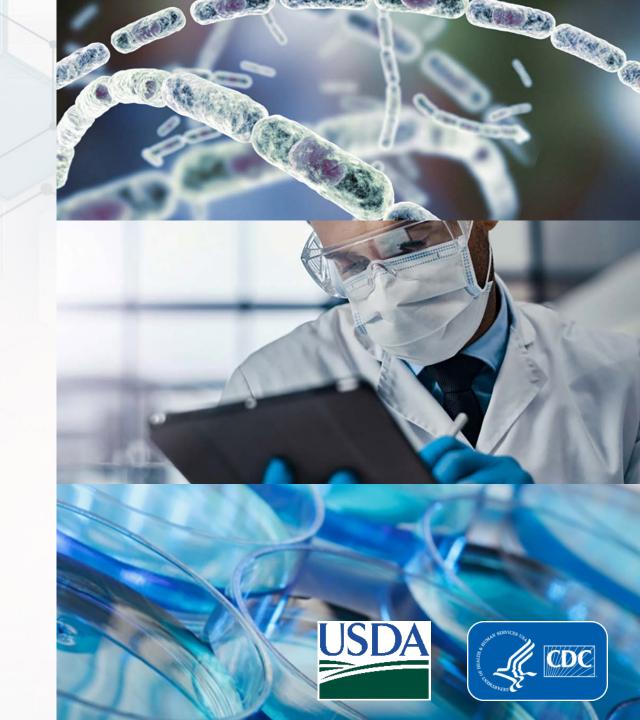
### eFSAP - Did You Know?

**2021 RO Webinar Series** 

August 18, 2021



# Objectives

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













### Did You Know?

- 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



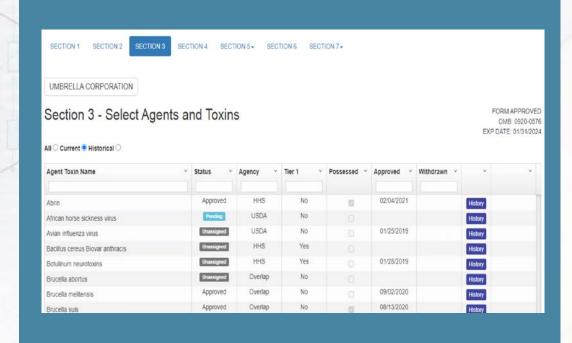
### Did You Know?

- 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

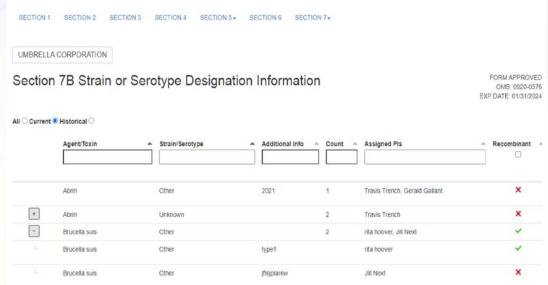


### Did You Know?

#### Section 3



### Section 7B













# APHIS/CDC Form 1 Amendments







### **Amendment Status**

 Draft Pending

Request for Information













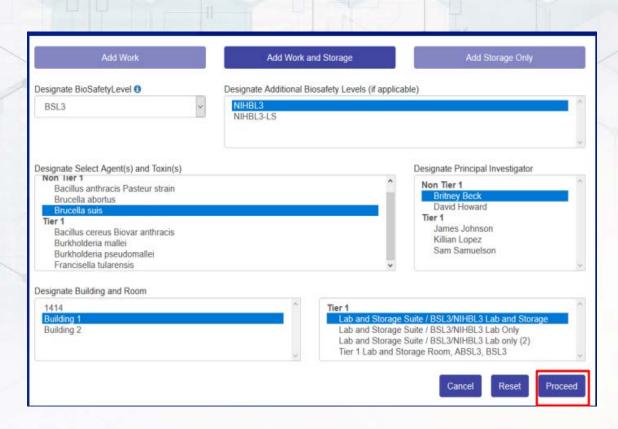
# Adding a Principal Investigator (PI)

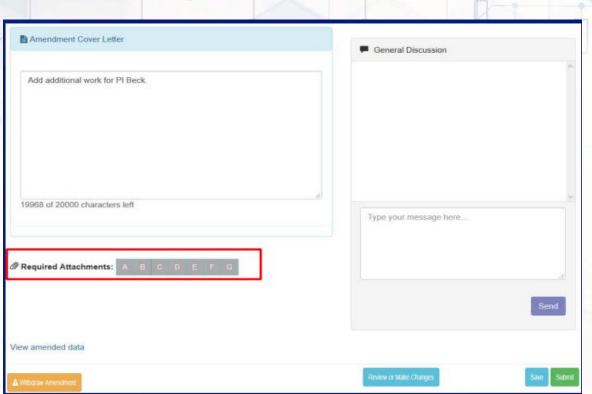
 Section 4 - submit "Add/Remove/Modify/Reapply Personnel" amendment

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



# Adding a Principal Investigator (PI)





**Add New Work Objective** 

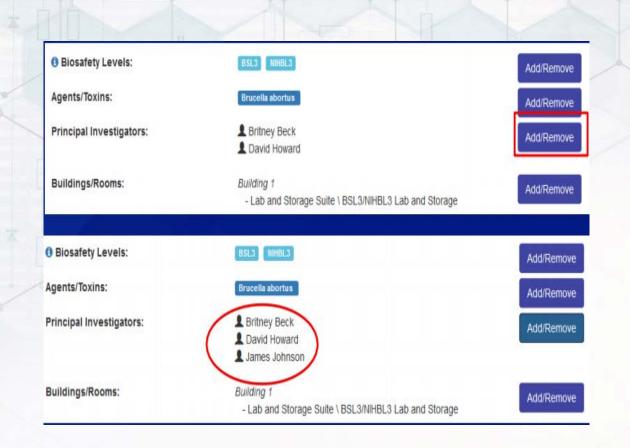


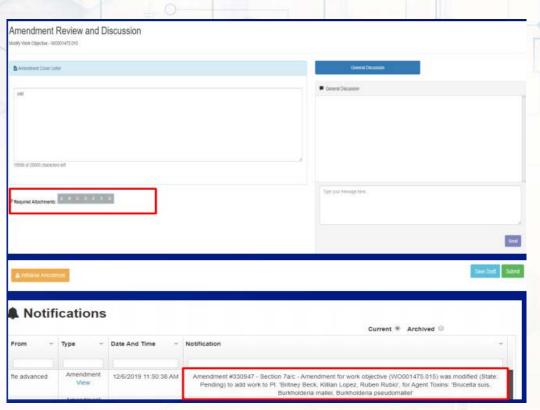






# Adding a Principal Investigator (PI)





**Modify Work Objective** 











### Replacing a Pl

 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 Pls can be named as replacements)









### Replacing a Pl

- 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 Pl

- 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 Pl

- 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

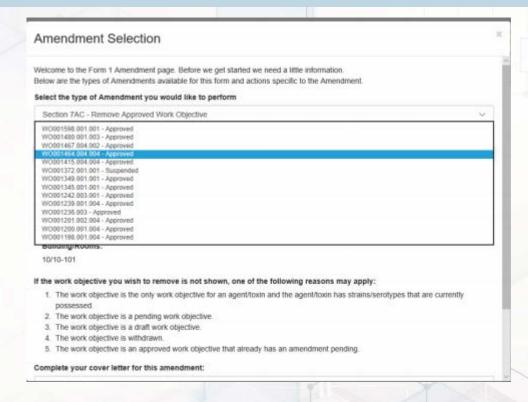


# Removing a Pl

#### Section 7B- Remove Strains



### Section 7AC- Remove Work Objective(s)













# **Uploading Documents**





### **Forms Documents**

#### 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

### **Forms**

### 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**

#### 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

### **Entity Home**

#### **Entity Select Agent and Program Documents**

- 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 ResolutionPost-inspectionDocuments

- 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

#### 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

- 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

 Incident Response Risk Assessment

Inspection Details – Inspection Documents (Collected on-site)

- 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

- 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

• 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**

 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











### **APHIS/CDC Form Resources**

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



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

**APHIS Contact Information** Division of Agricultural **Select Agents and Toxins** 301-851-2070









