓	X	11/15/2019
1	Bruceella melitensis	biovar 2	68			X	X	✓	06/11/2020
1	Bruceella melitensis	biovar 2	2020			X	X	✓	06/11/2020
2	Bruceella suis	biovar 2	2			✓	X	✓	02/20/2019
	Burkholderia mallei	NCTC 120	1			X	X	✓	06/10/2020
	Burkholderia pseudomallei	1106a	K36 243	1		X	✓	X	02/20/2019
	Synchytrium endobioticum	Race 2 NFLD	1			X	X	✓	06/10/2020

21 Total Strains

Section 7AC- Remove Work Objective(s)

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

Section 7AC - Remove Approved Work Objective

- W0001598.001.001 - Approved
- W0001480.001.003 - Approved
- W0001467.004.002 - Approved
- W0001464.004.004 - Approved
- W0001415.004.004 - Approved
- W0001372.001.001 - Suspended
- W0001349.001.001 - Approved
- W0001345.001.001 - Approved
- W0001242.003.001 - Approved
- W0001239.001.004 - Approved
- W0001236.003 - Approved
- W0001201.002.004 - Approved
- W0001200.001.004 - Approved
- W0001198.001.004 - Approved

Building Rooms

10/10-101

If the work objective you wish to remove is not shown, one of the following reasons may apply:

1. The work objective is the only work objective for an agent/toxin and the agent/toxin has strains/serotypes that are currently possessed
2. The work objective is a pending work objective.
3. The work objective is a draft work objective.
4. The work objective is withdrawn.
5. The work objective is an approved work objective that already has an amendment pending.

Complete your cover letter for this amendment:



Uploading Documents



Forms Documents

Forms

Form 1 Sections 1-5

- Section 1
- Section 2
- Section 3
- Section 4
- Section 5a
- Section 5b
- Section 5c

Form 1 Section 6

- Floor Plan
- Other

Form 1 Section 7A/C

- Attachment A
- Attachment B
- Attachment C
- Attachment D
- Attachment E
- Attachment F
- Attachment G
- Other

Form 1 Section 7B

- Destruction Records
- Intra-entity Transfer Records
- Other

Form 2 (all sections)

- Supporting Documentation
- Response to Request for Information
- Other

Form 3

- Response to Request for Information
- Other

Form 4A/B/C

- Response to Request for Information
- Other



Program-Related Documents

Entity Home

Entity Select Agent and Program Documents

Form 5

- Completed Form 5
- Correspondence
- Other

Facilities

- Floorplan
- HVAC Schematic
- Commissioning Documents
- Plumbing Schematics
- Other

Other

Restricted Experiments/ Exclusions

- Request for Exclusion
- Request for Restricted Experiment
- Response for Information
 - ❖ Restricted Experiment
 - ❖ Exclusion
 - ❖ Inactivation
 - ❖ Other
- Other

Policy

- Request for Regulatory Interpretation
- Other

- Access Permissions
- Allergy Prevention Information
- Allergy Prevention Program Records
- Animal/Plan Accounting Record
- Biosafety Drill/Exercise Documentation
- Biosafety Plan
- Biosafety Plan Review
- Biosafety Risk Assessment
- Biosafety SOP
- Biosafety SOP Review
- BSC Certification
- Chemical Hygiene Plan
- Chemical Hygiene Plan Review
- Decontamination System Information

- Decontamination System Validation
- Discrepancy Explanation
- Due Diligence Record
- Entity Self Inspection
- Exhaust HEPA Certification
- Facility Initial Verification
- Facility Reverification
- Fit Testing Record
- HVAC Information
- IACUC Document
- IBC Document
- Inactivation Certificate
- Inactivation Protocol
- Incident Response Drill/Exercise Documentation
- Incident Response Plan
- Incident Response Plan Review

- Incident Response Risk Assessment
- Incident Response SOP
- Incident Response SOP Review
- Insider Threat Awareness Information
- Insider Threat Awareness Record
- Intra-entity Transfer Record
- Inventory Record
- Occupational Health Program Information
- Occupational Health Program Record
- Other Standard Operating Procedure
- Other SOP Review
- Quarantine Information

- Quarantine Record
- Respiratory Protection Program
- Security (Plan) Risk Assessment
- Security Drill/Exercise Documentation
- Security Plan
- Security Plan Review
- Security SOP
- Staff Access Record
- Staff Training Curriculum
- Staff Training Record
- Tier 1 Suitability Information
- Tier 1 Suitability Record
- Visitor Access Record
- Visitor Training Curriculum
- Visitor Training Record
- Other

<https://www.selectagents.gov/efsap/using/docs/Document-Upload-Categories-Locations.pdf>



Inspection Documents

Inspection Module

Inspection Details – Pre-inspection Documents

- Directions to Entity
- Entry Requirements
- Other

Inspection Resolution – Post-inspection Documents

- Dispute of Inspection Finding
- Response to Dispute of Inspection Finding
- Response to Immediate Action Departure(s)
- Response to Final Departure(s)
- Response to Request for Information
- Other

Inspection Details – Inspection Documents (Collected on-site)

- | | | | |
|---|--|---|--|
| <ul style="list-style-type: none">• Access Permissions• Allergy Prevention Information• Allergy Prevention Program Records• Animal/Plan Accounting Record• Attendance List• Biosafety Drill/Exercise Documentation• Biosafety Plan• Biosafety Plan Review• Biosafety Risk Assessment• Biosafety SOP• Biosafety SOP Review• BSC Certification• Chemical Hygiene Plan• Chemical Hygiene Plan Review• Decontamination System Information• Decontamination System Validation | <ul style="list-style-type: none">• Discrepancy Explanation• Due Diligence Record• Entity Self Inspection• Exhaust HEPA Certification• Facility Initial Verification• Facility Reverification• Fit Testing Record• Floor Plan• Form 2• Form 3• Form 4• HVAC Information• IACUC Document• IBC Document• Inactivation Certificate• Inactivation Protocol• Incident Report (non-Form 3)• Incident Response Drill/Exercise Documentation• Incident Response Plan• Incident Response Plan Review | <ul style="list-style-type: none">• Incident Response Risk Assessment• Incident Response SOP• Incident Response SOP Review• Insider Threat Awareness Information• Insider Threat Awareness Record• Intra-entity Transfer Record• Inventory Record• Occupational Health Program Information• Occupational Health Program Record• Other Standard Operating Procedure• Other SOP Review• Pest Management Information• Quarantine Information• Quarantine Record | <ul style="list-style-type: none">• Respiratory Protection Program Record• Respiratory Protection Program Information• Security (Plan) Risk Assessment• Security Drill/Exercise Documentation• Security Plan• Security Plan Review• Security Response Time Documentation• Security SOP• Staff Access Record• Staff Laboratory Notebook• Staff Training Curriculum• Staff Training Record• Tier 1 Suitability Information• Tier 1 Suitability Record• Visitor Access Record• Visitor Training Curriculum• Visitor Training Record• Other |
|---|--|---|--|



eFSAP Resource Center



eFSAP User Manual



eFSAP User Manual

- In 2021, a manual was developed to help users navigate eFSAP.
- The manual provides step by step instructions on how to use the system.

Electronic Federal Select Agent
Program (eFSAP)
Information System
2021 User Manual

<https://www.selectagents.gov/efsap/using/docs/eFSAP-User-Manual.pdf>



Inspection Module Training



Inspection Module Training

- Tutorial that walks the user through using the inspection module within eFSAP
- Provides step by step instructions to include how to upload responses to an inspection report

<https://www.selectagents.gov/efsap/using/docs/eFSAP-Inspections-Module.pdf>



APHIS/CDC Form Resources



APHIS/CDC Form Resources

- Form 1: Registrations and Amendments- [APHIS/CDC Form 1: Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins | Using eFSAP | Federal Select Agent Program](#)
- Form 2: Transfer Requests- [APHIS/CDC Form 2: Request to Transfer Select Agents and Toxins | Federal Select Agent Program](#)
- Form 3: Report of Theft, Loss, or Release- [APHIS/CDC Form 3: Report of a Release/Loss/Theft | Federal Select Agent Program \(selectagents.gov\)](#)
- Form 4: Report of Identification- [APHIS/CDC Form 4: Reporting the Identification of a Select Agent or Toxin | Federal Select Agent Program \(selectagents.gov\)](#)

<https://www.selectagents.gov/efsap/using/index.htm>



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
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404-718-2000

APHIS Contact Information
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Select Agents and Toxins
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