APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 1)

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Introduction

The APHIS/CDC Form 1, Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins, provides a method for entities to register to possess, use, or transfer select agents and toxins (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73). The APHIS/CDC Form 1 is provided as individual sections in an electronic format to assist entities in data input and revisions as necessary. The information requested in this electronic form includes facility information; a list of select agents or toxins to be possessed, used, or transferred by the entity; a list of individuals who will have access to select agents and toxins; and a description of the work to be performed with the agent. This guidance document provides the information on how to fill in the electronic Form 1 sections within the electronic Federal Select Agent Program Information System (eFSAP).

To begin the application process, review the information available at http://www.selectagents.gov, and contact the Federal Select Agent Program (FSAP) at either LRSAT@cdc.gov or dasat@usda.gov to request a user profile. See the New Registration with FSAP section below for further details. If you are completing the APHIS/CDC Form 1 for the first time, please review these application instructions before completing and submitting your application for registration to the Animal and Plant Health Inspection Service (APHIS) Division of Agricultural Select Agent and Toxins (DASAT) or the Centers for Disease Control and Prevention (CDC) Division of Regulatory Science and Compliance (DRSC).

If you are a registered entity and are submitting an amendment to your registration, review the Amendment Guidance Document to determine the submission requirements for the particular type(s) of amendment(s) you are requesting. Additional guidance documents and tutorial videos are available at http://www.selectagents.gov.

New Registration with FSAP

Individuals or entities that wish to register with the federal select agent program (FSAP) should initiate the request by emailing FSAP at either DRSC (lrsat@cdc.gov), or DASAT (dasat@usda.gov). The agents on the registration will determine oversight agency.

- If registering for only HHS-only agents or toxins use lrsat@cdc.gov
- If registering for only USDA-only agents use dasat@usda.gov
- If registering for overlap agents and/or a mix of HHS-only and USDA-only agents or toxins, you may choose one agency for primary oversight

Provide the following information in the email:

- Entity name and the physical address of the location(s) to be registered
- Name and contact information of the individual who will be the Responsible Official (RO) and for any Alternate Responsible Official (ARO)
    - Contact information must include email address and phone number
- The select agent(s) or toxin(s) that you intend to register for and a brief description of the work objectives.

Once the request has been received, you will be assigned a point of contact (POC) who will assist you in gaining access to eFSAP and setting up the registration. The POC will:

- Submit the initial request for Secure Access Management Services (SAMS) accounts using the RO and ARO email addresses you provided them. A SAMS account is necessary to gain access to the eFSAP web portal. After the POC makes the request, you will receive an email with directions from SAMS for setting up your individual accounts.
- Email you a temporary entity registration number and Unique Identification Number (UIN) (also called Department of Justice (DOJ) number(s)) for the RO and any AROs to begin the Security Risk Assessment Process (SRA).
    - Use the UIN number to fill out the FD-961 form and submit it to the FBI BRAG per the form instructions.

Approval of the application/Form 1 by FSAP is required before possession of select agents or toxins. Additionally, any individual must have an SRA completed by FBI BRAG and be approved for access by before he/she may access select agents or toxins.

After acquiring eFSAP access, the RO/AROs will work with the POC and follow the steps in this guidance document to complete the Form 1 information. This will include the following steps:

1. Complete data entry in Sections 1, 3, 4, 5 and 6.
    a. Entity information, abstract, and additional locations in Section 1.
    b. Select agents and toxins in Section 3.
    c. Principal investigators (PIs) and other personnel to the registration in Section 4.
        i. For PIs, assign them the role of Other; after they are approved, change their role to PI
    d. Physical security and inspection information in Section 5.
    e. Buildings, rooms, and suites information in Section 6.
2. Once a PI has received FSAP SRA approval and their role has been modified to say PI in Section 4, submit a Section 7 amendment to add work objectives.
    a. Adding work objectives will initiate scheduling of the inspection process.
3. Once the Form 1 information has been completed, sign the RO statement in Section 2.

FSAP will work with the RO to schedule the initial inspection once the Form 1 information is complete. The RO should begin uploading the documents listed below while completing the Form 1 to expedite pre-inspection reviews:

1. Biosafety, Security, Incident Response plans.
2. Supporting documents including standard operating procedures and risk assessments.
3. Chemical Hygiene plan if working with toxins, quarantine policies if registered for Highly Pathogenic Avian Influenza Viruses, and Occupational Health plan if registered for Tier 1 select agents or toxins, SARS-CoV or 1918 influenza virus.
4. Facility information and commissioning documents.
    a. For BSL-3/ABSL-3 facilities please see https://www.selectagents.gov/regBSL3ABSL3policy.html

Once the initial inspection has been completed, any departures corrected, and the inspection closed, the entity registration will be approved, and you will receive a permanent registration number. Following FSAP approval of your registration you may submit a Form 2 request to initiate a shipment of the select agent or toxin(s) on the registration.

See the Amendments Guidance document for instructions on submitting amendments, to update your registration, as needed. This includes changes to locations, people, and work objectives. Your POC will also provide guidance on these procedures.

Instructions for Completion of APHIS/CDC Form 1

Overview

This form is organized in seven (7) sections. Sections 1 – 5 capture entity wide information, Section 6 captures information specific to each building and suite/room and Section 7 captures information about the work each PI will perform. Multiple entries in Section 6 and Section 7 may be required depending on the complexity of the registration. The structure of these eFSAP sections is designed to facilitate submittal of amendments.

Section 1 requests information about the entity: the physical address, application and registration numbers, and entity abstract.

Section 2 is the Responsible Official (RO) certification statement and RO digital signature.

Section 3 is a list of all select agents, toxins, and regulated nucleic acids for which the entity is registered for and indicates the possession status for each.

Section 4 lists all the individuals who will have approval from the APHIS Administrator or HHS Secretary following a security risk assessment conducted by the Attorney General, who subsequently may be given access to select agents, toxins, and regulated nucleic acids at the entity. Information for the Responsible Official (RO), Alternate Responsible Official (ARO), Owner/Controller (if applicable), and Principal Investigator (PI) is captured in Section 4, including additional contact information for the RO and ARO roles.

Section 5 captures entity wide information on security, incident response, biosafety, and entry requirements for inspections.

Section 6 will be completed for each building and suite/room.

Section 7 will be completed for each work objective performed by the PI(s). Attachments A through G (toxin, recombinant/synthetic DNA, animal, plant, arthropod, BSL3Ag, BSL4, ABSL4) may need to be completed based on the type of work being performed.

DEFINITIONS AND TERMS USED THROUGHOUT THIS DOCUMENT CAN BE FOUND IN the Definitions Section at the end of the document.

Section 1A - Entity Information

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.
- Do not abbreviate the organization name (e.g., International Business Machine Corporation instead of IBM).

Physical Address

- Provide the complete physical address of the entity listed in the Entity Name field. This address will be entered on the FD-961 and used to perform the entity security risk assessment, if applicable.

Note: The physical address may be different from the mailing address to which official correspondence will be sent. The mailing address is entered under the Responsible Official Information in Section 4.

Additional Physical Address(es)

- For an entity that has more than one physical address, enter additional addresses. Entities with multiple laboratories with differing physical addresses (e.g., laboratory located on a different campus of academic institution or a satellite facility) should list all relevant addresses.

Type of Entity

- Refer to the definitions below when specifying the type of entity:

  - **Academic (Private)** – a university that is neither owned nor controlled by any government entity. This entity must identify an individual(s) that own or control the entity. For example, if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals who will have access to the select agents or toxins possessed, used, or transferred by the entity, this individual would be considered someone who owns or controls the entity.
  - **Academic (State) –** a university that is predominantly funded by public means through the government. Public accredited academic institutions are exempt from the entity security risk assessment requirement.
  - **Commercial (Profit) –** a privately owned company including partnerships and those corporations either privately held or whose shares are traded on the open market. This entity must identify individual(s) that own or control the entity. For example, 1) if an individual owns 50 percent or more of the entity, or 2) is a holder or owner of 50 percent or more of its voting stock or 3) an individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity, this individual would be considered someone who owns or controls the entity.
  - **Government (Federal)** – an entity that is part of an agency of the Federal government. These entities are exempt from the entity security risk assessment requirement.
  - **Government (State/Local)** – an entity that is part of an agency of a State or Local government. An example would be a state or local laboratory that provides certain medical and environmental laboratory services (testing, consultation, and training) to the public and is predominately funded by a state or local government. These entities are exempt from the entity security risk assessment requirement.
  - **Private, Non-Profit** – a privately owned company including partnerships and corporations no part of the income which is distributed to its owners, directors, officers, members or stockholders and whose principal purpose is for charitable or benevolent purposes. This entity must identify individual(s) that own or control the entity. For example, 1) if an individual owns 50 percent or more of the entity, or 2) is a holder or owner of 50 percent or more of its voting stock or 3) an individual is in a managerial or executive capacity with regards to the entity's select agents or toxins or with regards to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity, this individual would be considered someone who owns or controls the entity.

Note: Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual(s) who owns or controls such entities. For other entity types, an individual(s) deemed to own or control the entity must be identified and a security risk assessment must be performed for the entity. The security risk assessment for the entity is a review initiated by the entity and completed by the FBI BRAG, that is performed upon initial registration and upon request for each registration renewal.

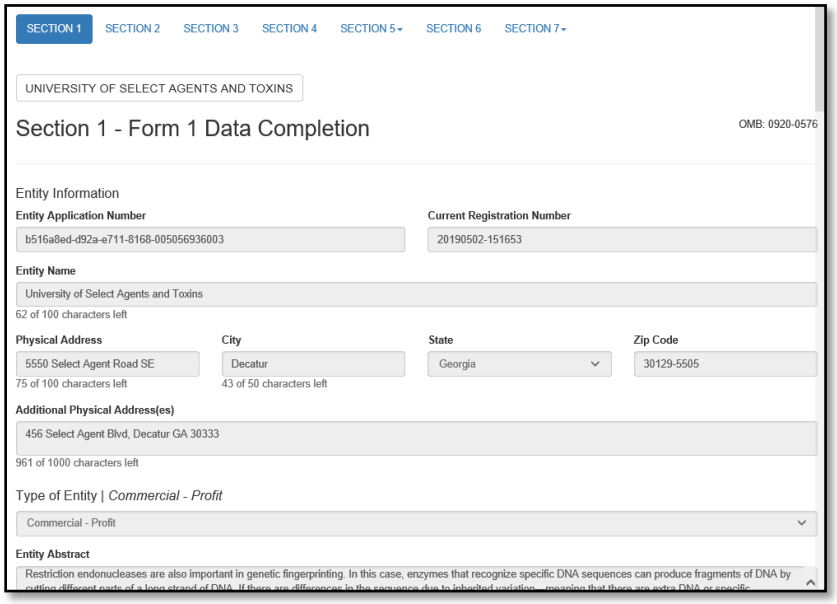
Entity Abstract

Provide a summary of the overall institution mission, functions, and size. This information can include a general estimated number of employees, square footage of entire campus or facility, number of laboratories, overall scope of research, and any international collaboration. Specialized areas of research, education, or expertise can be highlighted. Include a brief description of the management structure of the institution related to oversight of the select agent facility/facilities. Provide a brief summary of the select agent and toxin work at the entity including mission, function, and size.

Note: Information specific to select agents and toxins will be required in later sections of this application. Work specific information that is subject to change and is documented in other areas of the Form 1 should not be included in the abstract (e.g. number of PI's, agent, number of rooms).

If further information or guidance is required contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Example of the Section 1



Section 2 – RO Certification of Personnel and Facility Activities

RO Signature

- For the initiation or the renewal of the registration, the RO must read the complete statement and digitally sign the Section 2 where indicated. An ARO may not sign in place of the RO for new registrations. An ARO may temporarily sign in place of the RO at the time of registration renewal; however, this must be updated as soon as the RO is able to provide his/her signature.

  Note: Refer to Section 9 of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

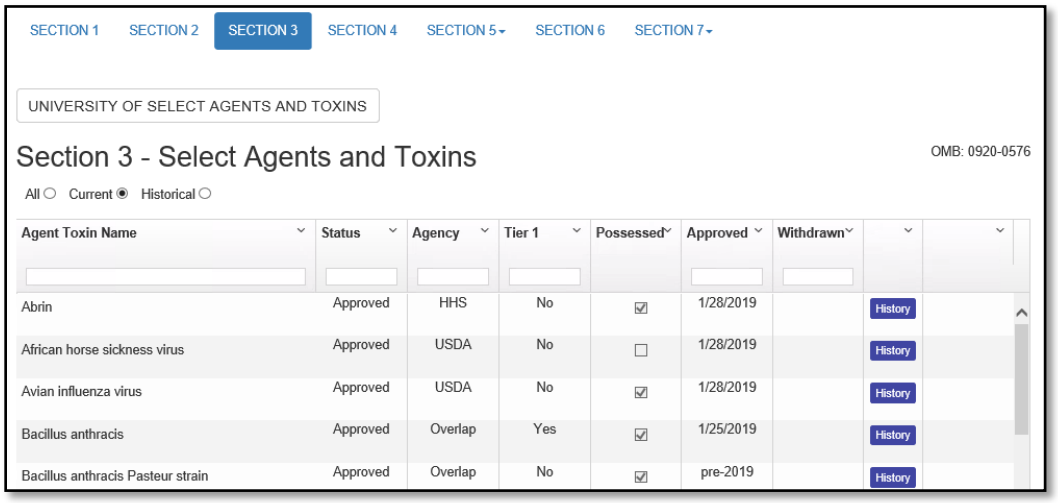
Additional Information
• By signing the bottom of Section 2, the RO is certifying that, as of the date indicated on the signature, all information is current and accurate and these requirements are met. This includes ensuring that plans are written and provisions and procedures described are in effect at the time of submission of the application, in accordance with the requirements of the Select Agent Regulations. See the Guidance Documents for additional information on developing plans and implementing a training program.

Section 3 – Select Agents and Toxins

The Select Agent/Toxin table will indicate each select agent (genus and species), toxin or regulated nucleic acid for which the entity is registered. An entity must be approved for at least one select agent or toxin in order to be registered with the FSAP. See Section 3 Amendments section for instructions on adding or removing agents from the registration.

If further information or guidance is required contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Example of the Section 3 Select Agent/Toxin table.



Select Agent or Toxin

- A subset of select agents and toxins have been designated as Tier 1 because these biological agents and toxins present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety. See Table A below.

Table A. Tier 1 Select Agents and Toxins		
HHS Agents and Toxins	**Overlap Agents**	**USDA Agents**
Bacillus cereus Biovar *anthracis* Botulinum neurotoxins Botulinum neurotoxin producing species of *Clostridium* Ebola virus *Francisella tularensis* Marburg virus Variola major virus (Smallpox virus) Variola minor virus (Alastrim) *Yersinia pestis*	*Bacillus anthracis*(1) *Burkholderia mallei* *Burkholderia pseudomallei*	Foot-And-Mouth Disease virus Rinderpest virus

(1) *Bacillus anthracis* (Pasteur strain) is a separate, non-Tier 1 select agent and must be registered separately from the Tier 1 select agent.

- Section 3 must include regulated nucleic acids listed below if you possess, transfer and/or use extracted and isolated nucleic acids that meet the requirements defined in section 3(c) and section 4(c) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). See Table B below.
  - The registration of intact, live agent is sufficient to cover the genomic material in that agent as long as it is not extracted and isolated for further testing or research purposes.
  - For additional information regarding regulated nucleic acids, refer to Guidance on the Regulation of Select Agent and Toxin Nucleic Acids.

Table B. Regulated Nucleic Acids
HHS Select Agent and Toxin Regulated Nucleic Acids
Genomic material – Eastern Equine Encephalitis virus Genomic material – Kyasanur Forest disease virus Genomic material – Omsk Hemorrhagic Fever virus Genomic material – SARS–associated coronavirus Genomic material – Tick-borne encephalitis virus, Far Eastern subtype Genomic material – Tick-borne encephalitis virus, Siberian subtype Recombinant/synthetic nucleic acids encoding Abrin Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin Recombinant/synthetic nucleic acids encoding Conotoxins Recombinant/synthetic nucleic acids encoding Ricin Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin
Overlap Select Agent Regulated Nucleic Acids
Genomic material – Venezuelan Equine Encephalitis virus
USDA Veterinary Services (VS) Select Agent Regulated Nucleic Acids
Genomic material – Classical Swine Fever virus Genomic material – Foot-And-Mouth Disease virus Genomic material – Swine Vesicular Disease virus

Additional Information

- After a formal request, evaluation and approval by the FSAP, certain strains, genotypes, biotypes, or subgroups of select agents or toxins may be excluded from regulation. For additional information see the Exclusion Guidance Document.

Select Agent/Toxin Possessed

- The possessed check box will be automatically filled in when the entity updates the strains list in Section 7B. It cannot be selected in the Section 3.
- New applicants who do not already have an approved registration certificate will see this box as unchecked because the entity has not yet been authorized to possess select agents and/or toxins.
- After approved to possess select agents and/or toxins, the entity must request approval to receive select agents and/or toxins using the Form 2. Once the select agents and/or toxins are received, the entity will need to update Form 1 Section 7B. See Amendment Requirements for how to update this information upon acquiring a select agent and/or toxin.

  Note: A registered entity is required to meet all of the regulatory requirements for each select agent and/or toxin listed on the APHIS/CDC Form 1 regardless of whether the select agent or toxin is in the actual possession of the entity and without regard to the actual amounts of toxins in possession as required in 7 CFR 331.7(b), 9 CFR 121.7(b), 42 CFR 73.7(b).

Section 4 – Entity Personnel

Entities will use Section 4 to assign personnel to the registration, to designate their role(s), and to provide all necessary information for each individual. This section describes how to complete Section 4 information. Additional information on updating Section 4 can be found on the select agent website, eFSAP resource guide: APHIS/CDC Form 1.

The entity's RO will have a Secure Access Management Service (SAMS) account provided so that they may access the eFSAP system and make these changes. At the RO's request additional individuals may be assigned a SAMS account. For information on requesting additional SAMS accounts, see the end of this section.

Since all communication between a registering entity and FSAP is completed through the Responsible Official (RO) or Alternate RO (ARO), it is imperative that the RO's and ARO's contact information is kept current and accurate. If any Section 4 RO/ARO information changes, you must immediately update the information in eFSAP. Verbal change requests cannot be accepted.

If further information or guidance is required contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Add New Personnel

Addition of any individual to the registration requires providing their legal name and date of birth and assigning them a role on the registration. During the process, a DOJ number will also be generated. The DOJ number will be used on the FD-961 form submitted to FBI BRAG for SRA approval review.

Name (Last and First name)

- Provide the full name of the applicant.
  - For the purposes of completing the APHIS/CDC Form 1, the term "full name" refers to an individual's first name and last name or surname, without use of nicknames.

    Note: The last name, first name and the date of birth must be identical to that provided on the FD-961 Form submitted to Criminal Justice Information Services (CJIS).

Date of Birth

- Enter the date of birth in the following eFSAP format: mm/dd/yyyy.

DOJ Number

- If the individual has never had a DOJ number, click the "Generate new DOJ number" button. Name and date of birth must be entered prior to generating the number. A DOJ number will be immediately generated for that individual for use in completion of the FD-961 Form submitted to CJIS.
  - This number is also called the Unique Identification Number (UIN) for the FD-961 form.
- If an individual has previously been assigned a DOJ number, list that DOJ number in the box provided, using the format XX123456.

  Note: Individuals who already have a DOJ number may have received it from previous work with select agents, or they may currently be assigned to a different entity. If the individuals SRA has expired, a complete FD-961 packet must be submitted to CJIS. If their SRA is active, contact your POC once you have

added them to your registration. An individual who has had a life event changing their name will not change their assigned DOJ number but will use the original number issued.

Tier 1 Access

- Check box if this individual will have access or have the ability to access Tier 1 select agents and toxins.

  Note: Individuals that have access or have the ability to access Tier 1 select agents and toxins require additional personnel security procedures. Refer to the Suitability Assessment Program Guidance for additional information on pre-access suitability and ongoing suitability assessments.

Inventory

- Check the box if this person will be responsible for inventory.
  - Individuals who access, audit, or are accountable for the accuracy of the inventory (e.g. PIs) should have this box checked.
- Check the box for the appropriate role(s) for the individual.
  - Refer to the definitions below when designating roles.

Role

- Select the primary and/or support role for the individual.

  Note: Individuals may have more than one role, and some roles require additional information or an additional amendment and sections of the Form 1. For example, an ARO who also has a PI role can be added in Section 4 but will need a separate Section 7 amendment adding work objectives and assigned room.

Primary Roles

Primary roles should be assigned to individuals who require access to and/or will handle select agents and toxins (performing work, conducting inventory reviews, responding in the event of an emergency).

Responsible Official (RO) – the individual designated by an entity with the ***authority and control*** to ensure compliance with the Select Agent Regulations.

Alternate Responsible Official (ARO) – the individual(s) designated by an entity with the authority and control to ensure compliance with the Select Agent Regulations in the absence of the Responsible Official. Multiple AROs may be specified.

Note: The role of the RO is independent of the organizational structure at the entity. Only one individual can be assigned the role of RO, and the request must be approved by FSAP. To change the RO an amendment must be submitted to FSAP and supporting documentation provided, **including a digital cover letter submitted by the current RO.** See Amendment Requirements for additional information on how to request a change in RO.

For additional information on the RO role and his/her responsibilities to ensure compliance with the Select Agent Regulations, refer to the Responsible Official Resource Manual.

Additional RO/ARO information

- RO/ARO Business Email Address

- Provide the business email address for the RO or ARO listed.
  - Ensure that you include the email domain (e.g., .org, .gov, .edu,.com, .net)

  Note: All official correspondence will be uploaded to the eFSAP system. Additional correspondence may be sent by email to the RO unless specifically requested otherwise by the entity.

- RO/ARO Title
  - Provide the institutional title for the RO or ARO listed.
- RO/ARO Business Telephone Number
  - Provide the direct dial 10-digit telephone number for the RO or ARO listed; include an extension, if required.
- RO/ARO Business Fax Number
  - Provide the 10-digit facsimile number for the RO or ARO listed.
- RO/ARO Emergency Telephone Number
  - The purpose of this emergency contact number is to provide the FSAP an after-hours emergency number. This can be a cell phone or a home phone. The phone number will only be used in emergency situations (e.g., natural disasters) when FSAP is unable to reach the RO or ARO at his/her designated business number.
  - Provide the direct dial 10-digit emergency telephone number for the RO or ARO listed; If required include an extension.
- RO/ARO Mailing Address
  - Provide a complete business mailing address for the RO or ARO listed (NOT a post office box). The mailing address for the RO or ARO should reflect the primary duty station and may be different from the entity physical address listed on Section 1.

    Note: Any official hardcopy correspondence will be sent to the mailing address specified for the RO.

Owner/Controller Information

An individual is considered an Owner/Controller if the individual owns 50 percent or more of the entity, and/or is a holder or owner of 50 percent or more of the entity's voting stock, and/or is an individual who is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity. The following entity types must include an Owner/Controller; Academic (Private), Commercial (Profit), Private (Non-Profit). Multiple Owner/Controllers may be specified.

Principal Investigator, Laboratorian, or Animal Care Staff

Refer to the definition below when specifying a Principal Investigator:

- **Principal Investigator (PI)** – the individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction ofthat project or program.
  - To add a PI to the registration, assign the individual a different role, such as Other, in Section 4. Once they receive FSAP approval in Section 4, create an amendment to modify the individual's role to PI.
  - Once an individual is FSAP approved in Section 4 and has been assigned the PI role, an amendment request can be made to assign a work objective to the individual.
  - Until a work objective assigned to the PI has been approved by FSAP, the individual's role as a PI is not approved.

Refer to the definition below when specifying a Laboratorian or Animal Care Staff.

- **Laboratorians and Animal Care Staff–** an individual who performs any of the work listed in a Section 7C, Objective of Work and manipulates select agents or toxins or handles select agent infected animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

  - Directing Principal Investigator (PI)
    - For each Laboratorian or Animal Care Staff, you must list the PI or PIs who directs the use of the select agents and toxins that each individual will work with.
    - If an individual works with more than one PI, select multiple principal investigators in the "Assigned PI" box, by holding "ctrl" and clicking on all applicable PI's . If the person will work with all PI's, then all PI's should be selected within the box.
    - If the person will work with at least one PI who is approved for a Tier 1 select agent or toxin, then the individual must also have Tier 1 access indicated.

Notes:

1) Only assign dual roles when necessary (e.g. ARO and PI).

2) If an individual is registered at multiple entities, the ROs for each entity must coordinate who is responsible for submitting a single SRA renewal packet to FBI BRAG for that individual's FSAP approval and renewals. If FSAP approval is removed for any reason by an RO, they must communicate the removal with each additional entity that the person is registered with.

Support Roles

Support roles are designated for individuals who provide an indirect service in support of the direct work with select agents or toxins, and though the individual does not work with select agents or toxins or select agent infected animals, bedding or plant hosts, they could potentially gain access to select agents/toxins.

Role

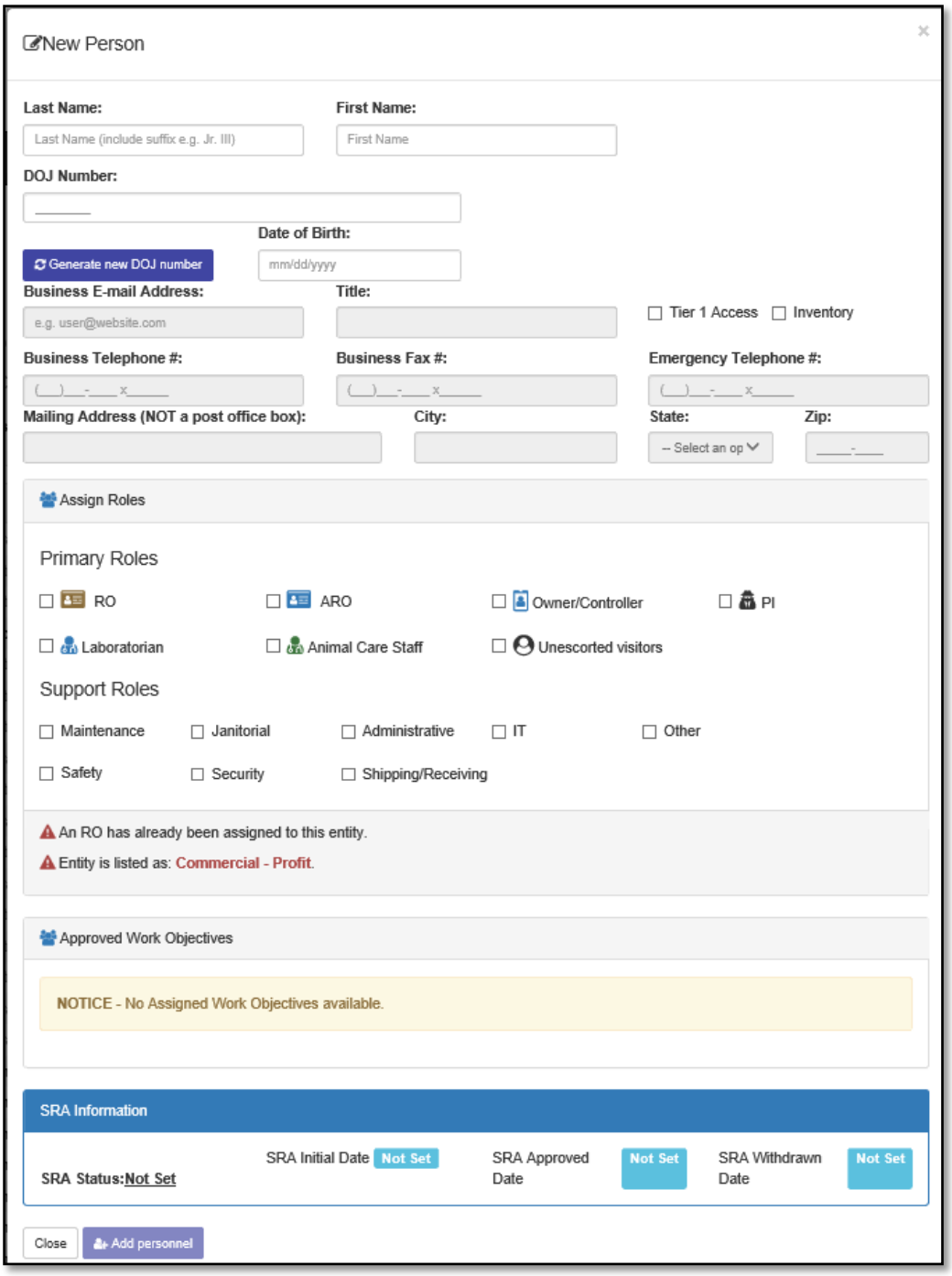
- Select the role below which most closely matches the individual's responsibilities:
  - IT
  - Security
  - Safety
  - Administrative
  - Maintenance
  - Janitorial
  - Shipping/Receiving
  - Other (individuals who do not fall under one of the roles above)

Note: Select only one role per individual.

Additional Information

- An entity must provide information and training on biosafety, security (including security awareness), and incident response to each individual with access approval from the HHS Secretary or APHIS Administrator within 12 months of receiving approval, and before he/she has access to select agents or toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.
- Refresher training must be provided at least annually as well as when the entity significantly amends its security, incident response, or biosafety plans.
- A record of each individual's training must be maintained in an electronic or paper format and must include the name of the individual, the date of training, a description of the training provided, and the means used to verify that the employee understood the training. These records must be promptly produced upon request and maintained for 3 years. Refer to the Guidance for Select Agent Regulation Training Requirements for additional information.

- **EXAMPLE OF THE SECTION 4 ADD NEW PERSONNEL SCREEN**



Requesting Additional SAMS Accounts for eFSAP Access

At the RO's request additional individuals may be assigned a SAMS account. The available account types include ARO, Entity Super Admin, Entity PI, and Entity Read Only access.

For RO and ARO accounts: The eFSAP POC must submit the request for an RO account to eFSAPSupport@cdc.gov. The entity RO or the eFSAP POC can submit a request for the ARO access. The FSAP systems team must have the POC validate any new RO or ARO prior to access being provided. Once the POC has provided validation the FSAP systems team will complete the invitation process. The request must include:

- First and Last Name
- Email Address
- Full Entity Name
- Role requested

For Entity Super Admin, Entity PI, and Entity Read Only Accounts: The Entity RO/ARO or the eFSAP POC can submit a request for the access to eFSAPSupport@cdc.gov. Once the FSAP systems team has the request from an approved individual then they will process the invitation. The request must include:

- First and Last Name
- Email Address
- Full Entity Name
- Role requested

The process for REMOVING a user access is similar. FSAP does not automatically remove access of users, a request must be submitted verifying the need to remove.

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

This section is used to assess the overall security precautions and procedures in place at an entity. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance, refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Facility Type (check all that apply)

- Check the classification that most accurately describes your facility. If none of the classifications describe your facility, select "Other" and describe.

Security Officer

- If you have a security officer or other individual(s) identified to assist the RO in security matters, check "Yes" and indicate if the security plan contains procedures for coordination between the RO and the entity's safety and security professionals.
- If you do not have a security officer or other individual(s) identified to assist the RO in security measures, check "No".

  Note: Tier 1 select agents and toxins require coordination between the RO and the entity's safety and security professionals. For additional information, refer to the Security Plan Guidance.

Threat Assessment

- If a threat assessment has been conducted, check "Yes".

- If a threat assessment was not conducted, check “No”. For additional information on entity threats, refer to the Security Plan Guidance.
- If “Yes” is indicated for b, c, and/or d, describe these incidents in the textbox provided below question d.

  Note: A threat assessment may be part of the site-specific risk assessment upon which the security plan is designed.

Insider risk assessment

- An insider risk assessment can be conducted by any organization within the entity (Human Resources, Security, etc.). Check all conditions which are verified prior to granting unescorted access to select agents and toxins and check whether you have policies for self and peer reporting as well as whether you have additional requirements for personnel suitability.

  Note: Tier 1 select agents and toxins require a pre-access and ongoing suitability assessment program, which includes provisions for self and peer reporting. For additional information, refer to the Suitability Assessment Program Guidance.

Natural hazards

- Indicate if your entity is located in any of the listed hazard zones. If you are in a hazard zone which is not listed, check other and describe. Also indicate what actions, with respect to select agents and toxins, will be performed in the event of a natural disaster with warning.

  Note: For additional information regarding natural hazard zones, refer to the Incident Response Plan Guidance document.

Electronic records and databases

- If you have electronic records and databases that would allow access to select agents and/or toxins, check “Yes”. Examples of electronic records or databases that would allow access to select agents and/or toxins may include a) an automated access control server (key card server) and/or a biometric access control server that controls access or b) a computer where a combination that allows access is stored.
- If yes, indicate the means to control access of the electronic records and databases by checking “Yes” for all applicable characteristics (questions a-f).
- If you do not have electronic records and databases, check “No”.

  Note: For additional information regarding information security controls, refer to the Information Systems Security Control Guidance Document.

Shipping/Receiving

- Check “Yes” if you have a central the receiving area where select agents and toxins are received. Check “Yes” if all personnel who ship or receive are SRA-approved or if shipments are stored in a registered and secured area prior to distribution to the PI. Otherwise, check “No”.
- Describe the receiving area, if applicable, as well as the receipt and storage of select agent and/or toxin shipments.

  Note: Requirements for shipping and receiving will differ depending on whether the entity is employing “lost in the crowd” practices. Refer to Guidance on the Transfer of Select Agents and Toxins for more information about the “lost in the crowd” policy.

Note: For additional information on select agent and toxin shipping/receiving procedures, refer to Guidance for Completing the Shippers Declaration for Dangerous Goods and the Security Plan Guidance.

Transport

- If select agents and/or toxins are transported within the entity and outside of the registered area(s) (e.g., from a PI's registered laboratory through an unregistered corridor to his/her registered animal room for the purpose of inoculation), check "Yes".
  Note: This question does not apply to movement of select agent and/or toxin packages for purpose of shipping and receiving.
- If yes, indicate the how the security plan addresses the movement of select agent and/or toxin material.
- If select agents and/or toxins are not transported outside of the registered area(s) or are inactivated or decontaminated prior to transport, check "No".

Additional Information

- Inventories can be controlled by individual PIs or shared. Transfers between PIs with distinct inventories are intra-entity transfers. Movement of inventory between PIs that share an inventory and between individuals working for the same PI are not considered intra-entity transfers. For additional guidance on inventory and intra-entity transfers see the Security Plan Guidance, the Guidance on the Transfer of Select Agents and Toxins, and the Guidance on the Inventory of Select Agents and Toxins.
- Entities must establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or APHIS Administrator. Entities must establish a protocol for intra-entity transfers that include chain-of-custody documents and provisions for safeguarding against theft, loss, or release.
- Entities that transfer quantities of select toxin(s) must ensure the amounts are transferred only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. The HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

Response Time

- If a response time for local law enforcement, guard force or other designated responders has been determined, check "Yes".
- If a response time has not been determined, check "No".

  Note: For additional information on response times, refer to the Security Plan Guidance.

After Hours Work

- If permission is required to conduct select agent and/or toxin work after established work hours, check "Yes".

- If yes, indicate the position description or title of the individual who grants permission.
- If an individual other than the RO/ARO/PI grants permission, indicate "Other" and include the position or title of the individual (e.g., security specialist). Do not list the name(s) for any of these individuals.
- If permission is not required for after-hours work, check "No".

Note: Tier 1 select agents and toxins require procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee. For additional information, refer to the Security Plan Guidance.

Section 5B – Entity-Wide Biosafety/Biocontainment

This section is used to assess the overall biosafety and biocontainment precautions and procedures in place at an entity. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Biosafety Program

- Briefly describe the biosafety program that develops and implements the biosafety and biocontainment procedures described in the site-specific biosafety plan (e.g., Environmental Health & Safety Office, Institutional Biosafety Committee (IBC), etc.).
- If an independent biosafety program is not in place at the entity, describe the biosafety expertise that is used to develop and implement the biosafety plan for work with the select agents and/or toxins (e.g., consultation with a biosafety professional, subject matter expert or the IBC as recommended for biological risk assessments in the BMBL.

Proficiency

- If laboratory personnel must demonstrate proficiency in standard and special microbiological practices and laboratory procedures prior to working with the select agent and/or toxin, check "Yes".
- If laboratory personnel do not demonstrate proficiency in these practices and procedures prior to working with the select agent and/or toxin, check "No".

Personal Protective Equipment

- If appropriate personal protective equipment is required for the select agent and/or toxin and the work performed, check "Yes".
- If PPE is not required based on biological risk assessment and in accordance with BMBL, check "No".

Occupational Health (Tier 1)

- If individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program (e.g., collection/storage of serum samples; available immunizations offered to at-risk personnel; or a system for reporting and documenting laboratory accidents, exposures and medical surveillance of potential Laboratory Associated Infections), check "Yes".

- If individuals with access to Tier 1 select agent and/or toxin are not enrolled in an occupational health program, check “No”.
- If the entity is not registered for Tier 1 Select agents and toxins, check “No.”

Note: For additional information on occupational health program requirements for individuals with access to Tier 1 select agents and toxins, refer to the Occupational Health Program Guidance.

Occupational Health (Non-Tier 1)

- If individuals with access to non-Tier 1 select agents and/or toxins are enrolled in an occupational health program (e.g., collection/storage of serum samples; available immunizations offered to at-risk personnel; or a system for reporting and documenting laboratory accidents, exposures and medical surveillance of potential Laboratory Associated Infections), check “Yes”.
- If individuals with access to non-Tier 1 select agents and/or toxins are not enrolled in an occupational health program, check “No”.

Note: The FSAP requires immediate notification and a report within 7 days on APHIS/CDC Form 3 upon the discovery of a release of a select agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area. Further, BSL3 safety standards described in the current edition of the BMBL state "laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory”. It is recommended that entities enroll individuals in occupational health programs for use and/or storage of non-Tier 1 select agents and toxins.

Sharps Handling

- If policies for the safe handling of sharps (e.g., glass slides/pipets, needles, scissors, scalpels, glass vials/columns) are in place and developed in accordance with BMBL, check “Yes”.
- If sharps are not used or there is no policy in place concerning the safe handling of sharps, check “No”.

Spill Protocol

- If there is a spill protocol in place, appropriate to the select agent and/or toxin work, and developed in accordance with BMBL, check “Yes”.
- If there is no spill protocol in place, check “No”.

Pest Management

- If an integrated pest management program developed in accordance with BMBL and relevant local, state and federal guidelines is in place, check “Yes”.
- If an integrated pest management program is not in place, check “No”.

Section 5C – Entry Requirements for Federal Select Agent Program Inspectors

This section is used to collect the entry requirements in place at each entity for FSAP Inspectors to conduct site visits of new and registered laboratories. Take into account all registered suites/rooms when completing this section, including any additional entry requirements considered when active work with select agents and/or toxins is conducted. Complete this section by checking either “Yes” or “No” for all questions and entering additional

information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Note: The FSAP is authorized to conduct announced or unannounced inspections per section 18 of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

Inspectors may conduct inspections without notification and while FSAP inspectors will make an effort to comply with entity entry policies, unreasonable entry requirements that result in considerable delays to the inspection process may be subject to administrative review and/or compliance actions. For additional information see the 04/12/2019 SA Gram on Entity Verification Requirements for FSAP Inspectors Performing Site Visits of Registered Entities. https://www.selectagents.gov/sagrams.html

Entry to the Facility

- Describe the procedure inspectors will use to gain entry to the facility. Include parking instructions.

Identification

- Indicate the type of identification that Federal Select Agent Inspectors should present to verify their identity.

  Note: Inspectors will only present federally issued credentials. This identification will not be surrendered to the entity. For additional information, see the SA Gram: Verifying Inspectors and Confidentially Agreement Policy posted on the FSAP website April 12, 2019.

Security Clearance

- If verification of security information is required between the Federal Select Agent Inspectors and an entity official, such as a Visitor Authorization Letter, check "Yes".
- If there are no security clearance requirements, check "No".
- If the entity has a process to collect security information in advance of the inspection, check "Yes". Describe what and how this should be managed. Examples of this may be a form to be filled out or an online login to enter information.

Respiratory Protection

- If respiratory protection is required to enter registered suites/rooms, check "Yes".
- If yes, indicate what types of respirators are required; if a Powered Air Purifying Respirator (PAPR) is required, indicate if it will be provided to FSAP Inspectors by the entity.
- If respiratory protection is not required to enter registered rooms/suites, check "No".

Personal Protective Equipment (PPE)

- List all other PPE required to enter laboratory or animal areas. Indicate if the listed PPE will be provided to FSAP inspectors by the entity.

Medical Documentation

- If medical documentation is required to enter registered suites/rooms, check “Yes” and proceed to the additional questions. If no medical documentation is required, check “No” and proceed to the next question.
- Indicate whether there are immunization requirements to enter a laboratory. If yes, specify the immunization entry requirement(s) to enter a laboratory as well as whether it is required or recommended.
- Indicate whether a PPD (Tuberculin skin test) is required for entry into animal or laboratory areas as well as the required interval.
- If documentation is not required to enter laboratories, check “No”.

Entity-specific training

- Indicate any onsite training which is required before entry into a laboratory.
- If the training can be taken in advance, describe the details.

Additional entry requirements

- If there are additional entry procedures not addressed by the above questions, provide this information here.

Section 6 – Building and Suite/Room Information

This section is used to assess building and suite/room specific security at an entity. Complete for each suite and room to be registered. Complete this section by checking either “Yes” or “No” for all questions and entering additional information when prompted. If the question does not apply to your entity, answer “No”. Guidance for answering the questions is provided here, for the procedures for adding or removing a room or suites and contained rooms see Section 6 amendment instructions.

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Note: Section 6 must be completed for each unique room and/or suite. If a series of rooms would result in an identical Section 6 being completed, multiple rooms may be included in the room name. Each suite must be individually added, so that the specific rooms within each suite can be identified.

Floor Plans

- Provide a floor plan for each suite and/or room to be registered. Upload plans at the bottom of the Section 6 main page.
- The floor plan for each suite or room should include, as applicable: points of entry and/or egress for personnel, Heating Ventilation and Air Conditioning (HVAC) supply and exhaust vents, cage washing area, and locations of equipment [including but not limited to: sink, eyewash, fume hood, freezer, refrigerator, floor drains, showers, incubator, centrifuge, animal caging, autoclave, Biological Safety Cabinet (BSC) including type (e.g. Class II, Type A2)].

  Note: A separate floor plan showing the suite/room in relation to the building and/or a separate floor plan

specifying airflow may also be requested.

Note: For a suite/room used for storage only, provide information for just the security questions and provide a floor plan. Leave the room physical information questions blank. Proceed to Section 7.

Building Specific Security:

For each building which is to be registered for select agents and/or toxins indicate the security measures in place.

Perimeter Security Measures

- Indicate the perimeter security measures which are in place outside of the building. Each respective security measure should be checked even if they are not dedicated to the select agent program or are 'incidental' based on the entity locations.
- If you have additional security measures not specified, check "Other" and describe.

Note: For additional information on security measures and physical security barriers, refer to the Security Plan Guidance.

Note: An exterior intrusion detection systems consists of an intrusion detection system associated with the perimeter of a facility, not the structure/building that houses the registered space. These are generally outdoor sensors, common types include: sensors employed along a perimeter fence, microwave sensors employed in a Clear Zone between fences, buried sensors in Clear Zone between fences.

Building Access

- Indicate which methods are used to control access to the building which houses the suite/room.
- If you have additional access controls not specified, check "Other" and describe.

Interior Security Measures

- Indicate all additional measures from the outside of the building to the suite/room where the agent or toxin is stored.

  Note: If "Yes" is chosen for the Intrusion Detection System or Video Surveillance, answer the follow up questions.
- Video surveillance is an optional security measure many entities choose to employ. It can be dedicated monitoring or a "rolling screen" among several/many camera views, and may be for safety or security reasons. Monitoring involves live, active viewing of video surveillance by individuals, such as security personnel, whereas the review of video recordings can happen at any time and typically is a replay to provide a retrospective view. The responsibility for monitoring laboratory live video should lie with individuals who are capable of responding to a laboratory emergency or can relay the situation to the appropriate emergency response personnel. The responsibility to review video recordings should lie with individuals who are familiar with work practices in the laboratory and can assess whether work is being performed in a safe manner (i.e. PI, laboratorians, RO).
- If you have other security measures not specified, check "Other" and describe.

Suite or Room Specific Information

Select the purpose of the space to be registered (storage/laboratory/both) and indicate if it is an individual room or a suite of rooms. For each suite or room which is to be registered for select agents and/or toxins

indicate the security measures in place.

Note: Designating a series of connected rooms or continuous areas as a suite may require an additional review and approval. Contact your PO, alternatively, contact the CDC DRSC at 404-718-2000 or APHIS DASAT at 301-851-3300 option 3 to determine whether your initial application should list each individual room or consolidate them into a single suite.

Laboratory or Storage

- Check appropriate box(es) to specify whether the location is a laboratory, a storage area, or both.
  - Any building and suite/room where work with select agents and/or toxins is performed should be designated as a laboratory.
  - Any building and suite/room that will only be used for storage and not active work with select agents and/or toxins should be designated as storage only.
  - Any building and suite/room where work with select agents or toxin is performed and where select agents or toxins may be stored should be designated as both.

Note: Decontamination/destruction suite/rooms may not need to be registered. Registration is specific to circumstances at the entity. For example, if the entity will need to temporarily store waste, other infectious select agent material, or active toxin material in this area, the room will need to be registered. Consult with your designated POC or contact DRSC at 404-718-2000 or DASAT at 301-851-2070.

Suite or Room Safety Level

- Enter the safety level for the location as designated in the Section 6 for that space. If multiple safety levels apply (e.g., BSL3, NIHBL3, ABSL3), indicate all safety levels. See Section 6 for a list of available levels.
  - For example, a single laboratory suite or room may operate at BSL3 for propagation of a select agent, NIHBL3 for recombinant DNA work performed using a select agent, and ABSL3 for select agent animal studies where inoculated animals are housed in the laboratory.
- If the area is storage only, no level can be indicated.
- If a room is designated as a laboratory **and** a storage area, enter the safety level for the laboratory only.
- Biological Safety Levels

Biosafety Levels	**Animal Biosafety Levels**
Biosafety Level 2 = BSL2 Biosafety Level 3 = BSL3 Biosafety Level 4 = BSL4	Animal Biosafety Level 2 = ABSL2 Animal Biosafety Level 3 = ABL3 Biosafety Level 3 Agriculture = BSL3Ag Animal Biosafety Level 4 = ABSL4
Recombinant DNA (rDNA) Biosafety Levels	**Arthropod Biosafety Levels**

rDNA BSL2 = NIHBL2 rDNA BSL3 = NIHBL3 rDNA BSL4 = NIHBL4 rDNA Large Animal BSL2 = NIHBL2N rDNA Large Animal BSL3 = NIHBL3N rDNA Large Animal BSL4 = NIHBL4N rDNA Large Scale BSL2 = NIHBL2-LS rDNA Large Scale BSL3 = NIHBL3-LS rDNA Large Scale BSL4 = NIHBL4-LS	Arthropod BSL 3 = ACL3 Arthropod BSL4 = ACL4

Note: Regardless of the funding source, an NIH biosafety level should be indicated for research involving the handling and/or construction of 1) nucleic acids that can produce recombinant infectious forms of any select agent virus, 2) recombinant and/or synthetic nucleic acids that encode for functional form(s) of any select toxin if the nucleic acids can be expressed in vivo or in vitro, or are in a vector or recombinant host genome and can be expressed in vivo or in vitro, 3) select agents whose genomes have been modified by recombinant/synthetic methods (e.g., genomic deletions or insertions, the introduction of plasmids), or 4) RNA isolated from positive (+) stranded select agent viruses that have been genetically modified by recombinant/synthetic methods. For more information please see the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

- **Note:** No provisions are made for work at NIHBL4-LS in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Requirements will be established by NIH on an individual basis.

List the References/Resources Used

- List the references and/or resources used to determine the biological safety level of the suite or room.

Suite or Room Specific Security

Tier 1 Use

- If the suite/room is to be used for Tier 1 select agents and/or toxins, check "Yes".
- If the suite/room will not be used for Tier 1 select agents and/or toxins, check "No".

Note: Tier 1 select agent and toxin registered areas require, at a minimum, three barriers where each subsequent barrier adds to the delay in reaching secured areas where Tier 1 select agents and toxins are used or stored. For additional information, refer to the Security Plan Guidance.

Access to Suite/room

- Indicate which methods are used to control access to the suite/room.
- If you have additional access controls not specified, check "Other" and describe.

Access to Storage Units

- Indicate which methods are used to control access to storage unit(s).
- If you have additional access controls not specified, check "Other" and describe.

Pass-Through Autoclave

- If there is a pass-through autoclave in the suite/room, check "Yes".
  - If yes, indicate whether the doors are interlocked.
- If there is no pass-through autoclave in the suite/room, check "No".

Autoclave Outside of Suite/Room

- If there is an autoclave outside of the suite/room used for decontamination of select agent and/or toxin waste, check "Yes".
  - If yes, indicate the distance from the suite/room to the autoclave.
- If this question does not apply, check "No".

Pass-Through Window or Box

- If there is a pass-through window or box at the perimeter of the suite/room, check "Yes".
  - If yes, indicate whether or not it is secured.
- If there is not a pass-through window or box, check "No".

Dunk Tank

- If there is a dunk tank at the perimeter of the suite/room, check "Yes".
  - If yes, indicate whether or not it is secured.
- If there is not a dunk tank, check "No".

Suite or Room Physical Information

BSC and Fume Hood

- If biosafety cabinets (BSCs) and fume hoods are certified at least annually and records are kept for at least 3 years, check "Yes".
- If BSC and fume hoods are not certified at least annually or do not have records kept for at least three years, check "No".

Sink

- If a sink is present in the laboratory for hand washing, check "Yes".
  - If yes, indicate if the sink is hands-free or automatically operated.
- If there is no sink present in the laboratory for hand washing, check "No".

Eyewash

- If an eyewash station is readily available, check "Yes".
- If an eyewash station is not readily available, check "No".

Liquid Effluent

- If liquid effluents originating from the laboratory are collected and treated for sterility prior to exiting the facility or entering a public sewage system, check "Yes".
    - If yes, indicate whether effluent from the containment shower areas are similarly treated and if the effluent decontamination is validated monthly.

      Note: Liquid effluent decontamination is an enhancement required in maximum containment facilities performing work at BSL4, ABSL4, and BSL3Ag and for propagative work with highly transmissible and pathogenic agents such as, but not limited to, highly pathogenic avian influenza virus, Classical swine fever virus, and Foot-and-mouth disease virus. Chemical inactivation of liquid waste prior to drain disposal is not considered treatment of effluent. Please reference Appendix Q of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules (NIH Guidelines) for guidance as to when monthly validation of the effluent decontamination system is required.
- If liquid effluents originating from the laboratory are not collected and treated, check "No".

Access doors

- If access to the suite/room is through two self-closing doors, check "Yes".
    - If yes, indicate if the doors from the anteroom open inward to the laboratory.
- If access is not through two self-closing doors, check "No".

Directional airflow

- If the ventilation system provides sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas, check "Yes".
- If the ventilation system does not provide sustained directional airflow, check "No".

No Reversal of Airflow

- If the laboratory is designed such that under failure conditions the airflow will not be reversed outside the containment barrier, check "Yes".
- If the laboratory is not designed to prevent reversal of airflow outside the containment barrier under failure conditions, check "No".

  Note: Refer to SelectAgents.gov and Containment Facility Design and Construction (Secondary Barriers) for additional information regarding reversal of airflow.

Verification

- If laboratory design and operational parameters are re-verified at least annually, check "Yes".
- If laboratory design and operational parameters are not re-verified at least annually, check "No".

  Note: Refer to SelectAgents.gov and Containment Facility Design and Construction (Secondary Barriers) for additional information regarding annual facility re-verification.

Monitoring

- If a visual monitoring device, which confirms directional airflow, is provided at the laboratory entry, check “Yes”.
- If there is no visual monitoring device, check “No”.

Exhaust

- If laboratory exhaust is not re-circulated to other areas of the building, check “Yes”.
- If laboratory exhaust is re-circulated, check “No”.

HEPA Filtering

- If room exhaust air leaving the laboratory is HEPA filtered, check “Yes”.
  - If yes, indicate whether the HEPA filter housing has decontamination or test ports and is certified at least annually.
- If the exhaust air leaving the laboratory is not HEPA filtered, check “No”.
  - If no, indicate if exhaust air is dispersed away from occupied areas and building air intake locations.

Emergency Shower

- If an emergency shower is readily available, check “Yes”.
- If an emergency shower is not readily available, check “No”.

Floor Drains

- If floor drains are present, check “Yes”.
- If floor drains are not present, check “No”.

Sink Traps and Floor Drains

- If sink traps and floor drains are filled with water and/or appropriate liquid to prevent the migration of vermin and gases, check “Yes”.
- If sink traps and floor drains are not filled with water and/or appropriate liquid, check “No”.

Mechanical Cage Washer

- If a mechanical cage washer is present within the facility, and it is used as the primary method of decontamination of cages, check “Yes”.
  - If cages are decontaminated through another means (e.g. chemical or autoclave) prior to being sent for cleaning with a mechanical cage washer, check “No”.
- If yes, indicate if the cage washer has a final rinse temperature of at least 180°F.
- If a mechanical cage washer is not present, check “No”.

Shower Out

- If the laboratory is designed with a shower and change room to permit personal showers when exiting the containment area, check “Yes”.
- If there is not a shower-out capability, check “No”.

Section 7A & & 7C – Principal Investigator Objective of Work and Select Agent and Toxin Locations

This section captures select agents and toxins, suites/rooms, and specific work performed by a Principal Investigator. Multiple, complete Work Objectives may need to be submitted depending on the number of Principal Investigators and the work performed at an entity. Complete this section by checking either “Yes” or “No” for all questions and entering additional information when prompted.

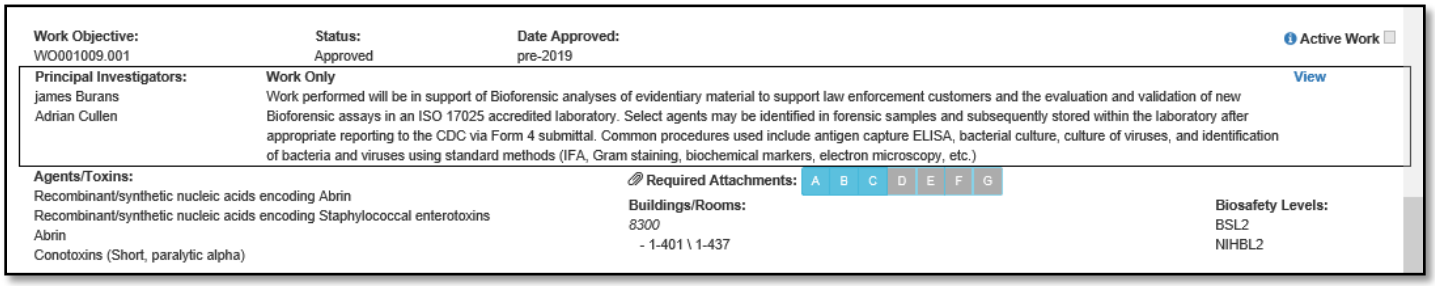
If the question does not apply to your entity, answer “No”.

Attachments A-G may need to be completed for each work objective depending on the work performed.

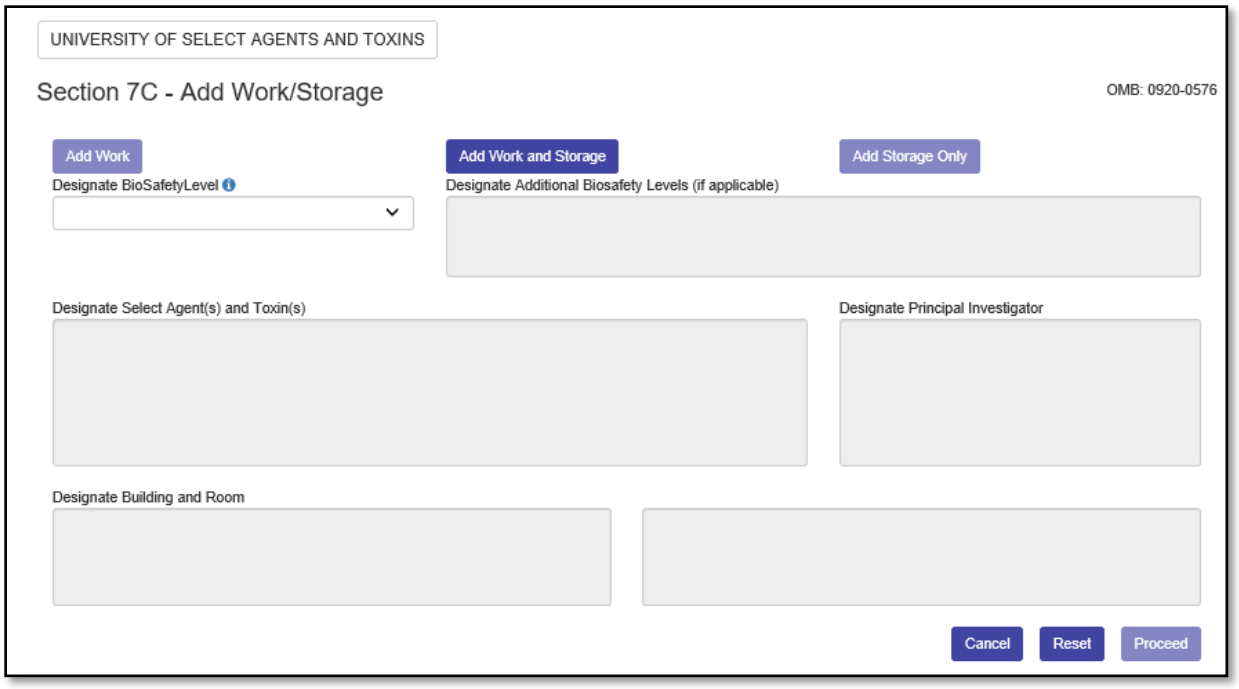
For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Note: A complete Section 7 must be submitted for each biosafety level where BSAT will be used or stored and the work objective of each PI. If multiple PIs conduct identical work with select agents and toxins at the same safety level and in the same spaces, the PIs can be listed in the same Work Objective.

Example of the Section 7A/C home page.



Example of the Add Work/Storage page.



Select Agent/Toxin, PI, and Suite or Room Requirements for Work Objectives

Work Objective Type

- The work objective will describe Work Only, Work and Storage, or Storage Only procedures for the PI and registered location.
  - A Storage Only objective should be selected for locations where no work with select agents or toxins (e.g. opening of a vial) will be performed. A storage location may be used for inventory purposes and storage only.
  - A Work Only objective should be selected for locations where procedures and manipulation of select agent or toxins will be performed, but not the long-term storage of select agent materials. For example, necropsy rooms with no carcass/tissue storage, injection/inoculation/exposure rooms, equipment rooms (Flow cytometers, IVIS imagers, plethysmography) are examples of Work Only work objectives.
  - A Work and Storage objective should be selected for locations where select agents or toxins will be manipulated and stored, including material contaminated with select agent or toxin.

Note: Storage Only and Work Only work objectives will only have the option of selecting rooms with the corresponding storage only or laboratory only designations as listed in the Section 6.

Biosafety Level

- The biosafety level at which the work will be performed. Secondary biosafety levels (NIH) can be selected as appropriate, however laboratory procedures, animal procedures, arthropod procedures, or multiple safety levels cannot be combined into the same work objective.

Note: Storage Only work objectives will not have the option of selecting a biosafety level. Work and Storage and Work Only work objectives will only have the option of selecting rooms with the corresponding biosafety level designations as listed in the Section 6.

Select Agent/Toxin/Regulated Nucleic Acid

- The select agent(s)/toxin(s) or regulated nucleic acid which will be used for the work objective.

  Note: Only select agents and toxins that are approved on the entity's registration will be options in the drop-down box for selection.

  An entity must list at least one select agent or toxin currently on the registration. To add a new select agent to the registration, see the instructions for submitting a Section 3 amendment.

PI Name

- Select the PI (s) who will direct the work.

  Note: Each PI must be assigned to at least one select agent or toxin and at least one room or suite.

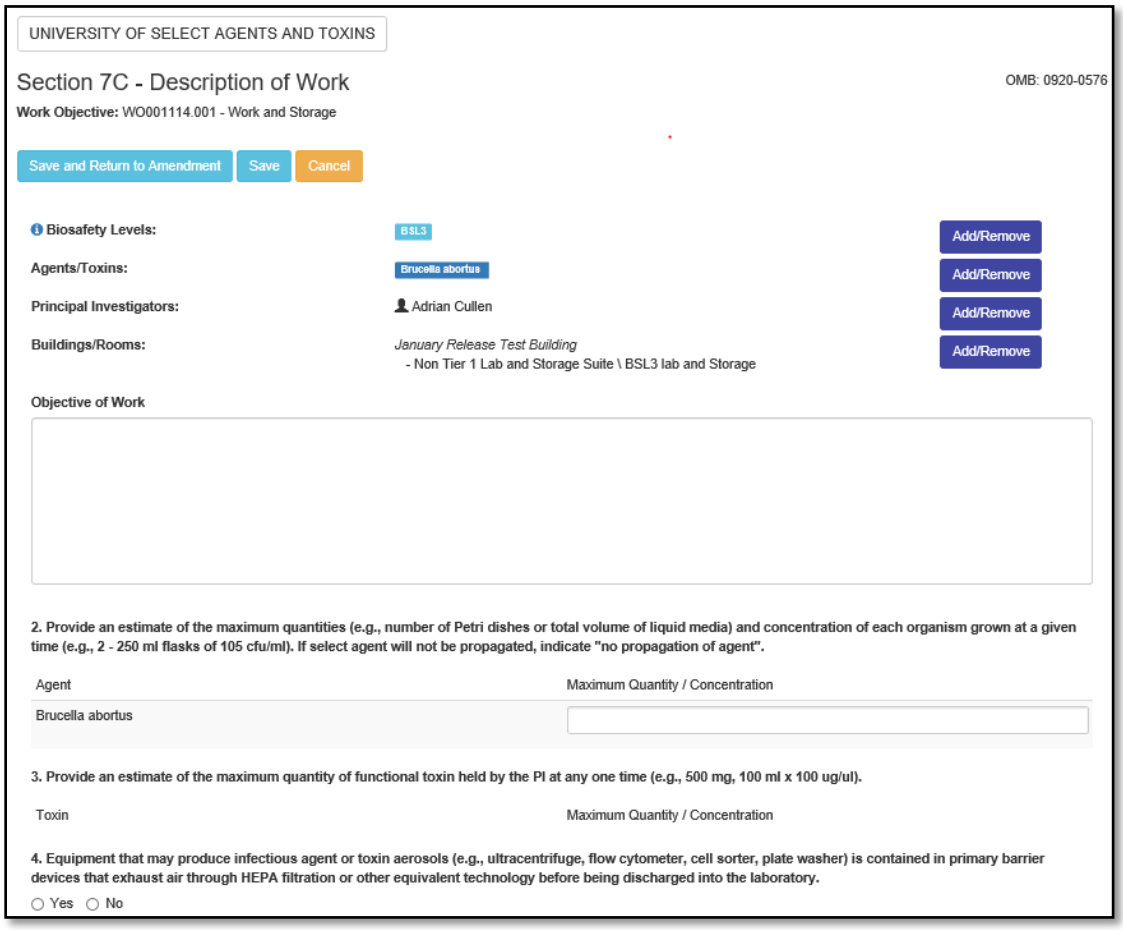
Location

- Select the building and suite/room for each area to be registered. Each room within a suite must be added by selecting it.

  Note: Each registered room or suite must be assigned to at least one select agent or toxin and one PI. Multiple rooms may be selected if:

  - They have the same laboratory or storage designation (ex. Lab, Storage or Both) and,
  - They have the same biosafety level(s).

Example of Section 7C


UNIVERSITY OF SELECT AGENTS AND TOXINS

Section 7C - Description of Work

OMB: 0920-0576

Work Objective: WO001114.001 - Work and Storage

Save and Return to Amendment | Save | Cancel

Biosafety Levels: BSL3 — Add/Remove

Agents/Toxins: Brucella abortus — Add/Remove

Principal Investigators: Adrian Cullen — Add/Remove

Buildings/Rooms: *January Release Test Building* - Non Tier 1 Lab and Storage Suite \ BSL3 lab and Storage — Add/Remove

Objective of Work

2. Provide an estimate of the maximum quantities (e.g., number of Petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 105 cfu/ml). If select agent will not be propagated, indicate "no propagation of agent".

Agent	Maximum Quantity / Concentration
Brucella abortus	

3. Provide an estimate of the maximum quantity of functional toxin held by the PI at any one time (e.g., 500 mg, 100 ml x 100 ug/ul).

Toxin	Maximum Quantity / Concentration

4. Equipment that may produce infectious agent or toxin aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory.

○ Yes ○ No

Objective of Work

- For each select agent and/or toxin listed for the selected rooms indicate the objective of work. Multiple select agents and/or toxins may be listed together if the biosafety level, rooms, PI's and objective of work are the same.
- The objective of work should include a description of the methodologies and laboratory procedures. For example, the types of *in vitro* and *in vivo* assays, diagnostic procedures, or other specialized procedures that will be performed at the indicated biosafety level.
    - Procedures for work with animals must be associated with an animal biosafety level and should not be listed on work objectives that have biosafety levels.
    - The statement should be tailored to primarily include information or specific aims for the work expected to be conducted within the 3-year approval period.
- If a storage only work objective is selected the box will be automatically populated with "storage only".

Maximum Quantity/Concentration of Select Agent

- For each select agent listed above, estimate the maximum quantity and concentration grown at a given time. The maximum quantity can be given, for example, in units of petri dishes or total volume and

concentration of liquid media (e.g., 2-250ml flasks; 10e5 cfu/ml). If select agents will not be propagated, then type "no propagation of agent."

Notes: a) The term propagation refers to sub-culturing or the culturing of the select agent to obtain additional select agent for diagnostic, research, or archival purposes.

b) A maximum quantity for all select agents listed in Section 7A for each PI must be provided.

c) A maximum quantity/concentration is NOT required for regulated nucleic acids. Type "not applicable" in the text box.

Maximum Quantity of Functional Toxin

- For each select toxin listed above, estimate the maximum quantity held by the PI at any given time. A maximum quantity for all select toxins listed above must be provided.
- The maximum quantity can be given as total amount (5 g) or volume and concentration (3 ml of 100 ng/ml).

Equipment Aerosols

- If equipment that has the potential to produce infectious aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is used with select agents or toxins and is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory, check "Yes".
- If no such equipment is used or if this equipment is used outside of primary containment, check "No".

Note: Equipment that exhausts air through HEPA filtration or other equivalent technology is not required to be contained in a primary containment barrier.

Regulated Nucleic Acids

- If regulated nucleic acids are held in long-term storage, check "Yes".
- If regulated nucleic acids are not held in long-term storage, check "No".

Note: Records of regulated nucleic acids held in long-term storage are required as defined in Section 17(a)(1) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

Note: If you do not possess extracted and isolated nucleic acids that meet the requirements defined in section 3(c) or section 4(c) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331), check "No". The registration of intact, live agent is sufficient to cover the genomic material in that agent as long as it is not extracted and isolated for further testing or research purposes.

Decontamination

- If all cultures, stocks, and other regulated waste are decontaminated before removal from the entity, check "Yes".
  - If yes, check the box next to the applicable method(s) used for the primary means of decontamination. If multiple methods are used on the same waste, only check the box for the initial method that renders the waste decontaminated. For example, if waste is only incinerated

after first being decontaminated via chemical or autoclave treatment, do not check the box for incineration but do check the box for chemical and autoclave

  - If chemical disinfection is used, indicate the type of disinfectant, the concentration, and the contact time.
  - If any other method of decontamination is used prior to removal of waste from the entity, check "Other" and describe the method used.

- If decontamination does not occur prior to removal of waste from the entity, check "No".

Security of Written Records

- Indicate the means used to secure written records that would allow someone the ability to gain access to select agents and toxins. Examples of such written records may include a paper list of PIN combinations that allow access or the combination to a box where a key allowing access is stored.
- If the security measures listed do not describe the control of written documents at the entity, check "Other" and describe the security measures in place.

Specific Types of Work

- Complete by answering "Yes" or "No" to all questions.
- If you answer yes to a question, complete the attachment specified using the directions provided.

  Note: If registering for recombinant/synthetic nucleic acids encoding a select agent toxin but not the toxin itself, Attachment A – Work with Toxins is not required, but Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms is required.

  Note: If the entity is not registered for a select toxin(s) but performs work with a select toxin(s) below the permissible amount, Attachment A will not be completed.

  Note: If the entity is registered for recombinant/synthetic nucleic acids in a storage only capacity, Attachment B will not be completed.

  Note: If entity is working with arthropods in a diagnostic capacity only with field collected specimens, only Question 1 of Attachment E will be completed.

BSL3Ag or BSL4 Laboratories

- Complete by answering "Yes" or "No" to all questions.
- If you answer yes to a question, complete the attachment specified using the directions provided.

Section 7B – Strain or Serotype Designation Information

This section is used to list the strains and serotypes possessed by each Principal Investigator. The list can be sorted by each column. A historical strain list can be viewed by selecting the "historical" option. The listed strains and serotypes can be updated as described in the amendment procedure to Add, Remove, or Modify Strains or Serotypes.

A strain or serotype is defined as a group of organisms of the same species, sharing certain hereditary

characteristics not typical of the entire species but minor enough not to warrant classification as a separate species or variety (e.g., Ames strain of *Bacillus anthracis).* Additional guidance is provided below for select agent strain designations and toxin types.

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call the CDC DRSC at 404-718-2000 or APHIS DASAT at 301-851-2070.

Assigning Select Agents or Toxins to a Principal Investigator:

Select Agent/Toxin

- Select from the list of agents or toxins approved on the registration (Only those with approved work objectives in Section 7A & 7C will be noted as approved in Section 3 and will be available in the drop-down box).

  Note: New agents will be added to the registration with the possession status unchecked on Section 3. Upon approval and receipt of select agent or toxin by Form 2, the RO must enter the strain in Section 7B, and the Section 3 possession status will automatically be updated. Section 7B must not be updated until the select agent or toxin has been received. Do not include agents or toxins not possessed.

- Accurate and current strain information should always be maintained.

Strain or Serotype Designations

- Select the strain or serotype for the select agent or toxin using the drop-down box.
  - Common strains or serotypes for each select agent have been included in eFSAP. If one of these is selected, additional information is not required.

- If the strain or serotype is not listed in the drop-down box, select “Other” and type in the strain or serotype in the Additional Information text box.
- If the entity possesses unknown strains of an agent (e. g. diagnostic samples that were not identified to the strain level), select “Unknown” in the drop-down box.
  - No additional information can be entered for “Unknown” strains.
  - If a strain is classified in the future, the entity can change it to a classical strain, or choose “Other” and include unique characteristics under Additional Information.
  - Select “Unknown” only once for each select agent or toxin; do not list out each sample separately.

Note: Do not list strains excluded from the Select Agent Regulations. A list of exclusions can be found on the FSAP website here.

Additional Information

- Unless Other was chosen from the drop-down menu, no additional information is necessary. -

Recombinant, Synthetic, or Not Applicable

- If an entered strain or serotype is recombinant, select Recombinant.
- If the strain or serotype is synthetically generated, select Synthetic.

Note: strains and serotypes can be both synthetic and recombinant, and both options may be selected for a given strain or serotype.

- If a strain or serotype is not recombinant or synthetic select N/A.

Note: Do not list each mutant version of a strain or serotype possessed. Include the parent strain (if possessed) and one additional line that captures information for all variants of the strain. For example, if a PI possesses wild type *Bacillus anthracis* Ames strain and several mutants of the Ames strain, the entity should enter the agent twice in Section 7B. One entry should be marked as N/A for the wild type strain and the other entry should be marked as recombinant and/or synthetic to reflect the other versions of Ames strain possessed.

Note: Multiple lines from the same parental strain will be collapsed together and shown in a summary row, and all options may be checked in the summary. For example, if there is a single strain of *Francisella tularensis* WT Schu4 marked N/A, and a strain of Synthetic/Recombinant strain of Schu4, then the summary row will indicate two strains of Schu4 and all three boxes will be checked in the summary.

Assigned PI

- Select the name of all Principal Investigator(s) who possess the strain at the entity. Use "ctrl" click to select multiple PI names.

Note: Only PI's who are registered for an agent or toxin on an approved work objective in Section 7A & 7C will be options for assigning strains or serotypes.

Attachment A – Work with Toxins

This attachment is used to assess work with select toxins. Each work objective in the Section 7A/C that indicates work will be performed with toxins must have a completed Attachment A. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Select Toxin Additional Information

- HHS toxins are **excluded** from the Select Agent Regulations only when the toxin under the control of a PI, treating physician or veterinarian, or commercial manufacturer or distributor is below the aggregate amount and does not, at any time, exceed the amounts defined in 42 CFR 73.3(d)(3) and shown below:

HHS Toxins	Amount
Abrin	1000 mg
Botulinum neurotoxin	1.0 mg
Conotoxins (1)	100 mg
Diacetoxyscirpenol	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal enterotoxins (2)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

(1) The conotoxins that are regulated by FSAP will be limited to the short, paralytic alpha conotoxins containing the following nucleic acid sequence, $X_1CCX_2PACGX_3X_4X_5X_6CX_7$, whereas:

(a) C= Cysteine residues;

(b) The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB

(c) X_1 = any amino acid(s) or Des-X;

(d) X_2 = Asparagine or Histidine;

(e) X_3 = Arginine or Lysine;

(f) X_4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan;

(g) X_5 = Tyrosine, Phenylalanine, Tryptophan; X_6 = Serine, Threonine, Glutamine, Asparagine, Asparagine; X_7 = Any amino acid(s) or Des X) and;

(h) "Des X" indicates that the amino acid can be absent at this position. For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-x.

(2) FSAP regulates A, B, C, D, E only.

Notes

- If registering for recombinant/synthetic nucleic acids encoding a select agent toxin but not the toxin itself, Attachment A – Work with Toxins is **not required**, but Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms **is required.**
- HHS toxins may be excluded from these requirements as defined in 42 CFR 73.3(d)(3) if the maximum amount possessed at any time by the PI is below the regulated aggregate amount.
- A registered entity is required to meet all of the regulatory requirements for each select agent and/or toxin listed on the APHIS/CDC Form 1 regardless of whether the select agent or toxin is in the actual possession of the entity and without regard to the actual amounts of toxins in possession as required in 7 CFR 331.7(b), 9 CFR 121.7(b), 42 CFR 73.7(b).
- Once the entity's registration has been approved for the select toxin, the entity must maintain compliance with the Select Agent Regulations for work and/or storage of the toxin regardless of the amount possessed. All activities related to the registered PI's work with functional select toxins must be in compliance with the Select Agent Regulations (e.g. stored/manipulated in registered rooms, inventory records, chemical hygiene plan in effect).
- All inoculations or exposures of animals to select toxins must occur in registered laboratories. Following inoculation or exposure, the animal is not considered a select toxin.
- The FSAP regulates recombinant and/or synthetic nucleic acids that encode for the functional toxic form(s) of any of the select toxins if the nucleic acids can be expressed in vivo or in vitro, or are in a vector or

recombinant host genome and can be expressed in vivo or in vitro. If the proposed work will involve the deliberate formation of recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins or the possession of such a product, Attachment B must be completed and will require approval by the FSAP. Recombinant and/or synthetic nucleic acids that encode functional domain(s) of select toxins meet these criteria and are also regulated. Functional domains are subunits of the toxin-encoding gene. Lack of biological effect cannot be assumed and experimental data from a recognized biological model (either in vivo or in vitro) of toxin activity should be submitted to the FSAP for consideration before subunits of regulated toxin genes can be excluded from regulations. For additional information regarding recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins, refer to Synthetic Genomics.

Chemical Hygiene Plan

- If a Chemical Hygiene Plan (CHP) that is both site- and toxin-specific is freely available to staff working with select toxins, check "Yes".
- If a CHP is not available, check "No".

  Note: Access to the CHP may be electronic, and the CHP must be reviewed annually by staff working with select toxins.

Toxin Manipulation or Production

- Indicate if you manipulate or produce dry (lyophilized, freeze-dried, or other) or liquid forms of any select toxins.

  Note: Dry forms of protein toxins and/or any procedures that could aerosolize toxin require special safety measures. If you perform any potential aerosol-generating procedures such as centrifugation or chromatography, indicate that work in the work objectives in Section 7.

Animal Exposure

- If animals are exposed to select toxins, check "Yes" and indicate if the exposure procedure(s) is/are performed in registered laboratories by checking yes or no in Question 3a.
- If animals are not exposed to select toxins, check "No".
- See the Guidance on the Inventory of Select Agents and Toxins for additional guidance in answering this question.

  Note: If animals are exposed to select toxins Attachment C – Work with Animals must be completed.

Toxin Production

- If select toxins are produced by the PI, check "Yes" and provide a brief description of the method and an estimate of the maximum quantities during production and purification and maximum concentration achieved at any point during the production or purification process. In the narrative, indicate if you have the capability of producing select toxins either chemically, in vitro, or in vivo onsite.
- If select toxins are not produced by the PI, check "No".

  Note: Describe your production capability fully so that the FSAP can assess its impact on the safety and security challenges faced by your entity.

Hazard Sign

- If a hazard sign is posted when select toxins are in use, check "Yes".
- If a hazard sign is not posted when select toxins are in use, check "No".

Select Toxin Inactivation

- If all select toxins, cultures, stock, materials coming into contact with toxins, and other regulated wastes are appropriately inactivated prior to disposal, check "Yes".
  - If yes, check the box next to the applicable method(s) used for the decontamination.
    - If chemical disinfection is used, indicate the type of disinfectant, the concentration, and the contact time.
    - If waste is incinerated, indicate whether incineration occurs onsite or if waste is transported to an offsite facility for incineration.
    - If waste is transported offsite, indicate whether another decontamination method is utilized prior to removal from the facility.
- If the other method of decontamination is not listed, check the box next to "Other" and describe the method used.
- If all select toxins, cultures, stock, materials coming into contact with toxins, and other regulated wastes are not appropriately inactivated prior to disposal, check "No".

  Note: Select toxins may be resistant to routine methods of inactivation used in the laboratory and must be treated appropriately. Special challenges may exist based on toxin structure and/or chemical resistance. Chemical inactivation of select toxins is affected by many factors. A risk assessment must be considered when establishing the most effective method to be used for toxin inactivation. Cross-contamination and absorption or adsorption of certain toxins is of special concern. Therefore, all materials that have the possibility of contact with toxins must be handled as if they were contaminated and treated accordingly.

Dilution/Manipulation of Concentrated Select Toxins

- If dilution procedures and other manipulations of concentrated select toxins are performed, check "Yes".
  - If yes, indicate where these activities are performed by checking all applicable locations and if two or more knowledgeable people are present.
- If dilution procedures and other manipulations of concentrated select toxins are not performed, check "No".

  Note: Select toxins are often potent in very dilute preparations; therefore, special care must be exercised when manipulating concentrated preparations of select toxins. Concentration(s) of manipulated select toxins should be listed in the work objectives in Section 7.

Intra-entity Select Toxin Transfers

- If select toxins are transferred (intra-entity transfer) to other individuals at the entity outside of the laboratory producing or receiving the toxin, check "Yes" and indicate whether amounts above and/or below the regulated aggregate amounts are transferred.
- If select toxins are not transferred to other individuals at the entity outside of the laboratory producing or receiving the toxin, check "No".

Note: Entities must ensure that select toxin amounts otherwise excluded under 42 CFR 73.3(d)(3) are transferred only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. The HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

Inter-entity Select Toxin Transfers

- If select toxins are transferred to other entities (inter-entity transfer) in quantities below the regulated aggregate amounts, check "Yes".
- If select toxins are not transferred to other entities in quantities below the regulated aggregate amounts, check "No".

  Note: Regulated toxin amounts are described in 42 CFR 73.3 (d)(3) and are available at SelectAgents.gov. Any transfer above the regulated aggregate toxin amounts must be approved using an APHIS/CDC Form 2 and be between SRA-approved PIs at registered entities registered to possess the toxin.

  Note: Entities must ensure that select toxin amounts otherwise excluded under 42 CFR 73.3(d)(3) are transferred only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. The HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

Commercial Distribution

- If select toxins are commercially distributed/shipped outside of the laboratory producing the toxin, check "Yes" and indicate if there is a hazard communication plan available.
- If select toxins are not commercially distributed/shipped outside of the laboratory producing the toxin, check "No".

  Note: Commercial entities are required to have a hazard communication plan that addresses the safety and security considerations of other federal agencies (e.g., the Department of Transportation).

Recombinant Work

- If work will involve possession, use or transfer of recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins as defined in 42 CFR 73.3 or 42 CFR 73.13, check "Yes".
- If work will not involve possession, use or transfer of recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins as defined in 42 CFR 73.3 or 42 CFR 73.13, check "No".

  Note: If yes, Attachment B - Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms must be completed. For additional information regarding recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins, refer to Synthetic Genomics.

Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms

This attachment is used to assess any work which may be performed with genetic elements, recombinant nucleic acids or recombinant organisms at an entity. Each work objective in the Section 7A/C that indicates work will be performed with these nucleic acids must have a completed Attachment B. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Possession, Use, or Transfer

- Check yes or no for Questions 1a-c to indicate if the entity will possess, use, or transfer of any of the listed materials.

(a) Positive-strand RNA viruses containing nucleic acids that can produce infectious virions (or particles).

HHS Select Agent Regulated Nucleic Acids
Genomic material – Eastern Equine Encephalitis virus
Genomic material – Kyasanur Forest disease virus
Genomic material – Omsk Hemorrhagic Fever virus
Genomic material – SARS–associated coronavirus
Genomic material – Tick-borne encephalitis virus, Far Eastern subtype
Genomic material – Tick-borne encephalitis virus, Siberian subtype
Overlap Select Agent Regulated Nucleic Acids
Genomic material – Venezuelan Equine Encephalitis virus
USDA Veterinary Services (VS) Select Agent Regulated Nucleic Acids
Genomic material – Classical Swine Fever virus
Genomic material – Foot-And-Mouth Disease virus
Genomic material – Swine Vesicular Disease virus

(b) Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro.

Note: Recombinant and/or synthetic nucleic acids that encode functional domain(s) of select toxins meet these criteria and are also regulated. Functional domains are subunits of the select toxin-encoding gene of any length that have a deleterious biological effect. Lack of biological effect should not be assumed, experimental data from a recognized biological model (either *in vivo* or *in vitro*) of toxin activity should be submitted to the FSAP for consideration before subunits of regulated toxin genes can be excluded from regulation.

HHS Select Toxin Regulated Nucleic Acids
Recombinant/synthetic nucleic acids encoding Abrin
Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin
Recombinant/synthetic nucleic acids encoding Conotoxins
Recombinant/synthetic nucleic acids encoding Ricin

(c) Genetic modifications include but are not limited to: point mutations, chimeras, insertions, truncations or any intentionally-generated modification of the primary nucleic acid sequence.

Note: Chimeric viruses whose genomes contain the backbone and replication machinery of a select agent virus or contain genes from different select agent viruses are regulated. Regulated chimeric viruses have to be evaluated on a case-by-case basis to determine if the viruses exhibit sufficient attenuation to be excluded. Chimeras that are comprised of select agent and non-select agent genes from the same virus family require careful review to determine select agent status. It is the entity's responsibility to determine if the resultant chimera is a select agent; however, the FSAP encourages entities to submit these types of chimeras for review. As defined in section 3(c) and section 4(c) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331), regulated select agent viral nucleic acids, recombinant and/or synthetic nucleic acids encoding select toxins, and genetically modified select agents should be indicated in Attachment B and include explanatory information regarding these experiments. Sufficient information should be included such that the FSAP can evaluate the safety and security considerations associated with recombinant and/or synthetic nucleic acids or genetic modification of select agents and toxins. Summarize any virulence testing that may have been completed on the described modifications, or state that they are uncharacterized.

Note: For additional information regarding regulated nucleic acids as defined in section 3(c) and section 4(c) of the Select Agent Regulations, refer to Synthetic Genomics.

Recombinant Work

- Check yes or no for Questions 2a-d to indicate if work will involve any of the listed materials and/or methods.

a) Genetic elements are sequences of nucleic acids. If work will involve the introduction and/or modification of genetic elements in a select agent or toxin, check "Yes".

- If work will not involve the introduction and/or modification of genetic elements, check "No".

b) Recombinant nucleic acids are defined as (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or (ii) molecules that result from the replication of those described in (i) above. Synthetic nucleic acids are (i) molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids) or (ii) molecules that result from the replication of those described in (i) above. If work will involve recombinant and/or synthetic nucleic acids with select agents or toxins, check "Yes".

- If work will not involve recombinant and/or synthetic nucleic acids with select agents or toxins, check "No".

c) If work will involve recombinant or synthetic organisms that are subject to the Select Agent Regulations (42 CFR 73.13, 7 CFR 331.13 or 9 CFR 121.13), check "Yes".

- If work will not involve recombinant or synthetic organisms, check “No”.

Note: If regulated recombinant and/or synthetic nucleic acids (as defined in Question 1a and 2b) are introduced into either a select agent organism, or a host organism used for molecular cloning (e.g., *E. coli* encoding botulinum neurotoxin or *Staphylococcus aureus* containing an expression vector encoding SEB), the resulting recombinant and/or synthetic organism would be subject to the regulations.

d) If work will involve a reverse genetics system to produce infectious forms of select agent viruses, or any complete set of reagents that would allow rescue of infectious virus available for use by a PI at the entity, check “Yes”.

- If a reverse genetic system or any complete set of reagents that would allow rescue of infectious virus is not used or available, check “No”.

Note: For additional information regarding genetic modification of select agents and toxins, recombinant and/or synthetic nucleic acids, or recombinant and/or synthetic organisms, refer to Synthetic Genomics.

Restricted Experiments

- If a restricted experiment(s) will be performed as defined in section 13 of the Select Agent Regulations (42 CFR 73.13, 7 CFR 331.13 or 9 CFR 121.13), check “Yes” and complete Questions 3a-b to indicate the type(s) of restricted experiment(s) that will be performed and the approval status of this restricted experiment.
  - Include drug or chemical resistant traits that could compromise the control of disease agents in humans, veterinary medicine, or agriculture. Note: Chemical resistance applies to plant pathogens.
  - If approval has been obtained from the APHIS Administrator or HHS Secretary, check “Yes”. If approval has not been obtained from the APHIS Administrator or HHS Secretary, check “No”.
- If a restricted experiment(s) will not be performed as defined in section 13 of the Select Agent Regulations (42 CFR 73.13, 7 CFR 331.13 or 9 CFR 121.13), check “No”.

  Note: For additional information regarding restricted experiments, refer to Restricted Experiments Guidance.

Products of a Restricted Experiment

- If work will involve possession, use or transfer of a product of a restricted experiment, check “Yes” and complete Questions 4a-b to indicate the type(s) of restricted product and the approval status of the restricted experiment.
  - Include all products of a restricted experiment created after December 4, 2012 whether created by the PI, acquired from a different PI at the same entity, or acquired from a different entity. These products include: chemical/drug resistant select agents and/or intermediate products with drug or chemical resistant traits that meet the definition of a restricted experiment, nucleic acids capable of expressing a functional select toxin or a functional subunit of a select toxin, and a host organism containing nucleic acids capable of expressing a functional select toxin or a functional subunit of a select toxin. Note: Chemical resistance applies to plant pathogens.
  - If approval has been obtained from the APHIS Administrator or HHS Secretary, check “Yes”. If approval has not been obtained from the APHIS Administrator or HHS Secretary, check “No”.
- If work will not involve possession, use or transfer of a product of a restricted experiment, check “No”.

Note: For additional information regarding products of a restricted experiment, refer to Restricted Experiments Guidance.

Enhanced/Restored Virulence

- If experiments will involve the acquisition of increased/restored virulence (*e.g.*, drug or chemical resistance, increased host range, enhanced transmissibility, infectivity, environmental stability) in select agents or toxins, check "Yes". If experiments will not involve the acquisition of increased/restored virulence (*e.g.*, drug or chemical resistance, increased host range, enhanced transmissibility, infectivity, environmental stability) in select agents or toxins, check "No".
- If unknown or not sure, check "Yes" and provide an explanation in Question 6.

Note: An individual or entity that possesses, uses, or transfers an excluded strain will again be subject to the regulations if there is any reintroduction of factor(s) associated with virulence or other manipulations of any kind that modify the attenuation such that virulence is restored or enhanced. Provide details on work and factors re-introduced to excluded strains.

Note: Chimeric viruses whose genomes contain the backbone and replication machinery of a select agent virus or contain genes from different select agent viruses are regulated.
Regulated chimeric viruses have to be evaluated on a case-by-case basis to determine if the viruses exhibit sufficient attenuation to be excluded. Chimeras that are comprised of select agent and non-select agent genes from the same virus family require careful review to determine select agent status. It is the entity's responsibility to determine if the resultant chimera is a select agent; however, the FSAP encourages entities to submit these types of chimeras for review.

Note: The purpose of this question is to assess the safety and security of modified select agents and toxins (or restoration of virulence to FSAP excluded strains of select agents and toxins) to laboratory personnel and the environment in the context of containment and potential increased risk(s) associated with the select agent or toxin. If this question is checked yes, provide further details on safety and/or security considerations that may be used to mitigate potential risk(s) to laboratory personnel and the environment in Question 6. The current list of select agent exclusions can be viewed at Select Agents and Toxins Exclusions.

Work Description

- For questions 1-5 in this attachment where "Yes" was indicated, provide a brief description of genetic modifications, any recombinant and/or synthetic constructs and any associated expression control elements, including what the recombinant and/or synthetic DNA encodes, if known. Also, describe any *in vitro* or *in vivo* assays.

Institutional Biosafety Committee Review/Approval

- If an IBC reviews and approves protocols to perform recombinant and/or synthetic work with select agents and toxins at this facility, check "Yes" and indicate if the IBC has approved the recombinant and/or synthetic work described in this attachment.
    - If an IBC does review and approve protocols to perform recombinant and/or synthetic work with select agents and toxins at this facility but has not approved the work described in the attachment, provide an explanation for the absence of review and/or approval.

If an IBC does not review and approve protocols to perform recombinant and/or synthetic work with select agents and toxins at this facility, check "No" and provide an explanation in the text box.

Attachment C – Work with Animals

This attachment is used to assess work with animals. Each work objective in the Section 7A/C that indicates work will be performed with animals must have a completed Attachment C. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

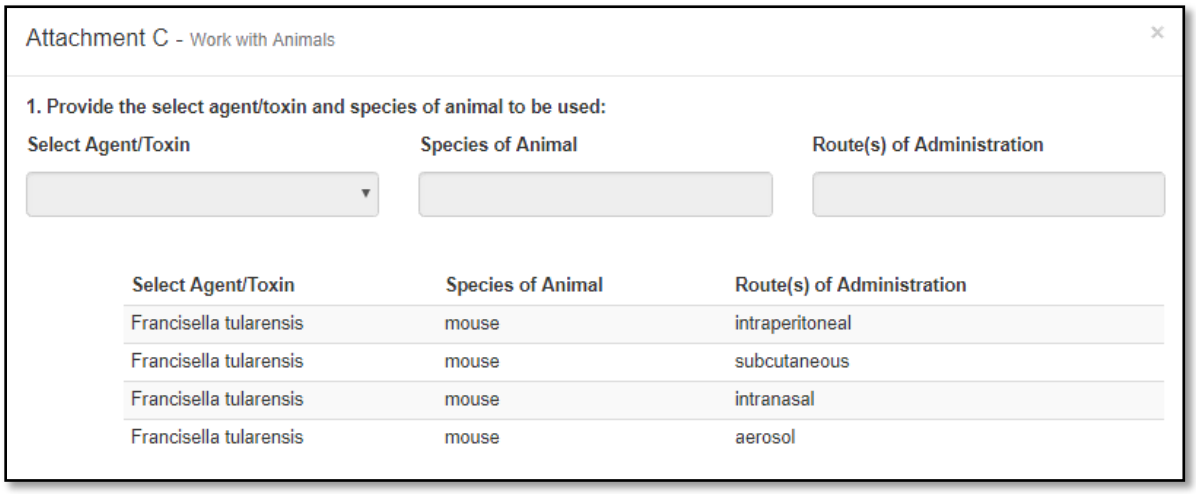
For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call the CDC DRSC at 404-718-2000 or APHIS DASAT at 301-851-2070.

Select Agents/Toxins, Animals and Routes of Administration

- Indicate each select agent listed in the corresponding Section 7A that will be used in animals, provide the species of animal (singular common name) and all routes of administration of the select agent or toxin.
  - Animal models should have singular common name, and no abbreviations. i.e. use "mouse" instead of "mice" or "*mus musculus*"; use "non-human primate" instead of "NHP" or "macaque.
  - Do not use abbreviations for the routes, rather spell out each route for each animal model and agent. Intracranial, Intranasal (i.e. with syringe or nasal cannula, not exposure with aerosol generating equipment – see below), Intratracheal, Intraperitoneal, Intrapleural, Intramuscular, Subcutaneous, Intradermal, Intravenous, Intra-arterial, ocular, oral, mucosal, intracapsular injection of joint spaces, intrathoracic injections, and any other routes of administration.
  - Each route and model should be listed separately.
    - If 50 or more lines would be required combinations may be permitted. Combine all routes into one entry first, while keeping agent and model separate.

  Note: Indicate "aerosol" if you use any equipment (e.g., nebulizer) to expose animals to aerosols.

Examples for Completing the Attachment C, Question 1



Aerosol Exposures

- If animals are exposed to select agents or toxins by the aerosol route, check "Yes" and indicate if the aerosol exposure equipment is used within a primary containment device.
- If animals are not exposed to select agents or toxins by any intentional aerosol generating route,

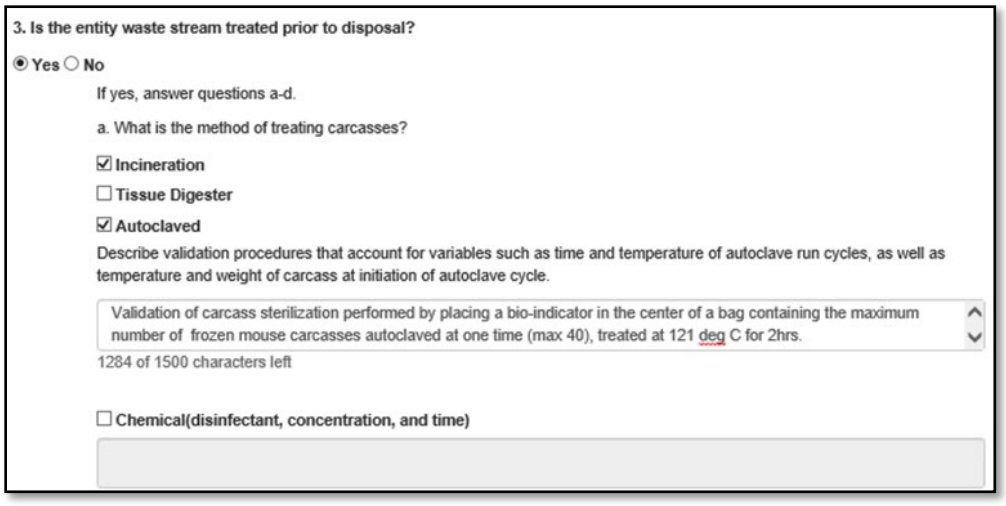
check “No”.

Waste Stream

- Describe the waste stream of the laboratory as it relates to animal work by completing Questions 3a-d and providing relevant details as appropriate.

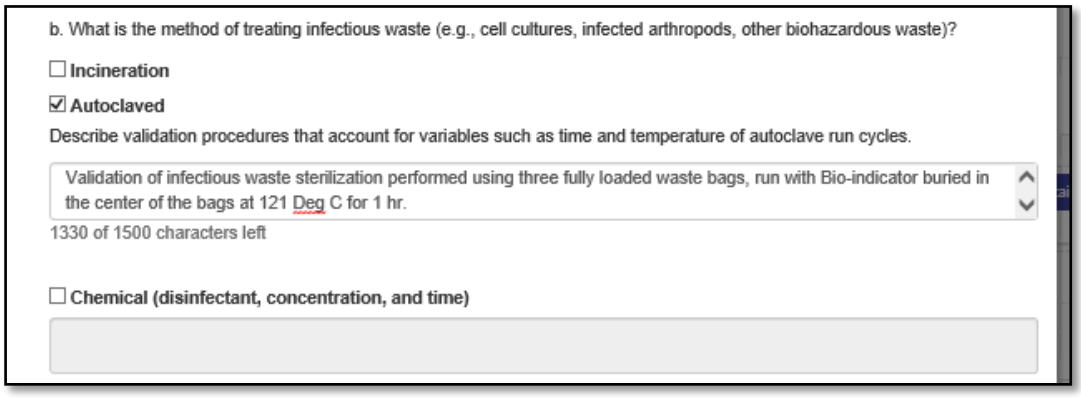
(a) Method of treating carcasses: If animal carcasses are treated prior to disposal by an approved method, check “Yes” and describe the treatment method(s) by checking all applicable methods and providing relevant details of the treatment method(s) as appropriate. Only check the box for the initial method(s) that renders the waste decontaminated or destroyed (e.g., if you autoclave and then incinerate, check the box for autoclave and describe your autoclave protocol including time, temperature, and pressure, but do not check the box for incineration; if some carcasses are autoclaved first and others are not autoclaved before incineration, then check both boxes). If animal carcasses are not treated prior to disposal by an approved method, check “No”.

Example for filling out Question 3a



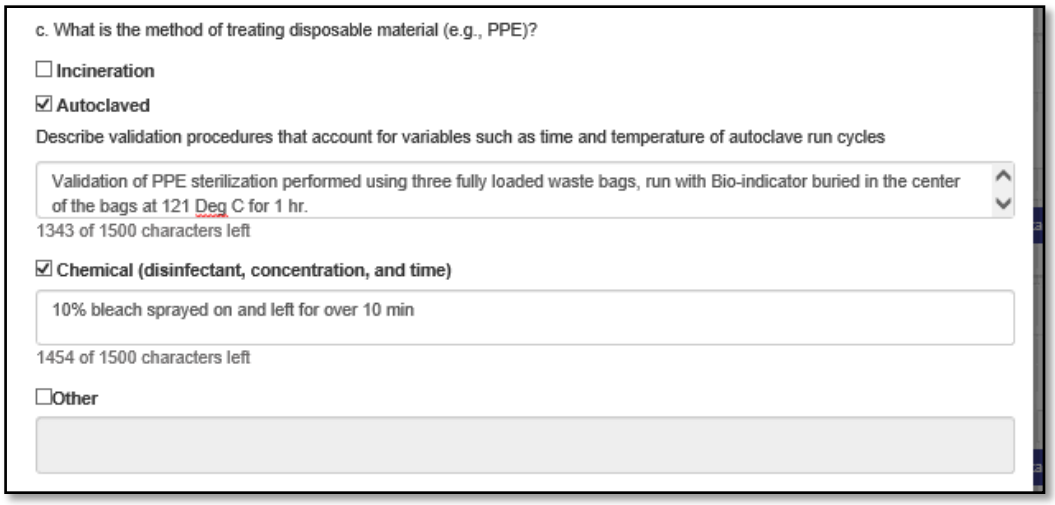
(b) Method of treating infectious waste (e.g., cell cultures, infected arthropods, other biohazardous waste): If infectious waste is treated prior to disposal by an approved method, check “Yes” and describe the treatment method(s) by checking all applicable methods and providing relevant details of the treatment method(s) as appropriate. Describe validation procedures for inactivation methods. For chemical inactivation methods indicate the disinfectant, concentration, and time.

Example for Question 3b



(c) Method of treating disposable material (e.g., PPE): Describe validation procedures for inactivation methods. For chemical inactivation methods indicate the disinfectant, concentration, and time.

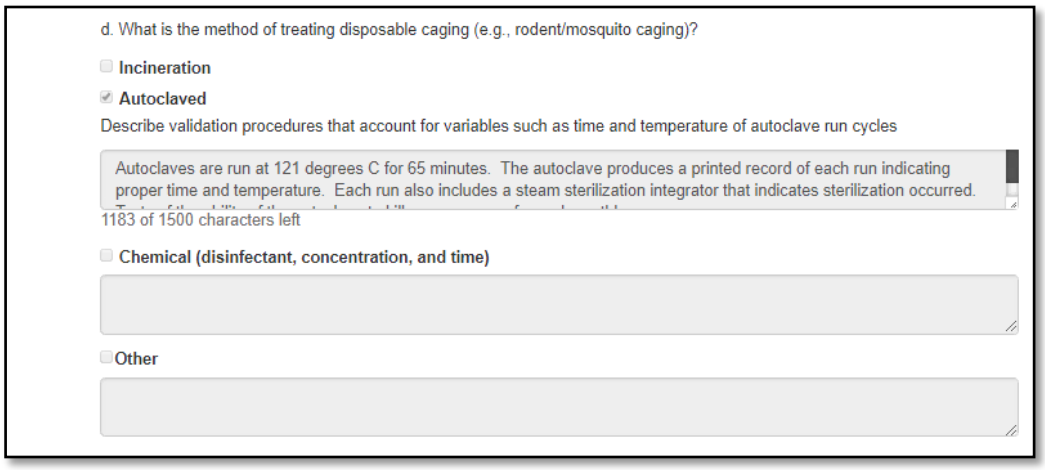
Example for Question 3c



(d) Method of treating disposable caging (e.g., rodent/mosquito caging): Describe validation procedures for inactivation methods. For chemical inactivation methods indicate the disinfectant, concentration, and time. Only check the box for the initial method(s) used to decontaminate the caging.

Note: If reusable caging is treated prior to being further cleaned within a facility this can be indicated here.

Example for Question 3d



Manipulation of Samples at Lower Biosafety Level

- Are samples (tissue, blood, nucleic acids, etc.) from exposed or infected animals manipulated at a lower biosafety level? If applicable check "Yes" and describe the process.
    - If yes, describe the inactivation process (e.g. formalin fixation, lysis of cells for nucleic acid extraction, irradiation) for the samples. Include concentration or dosage and contact/exposure time, as applicable.

Institutional Animal Care and Use Committee (IACUC)

- If the entity requires that an IACUC review and approve protocols prior to work with animals at this entity, check "Yes" and indicate whether the proposed work has been approved.
    - If an IACUC reviews protocols prior to work with animals at this entity but has not approved the work described here, provide an explanation for the absence of review and/or approval.

      Note: If the entity's IACUC approval has not yet been sought, but work will not begin until it is approved by the IACUC, indicate this in the explanation.
- If the entity does not require that an IACUC review and approve protocols prior to work with animals at this entity, check "No".

  Note: Corporate or private entities may not have these committees.

AAALAC Accreditation

- If the laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), check "Yes" and provide the most recent accreditation or re-accreditation date.
- If the laboratory is not accredited by the AAALAC, check "No".

  Note: Some corporate or private entities may not seek this accreditation; check "No".

Animal Tracking

- If there is a system in place for recording the number of animals infected, the number of animals disposed of, and these records are reviewed frequently, check "Yes" and describe the method used to track and account for animals from the time of exposure to the select agent until final disposition (e.g., daily counts

recorded manually by laboratorians and/or animal care staff, computerized inventory systems that include barcoding of cages as well as daily counts of individual animals). Indicate if unique animal identifiers such as ear tags or brands are used and include the frequency of reconciliation of records (e.g., daily counts checked against inventory database).

- Check "No" if there is not a system in place for recording each of the following elements: the number of animals infected, the number of animals disposed, and the frequency of records review.

  Note: A current accounting of animals as described in section 17(a)(2) of the Select Agent Regulations is required. For additional information, refer to the Guidance on the Inventory of Select Agents and Toxins.

Note for Questions 8 – 12 below: The purpose of these questions is to assess that the biosafety and containment practices are commensurate with the risk of the select agent or toxin given its intended use.

Animal Restraint

- If animals are restrained for experimental manipulation, check "Yes".
- If animals are not restrained for experimental manipulation, check "No" and provide an explanation.

Animal Monitoring

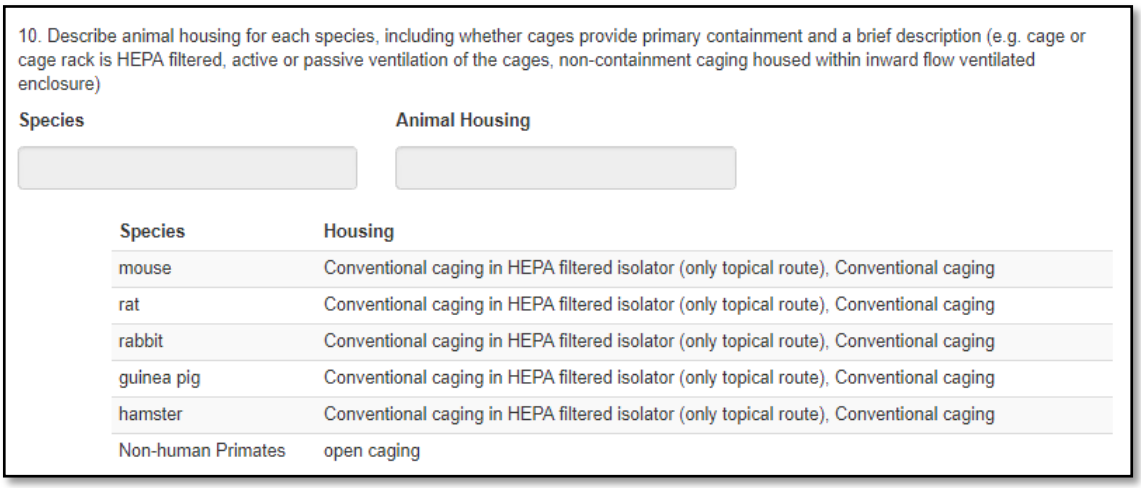
- If animals are monitored before experimental endpoint (e.g., daily checks), check "Yes".
- If animals are not monitored before experimental endpoint (e.g., daily checks), check "No" and provide an explanation.

Animal Housing

- Describe how animals are housed by species, including whether cages provide primary containment.
  - The following are examples of housing: Conventional caging, Conventional caging in HEPA filtered isolator, HEPA filtered caging, Open cages, loose-housing. Do not include brand names. Actively ventilated caging systems have both a supply and exhaust fan; passive ventilation is provided by an exhaust fan only.
- Each species can only be added on a single line, list all forms of caging used for the species on that line.

  Note: For entities performing work with recombinant select agents in non-human primates housed in conventional/non-containment caging at ABSL4, refer to Appendix G of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Molecules (NIH Guidelines).

Example for Completing the Attachment C, Question 10



10. Describe animal housing for each species, including whether cages provide primary containment and a brief description (e.g. cage or cage rack is HEPA filtered, active or passive ventilation of the cages, non-containment caging housed within inward flow ventilated enclosure)

Species **Animal Housing**

Species	Housing
mouse	Conventional caging in HEPA filtered isolator (only topical route), Conventional caging
rat	Conventional caging in HEPA filtered isolator (only topical route), Conventional caging
rabbit	Conventional caging in HEPA filtered isolator (only topical route), Conventional caging
guinea pig	Conventional caging in HEPA filtered isolator (only topical route), Conventional caging
hamster	Conventional caging in HEPA filtered isolator (only topical route), Conventional caging
Non-human Primates	open caging

Method of Euthanasia

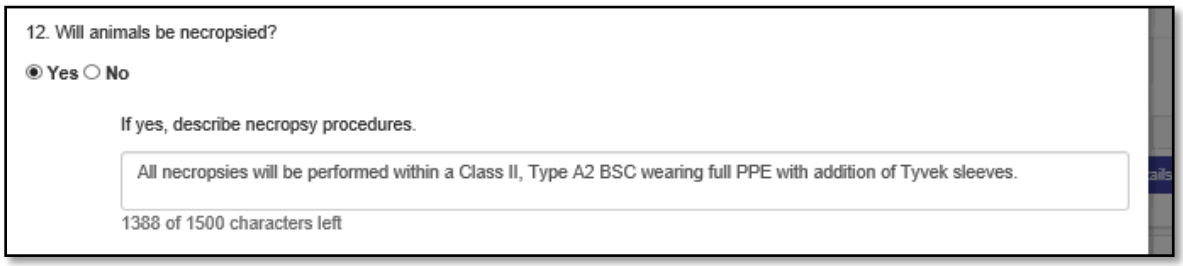
- If animals will be euthanized, check "Yes".
- If animals will not be euthanized, check "No" and provide an explanation.

Necropsies

- If animals will be necropsied, check "Yes" and describe the necropsy procedures (instruments or implements used, location of necropsy, e.g. on downdraft table or in BSC).
- If animals will not be necropsied or sampled post- or peri-mortem, check "No".

  Note: Materials collected (e.g., blood and tissue samples) from select agent infected animals are select agents and must be handled only by SRA-approved individual(s) and stored in registered areas until inactivated or shown to not contain select agent.

  Note: For additional information regarding inventory of material collected from experimentally- inoculated animals, refer to the Guidance on the Inventory of Select Agents and Toxins.



12. Will animals be necropsied?

◉ Yes ○ No

If yes, describe necropsy procedures.

All necropsies will be performed within a Class II, Type A2 BSC wearing full PPE with addition of Tyvek sleeves.

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Securing Animal Carcasses

- Describe how animal carcasses are secured prior to decontamination by checking all methods used.
- If "Other" is selected, enter explanation.

Attachment D – Work with Plants

This section is used to assess work with plants. Each work objective in the Section 7A/C that indicates work will be performed with plants must have a completed Attachment D. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

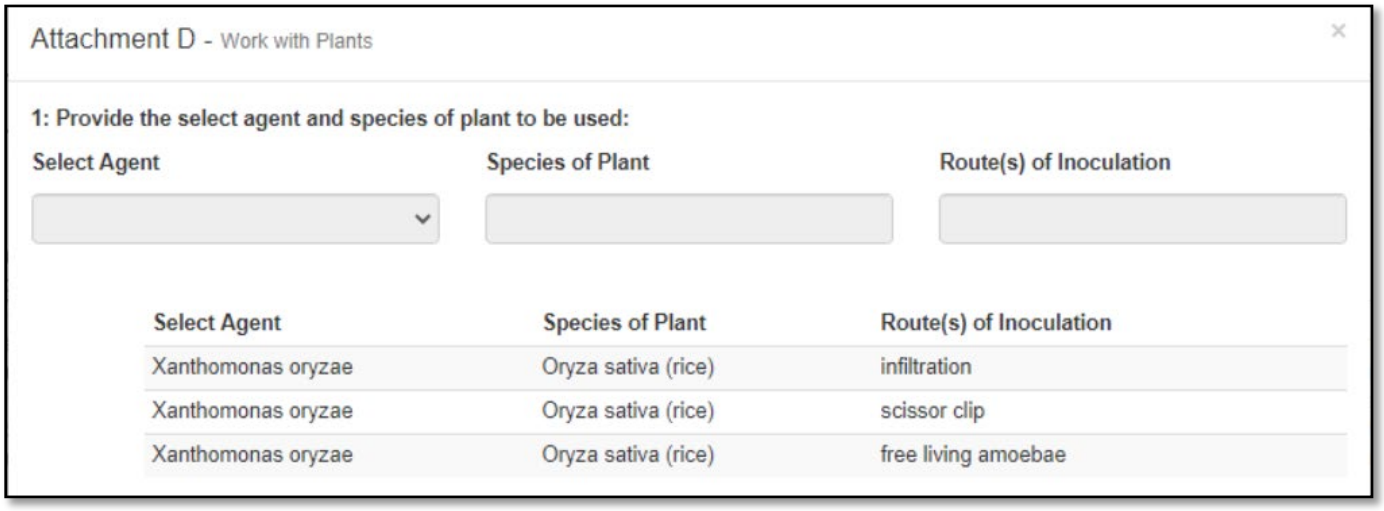
If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Select Agents, Plants and Routes of Inoculation

- Indicate each select agent listed in the corresponding Section 7A that will be used in plants. Enter the species of plant(s) used for inoculation (genus & species name, as well as common name) and any and all routes of inoculation of the select agent.

Example of Attachment D, question 1



Plant Waste Treatment

- If all plant waste is treated prior to disposal (e.g., soil, plant material, material accompanying plants or samples) by an approved method, check "Yes."
- If yes, describe the treatment method(s) by checking all applicable methods and providing relevant aspects of the method(s) selected for decontamination as appropriate. Include the disinfectant, concentration, and contact time.
- If all plant waste is not treated prior to disposal (e.g., soil, plant material, materials accompanying plants or samples) by an approved method, check "No."

Vectors

- If experiments will involve vectors, check "Yes" and complete Questions 3a-d to describe the vectors and their containment parameters.
- If experiments will not involve vectors, check "No".

Note: If yes, Attachment E – Work with Arthropods must be completed.

Glass House

- If plants exposed to select agents will be housed or manipulated in a glass house, check "Yes" and complete Questions 4a-f to describe the glass house.
- If plants exposed to select agents will not be housed or manipulated in a glass house, check "No".

Greenhouse

- If plants exposed to select agents will be housed or manipulated in a greenhouse, check "Yes" and complete Questions 5a-f to describe the greenhouse.
- If plants exposed to select agents will not be housed or manipulated in a greenhouse, check "No".

Screen House

- If plants exposed to select agents will be housed or manipulated in a screen house, check "Yes" and complete Questions 6a-g to describe the screen house.
- If plants exposed to select agents will not be housed or manipulated in a screen house, check "No".

Growth Chamber

- If plants exposed to select agents will be housed or manipulated in a growth chamber, check "Yes" and complete Questions 7a-i to describe the growth chamber.
- If plants exposed to select agents will not be housed or manipulated in a growth chamber, check "No".

Recombinant Work

- If work will be performed with regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms, check "Yes".
- If work will not be performed with regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms, check "No".

Note: If yes, Attachment B - Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms must be completed.

Attachment E – Work with Arthropods

This attachment is used to assess any work which may be performed with arthropods at an entity. Each work objective in the Section 7A/C that indicates work will be performed with arthropods must have a completed Attachment E. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

If the question does not apply to your entity, answer "No".

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Note: A useful reference to aid in completing this attachment is: Vector Borne Zoonotic Dis. 2003 Summer;3(2):61-98, Arthropod containment guidelines: A project of the American Committee of Medical Entomology and American

Society of Tropical Medicine and Hygiene (as referenced in the BMBL Appendix E).

Field-Collected Arthropods

- If work is performed with field-collected arthropods in a diagnostic capacity only (e.g., protein and/or nucleic acid extraction) for identification of select agents, check "Yes".
- If work is not performed with field-collected arthropods in a diagnostic capacity for identification of select agents, check "No".

  Note: If any work beyond destructive diagnostic testing is performed with arthropods (e.g., colonization of arthropods from the field, cultivation of select agents in field-collected arthropods), check "No" and proceed to questions 2-16.

  Note: If you perform work with select agents and arthropods but check no to both Questions 1 and 2, and consult with APHIS/CDC as to how to complete Attachment E.

  Note: Work with select agents in their naturally occurring environment is not regulated as long as the select agent has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. Exposing naïve animals to naturally infected arthropods would be regulated. Moving naïve animals into a location where they may be exposed to infection would be regulated.

Experimental Inoculations

- If work is performed to experimentally inoculate or infect any life stage (i.e. larvae, pupae, or adult) of arthropods with select agents, check "Yes" and complete Questions 3-16.
- If work is not performed to experimentally manipulate arthropods and select agents, check "No."

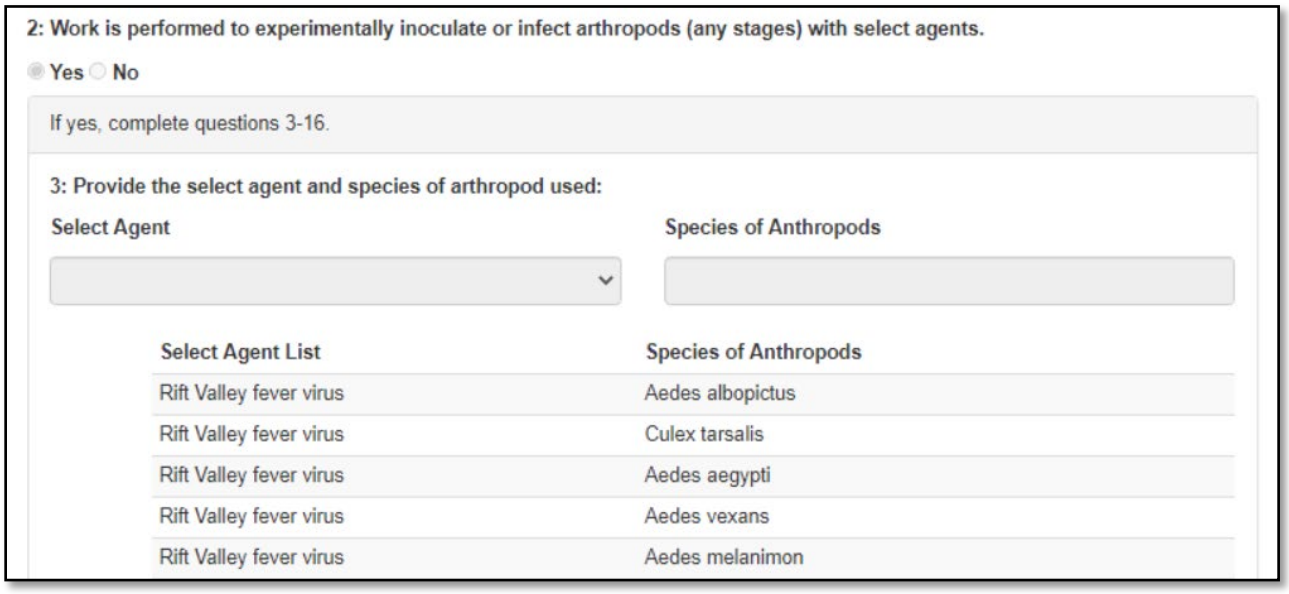
  Note: Questions 3-16 of this attachment will only appear if "Yes" is checked for Question 2.

  Note: Work with select agents in their naturally occurring environment is not regulated provided that the agent has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

Select Agents and Arthropods

- Indicate each select agent listed in the corresponding Section 7A that will be used in arthropods. Enter the species of arthropod (genus & species name, as well as common name).
- Each paring of agent and arthropod should be listed on individual rows.

Example for Completing Attachment E, Question 3


2: Work is performed to experimentally inoculate or infect arthropods (any stages) with select agents.

Yes No

If yes, complete questions 3-16.

3: Provide the select agent and species of arthropod used:

Select Agent | Species of Anthropods

Select Agent List	Species of Anthropods
Rift Valley fever virus	Aedes albopictus
Rift Valley fever virus	Culex tarsalis
Rift Valley fever virus	Aedes aegypti
Rift Valley fever virus	Aedes vexans
Rift Valley fever virus	Aedes melanimon

Exposure Routes

- Describe the method of arthropod exposure by completing Questions 4a-d and providing relevant aspects of the exposure method(s) as appropriate.
- If insects are fed on select agent-infected plants, check box 4c and fill out Attachment D - Work with Plants.
- If the arthropod exposure route is not listed check box 4d (Other) and provide a description.

  Note: If uninfected blood is used to feed arthropods for colony maintenance only, check "No" to 4b.

  Note: If collected blood is inoculated with agent and used to feed arthropods indicate this by checking "Collected blood".

Containment and Transfer of Infected Arthropods

- Describe procedures used for primary containment and any transfer(s) of infected arthropods. Address primary containment features of caging systems and include any secondary containment equipment used to transfer arthropods within or between insectaries, laboratories and/or containment facilities. Provide a description of the procedures used for primary containment and any transfer(s) of infected arthropods (e.g., "clear, latched secondary containers to assess escape of arthropods from the primary container before opening the secondary container", "opaque friction-closing secondary containers opened in primary containment glove box to prevent accidental release").

  Note: The purpose of this question is to assess the safety and security of laboratory staff and the environment in the context of containment and movement of arthropods. Answer the question with sufficient detail to allow APHIS or CDC to assess the adequacy of caging and containment in the context of exposure of personnel or the environment to select agent- infected vectors.

Infected Arthropods Records

- If there is a system in place for recording the number of arthropods infected, the number of arthropods disposed of, and these records are reviewed frequently, check "Yes" and describe the system. Include

sufficient detail to allow a person unfamiliar with your specific system to understand the concepts and check-points that exist in the system (e.g., daily counts recorded manually by laboratorians, computerized inventory systems that include barcoding of cages as well as daily counts of individual arthropods). Indicate if unique arthropod identifiers such as fluorescent dye spots or visible genetic mutations (e.g. red eyes) are used and the frequency of records reconciliation (e.g., daily counts checked against inventory database).

- If there is not a system in place for recording each of these elements, check "No".

  Note: A current and accurate accounting of arthropods experimentally inoculated with select agents is required as defined in section 17(a)(2) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). For additional information, refer to the Guidance on the Inventory of Select Agents and Toxins.

Containment Design and Operational Procedures

- If arthropod containment laboratory design and operational procedures are developed and implemented in accordance with guidance found in the current edition of the Arthropod Containment Guidelines, check "Yes".
- If arthropod containment laboratory design and operational procedures are not developed and implemented in accordance with guidance found in the current edition of the Arthropod Containment Guidelines, check "No".

  Note: Consult with your designated FSAP representative or contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3 for further information if you are unsure as to how to answer this question.

Institutional Biosafety Committee Review/Approval

- If an IBC reviews and approves arthropod work with select agents at this facility, check "Yes" and indicate if the IBC has approved the arthropod containment laboratory design and operational procedures and if the IBC has reviewed and approved the arthropod work.
  - If an IBC reviews and approves arthropod work with select agents at this facility but has not approved the work described in the attachment, provide an explanation for the absence of review and/or approval.
- If an IBC does not review and approve arthropod work with select agents at this facility, check "No".

  Note: Some corporate or private entities do not have these committees; check "No" if this is the case.

Accidental Contact and Release Prevention

- If arthropods, including those experimentally infected, are housed and manipulated in a suite/room such that accidental contact and release is prevented, (i.e. within primary containment such as a glove box), check "Yes."
- Check "Yes" if you have a "room within a room" style vivarium cage that is contained within a laboratory room, but the arthropods are prevented from accessing the walls or fixtures such as lights, outlets, etc.
- If arthropods are not prevented from release into the suite/room (i.e. they normally have access to the suite/room walls or wall fixtures), check "No".

  Note: This question relates to the secondary containment design features of the laboratory for maintenance of arthropods, this question additionally relates primarily to active work and manipulation of arthropods, not maintenance of them in the insectary as described in Question 5.

Accidental Escape Prevention

- If protocols include procedures to prevent accidental escape of arthropods, check “Yes”.
- If protocols do not include such procedures, check “No”.

Ventilation Escape Barriers

- If suite/room ventilation filters or other barriers over the vents and/or doors and wall penetrations are installed to prevent arthropod escape, check “Yes”.

  Note: Many arthropods have a flighted life stage, and escape through ventilation penetrations of the insectary, laboratory or containment facility is a concern.

- If ventilation filters/barriers are not installed to prevent arthropod escape, check “No”.
  - If no, provide additional information as to the method by which you prevent arthropod escape through the ventilation system (e.g. “no flighted stage, moat and petroleum jelly on rim of pan used for containment of tick vectors”).

Floor Drains

- If floor drains are present in the laboratory, check “Yes” and indicate if the floor drains are modified to prevent accidental release of arthropods and agents.

  Note: Many arthropods have an aquatic life stage, and escape through plumbing penetrations is a concern.

- If floor drains are not present in the laboratory, or there are no modifications to prevent accidental release of arthropods and agents, check “No”.
  - If no, provide additional information as to the method by which you prevent arthropod colonization and escape through the plumbing (e.g. “no aquatic stage, moat and petroleum jelly on rim of pan used for containment of tick vectors”).

Plumbing Escape Barriers

- If suite/room plumbing is suitable to prevent arthropod escape, check “Yes”.
  - Check “Yes” if you have floor and sink drain modifications and/or downstream plumbing features that prevent the colonization of the plumbing by arthropods and/or their escape.
- If suite/room plumbing is not suitable to prevent arthropod escape (i.e. if there are no plumbing modifications), check “No”.

Disposal

- If all stages of arthropods are killed before disposal (e.g. through freezing before discarding into trash that will be autoclaved), check “Yes”.
- If all stages of arthropods are not killed before disposal, check “No”.

  Note: This question relates to the killing of the arthropod separate from the decontamination of the agent. The escape of live arthropods from insectary waste before decontamination is a concern.

Waste Treatment

- If all wastes from the arthropod containment laboratory are treated for disposal using an approved method, check "Yes". This question relates to the decontamination of the select agent separate from the killing of the arthropod.
    - If yes, describe the treatment method(s) by checking all applicable methods and providing relevant aspects of the method(s) selected for decontamination as appropriate. Information provided for chemical methods should include the disinfectant, concentration, and contact time.
- If all wastes from the arthropod containment laboratory are not treated for disposal using an approved method, check "No".

Animals/Plants in Arthropod Containment Laboratory

- If animals or plants are permitted in the arthropod containment laboratory, check "Yes" and complete Questions 16a-b.
    - For 16a, check "Yes" if the animals or plants allowed in the laboratory are an integral part of the active work being performed (i.e. they are research animals or plants housed in the laboratory for other work and are not pets or ornamental plants). Otherwise, check "No".
    - For 16b, check "Yes" if the animals or plants are accessible to escaped arthropods (i.e. if there is normally only one containment barrier between the arthropods and the animals or plants).
- If animals or plants are not permitted in the arthropod containment laboratory, check "No".

Attachment F – BSL3 Ag Laboratories

This section is used to assess any work which may be performed in BSL3Ag laboratories at an entity. Complete this section by checking either "Yes" or "No" for all questions and entering additional information when prompted.

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Supply, Material and Equipment Decontamination

- If supplies, material and equipment enter and exit BSL3Ag areas only through an airlock, fumigation chamber, interlocked and double-door autoclave or shower, check "Yes".
- If supplies, material and equipment enter and exit BSL3Ag areas through other means, check "No".
- If a gas sterilizer, pass-through liquid dunk tank, or a cold gas decontamination chamber is provided for temperature sensitive materials, check "Yes".
- If a gas sterilizer, pass-through liquid dunk tank, or a cold gas decontamination chamber is not provided for temperature sensitive materials, check "No".

Shower

- If a shower is required when leaving the containment boundary, check "Yes".
- If a shower is not required when leaving the containment boundary, check "No".

Disposable Material Decontamination

- If disposable materials (e.g., animal waste, carcasses, liquid drainage, personal protective equipment) are decontaminated by a verified method, check "Yes".
    - If yes, describe the treatment method(s) by checking all applicable methods and providing relevant aspects of the method(s) selected for decontamination as appropriate.
- If disposable materials are not decontaminated by a verified method, check "No".

Containment Area Construction

- If all containment areas are designed, constructed and verified to function as a primary containment barrier; all walls are constructed slab-to-slab and walls, floors, and ceilings are sealed; and all penetrations (including the ductwork) into the laboratory are sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination, check "Yes".
- If all containment areas are not designed, constructed and verified to function as a primary containment barrier; all walls are not constructed slab-to-slab and walls, floors, and ceilings are not sealed; and all penetrations (including the ductwork) into the laboratory are not sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination, check "No".

Airflow Monitoring

- If differential pressures/directional airflow are monitored and alarmed to indicate system failure, check "Yes".
- If differential pressures/directional airflow are not monitored and alarmed to indicate system failure, check "No".

HEPA Filtration

- If there is HEPA filtration of all supply and exhaust air to and from the containment space (e.g., animal suite/room(s), inner/dirty change room(s), anteroom(s), plumbing exhaust vents), check "Yes" and indicate if all HEPA filters are certified annually.
- If all supply and exhaust air to and from the containment space (e.g., animal suite/room(s), inner/dirty change room(s), anteroom(s), plumbing exhaust vents) is not HEPA filtered, check "No".

Laboratory Procedures and Design Features

- Describe the ABSL-3Ag laboratory procedures and design features by completing Questions 7a- e.

Second Shower

- If a second shower is required at the facility access control point before donning street clothing, check "Yes".
- If a second shower is not required at the facility access control point before donning street clothing, check "No".

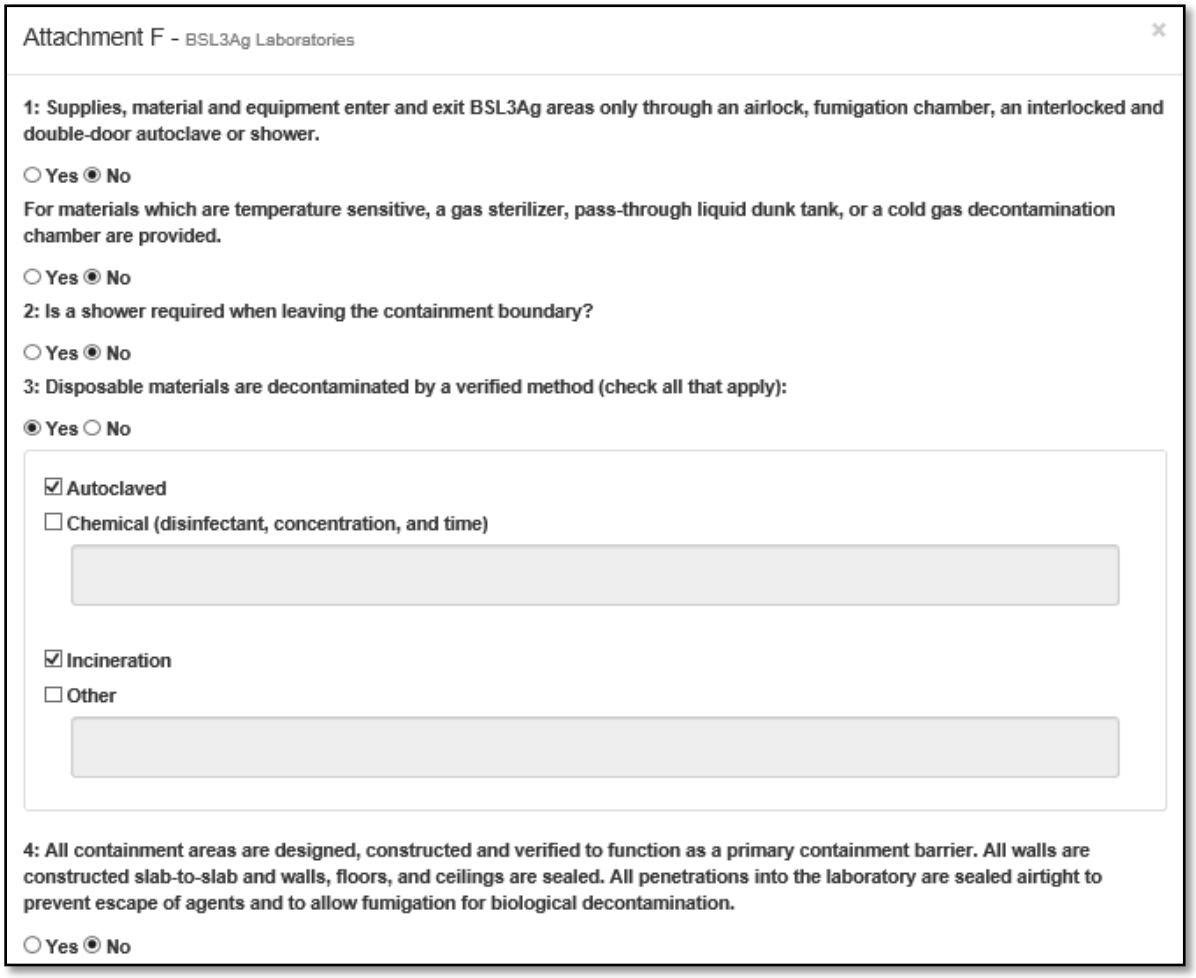
Humane Restraining Devices

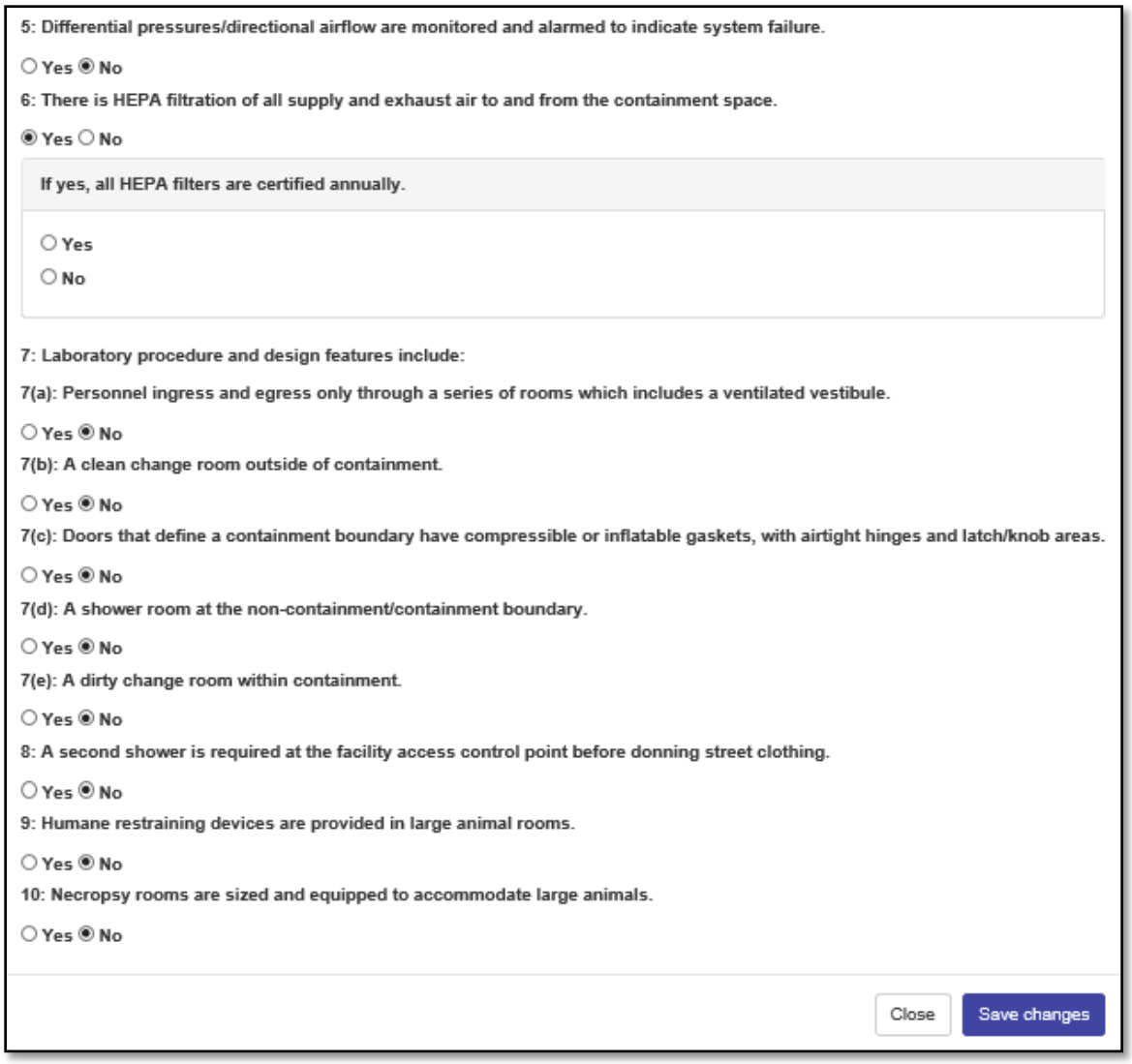
- If humane restraining devices are provided in large animal rooms, check "Yes" and provide a description in the box that opens of what restraining devices are provided and how they will be used.

- If humane restraining devices are not provided in large animal rooms, check "No".

Large Animal Necropsy Rooms

- If necropsy rooms are sized and equipped to accommodate large animals, check "Yes" and describe these features in the box that opens.
- If necropsy rooms are not sized and equipped to accommodate large animals, check "No".





Attachment G – BSL4/ABSL4 Laboratories

This attachment is used to assess work performed in BSL4 or ABSL4 laboratories. Complete this attachment by checking either “Yes” or “No” for all questions and entering additional information when prompted.

For additional guidance refer to the eFSAP guidance information. If further information or guidance is required, contact your POC or call DRSC at 404-718-2000 or DASAT at 301-851-2070.

Cabinet Laboratory

- If work will be performed in a BSL4/ABSL4 Cabinet Laboratory, check “Yes” and complete Questions 2-8.
- If work will not be performed in a BSL4/ABSL4 Cabinet Laboratory, check “No” and skip to question 9.

Personal Protective Equipment (Cabinet Laboratory)

- Describe the type of personal protective equipment that will be used.

Decontamination Methods (Cabinet Laboratory)

- Describe the decontamination methods for materials/equipment in the Class III cabinet.

Liquid Effluent Decontamination (Cabinet Laboratory)

- Describe what liquid effluents are decontaminated and how they are decontaminated.

Room Ventilation (Cabinet Laboratory)

- Describe the supply and exhaust components of the ventilation system, including how the ventilation system of the Class III cabinet is manifolded to the room ventilation.

Ventilation Failure (Cabinet Laboratory)

- In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow.

Airflow Monitoring (Cabinet Laboratory)

- Describe how differential pressures and directional airflow are monitored and analyzed.

Containment Parameters Monitoring (Cabinet Laboratory)

- Describe how containment parameters are monitored daily.

Suit Laboratory

- If work will be performed in a BSL4/ABSL4 Suit Laboratory, check "Yes" and complete Questions 10-16.

Personal Protective Equipment (Suit Laboratory)

- Describe the type of personal protective equipment that will be used.

Liquid Effluent Decontamination (Suit Laboratory)

- Describe what liquid effluents are decontaminated and what measures are used.

Room Ventilation (Suit Laboratory)

- Describe the supply and exhaust components of the ventilation system, including how negative pressure is maintained and HEPA filtration of supply and exhaust air.

Ventilation Failure (Suit Laboratory)

- In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow.

Airflow Monitoring (Suit Laboratory)

- Describe how differential pressures and directional airflow are monitored and analyzed.

Breathing Air Failure (Suit Laboratory)

- Describe what facility redundancies are in place in the event of a breathing air failure.

Containment Parameters Monitoring (Suit Laboratory)

Describe how containment parameters are monitored daily.

Definitions

Access – An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

Alternate Responsible Official (ARO) – The individual(s) designated by an entity that acts for the Responsible Official.

Animal and Plant Health Inspection Service (APHIS) – A multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues.

Animal Biosafety Level (ABSL) – An ascending order of four combinations of practices, safety equipment, and facilities recommended by the BMBL for experimentally infected animals.

Arthropod Containment Level (ACL) – An ascending order of four combinations of practices, safety equipment, and facilities recommended by the American Committee of Medical Entomology and the American Society of Tropical Medicine and Hygiene for work with arthropods that transmit pathogens.

Biosafety Cabinet (BSC) – The primary means of containment developed for working safely with infectious microorganisms. BSCs are designed to provide personal, environmental and product protection when appropriate practices and procedures are followed.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – A publication by the Centers for Disease Control and Prevention and the National Institutes of Health that serves as a nationally and internationally recognized source for the standards and special microbiological practices, safety equipment, and facilities to work with a variety of infectious agents in various laboratory settings. The BMBL utilizes 4 biosafety levels (BSL 1 through 4) for work with pathogenic microorganisms based upon a risk assessment.

Biosafety Level (BSL) – The primary risk criteria used to define the four levels of containment, referred to as biosafety levels 1 through 4, are infectivity, severity of disease, transmissibility, and the nature of the work being conducted. Another important risk factor for agents that cause moderate to severe disease is the origin of the agent, whether indigenous or exotic. Each level of containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling a particular agent. The basic practices and equipment are appropriate for protocols common to most research and clinical laboratories. The facility safeguards help protect non-laboratory occupants of the building, the public health and the environment.

Bioterrorism Security Risk Assessment Form (FD-961 Form) – The FBI's Application for Security Risk Assessment that assists the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS) to perform an electronic records check to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.

Centers for Disease Control and Prevention (CDC) – One of the major operating components of the Department of Health and Human Services. Its mission is to collaborate to create the expertise, information, and tools that people and

communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

Chemical Hygiene Plan (CHP) – Written program stating the policies, procedures and responsibilities that protect workers from the health hazards associated with the hazardous chemicals used in that particular workplace.

Criminal Justice Information Services (CJIS) – The Division of the Federal Bureau of Investigation that conducts security risk assessments of all individuals, Responsible Officials, Alternate Responsible Officials and non-governmental entities that request access to select agents and toxins.

Containment – Microbiological practices, safety equipment, and facility safeguards in place to protect laboratorians, the public, and the environment from exposure to infectious microorganisms or toxins that are handled or stored in the laboratory.

Department of Justice (DOJ) Number or Unique Identifying Number (UIN) – Number provided to the Responsible Official through eFSAP for each individual listed on the APHIS/CDC Form 1. Each individual that completes the FD-961 Form must include the DOJ/UIN in Section II, item #11 of the form.

Division of Agricultural Select Agent and Toxins (DASAT) – A unit within the Animal and Plant Health Inspection Service that regulates the possession, use, and transfer of biological agents that have the potential to pose a severe threat to animal or plant health and/or animal or plant products.

Division of Regulatory Science and Compliance (DRSC) – The division of the Center for Preparedness and Response that regulates the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety.

Effluents –Liquids such as those originating from laboratory sinks, floor drains, and other sources that are discharged into a sewer system. Where required*, these effluents are collected and decontaminated before disposal. A heat decontamination system holds contaminated liquid effluents to temperatures, pressures, and times sufficient to inactivate biohazardous materials. A chemical decontamination system treats contaminated liquid effluents with an appropriate chemical disinfectant for a prescribed period of time to inactivate biohazardous materials. Chemical inactivation of liquid wastes including cultures and stocks prior to drain disposal would not be considered effluent.

* Effluent decontamination is required for maximum containment facilities performing work at BSL4, ABSL4, and ABSL-3Ag. For propagative work performed at BSL3 with highly transmissible and pathogenic agents, such as highly pathogenic avian influenza virus, classical swine fever virus, and African swine fever virus, liquid effluents must be decontaminated prior to release into a sewer system.

Electronic Federal Select Agent Program Database (eFSAP) – The select agent and toxin national database containing entity registration information, including the list of select agents and toxins registered to each entity, the list of individuals who are approved to have access to select agents and toxins, and, if appropriate, how each select agent or toxin will be used or stored.

Entity – Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. See also “Facility”.

Facility – As used in this document, a “facility” is the physical structure where select agents or toxins are used, manipulated, and/or stored. An entity can be composed of multiple facilities, and a facility may contain multiple suites/rooms where work is performed and/or select agents or toxins are stored.

Federal Select Agent Program (FSAP) – The Federal Select Agent Program is jointly comprised of DASAT and DRSC, and oversees the possession, use, and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health, and/or to animal or plant products.

High Efficiency Particulate Air (HEPA) filter – An air filter composed of a mat of dense fibers arranged in folds, designed according to federal standards to trap at least 99.97% of airborne particles measuring 0.3 microns in diameter. HEPA filters remove bacteria, spores, and viruses from the air with an efficiency of 99.97% or greater. HEPA filters and HEPA filter housings must be inspected annually.

Institutional Animal Care and Use Committee (IACUC) – A self-regulating body that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution's animal care and use program.

Institutional Biosafety Committee (IBC) – An institutional committee created under the National Institutes of Health (NIH) Guidelines to review research involving recombinant DNA. The role of IBCs has evolved over time, and many committees also review other forms of research that entail biohazardous risks as part of their institutionally assigned responsibilities.

In vitro – In glass, as in a test tube. An *in vitro* test is one done in the laboratory, usually involving isolated tissue, organ, or cell preparations.

In vivo – In the living body or organism. An *in vivo* test is one performed on a living organism.

Laboratorians and Animal Care Staff – Individuals who perform any of the work listed in a Section 7A & 7C, Objective of Work and/or handle or manipulate select agents or toxins or handle select agent infected animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

Loss – A failure to account for a select agent or toxin.

NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) – A document that provides risk assessment, physical containment, and biological containment provisions relating to genetic elements, recombinant nucleic acids and recombinant organisms of select agents and toxins.

Occupational Health – Occupational health is a cross-disciplinary area concerned with protecting the safety, health and welfare of people engaged in work or employment. The goals of occupational health programs include fostering a safe and healthy work environment. They also seek to protect co- workers, family members, employers, customers, and many others who might be affected by the workplace environment. Occupational health may involve interactions among many subject areas, including occupational medicine, occupational hygiene, public health, safety engineering, industrial engineering, chemistry, health physics, ergonomics and occupational health psychology.

Occupational Safety and Health Administration (OSHA) regulations – 29 CFR Parts 1910.1200 and 1910.1450 provides specific requirements for handling toxins.

Owner/Controller – An individual is considered an Owner/Controller if the individual owns 50 percent or more of the entity, and/or is a holder or owner of 50 percent or more of the entity’s voting stock, and/or is an individual who is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

Principal Investigator (PI) – The individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Point of Contact (POC) – The person serving as the coordinator or focal point of information concerning an activity or program.

Personal Protective Equipment (PPE) – Any protective clothing, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, goggles, or other garment or equipment designed to protect the wearer's body from injury by blunt or sharp impacts, electrical hazards, heat, chemicals, and infection, for job-related occupational safety and health purposes. PPE is used to reduce employee exposure to hazards when engineering and administrative controls are not feasible or effective to reduce these risks to acceptable levels. In these cases, PPE is often used in combination with BSCs and other devices that contain the agents, animals, or materials being handled to reduce risk of exposure or escape. In some situations in which it is impractical to work in BSCs, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

Purified Protein Derivative (PPD) test – A diagnostic tool used to determine exposure to tuberculosis bacilli. The PPD test consists of an intradermal injection of PPD tuberculin, and the size of induration is measured 48–72 hours later. This test is generally required as part of an occupational health program as an initial and ongoing assessment for personnel who work with animals. Also known as the Mantoux screening test, tuberculin sensitivity test, or Pirquet test.

Release – A discharge of a select agent or toxin outside the primary containment barrier due to failure in the containment system, an accidental spill, occupational exposure, natural hazard or a theft. Any incident that results in the activation of a post exposure medical surveillance/prophylaxis protocol must be reported as a release.

Responsible Official (RO) – The individual designated by an entity with the authority and control to ensure compliance with the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). The purpose of the RO is to provide an established point of contact for the entity concerning the application or other matters related to the entity registration.

Room – As used in this document, a “room” is the physical location where select agents or toxins are used, manipulated, or stored. A facility may contain multiple rooms where work is performed and/or select agents/toxins are stored. Also see “Suite”.

Secure Access Management Service (SAMS) – SAMS is a web site that allows public health partners and providers to access information and computer applications operated by the U.S. Centers for Disease Control and Prevention (CDC).

Security Risk Assessment (SRA) – Electronic records check performed by CJIS to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.

Select Agent and Toxin – The biological agents and toxins listed in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331 that have the potential to pose a severe threat to public health and safety, to animal health or products, or to plant health or products.

Suite – As used in this document, a “suite” is a collection of rooms with the same biosafety level (2, 3, or 4) that share a containment envelope or that are grouped together. A facility may have multiple suites where work is performed and/or select agents/toxins are stored. Also see “Room”.

Support Staff – An individual who provides an indirect service in support of the direct work with select agents or toxins but does not work with select agents or toxins or select agent infected animals, bedding or plant hosts. These personnel are SRA approved and registered with the FSAP because they could potentially gain access to select agents/toxins.

Theft – The unauthorized removal of a select agent or toxin.

Tier 1 Select Agents and Toxins – A subset of the select agents and toxins list that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety and have additional security requirements. This list can be found in the Form 1 instructions for Section 3 and at SelectAgents.gov.

United States Department of Agriculture (USDA) – The federal department that administers programs that provide leadership on food, agriculture, natural resources and related issues based on public policy, science and management

Work Objective – A description of the research goals and methods that will be performed under the direction of the PI(s), with specified select agents or toxins, in the indicated registered rooms.