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

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2018

The APHIS/CDC Form 1, *Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins*, is provided as individual Sections to assist entities in data input and revisions as necessary. Please enter information into the following sections and attachments, according to your entity's characteristics.

The APHIS/CDC Form 1, Application for Registration, 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 information requested in this form includes: facility information; a list of select agents or toxins to be possessed, used, or transferred by the entity; a list of individual(s) who will have access to select agents and toxins; characterization of the select agents and toxins and additional laboratory information. Submissions using expired forms or tables will not be accepted. The current, approved form can be downloaded from http://www.selectagents.gov/form1.html.

If you are completing the APHIS/CDC Form 1 for the first time or as part of your registration renewal, use this document for assistance in completing the APHIS/CDC Form 1 and submitting it to the Federal Select Agent Program (FSAP), either the Animal and Plant Health Inspection Service, Select Agent Program or Centers for Disease Control and Prevention, Division of Select Agents and Toxins.

Entities may also use this form to amend their registration. To apply for an amendment to a certificate of registration, an entity must submit relevant portion(s) of the APHIS/CDC Form 1 as described in the amendments section of this document to the FSAP.

Instructions for Completion of APHIS/CDC Form 1

OMB NO. 0579-0213 / 0920-0576

EXP DATE 11/30/2015

Prior to completing APHIS/CDC Form 1 ensure that you are using the current, OMB approved form and/or optional tables. Submissions using expired forms or tables will not be accepted. The current, approved form and optional tables can be downloaded from http://www.selectagents.gov/form1.html.

If you are completing the APHIS/CDC Form 1 for the first time, please review application instructions before completing and submitting your application for registration to APHIS or CDC.

If you are a registered entity and are submitting an amendment to your registration, review the Amendment Requirements section of this document to determine the submission requirements for the particular type(s) of amendment(s) you are requesting.

Overview

This form is organized in seven (7) sections. Sections 1 – 5 capture entity wide information, Section 6 captures information specific to each suite/room and Section 7 captures information about the work each PI will perform. Multiple Section 6s may be required if the entity has multiple suites/rooms, and multiple Section 7s may be required if the entity has multiple PIs. The structure of this form is designed to facilitate submittal of amendments.

Section 1 requests information about the entity and the Responsible Official (RO), Alternate Responsible Official (ARO), and Owner/Controller (if applicable). Information for the RO, ARO, and Owner/Controller (if applicable) is only captured in Section 1.

Section 2 is the RO certification statement.

Section 3 is a list of all select agents, toxins, and regulated nucleic acids for which the entity wishes to register.

Section 4 lists the individuals who will have access to select agents, toxins, and regulated nucleic acids at the entity. Information for RO/ARO, Owner/Controller (if applicable), and Principal Investigator (PI) is captured in Sections 1A and 7A, respectively.

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

Section 6 will be completed for each suite/room. Multiples suites or rooms may be included in this section only if all information captured here is the same for each suite/room listed.

Section 7 will be completed for each PI. Multiple PIs may be included in this section only if they conduct identical work with select agents or toxins. Attachments A through G (toxin, recombinant/synthetic DNA, animal, plant, arthropod, BSL3Ag, BSL4) may need to be completed based on the type of work being performed.

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Application Instructions

Amendment Instructions

Definitions and terms used throughout this document can be found in the Definitions Section at the end of the document.

Section 1A - Entity and Contact Information

Since all communication between a registering entity and APHIS and/or the CDC 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 1 information changes, you must immediately report the change(s) to APHIS or the CDC by submitting an update using the current OMB approved APHIS/CDC Form 1. Verbal change requests cannot be accepted. If further information or guidance is required contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

Entity Application Number

- Leave this field blank if this is a new application. This number is assigned to an entity after APHIS/CDC has accepted the initial application.

  Note: The Entity Application Number, also called the Entity ID number, can be located on a DOJ issuance letter, or the number can be provided by your file manager.

Current Registration Number

- Leave this field blank if this is a new application. The Current Registration Number is assigned to an entity after APHIS/CDC has approved an initial application or a subsequent renewal of an existing registration.

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 section below.

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:

  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.

  - **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 of which is distributed to its owners, directors, officers, members or stockholders and whose principle 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

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.

Responsible Official Information

Refer to the definition below when designating a RO:

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

Note: The role of the RO is independent of the organizational structure at the entity.

For additional information on the RO role and his/her responsibility to ensure compliance with the Select Agent Regulations, refer to the Responsible Official Guidance Document.

RO 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 RO's 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).

RO DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by CDC/APHIS and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

  Note: If the RO is also a PI, a corresponding Section 7 must be submitted.

RO Date of Birth

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

RO Business Email Address

- Provide the business email address for the RO listed above.
- Print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

RO Title

- Provide the institutional title for the RO listed above.

  Note: The role of the RO is independent of the organizational structure at the entity.

RO 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 Guidance for Suitability

Assessments for additional information on pre-access suitability and ongoing suitability assessments.

RO Business Telephone Number

- Provide the direct dial 10-digit telephone number for the RO listed above; include an extension, if required.

RO Business Fax Number

- Provide the 10-digit facsimile number for the RO listed above.

  Note: All official fax correspondence will be sent to the fax number specified for the RO unless specifically requested otherwise by the entity. This number should reflect the primary work location for the RO. The fax machine should have limited access due to the potentially sensitive nature of the documents.

RO Emergency Telephone Number

The purpose of this emergency contact number is to provide APHIS or the CDC 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 APHIS or the CDC is unable to reach the RO at his/her designated business number.

- Provide the direct dial 10-digit emergency telephone number for the RO listed above; include an extension, if required.

RO Mailing Address

- Provide a complete business mailing address for the RO listed above (NOT a post office box). The mailing address for the RO should reflect the primary duty station for the RO 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.

Alternate Responsible Official Information

Refer to the definition below when designating an ARO:

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.

Note: Multiple AROs may be specified.

ARO 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 ARO’s last name, first name and the date of birth must be identical to that provided on the FD-961 Form submitted to CJIS.

ARO DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by APHIS/CDC and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

  Note: If the ARO is also a PI, a corresponding Section 7 must be submitted.

ARO Date of Birth

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

ARO's Business Email Address

- Provide the email address for the ARO listed above.
- Print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net)

ARO Title

- Provide the institutional title for the ARO listed above.

  Note: The role of the ARO is independent of the organizational structure at the entity.

ARO Tier 1 Access

- Check box if this individual will have access (e.g., the ability to carry, use, or manipulate) 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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments.

ARO Business Telephone Number

- Provide the direct dial 10-digit telephone number for the ARO listed above; include an extension, if required.

ARO Business Fax Number

- Provide the 10-digit facsimile number for the ARO listed above.

  Note: All official fax correspondence will be sent to the fax number specified for the RO unless specifically requested by the entity.

ARO Emergency Telephone Number

The purpose of this emergency contact number is to provide APHIS or the CDC 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 APHIS or the CDC is unable to reach the ARO at his/her designated business number.

- Provide the direct dial 10-digit emergency telephone number for the ARO listed above; include an extension, if required.

ARO Mailing Address

- Provide a complete business mailing address for the ARO listed above (NOT a post office box). The mailing address for the ARO should reflect the primary duty station for the ARO 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

Refer to the definition below when specifying an 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.

Note: Multiple Owner/Controllers may be specified.

Owner/Controller 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 Owner/Controller's last name, first name and the date of birth must be identical to that provided on the FD-961 Form submitted to CJIS.

Owner/Controller DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by CDC/APHIS and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

  Note: If the Owner/Controller is also a PI, a corresponding Section 7 must be submitted.

Owner/Controller Date of Birth

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

Owner/Controller 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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments.

Section 1B - Certificate of Responsibility

RO/ARO Signatures

- If your entity does not have a current registration with either APHIS or the CDC, you must submit written or digital signatures and signing date from the RO and all AROs.
- If submitting an amendment to a pending application to change/update name for the RO, add/remove/update name for an ARO, or update entity information, you must submit written or digital signatures from the RO and all AROs using Section 1B of APHIS/CDC Form 1.

Section 1C - Entity Abstract

•Header Information

This Submission Is

- Check “A new registration” to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select “An update to an existing registration” to amend your entity’s APHIS/CDC Form 1 or indicate “A renewal” if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

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.

If further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Section 2 - RO Certification of Personnel and Facility Activities

Header Information

This Submission Is

- Check “A new registration” to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select “An update to an existing registration” to amend your entity’s APHIS/CDC Form 1 or indicate “A renewal” if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

RO Signature

- If your entity does not have a current registration with either APHIS or the CDC, the RO must read each line and manually or digitally sign where indicated. An ARO may not sign in place of the RO. A completed Section 2 is also required as part of the complete Form 1 required for registration renewal.

  Note: Refer to the Responsible Official Guidance Document.

  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 application or amendment submitted to the FSAP, 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. • The entity must develop and implement a site-specific security plan that is sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. In developing a security plan, it is recommended that an entity or individual refer to the Security Guidance for Select Agent or Toxin Facilities.

Additional Information

- Access to select agents or toxins must only be granted to those individuals with access approval from the APHIS Administrator or HHS Secretary following a security risk assessment conducted by the Attorney General. In addition, if the entity is registered for Tier 1 select agents and toxins, the entity must limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or APHIS Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment.

- The entity must develop and implement an agent-specific, site-specific biosafety/biocontainment plan that meets the requirements of Section 12 of the Select Agent Regulations. In developing a biosafety/biocontainment plan, an individual or entity should consider the current edition of the BMBL, the Occupational Safety and Health Administration (OSHA) regulations in 29 CFR Parts 1910.1200 and 1910.1450 for toxins, and the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules for recombinant work. The biosafety/biocontainment plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

- The entity must develop and implement an incident response plan that meets the requirements of Section 14 of the Select Agent Regulations. In developing an incident response plan, the entity should consider the Incident Response in Select Agent or Toxin Facilities guidance available at SelectAgents.gov. The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin.

- The security, biosafety and incident response plans must be reviewed and revised, as necessary, after any drill or exercise and after any incident. The review must occur at least annually. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plans.

- 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 before he/she has such access. 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

Additional Information
for 3 years. Refer to the Guidance for Training Requirements for additional information.

Section 3 - Select Agents and Toxins

Complete the Select Agent/Toxin table to indicate each select agent (genus and species), toxin or regulated nucleic acid for which the entity wishes to register.

If further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

- Check “A new registration” to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select “An update to an existing registration” to amend your entity’s APHIS/CDC Form 1 or indicate “A renewal” if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

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:

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.

Notes: a) An entity must list at least one select agent or toxin in order to be registered with the FSAP.

b) An entity is not authorized to possess, use and/or transfer select agents and/or toxins without an approved registration certificate.

c) Entities must register for the possession, use, or transfer of select agents and toxins, including regulated nucleic acids (e.g., positive strand RNA viruses) and recombinant and/or synthetic construct(s) that encode for the functional form of select toxins 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).

d) An entity should consider the current edition of the BMBL containment recommendations for each select agent and toxin based on the entity's proposed work objectives. The biosafety level of the laboratory where the select agent or toxin will be used should be consistent with the BMBL guidelines.

e) 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. The exclusion of a strain of a select biological agent or toxin is based on adequate evidence that it does not pose a severe threat to public health and safety, and/or animal health, plant health, and animal or plant products. Excluded strains are usually sought out and approved for use in basic or applied research, as positive controls, for diagnostic assay development, or for the development of vaccines and therapeutics. However, 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. Unless specifically excluded under 42 CFR 73.3 and 73.4, 7 CFR 331.3 and 331.4, and 9 CFR 121.3 and 121.4, any select agent or toxin is subject to the entirety of the Select Agent Regulations. The current list of select agent exclusions can be viewed at Select Agents and Toxins Exclusions.

f) 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.

- List only one select agent or toxin per box.
- Do not list any biological agents or toxins that are not on the current, approved Select Agent/Toxin List.
- Enter the select agent or toxin in the appropriate column (HHS, Overlap, USDA Agents) exactly as they appear on the current, approved Select Agent/Toxin List. Do not abbreviate.
- If you need to remove an entry, choose the "blank" at the top of the drop down list in the PDF.
- Enter regulated nucleic acids exactly as they appear below:

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

- Section 3 must include regulated nucleic acids listed above 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).
- 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.

Check if Select Agent/Toxin Possessed

- New applicants who do not already have an approved registration certificate must leave this box 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 will need to submit an updated Section 3 and Section 7B indicating which select agents and/or toxins are in its possession within **7 days** of acquiring those agents or toxins. See Amendment Requirements for how to update this information upon acquiring a select agent and/or toxin.

- Indicate toxin is possessed if you are registered for a select toxin but possess below the regulated amount.

  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. Refer to the Policy Statement posted to the FSAP website August 25, 2014 for more information.

Examples for Completing the Section 3 Table

This section is intended to provide examples on how to complete the Section 3 table for the most common application conditions.

- **Example:** An entity wishes to register for work with two select agents, *Bacillus anthracis* and *Yersinia pestis*. The entity has not yet been approved to work with select agents or toxins.

HHS Agents and Toxins (Check if Possessed)	Overlap Agents and Toxins (Check if Possessed)	USDA Agents and Toxins (Check if Possessed)
Yersinia pestis ☐	Bacillus anthracis ☐	☐

- **Example:** An entity wishes to register for work with SARS-associated coronavirus and its viral genomic material. The entity has not yet been approved to work with select agents or toxins.

HHS Agents and Toxins (Check if Possessed)	Overlap Agents and Toxins (Check if Possessed)	USDA Agents and Toxins (Check if Possessed)
SARS-associated coronavirus (SARS-CoV) ☐	☐	☐
Genomic material - SARS-associated coronavirus (SARS-CoV) ☐	☐	☐

Section 4A - Laboratorians and Animal Care Staff

Complete this section by providing the information for all Laboratorians and Animal Care Staff. 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 [7 CFR Part 331.10(b), 9 CFR Part 121.10 and 42 CFR Part 73.10(b)].

This section can be completed using either the pdf or excel version found at http://www.selectagents.gov/form1.html. If further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

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, Question 1 and manipulates select agents or toxins or handles select agent infected animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

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Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

Tier 1 Access

- Check box if this individual will have access or have the ability to access Tier 1 select agents or toxins or handle Tier 1 select agent inoculated animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

  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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments.

Name (Last and First name)

- Provide the full name of the individual.

  Note: 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.

DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by CDC/APHIS and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

Date of Birth

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

Role

- Select the role below which most closely matches the individual’s primary responsibilities:
  - Laboratorian
  - Animal Care Staff

  Note: Select only one role per individual.

Supervising Principal Investigator (PI)

- For each individual, you must list the PI or PIs who control(s) the use of the select agents and toxins that each Laboratorian or Animal Care Staff will work with.
- If an individual works with more than one PI, list each principal investigator in the “Supervising Principal Investigator” column.
- If the person will work with all PIs, the term "All PIs" should be listed in the “Supervising Principal Investigator” column for that individual.

RO/ARO Signature

- An RO or ARO must manually or digitally sign and date Section 4A. If multiple pages are needed, the RO/ARO may sign and date the last page.

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 before he/she has such access. 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

Additional Information
upon request and maintained for 3 years. Refer to the Guidance for Training Requirements for additional information.

Section 4B - Support Staff

Complete this section by providing the information for all Support Staff. 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 [7 CFR Part 331.10(b), 9 CFR Part 121.10 and 42 CFR Part 73.10(b)].

This section can be completed using either the pdf or excel version found at http://www.selectagents.gov/form1.html. If further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Refer to the definition below when specifying Support Staff:

- **Support Staff –** an individual who provides an indirect service in support of the direct work with select agents or toxins, does not work with select agents or toxins or select agent infected animals, bedding or plant hosts, but could potentially gain access to select agents/toxins.

Header Information

This Submission Is

- Check “A new registration” to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select “An update to an existing registration” to amend your entity’s APHIS/CDC Form 1 or indicate “A renewal” if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments.

Name

- Provide the full name of the applicant.

Note: 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.

DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by CDC/APHIS and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

Date of Birth

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

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.

RO/ARO Signature

- An RO or ARO must manually or digitally sign and date Section 4B. If multiple pages are needed, the RO/ARO may sign and date the last page. No supervising PI is required to be designated as the RO is responsible for ensuring compliance with the Select Agent Regulations for these personnel.

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 before he/she has such access. 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 Training Requirements for additional information.

Section 4C - Unescorted Visitors

Complete this section by providing the information for **all** visitors that are SRA approved at another entity and **will be performing work with, or have access to**, select agents and/or toxins at your facility. 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 [7 CFR Part 331.10(b), 9 CFR Part 121.10 and 42 CFR Part 73.10(b)].

This section can be completed using either the pdf or excel version found at http://www.selectagents.gov/form1.html. If further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Visitors that are continually escorted as described in Section 11(d)(2) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) do not require the documentation below. These individuals must not work with, have access to, or have the ability to have access to select agents or toxins while visiting registered room(s).

Unescorted Visitor – an individual who has access approval at a registered entity (the "home" entity) other than yours (the "host entity") and will temporarily work with, or have access to, select agents or toxins, and receive site-specific training, at your registered entity. Additional information for visitors can be found on the Select Agents website located at Security Risk Assessments FAQ's under the Visitors section.

Note: Visitors should only be listed on Section 4C.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

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Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments for visitors.

Name

- Provide the full name of the applicant.

  Note: 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.

Home Entity DOJ Unique Identifier Number

- Enter the DOJ Number the individual is assigned at their home entity. A home entity is defined as the entity where the individual's current SRA approval was granted.

  Note: The DOJ number for the home entity will continue to be listed for the individual on subsequent Section 4C submissions. Do not use the Host Entity DOJ number**.**

Unescorted Visitor Date of Birth

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

Unescorted Visitor Supervising Principal Investigator

- For each individual you must list the PI or PIs who control(s) the use of the select agents and toxins that the person will work with or provide support services for.
- If an individual works with more than one PI, list each PI in the supervising PI column.
- If the person will work with or support all PIs, the term "All PIs" should be listed in the PI column for that individual.

RO/ARO Signature

- An RO or ARO must manually or digitally sign and date Section 4C. If multiple pages are needed, the RO/ARO may sign and date the last page.

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 before he/she has such access. 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 Training Requirements for additional information.

Examples for Completing the Section 4 Tables

This section is intended to provide examples on how to complete the Section 4 tables for the most common application conditions.

- **Example:**
  - An entity has 3 individuals who will be working directly with Tier 1 select agents or toxins under the direct supervision of PI Smith.
  - The entity also has 1 individual who will be working directly with non-Tier 1 select agents or toxins under the direct supervision of PI J. Clark.
  - The entity also has 2 individuals who perform support work, including maintenance and biosafety surveys of Tier 1 laboratory areas. These individuals do not directly work with select agents or toxins, but have the ability to gain access to Tier 1 select agents and toxins.
  - Finally, the entity is requesting that two unescorted visitors be added. These two visitors will have Tier 1 access and the Home Entity RO has submitted all required documentation to the Host Entity, including the individuals DOJ Numbers at the Home Entity. These individuals will be onsite for a brief training program supervised by PI Smith lasting less than 30 days and the Home Entity RO/ARO has also submitted documentation of the pre-access suitability assessment conducted for these individuals.

    Note: These individuals may be subject to the Host Entity's pre-access suitability program and will be subject to the Host Entity's ongoing suitability assessment program. For additional information, refer to the Guidance for Suitability Assessments for visitors.

Section 4A - Laboratorians and Animal Care Staff

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role	Supervising Principal Investigator
☑	Jones	Mary		01/01/1970	Laboratorian	John Smith
☑	Johnson	Bill		02/02/1980	Laboratorian	John Smith
☑	Taylor	John		03/03/1985	Animal Care Staff	John Smith
☐	White	Doug		04/01/1990	Animal Care Staff	J. Clark

Section 4B - Support Staff

Tier 1 Access	Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Role
☑	Williams	Sue		12/22/1945	Maintenance
☑	Anderson	James		03/03/1974	Safety

Section 4C - Unescorted Visitors

Tier 1 Access	Last Name	First Name	Home Entity DOJ Unique Identifier Number	Date of Birth (mm/dd/yyyy)	Supervising Principal Investigator
☑	Johnson	Christy	C-CJ-123456	01/01/1975	John Smith
☑	Simmons	Andrew	C-AS-654321	02/02/1979	John Smith

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".

Additional guidance is provided below; if further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

This Submission Is

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Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

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Question 1, 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.

Question 2, 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 Guidance for Select Agent or Toxin Facilities.

Question 3, 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 Guidance for Select Agent or Toxin Facilities.
- 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.

Question 4, 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 Guidance for Suitability Assessments.

Question 5, 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.

Question 6, 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 all applicable characteristics.
- 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.

Question 7, Shipping/Receiving

- 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 whether the entity is employing “lost in the crowd” practices. Refer to Guidance on the Shipment and Receipt of Packages with 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 Security Guidance for Select Agent or Toxin Facilities.

Question 8, 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.
- 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.

Question 9, 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 Guidance for Select Agent or Toxin Facilities.

Question 10, 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 Guidance for Select Agent or Toxin Facilities.

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".

Additional guidance is provided below; if further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.
  Note: This header information must be consistent for all sections and attachments submitted at one time.

Question 1, 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.

Question 2, 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".

Question 3, 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”.

Question 4, 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”.

  Note: Individuals with access to Tier 1 select agents and toxins must be enrolled in the occupational health program. For additional information on Tier 1 select agents and toxins occupational health programs, refer to the Occupational Health Program Guidance Document for Working with Tier 1 Select Agents or Toxins.

Question 5, 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.

Question 6, Sharps

- 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”.

Question 7, 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”.

Question 8, 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".

Additional guidance is provided below; if further information or guidance is required, contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: This header information must be consistent for all sections and attachments submitted at one time.

Question 1, Entry to the Facility

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

Question 2, 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 Verifying Inspectors and Confidentially Agreement Policy.

Question 3, Security

- 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.

Question 4, Respirator

- 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”.

Question 5, 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.

Question 6, 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”.

Question 7, 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.

Question 8, Additional entry requirements

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

Note: CDC and APHIS are 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.

Section 6A - Building and Suite/Room Specific Security

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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Note: A corresponding Section 6B will be required for each Section 6A with a unique room and/or suite identified in the header.

Note: A complete Section 6 must be submitted for each unique room and/or suite. If a series of rooms and/or suites would result in an identical Section 6 being completed, multiple rooms and/or suites may be listed in the header.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

Building/Suite or Room:

- Fill out the Building and Suite/Room which is to be registered for select agents and/or toxins.

Question 1, 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 Guidance for Select Agent or Toxin Facilities.

Question 2, 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 Guidance for Select Agent or Toxin Facilities.

  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.

Question 3, 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.

Question 4, Interior Security Measures

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

Question 5, 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.

Question 6, 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.

Question 7, 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”.

Question 8, 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”.

Question 9, 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”.

Question 10, 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”.

Section 6B - Suite/Room Physical Information

This section is used to assess the physical information for each suite and/or room at an entity. Multiple, complete Section 6's may need to be submitted depending on the number of rooms and/or suites 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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Note: A complete Section 6 must be submitted for each unique suite and/or room. If a series of rooms and/or suites would result in an identical Section 6 being completed, multiple rooms and/or suites can be listed in the header.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

Building/Suite or Room

- Fill out the Building and Suite/Room which is to be registered for select agents and/or toxins.

Floor Plans

- Provide a floor plan for each suite and/or room to be registered.
- The floor plan for each suite or room should include, as applicable: points of entry and/or egress for personnel, 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)], Heating Ventilation and Air Conditioning (HVAC) supply and exhaust vents, and cage washing area.

  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 the first page of Section 6B with the header completed and floor plan. Proceed to Section 7.

Question 1, Biological Safety Level

- Indicate the biological safety level(s) at which the laboratory is operated. If the laboratory is operated at more than one safety level (e.g., BSL3 and ABSL3) or if the laboratory can operate at different containment levels and the safety level changes based on usage (e.g., ABSL3 and ABSL4), indicate all applicable safety levels.
- Biological Safety Levels

Biosafety Levels
Biosafety Level 2 = BSL2 Biosafety Level 3 = BSL3 Biosafety Level 4 = BSL4
Animal Biosafety Levels
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
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 Biosafety Levels
Arthropod BSL 3 = ACL3 Arthropod BSL4 = ACL4

Note: The entity's biosafety or biocontainment plan must define the operational and procedural safeguards that are implemented prior to operating a suite/room at different containment levels when the safety level changes based on usage.

Note: Rooms within a suite should be included together in one Section 6 provided that the rooms operate as a unit at the same containment level.

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

Note: Safety levels should be determined in accordance with guidance found in the current edition of the BMBL.

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 DNA Molecules.

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

Question 2, 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”.

Question 3, 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”.

Question 4, Eyewash

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

Question 5, 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:** 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”.

  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.

Note: If you have questions about liquid effluents, please see "effluents" in the Definitions section.

Note: If BSL3Ag, BSL4, or ABSL4 is selected as the biosafety level the laboratory is operated at, proceed to Section 7.

Question 6, 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".

Question 7, 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".

Question 8, 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.

Question 9, 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.

Question 10, 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".

Question 11, Exhaust

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

Question 12, 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 laboratory is a suite, record the specific rooms that have HEPA filtered exhaust or record "All" if all rooms in the suite are HEPA filtered.
- 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.

Question 13, Emergency Shower

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

Question 14, Floor Drains

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

Question 15, 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".

Question 16, Mechanical Cage Washer

- If a mechanical cage washer is present within the facility, check "Yes".
- 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".

Question 17, 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 - Principal Investigator Information 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 Section 7s may need to be submitted depending on the number of Principal Investigators 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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Note: A complete Section 7 must be submitted for each PI. If multiple PIs conduct identical work with select agents and toxins, complete one Section 7 and list all of the relevant PIs in the header.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

Principal Investigator

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 of that project or program.

PI Name

- Provide the individual's first name and last name or surname, without use of nicknames.

PI DOJ Number

- The DOJ Number field should be left blank for new applications. This number will be assigned by CDC/APHIS and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

PI Date of Birth

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

PI Tier 1 Access

- Check box if PI will have access to Tier 1 select agents or 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 Guidance for Suitability Assessments for additional information on pre-access suitability and ongoing suitability assessments for visitors.

Update PI Header button

If entering information into a complete Section 7 (inclusive of Section 7A, 7B, and 7C) or into Section 7A which grows onto a second page, the Update PI Header button must be used to populate the PI name(s) in the header of all subsequent pages.

Section 7A Table

This table lists those select agents/toxins which will be under the direct control of the PI listed in the Section 7 header. Additionally, the laboratory locations (including safety levels) and storage locations should be listed for each select agent/toxin.

Select Agent/Toxin/Regulated Nucleic Acid

- An entity must list at least one select agent or toxin in order to be registered with the FSAP.
- List only one select agent, toxin, or regulated nucleic acid per row.
- Do not list any biological agents or toxins that are not on the current, approved Select Agent/Toxin List. If you possess an agent or toxin that you believe should be included in Section 7A but is not on the list, consult with your designated FSAP representative or contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.
- Do not abbreviate the name of a select agent or toxin. Enter select agents or toxins exactly as they appear on the current, approved Select Agent/Toxin List.
- Enter regulated nucleic acids exactly as they appear below:

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

HHS Select Agent and Toxin 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

Location

- Enter the building and suite/room for each area to be registered.

  Note: Multiple rooms may be listed in the same row if:

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

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.

    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 FSAP representative or contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Laboratory Safety Level

- Enter the safety level for the location. If multiple safety levels apply (e.g., BSL3, NIHBL3, ABSL3), indicate all safety levels.
- It is acceptable to enter additional laboratory safety levels on a single row providing that the containment level number is the same (e.g., BSL3/ABSL3/NIHBL3, or BSL2/ABSL2).
  - 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, leave this column blank.
- 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
Biosafety Level 2 = BSL2
Biosafety Level 3 = BSL3
Biosafety Level 4 = BSL4

Biosafety Levels
Animal Biosafety Levels
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
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 Biosafety Levels
Arthropod BSL 3 = ACL3 Arthropod BSL4 = ACL4

Note: The selected laboratory safety level for each laboratory area should be consistent with the containment recommendations in the current edition of the BMBL for each select agent and toxin.

Note: The selected laboratory safety level for each laboratory area used for the manipulation of regulated nucleic acids should be indicated. The safety level should be consistent with the work performed (e.g., NIHBL2 for manipulation of recombinant DNA in a BSL2 laboratory) and with the Laboratory Facilities (Secondary Barriers) standards in the current edition of the BMBL for each laboratory area.

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 DNA Molecules.

Suite Legend

- If suites are designated in the location column, identify the suite name at the bottom of the page in the space provided and indicate all individual room designations which comprise the suite.

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

Examples for Completing the Section 7A Table

Example 1: An entity wishes to work with two select agents, *Bacillus anthracis* and *Yersinia pestis* in Building 1. Work with both agents will be conducted by PI Smith in Room 100 at BSL3 and both agents will only be stored in Room 103.

PI Last Name	PI First Name	PI DOJ Number	PI Date Of Birth	PI Tier 1 Access
Smith	John		01/01/1970	☑

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Building	Suite / Room	Lab	Storage	
Bacillus anthracis	1	100	☑	☐	BSL3
Yersinia pestis	1	100	☑	☐	BSL3
Bacillus anthracis	1	103	☐	☑	
Yersinia pestis	1	103	☐	☑	

Note: If a room is designated as a storage room only, leave the Laboratory Safety Level column blank.

Example 2: An entity wishes to work with one select agent, avian influenza virus in building XYZ. Work with avian influenza virus will be conducted by PI Anderson in Suite 800, which is comprised of Rooms 800, 801 and 802. The entity will also perform recombinant work with avian influenza virus. The safety level of the suite is BSL3 and all rooms in the suite will also be used for storage.

PI Last Name	PI First Name	PI DOJ Number	PI Date Of Birth	PI Tier 1 Access
Anderson	Jane		01/01/1962	☐

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Building	Suite / Room	Lab	Storage	
Avian influenza virus	XYZ	Suite 800	☑	☑	BSL3 NIHBL3

Suite Legend: (If Applicable) Suite 800 = Rooms 800, 801, and 802.

Example 3: An entity wishes to work with two select agents, *Brucella abortus* and *Yersinia pestis* in Building 1. Work with both agents will be conducted by PI Jones in Rooms 100, 200, 300, 400 and 500 at BSL3. Laboratory Room 500 will also serve as the only storage room for both agents.

PI Last Name	PI First Name	PI DOJ Number	PI Date Of Birth	PI Tier 1 Access
Jones	Robert		01/01/1970	☑

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Building	Suite / Room	Lab	Storage	
Brucella abortus	1	100, 200, 300, 400	☑	☐	BSL3
Yersinia pestis	1	100, 200, 300, 400	☑	☐	BSL3
Brucella abortus	1	500	☑	☑	BSL3
Yersinia pestis	1	500	☑	☑	BSL3

Note: Multiple rooms may be listed for the same agent if:

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

Note: If a room is designated as a laboratory and a storage room, enter the safety level for the laboratory only.

Example 4: An entity will perform clinical diagnostic work using *Bacillus anthracis* Pasteur strain, excluded strains only of *Francisella tularensis*, *Yersinia pestis*, and ricin A-chain. This entity will transfer or destroy any samples confirmed as select agents or toxins within seven days of identification.

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Building	Suite / Room	Lab	Storage	
Bacillus anthracis Pasteur strain	PHL	Suite 4-93	☑	☑	BSL3

Suite Legend: (If Applicable) Suite 4-93 = Rooms 4-89, 4-91, and 4-95.

Example 5: An entity has two PI's performing the same work with SARS-CoV. Drs. Werner and Sun propagate SARS-CoV virus, modify viral genes and test pathogenesis of these recombinant viruses in the natural host.

PI Last Name	PI First Name	PI DOJ Number	PI Date of Birth	PI Tier 1 Access	
Werner	Jennifer		3/21/1962	☐	Delete
Sun	Xie		11/8/1973	☐	Delete

Update PI Header | Add Row

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)	
	Building	Suite / Room	Lab	Storage		
SARS-associated coronavirus (SARS-CoV)	MSTB	Suite B28	☑	☑	BSL3 NIHBL3 ABSL3	Delete
Genomic material - SARS-associated coronavirus (SARS-CoV)	MSTB	615, 617	☑	☑	BSL2 NIHBL2	Delete

Add Row

Suite Legend: (If Applicable) Suite B28 = Rooms B28A, B28B, B28C, B28D, B28E, and B28F

Example 6: An entity is requesting to produce regulated quantities of botulinum neurotoxin using a recombinant construct encoding the functional toxin in Building C. Within Building C, Room 301 will be operated at BSL2 for work with botulinum neurotoxin and manipulation of a recombinant nucleic acids encoding botulinum neurotoxin under the direction of PI Jane Smith. Both botulinum neurotoxin and the recombinant nucleic acids encoding botulinum neurotoxin will be stored in Room 303 in a locked freezer.

PI Last Name	PI First Name	PI DOJ Number	PI Date Of Birth	PI Tier 1 Access
Smith	John		01/01/1970	☑

Select Agent / Toxin / Regulated Nucleic Acid	Location		Laboratory or Storage (Select one or both)		Laboratory Safety Level (Leave blank if storage only)
	Building	Suite / Room	Lab	Storage	
Botulinum neurotoxins	C	301	☑	☐	BSL2
Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin	C	301	☑	☐	NIHBL2
Botulinum neurotoxins	C	303	☐	☑	
Recombinant/synthetic nucleic acids encoding Botulinum neurotoxin	C	303	☐	☑	

Section 7B - Strain or Serotype Designation Information

This section is used to list the inventory's strain or serotype designations for the Principal Investigator indicated in the header. This section can be completed using either the pdf or excel version found at http://www.selectagents.gov/form1.html.

If further information or guidance is required contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information (if completing a stand-alone Section 7B only)

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

PI

- Fill out the name of the Principal Investigator(s) for which the Section 7 is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Select Agent/Toxin

- List only one select agent, toxin or regulated nucleic acid per row.
- Enter select agents or toxins exactly as they appear on the current, approved Select Agent/Toxin List. Do not abbreviate.
- Do not list any biological agents or toxins that are not on the current, approved Select Agent/Toxin List

Strain or Serotype Designations

- For new applications, list "TBA" (To Be Acquired) for each select agent, toxin or regulated nucleic acid.

Once your entity is registered, complete the table as follows:

- List only one strain or serotype per row.

- List the strain or serotype designation(s) for all select agents and toxins listed in Section 7A only if known, or "TBD" (To Be Determined) if strains of the agent are defined and used scientifically, but are unknown to the entity (e.g., diagnostic samples that were not identified to the strain level).
- If you do not yet possess the select agent, toxin, or regulated nucleic acid but intend to acquire it in the future, indicate "TBA" (To Be Acquired) as the strain designation.
- Do not list strains excluded from the Select Agent Regulations.
- **A strain or serotype is defined,** for the purposes of the APHIS/CDC Form 1, 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 breed or variety (e.g., Ames strain of *Bacillus anthracis*). For agents that have been genetically modified due to passage in vivo or in vitro and have become differentiated from the parental organism, the modified agent or toxin should be recorded as a separate strain on the strain table (examples may include: extended in vitro passage under increasing concentrations of one or more antimicrobials in order to generate a desired enhanced resistance profile; in vivo passage of an attenuated strain to select for the restoration of virulence). Additional guidance is provided below for select agent strain designations and toxin types, but may not be all inclusive of "unique" select agent strains or toxin types an entity may possess.
- **For select bacterial/fungal agents**, if a unique phenotypic or genotypic marker is purposely enriched/selected for or introduced to differentiate progeny from the parent organism then this needs to be recorded as a "unique" strain on the strain table.
    - Select agents resistant to specific antimicrobials should be designated using generally accepted nomenclature (e.g., Y.p. xyzK237A CmR), if characterized. Additional information for the introduction of antimicrobial resistance must be provided regarding these experiments in Attachment B.
    - For agents that have been genetically modified due to the introduction of foreign genes (whether integrating into the chromosome or maintained exogenously) or the modification or deletion of genetic elements, the modified strain should be recorded as a separate strain on the strain table. Recombinant select agents should designated using generally accepted nomenclature (e.g., B.ps.Δxyz::zeo Δabc::kan; B.m. Δxyz::zeo (pBHR2abc::kan)). Additional information regarding these experiments should be described in Attachment B.
- **For select agent viruses,** if a unique phenotypic/genotypic marker is purposely used to differentiate a virus from the parent strain then this needs to be recorded as a "unique" strain on the strain table.
    - For genomic material of select agent viruses, indicate the parent strain used for viral nucleic acid extraction.
    - Select viruses resistant to specific antivirals should be designated using generally accepted nomenclature, if characterized. Additional information for the introduction of antiviral resistance must be provided regarding these experiments in Attachment B.
    - Recombinant and/or synthetic nucleic acids capable of producing infectious form(s) of select agent viruses should be designated in the strain table. Special emphasis should be given to recombinant constructs containing select agent genes that (a) can generate a live, infectious virus [including chimeras] and (b) could produce a virus with increased pathogenic potential when compared to the parent virus. Additional information regarding these experiments should be described in Attachment B.

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.

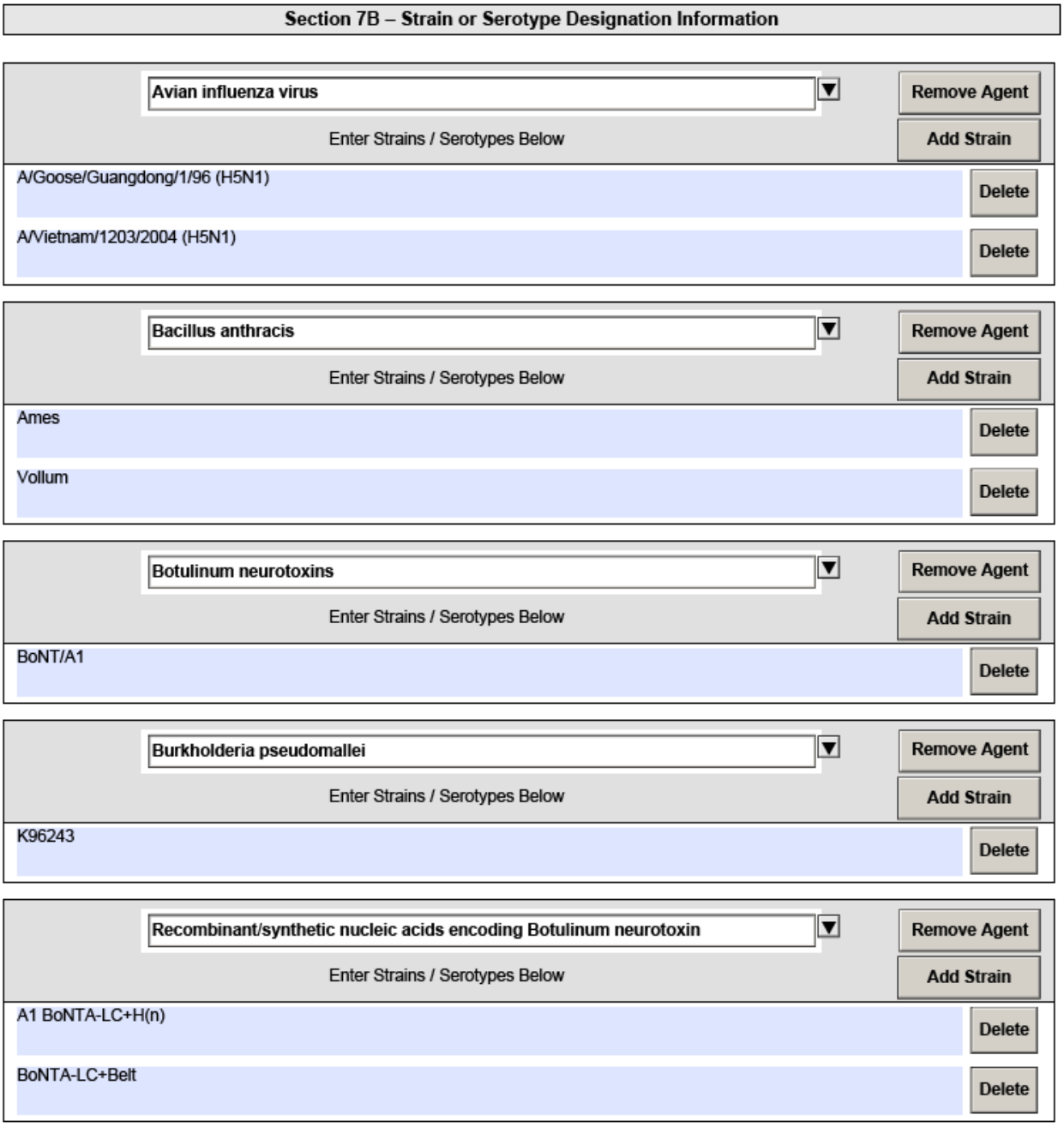
- **For select toxins,** indicate the serotype and subtype of each toxin (e.g., botulinum neurotoxin, BoNT/A1). If a "unique" phenotypic/genotypic marker is used to purposely differentiate toxin types, then this needs to be recorded as a "unique" subtype on the strain table.
    - For recombinant and/or synthetic nucleic acids that encode for the functional form(s) of 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, record the gene(s) that encode for the functional form(s) of the select toxin (e.g., BoNTA-LC+Belt). Any genetic modifications of the toxin gene(s) should also be indicated.
    - Additional information regarding the deliberate formation of recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins or subunits of those toxins must be described in Attachment B.

- Genetic modification of select agents or toxins should be designated in the strain table and described in Attachment B. For the purposes of APHIS/CDC Form 1, a distinct set of genetic modifications may be defined as a group of genetic mutations that (a) were generated using a common technique (e.g., in a single set of related experiments) and (b) are expected to encode gene products with a similar set of pathogenic characteristics. For example, a set of mutants could be entered in the strain table with a single entry stating "randomly-generated transposon mutants of *Bacillus anthracis* Ames for vaccine development", "50bp overlapping deletion mutants of Botulinum toxin A1 for use in pathogenesis studies", "mutants generated by DNA shuffling of the protective antigen (PA) of *Bacillus anthracis* (Ames) for vaccine development", "mutants of EEE (NJ-60) that remove the non-structural genes to generate a replicon containing only the structural genes and a reporter gene", or "the 5' (structural) genes of VEE (V3000) with the 3' (non-structural) genes of Sindbis, rearranged to test for attenuation and gene-order effects". Targeted mutagenesis where the characteristic is known should be designated separately as unique strains or serotypes.
- 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.
- **Updated strain information should be: 1) maintained on a real time basis; 2) submitted quarterly if strain related changes in your entity's inventory occur; or 3) submitted annually if no strain related changes have occurred in your entity's inventory since your last submission.**

Note: At any time the FSAP may request an accurate listing of all select agent and toxin strains possessed by your entity. One document containing the strain information for your entity's complete inventory or individual documents listing the strain information for each PI's inventory may be submitted.

Example for Completing the Section 7B Table

Following FSAP approval, PI Jones acquires strains for the following select agents and toxins.



Section 7C - Description of Work

This section captures information about the work each Principal Investigator performs. 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 depending on the work performed.

Header Information (if completing a stand-alone Section 7C only)

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

PI

- Fill out the name of the Principal Investigator(s) for which the Section 7 is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Question 1, Objective of Work

- For each select agent and/or toxin listed in Section 7A, indicate the biosafety level and objective of work. Multiple select agents and/or toxins may be listed together if the biosafety level and objective of work are the same.
- The objective of work should include a description of the methodologies and laboratory procedures. The statement should indicate any in vitro and/or in vivo assays used for research, any aerosolization protocols involving select agents and toxins, and/or identification of the select agents/functional toxins listed in Section 7A.
- 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 no work is being performed with a select agent, then indicate "storage only".
- It is acceptable to enter additional laboratory safety levels on a single row providing that the containment level number is the same (e.g., BSL3/ABSL3/NIHBL3, or BSL2/ABSL2).

Example for Completing the Section 7C Table

PI is performing diagnostic work with *Brucella* species at BSL2 and research at BSL3.

Select Agent(s) / Toxin(s)
Brucella abortus
Brucella melitensis
Brucella suis

Objective of Work	Biosafety Level(s): BSL2
Perform molecular diagnostic assays for the detection of select agents in human clinical samples. This work will include the propagation of agents on solid media and extraction of genomic material.	

Select Agent(s) / Toxin(s)
Brucella abortus
Brucella melitensis
Brucella suis

Objective of Work	Biosafety Level(s): BSL3
The goal of this work is to define key bacterial virulence determinants required to maintain an active infection within phagocytes. Regulation of antioxidant activity, copper uptake, and the utilization of alternative sigma factors are three primary bacterial host-mediated responses that will be investigated during these studies. All work with viable, select agents will be conducted under BSL-3 and ABSL-3 containment unless otherwise stated. Mutants of *Brucella spp.* will be constructed using gene replacement methodologies and oligonucleotide-mediated, site-directed mutagenesis. The generation of intermediate genetic constructs, starting with wild-type bacteria, will employ kanamycin and ampicillin resistance determinants as selective markers. The ultimate goal will be the construction of bacterial strain derivatives with "clean" deletions and gene "knock-out" insertions devoid of selective markers. DNA extracted from all wild-type *Brucella spp.* and mutant derivatives will be validated as non-viable and non-infectious, prior to removal to a BSL-2 laboratory, for sub-cloning and further genetic manipulation in strains of *E. coli* K-12. Shuttle vectors for homologous recombination within wild-type *Brucella spp.* will consist of a backbone containing antibiotic resistance determinants and homologous markers for mutational purposes (as described above). Recombinant plasmid constructs will be introduced into wild-type bacteria by electroporation, and recovered by growth in broth and solid media. Antibiotic resistance marker-free deletion mutant strains will be compared to wild-type bacteria in experiments employing *ex vivo* and *in vivo* models of infection. *Ex vivo* studies will employ immortalized cell culture lines and peritoneal macrophages harvested from mice. Techniques will include low-speed micro-well plate centrifugation using sealed plates for bacterial infection, microscopy for cell confluence assays, and viable plate counts for bacterial cell enumeration. Mice will be injected with wild-type or mutant bacterial strains via the intraperitoneal route. These studies will include tissue harvesting (spleen and kidney), homogenization, and plating for bacterial cell survival. Standard ABSL-3 biosafety practices will be conducted in accordance to the BMBL, 5th edition.	

Note: The objectives of work above are regulated under Section 4(c)(3). The antibiotics in this example, ampicillin and kanamycin are not used to control *Brucella abortus, Brucella melitensis, or Brucella suis* in humans or veterinary medicine. Therefore, this work would not meet the definition of a restricted experiment under Section 13 as long as the method used to confer resistance to kanamycin does not also confer cross resistance to gentamicin. If the introduction of kanamycin

resistance does confer resistance to gentamicin, this aspect of the work would meet the definition of a restricted experiment. Genetic modifications would be described in Attachment B. 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.

Question 2, Maximum Quantity/Concentration of Select Agent

- For each select agent listed in Section 7A, 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 of 10^5 cfu/ml). If select agents will not be propagated, then indicate "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. If Section 7A includes regulated nucleic acids, indicate if these materials are held in long-term storage in Question 6 below and complete Attachment B.

- If no select agent organisms are indicated on Section 7A, indicate N/A or leave blank.

Examples for Completing the Section 7C, Question 2

Example 1: PI John Smith propagates *Bacillus anthracis* and *Xanthomonas oryzae*, and stores avian influenza virus isolates (but does not propagate the virus).

Agent	Maximum Quantity / Concentration
Avian influenza virus	No propagation of agent.
Bacillus anthracis	200 petri dishes, 10 X 100 ml at 10^8 cfu/ml
Xanthomonas oryzae	50 ml flask at 10^8 cfu/ml

Example 2: PI Jane Williams maintains a repository of *Bacillus anthracis*, *Francisella tularensis*, *Yersinia pestis, Brucella abortus*, *Brucella melitensis*, and *Brucella suis* isolates with no propagation of the agents.

Agent	Maximum Quantity / Concentration
All select agents on PI's Section 7A	No propagation of agent

Example 3: PI Matt Jones conducts Laboratory Response Network (LRN) confirmatory tests for *Bacillus anthracis*, *Brucella abortus*, *Brucella melitensis*, and *Brucella suis* from diagnostic specimens, with propagation of agents.

Agent	Maximum Quantity / Concentration
Bacillus anthracis Pasteur strain	2 plates per specimen
Brucella abortus	2 plates per specimen
Brucella melitensis	2 plates per specimen
Brucella suis	2 plates per specimen

Question 3, Maximum Quantity of Functional Toxin

- For each select toxin listed in Section 7A, estimate the maximum quantity held by the PI at any given time. A maximum quantity for all select toxins listed in Section 7A for each PI must be provided.
- The maximum quantity can be given as total amount (5 g) or volume and concentration (3 ml of 100 ng/ml). Additional sheets may be attached if necessary.
- If no toxins are indicated on Section 7A, indicate N/A or leave blank.

Examples for Completing the Section 7C, Question 3

PI Cynthia Boxwood receives botulinum neurotoxin from a commercial vendor and has diagnostic specimens confirmed to contain ricin.

Toxin	Maximum Quantity
Botulinum neurotoxins	25 mg
Ricin	500 mg

Question 4, 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.

Question 5, Responsibility for Inventory

- List the name(s) of the individual(s) responsible for tracking use of the select agent and/or toxin inventory (e.g., individual(s) who update or log additions and deletions to the physical inventory).

- Indicate how often these inventory record(s) are reconciled by the RO (or designee). If the inventory is reconciled other than annually, specify the frequency (e.g., weekly, monthly, every 6 months).

Question 6, 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)(i) 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.

Question 7, 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 decontamination. If chemical disinfection is used, indicate the type of disinfectant, the concentration, and the contact time.
- If decontamination does not occur prior to removal of waste from the entity, check "No".
- 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.
- For any other method of decontamination, describe the method used.

Question 8, 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.

Question 9, 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.

Question 10, 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.

Attachment A - Work with Toxins

This attachment is used to assess work with select toxins. Multiple, complete Attachment As for a PI's Section 7 may need to be submitted if work is performed at different biosafety levels. 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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

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.

The short, paralytic alpha conotoxins containing the following nucleic acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$ will be considered a select toxin if the total amount (all forms) under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor exceeds 100mg at any time.

(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.
- 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. An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety. Excluded strains are usually sought out and approved for use in basic or applied research, as positive controls, for diagnostic assay development, or for the development of vaccines and therapeutics. However, 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. Unless specifically excluded under 42 CFR 73.3 and 73.4, 7 CFR 331.3 and 331.4, and 9 CFR 121.3 and 121.4, any select agent or toxin is subject to the entirety of the Select Agent Regulations. The current list of select agent exclusions can be viewed at Select Agents and Toxins Exclusions.
- 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. Refer to the Policy Statement posted to the FSAP website August 25, 2014 for more information.
- 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. 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 select agent and toxin nucleic acids that encode for the functional 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 regulation. For additional information regarding recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins, refer to Synthetic Genomics.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

PI

- Fill out the name of the Principal Investigator(s) for which this attachment is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Laboratory Safety Level:

- Choose the appropriate laboratory safety level for the work described. If the questions within this attachment will be answered differently for specific safety levels, provide a separate attachment for each safety level.

Question 1, 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.

Question 2, 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.

Question 3, 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" posted to Long Term Storage for additional guidance in answering this question.

  Note: If animals are exposed to select toxins, Questions 1, 2, and 8 in Attachment C – Work with Animals must be completed.

Question 4, 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, 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.

Examples for Completing Attachment A, Question 4

4. Select toxin is produced at the entity. ..... Yes ☐ No ☐

If yes, provide a brief description of the method and an estimate of the maximum quantities during production, purification, and concentration.

Plasmids expressing staphylococcal enterotoxin genes (*e.g.*, A - E) will be introduced into *E. coli*, and grown in nutrient broth, in 250 ml flasks with aeration. Bacterial growth will be monitored turbidometrically and serial dilutions of cultures plated to determine viable counts. Correlation curves between culture turbidity and viable cell counts will be generated for standardization purposes. At cell densities of 0.5 - 1.0 x 10^9 CFU/ml, the cultures will be harvested by low speed centrifugation. Initial protein concentrations will be estimated at time points throughout the growth cycle using a standard BCA protein assay. High resolution protein quantification will employ fluorescent proteins standards in a microliter plate format and automated plate reader. Toxin will be purified using affinity high performance liquid chromatography, mass spectrometry, and/or non-denaturing acrylamide gel electrophoresis depending on the desired yield, purity and activity of the toxins desired. All work will be performed at BSL2 containment.

Question 5, 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".

Question 6, 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.

- For any other method of decontamination, 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.

Question 7, 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.

Question 8, 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: Regulated toxin amounts are described in 42 CFR 73.3 (d)(3) and are available at SelectAgents.gov.

  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.

Question 9, 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.

Question 10, 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).

Question 11, 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.

  Note: 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. Multiple, complete Attachment Bs for a PI's Section 7 may need to be submitted if work is performed at different biosafety levels.

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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

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PI

- Fill out the name of the Principal Investigator(s) for which this attachment is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Laboratory Safety Level:

- Choose the appropriate laboratory safety level for the work described. If the questions within this attachment will be answered differently for specific safety levels, provide a separate attachment for each safety level.

Question 1, 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
Recombinant/synthetic nucleic acids encoding Staphylococcal enterotoxin

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

Note: Any unique markers or phenotypic characteristics that differentiate a strain from the parental organism must be indicated in Section 7B strain table.

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.

Question 2, 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".

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.

If work will not involve recombinant or synthetic organisms, check "No".

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.

Question 3, 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.
- 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".

(a) 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.

(b) 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".

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

Question 4, 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.
- If work will not involve possession, use or transfer of a product of a restricted experiment, check "No".

(a) Include all products of a restricted experiment created after December 4, 2012 whether acquired from a different PI at the same entity or 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.

(b) 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".

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

Question 5, 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.

Question 6, 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.
- Attach additional pages and/or maps of the recombinant/synthetic construct(s), cloning/expression vector(s) as applicable.

Examples for Completing Attachment B, Question 6

Example 1, yes to Question 1a

6. For any question 1-5 above answered "yes", provide a brief description of the work.

Nucleic acids that can produce infectious forms of select agent viruses: Clinical (human CSF and brain tissue) and environmental samples (pooled mosquitoes, collected animals tissues) will be assayed to detect Eastern Equine Encephalitis (EEE) viral RNA. Viral genomic material will be extracted from clinical and environmental samples using commercial RNA extraction kits, and real-time, reverse transcriptase PCR (RT-PCR) will be performed employing EEE genomic RNA as a positive control in the BSL3 laboratory.

Example 2, yes to Questions 1a and1b

6. For any question 1-5 above answered "yes", provide a brief description of the work.

Mutational and phylogenetic analysis of the SARS-CoV genome will be compared in natural viral isolates, and after passage in Vero cell culture. Sequence analysis will be performed to identify specific virulence-attenuating mutations following passage in animal models. Laboratory methods will include extraction of viral genomic material for real-time reverse transcriptase PCR (RT-PCR), cDNA synthesis, and DNA sequencing from virus cultured in both Vero cells and infected animal tissues. Trizol reagent will be used for viral lysis and RNA extraction in the BSL3 laboratory. Real-time RT-PCR and cDNA synthesis will be performed in the BSL2 laboratory. cDNA constructs will also be assembled to produce RNA transcripts using commercial *in vitro* synthesis kits with either T3 or T7 RNA polymerase. The RNA transcripts will be introduced into BHK cells by electroporation, and the transfected BHK cells will be seeded onto Vero cell culture for the recovery of virus progeny. Electroporation and recovery of live virus will occur in the registered BSL3 laboratory.

Example 3, yes to Question 5

6. For any question 1-5 above answered "yes", provide a brief description of the work.

A transposon library constructed in a *Y. pestis* strain lacking the low calcium response (Lcr) plasmid will be used to identify genes required for manganese transport. Site-directed mutagenesis, yielding non-polar mutations will be constructed in the excluded (Lcr^-) strain, and mutants screened for deficiency in manganese uptake. For confirmatory work in animals, the *lcr* plasmid will be introduced into isogenic strains of interest and bacterial virulence examined in a mouse model.

Question 7, 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.

Attachment C - Work with Animals

This attachment is used to assess work with animals. Multiple, complete Attachment Cs for a PI's Section 7 may need to be submitted if work is performed at different biosafety levels. 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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

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PI

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Laboratory Safety Level

- Choose the appropriate laboratory safety level for the work described. If the questions within this attachment will be answered differently for specific safety levels, provide a separate attachment for each safety level.

Question 1, Select Agents/Toxins, Animals and Routes of Administration

- Indicate each select agent listed in Section 7A that will be used in animals, provide the species of animal (genus & species name, as well as common name) and all routes of administration of the select agent or toxin. Enter select agents or toxins exactly as they appear on the current, approved Select Agent/Toxin List. Do not abbreviate.
  Note: IC = Intracranial, IN = Intranasal (i.e. with syringe or nasal cannula, not exposure with aerosol generating equipment – see below), IT = Intratracheal, IP = Intraperitoneal, IM = Intramuscular, SC = Subcutaneous, ID = Intradermal, IV = Intravenous, IA = Intra-arterial.

Spell out ocular, oral, mucosal, intracapsular injection of joint spaces, intrathoracic injections other than IT, and any other routes of administration.

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

Examples for Completing the Attachment C, Question 1

Example 1:

Select Agent/Toxin	Species of Animal	Route(s) of Administration
Lassa fever virus	Mouse	IC, IP, IM, aerosol

Example 2:

Select Agent/Toxin	Species of Animal	Route(s) of Administration
Avian influenza virus	Pig	Intrabronchial, IN, IT

Question 2, 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".

Question 3, Waste Stream

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

(a) If animal carcasses, cages, and waste (e.g., sewage, bedding) 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 (e.g., if you autoclave and then incinerate, check the box for autoclave and describe your autoclave protocol including time, temperature, and pressure and check the box for incineration). If animal carcasses, cages, and waste (e.g., sewage, bedding) are not treated prior to disposal by an approved method, check "No".

Example for Question 3a:

☑ Autoclaved

Describe validation procedures that account for variables such as time and temperature of autoclave run cycles, as well as temperature and weight of carcass at initiation of autoclave cycle.

Validation of cage sterilization performed using a clean cage with bedding, food, and water bottle emptied into bedding run with bio-indicator buried in bedding.
Validation of carcass sterilization performed by placing a bio-indicator into bag containing the maximum number of frozen mouse carcasses autoclaved at one time.

(b) Indicate if waste is decontaminated inside the containment area (e.g., pass-through autoclave loaded within containment in the animal facility) or if waste is transported outside the containment area for decontamination. If waste is transported outside the containment area for decontamination, describe when and how waste is treated before transport out of the containment area.

Example for Question 3b:

b. Waste Handling Procedures.

☐ Waste decontaminated inside the containment area (e.g., pass-through autoclave loaded within the animal facility)

☑ Waste transported outside of the containment area for decontamination. Describe when and how waste is treated before transport out of the containment area.

Dirty cages are placed in autoclave bags in the animal room. Bags are double bagged and outer bag is sprayed down with 10% bleach. Bagged cages are transported in a leak proof container outside of the BSL3/ABSL3 suite to the autoclave in the animal facility and autoclaved immediately.

Question 4, Inactivation

- Describe any inactivation (e.g., formalin fixation, lysis of cells for nucleic acid extraction, irradiation) of samples collected from infected animals that will be manipulated at a lower biosafety level. Include concentration or dosage and contact/exposure time, as applicable.

  Note: Refer to Guidance for the Inactivation of Select Agents and Toxins and Rending Samples Free of Select Agents and Toxins.

Example for Completing the Attachment C, Question 4

4. Describe any inactivation (e.g., formalin fixation, lysis of cells for nucleic acid extraction, irradiation) of samples collected from infected animals that will be manipulated at a lower biosafety level. Include concentration or dosage and contact/exposure time, as applicable.

A manufacturer's proprietary fixative is used to inactivate select agent infected animal materials. In-house validation determined that 24 hour contact time renders the material non-viable for select agent.

Question 5, 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”.
- 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.
- 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.

Question 6, 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".

Question 7, 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 Document on the Inventory Requirements for Select Agents or 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.

Question 8, 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.

Question 9, 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.

Question 10, Animal Housing

- Describe how animals are housed by 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 enclose). Actively ventilated caging systems have both a supply and exhaust fan; passive ventilation is provided by an exhaust fan only. The following are examples of housing: conventional caging housed within HEPA filtered isolators, HEPA filtered cage racks, individual HEPA filtered cages, open cages, loose-housing.

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

Species	Animal Housing
Mouse	Actively ventilated HEPA filtered cages.
Ferrets	Open caging housing within an inward flow ventilated enclosure.

Question 11, Method of Euthanasia

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

Question 12, Necropsies

- If animals will be necropsied, check “Yes” and describe the necropsy procedures (e.g., instruments or implements used, on downdraft table).
- 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 assayed and shown that the select agent is absent.

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

Example for Completing Attachment C, Question 12

12. Will animals be necropsied? ..... Yes ☑ No ☐

If yes, describe necropsy procedures.

All necropsies are conducted in a Class II, Type A2 biosafety cabinet or downdraft table that is centrally exhausted. Required PPE for individuals performing the work include PAPRs, double gloves, Tyvek suites, booties, and disposable aprons. If using sharps, cut resistant gloves are provided. All sharps are maintained in hard-walled plastic containers and autoclaved after completion of the procedure. Animal material is manipulated and/or stored in registered space for the duration of the ongiong experiment.

Question 13, 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. Multiple, complete Attachment Ds for a PI's Section 7 may need to be submitted if work is performed at different biosafety levels. 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".

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Laboratory Safety Level

- Choose the appropriate laboratory safety level for the work described. If the questions within this attachment will be answered differently for specific safety levels, provide a separate attachment for each safety level.

Question 1, Select Agents, Plants and Routes of Inoculation

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

Example for Completing Attachment D, Question 1

Select Agent	Species of Plant	Route(s) of Inoculation
Ralstonia solanacearum	Lycopersicon esculentum	Root drench
Xanthomonas oryzae	Oryza sativa	Stem inoculation

Question 2, Plant Waste Treatment

- If all plant waste is treated prior to disposal (e.g., soil, plant material, materials 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.
- 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."

Question 3, 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.

Question 4, 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".

Question 5, 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".

Question 6, 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".

Question 7, Growth Chamber

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

Question 8, 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. Multiple, complete Attachment Es for a PI's Section 7 may need to be submitted if work is performed at different biosafety levels. 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".

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

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).

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PI

- Fill out the name of the Principal Investigator(s) for which this attachment is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Laboratory Safety Level

- Choose the appropriate laboratory safety level for the work described. If the questions within this attachment will be answered differently for specific safety levels, provide a separate attachment for each safety level.

Question 1, 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, attach additional sheets as necessary to explain your work, 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.

Question 2, 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” and do **not** complete the remaining questions (3-16) in this attachment.

  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.

Question 3, Select Agents and Arthropods

- Indicate each select agent listed in Section 7A that will be used in arthropods. Enter the species of arthropod (genus and species name).

Example for Completing Attachment E, Question 3

Select Agent	Species of Arthropod
Eastern Equine Encephalitis virus	*Culiseta melanura*
Rift Valley fever virus	*Culex quinquefasciatus*

Question 4, 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”.

Question 5, Containment and Transfer of Infected Arthropods

- Describe procedures used for primary containment during maintenance and any transfer(s) of infected arthropods. Address primary containment features of caging systems and include any secondary containment equipment used to transfer of 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.

Question 6, 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 Requirements for Select Agents and Toxins.

Question 7, 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.

Question 8, 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.

- 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.

Question 9, Release Prevention

- If arthropods are prevented from release into the suite/room, check "Yes" and indicate if procedures include a protocol for accidental escape.
- 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, not active work and manipulation of them or the primary containment described in Question 5.

Question 10, Infected Arthropod Contact and Release Prevention

- If experimentally infected arthropods are 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".
- If experimentally infected arthropods are not housed and manipulated in a suite/room such that accidental contact and release is prevented, check "No".

  Note: This question relates primarily to active work and manipulation of arthropods, not maintenance of them in the insectary as described in Question 5.

Question 11, Ventilation Escape Barriers

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

Question 12, Floor Drains

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

- 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”).

Question 13, Plumbing Escape Barriers

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

Question 14, Disposal

- The escape of live arthropods from insectary waste before decontamination is a concern. 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.

Question 15, Waste Treatment

- This question relates to the decontamination of the select agent separate from the killing of the arthropod. If all wastes from the arthropod containment laboratory are treated for disposal using 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.
- If all wastes from the arthropod containment laboratory are not treated for disposal using an approved method, check “No”.

Question 16, Animals/Plants in Arthropod Containment Laboratory

- If animals or plants are permitted in the arthropod containment laboratory, check “Yes” and complete Questions 16a-b.
- If animals or plants are not permitted in the arthropod containment laboratory, check “No”.
- 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).

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.

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

PI

- Fill out the name of the Principal Investigator(s) for which this attachment is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Question 1, 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".

Question 2, 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".

Question 3, 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”.

Question 4, 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”.

Question 5, 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”.

Question 6, 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”.

Question 7, Laboratory Procedures and Design Features

- Describe the BSL3Ag laboratory procedures and design features by completing Questions 7a-e.

Question 8, 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”.

Question 9, Humane Restraining Devices

- If humane restraining devices are provided in large animal rooms, check “Yes” and state what restraining devices are provided and describe how they will be used.

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

Question 10, Large Animal Necropsy Rooms

- If necropsy rooms are sized and equipped to accommodate large animals, check “Yes” and describe these features.
- 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.

Additional guidance is provided below; if further information or guidance is required, please contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3.

Header Information

This Submission Is

- Check "A new registration" to indicate an initial application, or revision to a pending initial application.

  Note: Once your entity is registered, select "An update to an existing registration" to amend your entity's APHIS/CDC Form 1 or indicate "A renewal" if submitting a complete APHIS/CDC Form 1 as part of the renewal process.

Entity Name

- Provide the complete legal name of your entity (corporation, partnership, sole proprietorship, etc.) under which operations are conducted.

Date

- Enter the date that the document is being submitted to APHIS/CDC in the following format mm/dd/yyyy.

  Note: The above header information must be consistent for all sections and attachments submitted at one time.

PI

- Fill out the name of the Principal Investigator(s) for which this attachment is being completed. Use first initial followed by last name, separate multiple PI names with commas.

Question 1, 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.

Question 2, Personal Protective Equipment (Cabinet Laboratory)

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

Question 3, Decontamination Methods (Cabinet Laboratory)

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

Question 4, Liquid Effluent Decontamination (Cabinet Laboratory)

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

Question 5, 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.

Question 6, Ventilation Failure (Cabinet Laboratory)

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

Question 7, Airflow Monitoring (Cabinet Laboratory)

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

Question 8, Containment Parameters Monitoring (Cabinet Laboratory)

- Describe how containment parameters are monitored daily.

Question 9, Suit Laboratory

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

Question 10, Personal Protective Equipment (Suit Laboratory)

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

Question 11, Liquid Effluent Decontamination (Suit Laboratory)

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

Question 12, 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.

Question 13, Ventilation Failure (Suit Laboratory)

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

Question 14, Airflow Monitoring (Suit Laboratory)

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

Question 15, Breathing Air Failure (Suit Laboratory)

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

Question 16, Containment Parameters Monitoring (Suit Laboratory)

- Describe how containment parameters are monitored daily.

Amendment Requirements

These instructions are intended to provide a list of the documentation the FSAP will need to process the most frequent registration changes.

An Amendment is defined as a request to update a registered entity's Certificate of Registration for Possession, Use and Transfer of Select Agents and Toxins (APHIS/CDC Form 1). An amendment is considered pending until final approval has officially been communicated to the entity via the FSAP. Approval is required before implementing the changes requested in the amendment.

In some cases, an Amendment Update will be requested by the FSAP in order to obtain clarification and/or additional information for an existing, pending amendment.

Amendment submissions from a registered entity may or may not require the submission of updated pages or sections of the APHIS/CDC Form 1. For example, the removal of a laboratorian requires a written request only from the Responsible Official (RO) or an Alternate Responsible Official (ARO). Other changes, such as the addition of a new select agent/toxin or suite/room, will require multiple sections of APHIS/CDC Form 1 to be updated.

Separate Amendment Requests to Help the Federal Select Agent Program Approve Amendments in a Timely Manner

The FSAP will not approve an amendment request until it has reviewed and found all of the documentation submitted as part of the request to be sufficient.

For example, if an entity submits a request to add a new laboratory room and to modify its objectives of work for a select agent or toxin currently on its registration as part of the same amendment, the FSAP will not approve the amendment until it has reviewed and found the documentation for both of these changes to be sufficient, including inspecting the new room and finding the inspection report to be satisfactory. Therefore, an entity can assist the FSAP in processing requests for distinct changes to its registration by submitting these requests as separate amendments.

Example: A registered entity is adding two new laboratory rooms (Rooms A and B) to their registration for work with a select agent currently on the registration. The addition of these rooms has also resulted in 2 new staff being hired (Jane Doe and John Smith). John Wilson has also recently retired.

Preferred submission of separate amendments:
Amendment 1 – Add John Smith and Jane Doe
Amendment 2 – Remove John Wilson
Amendment 3 – Add Rooms A and B

Note: Send your amendment documentation only once. For example, if you email your amendment documentation to your designated FSAP representative, you do not need to fax a duplicate copy.

Amendment Request

All amendments and amendment updates submitted to the FSAP should contain a request which details the changes to be made. The request can be made in the form of a cover letter signed by the RO or an ARO or as an email sent from the RO or an ARO's email account on file. Registered entities are also urged to use their FSAP Application Number (ex. CDC050555) within the request in order to help route documents efficiently.

Requests should be as descriptive as possible. **Requests that do not clearly explain the changes to be made to your registration or conflict with the forms submitted may require the submission of additional documentation and result in delayed approval of your amendment request. Any changes made to your APHIS/CDC Form 1 must be contained in a request**. If a

cover letter is used, it should be written on official letterhead or have other characteristics which clearly indicate the origin of the request.

Examples of Request Language

Request language should be as descriptive as possible and reference the sections of the APHIS/CDC Form 1 being updated. Although providing a DOJ number is not required to remove an individual, doing so will increase the accuracy of the requested actions and the speed at which the amendment is approved.

The examples below are intended to represent some of the most frequent amendment requests submitted by registered entities:

- Please remove John Smith (C-JS-000000) from our registration. John Smith has voluntarily terminated employment at our facility to pursue a graduate degree.
- Please add Mike Smith to our registration as a laboratorian under PI Andrews, see attached Section 4A. Mr. Smith will not have access to Tier 1 agents.
- Please update Mike Smith's (C-MS-000000) role to ARO. Mike Smith is currently security risk assessment (SRA) approved at our entity and has an assigned role of laboratorian. Updated Sections 1A and 1B including Mr. Smith are attached.
- Please remove rooms 101, 102, 103 and 104 from Principal Investigator (PI) Jones. These rooms will continue to be used by other PIs and should not be removed from our overall registration. PI Jones inventory has been audited and has been relocated to laboratory room 105, currently approved for PI Jones.
- Please remove BSL3 rooms 205, 206, and 208 from our registration. See attached Section 7 for PI Cheng and PI Anderson with these rooms removed. All select agents have been reconciled and transferred to long-term storage in room 315. Rooms 205, 206, 208 have been decontaminated with vaporized hydrogen peroxide (VHP) performed by a contracted vendor. See attached documentation of decontamination procedures.
- Please remove PI Williams (C-MW-000000) from our registration. PI Williams has accepted a position at another university, effective date January 1, 2013. See the attached Section 7 for co-PIs Williams and Johnson with PI Williams' name removed from Section 7A and Attachment headers and a Section 4A assigning laboratorians to PI Johnson only.
- Please remove *Bacillus anthracis* from our registration. All *B. anthracis* stocks and working samples have been reconciled, autoclaved, and the destruction witnessed by the RO and PI Smith. See the attached Section 3 with *B. anthracis* removed, PI Smith's Section 7 with her work objectives updated and *B. anthracis* removed, and documentation of destruction (autoclave records) with witness signatures.
- Please add *Bacillus anthracis* to our registration. Attached is documentation delineating facility improvements to achieve BSL3 standards for our registered laboratory as well as updated Sections 3, 6 and 7.
- Please add *Francisella tularensis* to our registration. We are also requesting to perform a restricted experiment with *Francisella tularensis*. Attached are updated Sections 3 and 7 and Attachment B describing the proposed restricted experiment.
- We have conducted a quarterly review of our inventory and would like to update our strain information on file with the FSAP. See the attached Section 7B for each registered PI.
- Principle Investigator John Doe (C-JD-000000) recently received grant funding to develop *Burkholderia mallei* rapid detection methodologies. Dr. Doe will work with *Burkholderia mallei*

in BSL3 laboratory rooms 100 and 101. Please see the updated Sections 3, 4A, 6, and 7 adding *Burkholderia mallei*, PI Doe's laboratory staff, rooms 100 and 101, and PI Doe to our registration. Dr. Doe and his staff will have access to Tier 1 select agents as indicated on Sections 4A and 7A.

- Jane Rogers (C-JR-000000) will no longer have the ability to access Tier 1 select agents and toxins but will continue to work with non-Tier 1 select agents. Please update her status to remove Tier 1 Access as indicated on the attached Section 4A.

Federal Select Agent Program Concurrence

CDC and APHIS work together to provide a single point of contact. This single point of contact is referred to as the "lead agency", and as such, is responsible for coordinating all activities and communications with respect to your registration, including coordination with the non-lead agency.

An amendment to the registration which concerns a select agent or toxin not regulated by your lead agency will require concurrence from the non-lead agency. In these instances, you may be required to submit additional documentation. The FSAP will initiate the concurrence process and all correspondence will be directed through your designated representative. Amendments requiring concurrence may require additional time for processing and review.

Amendment Submission

Submit the required documentation to your designated FSAP representative. Upon receipt of the amendment, a confirmation letter with the assigned amendment number will be faxed to the number currently on file for the RO. Subsequent communications with the FSAP regarding this request should include the assigned amendment number.

- The FSAP encourages entities to communicate any amendments or amendment updates via email to their designated FSAP representative. Emails from other personnel at the entity (ex. Administrative Staff) will be accepted if a cover letter signed by the RO or ARO is attached.
- Electronic versions (.doc, .xls, .pdf) of the approved forms or scanned images of the cover letter and APHIS/CDC Form1 sections may be attached to an email in lieu of faxing or mailing the documentation.
- All electronically submitted APHIS/CDC Form 1 sections must have the required signatures. Digital/electronic signatures are accepted.
- An email may serve as the request provided it includes all required information and is sent from the email address on file for the RO or ARO.
- Amendments and amendment updates can also be faxed or mailed.

The amendment will be processed for approval following the submission of sufficient documentation and, if applicable, pending satisfactory closure of an inspection. The entity will receive notification from the FSAP once the amendment has been approved.

If you have any questions about the amendment process, these examples or any other types of amendments, contact your designated FSAP representative.

Amendment Reference Table

Amendment type	Request	Sections 1A-C	Section 2	Section 3	Sections 4 A-C	Sections 5A-D	Sections 6A-6B	Sections 7A-7C (including Attachments)
Personnel								
Addition/Reactivation RO Addition/Reactivation ARO	State changes (a)	Updated 1A, 1B	Updated (RO only)					
Addition/Reactivation Owner/Controllers	State changes (a)	Updated 1A						
Addition/Reactivation of Laboratorian, Animal Care Staff	State changes (name, role) and (a)				Updated 4A			Updated 7C if responsible for inventory
Addition/Reactivation of Support Staff	State changes (name, role) (a)				Updated 4B			
Addition/Reactivation of Unescorted Visitor	State changes (name). Signed letter from RO at home entity.				Updated 4C			
Addition/Reactivation of PI	State changes (a)				Updated 4A, 4C as applicable			Section 7 for new PI
Removal of RO or ARO	Reason for removal. New RO must be appointed.	Updated 1A, 1B	Updated (RO only)					
Removal of Owner/Controller	Reason for removal							
Removal of Personnel: Laboratorian, Animal Care Staff, Support Staff, Visitor	Reason for removal							Updated 7C if responsible for inventory
Removal of PI	State disposition of agents, reason for removal.				Updated 4A, 4C as applicable			Updated Section 7 if a co PI
Updates to Names, Titles or Supervising PI for Laboratorian, Animal Care Staff, Support Staff, Unescorted Visitor	State changes				Updated 4A, 4B, 4C as applicable			
Updates to PI Name	State changes				Updated 4A, 4C as applicable			Updated 7A; updated headers for 7B, 7C and attachments
Updates to RO/ARO/Owner Controller Name or Contact Information	State changes	Updated 1A; 1B for name change only						
Updates to Tier 1 access	State changes and reason for change	Updated 1A, 1B as applicable			Updated 4A, 4B, 4C as applicable			Updated 7A as applicable

(a) Requires SRA Approval **(b) Inspection may be required**

Amendment type	Request	Sections 1A-C	Section 2	Section 3	Sections 4 A-C	Sections 5A-D	Sections 6A-6B	Sections 7A-7C (including Attachments)
Select Agent/Toxin								
Addition of Agent or Toxin	Consider BSL of work, agent/toxin, laboratory (b)			Updated				Updated for each PI adding agent/toxin
Addition of Tier 1 Agent or Toxin	Consider BSL of work, agent/toxin, laboratory (b)	Updated 1A, as applicable		Updated	Updated 4A, 4B, 4C as applicable	Updated 5A, 5B as applicable	Updated 6A for affected suite/room	Updated 7A and 7C for each PI adding agent/toxin
Update Possession Status of Select Agents/Toxins	State changes			Updated				Updated 7B for each affected PI upon possession
Removal of Agent or Toxin from Entity	State disposition of agent/toxin			Updated				Updated for each PI registered for agent/toxin
Removal of Agent or Toxin from PI (but not Entity)	State disposition of agent/toxin							Updated for each PI registered for agent/toxin
Addition of New Work	State changes (b)							Updated 7C for PI adding new work
Removal of Work	State changes							Updated for PI removing work
Strain Update	State changes							Updated 7B for each PI
Facility								
Addition of Suite/Room	State changes (b)						Section 6 for each suite/ room added and floor plan	Updated 7A for each PI to store and/or work in the new suite/room
Removal of Suite/Room	State disposition of agents, decon of suite/room							Updated 7A for each affected PI
Update to Building and Suite/Room Specific Security	State changes						Updated 6A for affected suite/room	
Update to Suite/Room Physical Information	State changes						Updated 6B for affected suite/room	
Other								
Entity Name or Address Changes	Explanation of changes	Updated 1A						
Update to Entity Institutional Mission, Function and/or Size	State changes	Updated 1C						
Update to Entity Wide Security	State changes					Updated 5A		
Update to Entity-Wide Biosafety/Biocontainment	State changes					Updated 5B		
Update to Entity Entry Requirements for FSAP Inspectors	State changes					Updated 5C		

(a) Requires SRA Approval **(b) Inspection may be required**

Personnel Amendments

Adding Individuals – General Information

When submitting an amendment to add new individuals to your registration, submit documentation for only those specific individuals being added. To validate your personnel records against those maintained by the FSAP you may periodically (e.g., quarterly) request a comprehensive DOJ List for your entity. The DOJ List will include all individuals, their DOJ Number, their current SRA status, and their SRA expiration date.

- The first and last name for each individual should match that which is entered in Block 4 on his/ her respective FD-961 Form.
- Upon receipt of your request, a DOJ Number will be provided for each individual to enter in Block 3 on his/her FD-961 form. The DOJ Numbers for all individuals added within an amendment will be sent to the RO in a DOJ Number Assignment Letter.
- SRA approval must be granted for every individual added within the amendment before the amendment is approved. However, an individual's access to select agents/toxins is granted upon receipt of the SRA Approval Letter (not the DOJ Number Assignment Letter) sent directly to the RO for each approved individual.
- Once assigned at an entity, an individual's DOJ number at that entity will not change.
-
- When entering an individual's DOJ number, capitalize the letters as in A-XX-123456 or C-AA-000000.
- For individuals currently registered at another entity (active SRA), the entity will follow the same procedure for requesting to add a new individual to the registration. The individual will be assigned a new DOJ number associated with their registration at the new entity.
    - Do not submit an FD-961 form, fingerprints or photograph to the FBI/CJIS. Once the existing SRA is verified, a *Notice of SRA Approval for Access to Select Agents and/or Toxins* letter will be sent to the requesting entity.
    - The SRA expiration date will be the same at all entities. The date will be based on the current expiration date and not three years from the time of approval at the second entity. For example, J. Doe is registered at Entity A with an SRA expiration date of May 15, 2017. When J. Doe registers at Entity B with access approval granted on October 17, 2016, his SRA expiration date for both entities will be May 15, 2017.

Adding or Reactivating a RO

The RO is the individual designated by an entity with the authority and responsibility to ensure compliance with the Select Agent Regulations.

Note: A new RO cannot self-appoint (i.e., a currently registered ARO cannot sign paperwork requesting to be the RO). When possible, the RO should send an amendment to appoint his/her successor. If the RO has already left the entity, the new RO must be appointed by an owner, controller or person of authority at the entity.

To add or reactivate a RO, submit the following documentation:

- ☐ Request stating the name of the RO to be added or reactivated.
  - The request should be made by the current, approved RO who will be replaced.
- ☐ Complete Section 1A (with the newly appointed RO).
  - For reactivations, use the RO's previously assigned DOJ number in the DOJ Number box.
- ☐ Complete Section 1B signed by the newly appointed RO and each ARO.
- ☐ Complete Section 2 completed by the newly appointed RO.

Additional Information

- By initialing each line on Section 2, the RO is certifying that as of the date indicated on the amendment submitted to the FSAP that 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 registration amendment in accordance with the requirements of the Select Agent Regulations.
- Since all communication between a registering individual or entity and the FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1A information changes, it must be immediately reported to the FSAP. Verbal change requests cannot be accepted.
- A *Curriculum Vitae* for the RO may be requested.

Adding or Reactivating an ARO

The ARO is the individual designated by an entity with the authority and responsibility to ensure compliance with the Select Agent Regulations when acting as the RO.

Note: A new ARO cannot self-appoint (i.e., a currently registered laboratorian cannot submit an amendment requesting to be an ARO). An ARO must be designated by the current RO.

To add or reactivate an ARO, submit the following documentation:

- ☐ Request stating the name of the ARO to be added or reactivated.
- ☐ Complete Section 1A (including the newly appointed ARO).
  - For reactivations, use the ARO's previously assigned DOJ number in the DOJ Number box.
- ☐ Complete Section 1B signed by the RO and each ARO (including the newly appointed ARO).

Additional Information

- Since all communication between a registering individual or entity and the FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1A information changes, it must immediately be reported to the FSAP. Verbal change requests cannot be accepted.
- It is recommended that an entity have at least one ARO to ensure continuity of operations.
- Once an individual is SRA approved, his/her DOJ number must be included on Section 1, 4, or 7 as applicable (e.g., if updating the individual's job title).
- An individual is deactivated upon the request to remove the individual. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will use their previously assigned DOJ number, and this number must be included in Section 1, 4, or 7 as applicable.

Addition or Reactivation of Owner/Controllers

To add or reactivate an Owner/Controller, submit the following documentation:

- ☐ Request stating the name of the Owner/Controller to be added or reactivated.
- ☐ Complete Section 1A (including the newly appointed Owner/Controller).
  - For reactivations, use the individual's previously assigned DOJ number in the DOJ Number box.

Additional Information

- Once an individual is SRA approved, his/her DOJ number must be included on Section 1, 4, or 7 as applicable (e.g., if updating the individual's job title).
- An individual is deactivated upon the request to remove the individual. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will use their previously assigned DOJ number, and this number must be included in Section 1, 4, or 7 as applicable.

Addition or Reactivation of Laboratorians or Animal Care Staff

To add or reactivate non-visiting Laboratorians or Animal Care Staff, submit the following documentation:

- ☐ Request stating the name of the individual to be added or reactivated.
- ☐ Manually or electronically signed and dated Section 4A with the individual being added or reactivated.
    - For reactivations, use the individual's previously assigned DOJ number in the DOJ Unique Identifier Number column.
- ☐ Complete Section 7C if the individual will be responsible for inventory.

Additional Information

- Once an individual is SRA approved, his/her DOJ number must be included on Section 1, 4, or 7 as applicable (e.g., if updating the individual's job title).
- An individual is deactivated upon the request to remove the individual. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will use their previously assigned DOJ number, and this number must be included in Section 1, 4, or 7 as applicable.

Addition or Reactivation of Support Staff

To add or reactivate Support Staff, submit the following documentation:

- ☐ Request stating the name of the individual to be added or reactivated.
- ☐ Manually or electronically signed and dated Section 4B with the individual being added or reactivated.
    - For reactivations, use the individual's previously assigned DOJ number in the DOJ Unique Identifier Number column.

Additional Information

- Once an individual is SRA approved, his/her DOJ number must be included on Section 1, 4, or 7 as applicable (e.g., if updating the individual's job title).
- An individual is deactivated upon the request to remove the individual. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will use their previously assigned DOJ number, and this number must be included in Section 1, 4, or 7 as applicable.

Addition or Reactivation of Unescorted Visitors

Unescorted visitors are defined as those individuals with SRA approval at a registered entity (Home Entity) who wish to visit another registered entity (Host Entity) for the purpose of having access to and/or conducting work with select agents or toxins at the host entity. When an unescorted individual is added, they do not require submission of a new FD-961, fingerprints or additional SRA approval at the Host Entity. To add an unescorted visitor to your registration, additional information is needed beyond that for a routine addition of personnel.

Note: Visitors who are continually escorted as described in section 11(d)(2) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) do not require the documentation below, as they will not have access to, and/or conduct work with, select agents or toxins.

To add an unescorted visitor, the Host Entity must submit the following documentation:

- ☐ Request stating the name of the individual to be added as an unescorted visitor.
- ☐ Signed letter from the RO at the individual's Home Entity which includes the following:
  - Affirmation that the individual will be visiting the entity
  - Name of the individual
  - Individuals' date of birth
  - Individual's DOJ number at his/her Home Entity
  - Individual's SRA approval date at his/her Home Entity
  - Information regarding Tier 1 suitability assessment of individual, if applicable
- ☐ Manually or electronically signed and dated Section 4C for the individual being added as an unescorted visitor.

Additional Information

- Upon receipt of your request, a host DOJ number will be provided for each unescorted visitor listed. Unescorted visitors will NOT submit a FD-961 form using this host DOJ Number.
- Once the visit is complete, a request to remove the individual will be submitted. See the Removal of Laboratorians, Animal Care Staff, Support Staff, and Unescorted Visitors for further information.

Addition or Reactivation of a PI

Each PI must have at least one select agent/toxin/regulated nucleic acids and at least one suite/room listed on his/her Section 7A. Provide a separate Section 7 for each new PI added or reactivated.

To add or reactivate a PI, submit the following documentation:

- ☐ Request stating the name of the PI to be added or reactivated, brief summary of the suites/rooms, select agents/toxins/regulated nucleic acids, and work objectives for this PI.
- ☐ Manually or digitally signed and dated Section 4A and/or Section 4C to include all staff assigned to this PI.
  - If a previously submitted Section 4A or 4C indicated "All PIs" in the supervising PI column, then no Section 4 update for the individuals affected is required.
- ☐ Complete Section 7.
  - For reactivations, use the individual's previously assigned DOJ Number in the DOJ Number box.
  - If multiple PIs conduct identical work with select agents and toxins, they may be listed on one Section 7.
- ☐ If a suite/room will be added to the entity registration for this PI, see Addition of a Suite/Room.
- ☐ If a select agent or toxin will be added to the entity registration for this PI, see Addition of Select Agent/Toxin.

Additional Information

- A PI is an individual 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, as defined in section 1 of the Select Agent Regulations.
- A *Curriculum Vitae* for the PI may be requested.

Removal of RO, ARO, or Owner/Controller

A RO or a sole Owner/Controller cannot be removed without a replacement being appointed.

To remove an RO, submit the following documentation:

The RO must submit an amendment to appoint his/her successor. If circumstances prevent this, the new RO must be appointed by an owner, controller or person of authority at the entity. Removal of an ARO does not require a replacement.

☐ Request stating the name of the RO to be removed and the reason for removal.

Note: If you are cancelling a request to add an individual in a pending amendment, submit an update to the amendment in which the initial request was made. (Example: John Smith was requested to be added in Amendment 123456 and subsequently took a different position prior to the amendment being approved. The request to remove John Smith would be submitted as an UPDATE to Amendment 123456.)

☐ Designate a new RO, see Adding or Reactivating a RO.

- Complete Section 1A with the new RO's information.
- Complete Section 1B.
- Complete Section 2 to be completed by the new RO.

☐ If the departing RO is also a PI, see Removal of a PI.

Additional Information

- In the event that an entity loses the services of its RO, it may continue to possess, use, or transfer select agents or toxins only if it appoints another individual as the RO, who meets the requirements of the regulations, and who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General.

To remove an ARO, submit the following documentation:

☐ Request stating the name of the ARO to be removed and the reason for removal.

Note: If you are cancelling a request to add an individual in a pending amendment, submit an update to the amendment in which the initial request was made. (Example: John Smith was requested to be added in Amendment 123456 and subsequently took a different position prior to the amendment being approved. The request to remove John Smith would be submitted as an UPDATE to Amendment 123456.)

☐ Complete Section 1A with the departing ARO's information removed.

☐ Complete Section 1B.

- If designating a new ARO, see Adding or Reactivating an ARO.
- If the departing ARO is also a PI, see Removal of a PI.

To remove an Owner/Controller, submit the following documentation:

☐ Request stating the name of the Owner/Controller to be removed and the reason for removal.

Note: If you are cancelling a request to add an individual in a pending amendment, submit an update to the amendment in which the initial request was made. (Example: John Smith was requested to be added in Amendment 123456 and subsequently took a different position prior to the amendment being approved. The request to remove John Smith would be submitted as an UPDATE to Amendment 123456.)

- If designating a new Owner/Controller, see Addition or Reactivation of Owner/Controllers.
- If the departing Owner/Controller is also a PI, see Removal of a PI.

Additional Information

- In the event that an entity loses the services of its sole Owner/Controller, it may continue to possess, use, or transfer select agents or toxins only if it appoints another individual as the Owner/Controller, who meets the requirements of the regulations, and who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General.

Removal of Laboratorians, Animal Care Staff, Support Staff, and Unescorted Visitors

To remove personnel (excluding a PI, RO, or ARO), submit the following documentation:

☐ Request stating the name of the individual to be removed and the reason for removal.

Note: If you are cancelling a request to add an individual in a pending amendment, submit an update to the amendment in which the initial request was made. (Example: John Smith was requested to be added in Amendment 123456 and subsequently took a different position prior to the amendment being approved. The request to remove John Smith would be submitted as an UPDATE to Amendment 123456.)

Additional Information

- Do not include the names of removed individuals on future Sections 1, 4, or 7 submissions.
- Once the individual is removed, he/she will be deactivated from the entity's registration. If the individual requires access approval in the future, the individual may be reactivated at that time. See the Addition or Reactivation of Laboratorians or Animal Care Staff as appropriate.

Removal of a PI

The removal of a PI requires additional documentation to account for the disposition of any inventory of select agents and/or toxins. It is important for entities to consider how the removal of a PI may affect other aspects of their registration (e.g., if the PI was the only PI assigned to a select agent/toxin, suite/room, laboratorian) and submit updates to appropriate sections of APHIS/CDC Form 1 as needed.

To remove a PI, submit the following documentation:

☐ Request stating the name of the individual to be removed and the reason for removal.

Note: If you are cancelling a request to add an individual in a pending amendment, submit an update to the amendment in which the initial request was made. (Example: John Smith was requested to be added in Amendment 123456 and subsequently took a different position prior to the amendment being approved. The request to remove John Smith would be submitted as an UPDATE to Amendment 123456.)

☐ Disposition of the PI's select agent(s) and/or toxin(s)

- Verification of inventory audit.
  - Destroyed – Provide documentation of destruction (*e.g.*, autoclave records and statement signed by witness)
  - Transferred – For transfers to another registered entity, provide the APHIS/CDC Form 2 transfer number (ex. CEA123456). For intra-entity transfers, provide chain of custody documentation.

☐ If the entity is removing a select toxin from its registration, but will continue to possess the select toxin under the regulated aggregate amount,

- Statement and/or records showing that the amount of toxin possessed by the registered PI is under the regulated aggregate amount.
- Statement of how the entity will ensure that each PI's select toxin inventory remains below the regulated aggregate amount.

☐ If the departing PI is assigned staff at the entity, an updated and manually or digitally signed Section 4A and/or Section 4C must be submitted as appropriate with the supervising PI column updated (e.g., staff reassigned to other PIs).

- If a previously submitted Section 4A or 4C indicated "All PIs" in the supervising PI column, then no Section 4 update for the individuals affected is required.

☐ If the departing PI is listed on the same Section 7 as another PI remaining on the registration (e.g., co-PIs), an updated Section 7 with the departing PI information removed is required.

- If a suite/room will be removed, see Removal of Suite/Room.
- If the departing PI is also an RO or ARO, see Removal of RO, ARO, or Owner/Controller.

Additional Information

- Each select agent/toxin, suite/room, laboratorian, animal care staff, and unescorted visitor must be assigned to a designated PI.
- An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.
- Entities must conduct inventory audits of all affected select agents and toxins in long-term storage per section 11(e) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) when any of the following occur:

  (1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;

  (2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or

  (3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.

  For additional information on inventory audits, refer to the Security Guidance for Select Agent or Toxin Facilities.

Update to Names, Titles or Supervising PI for Laboratorians, Animal Care Staff, Support Staff, and Visitors

In the event that an individual changes their name, title, or is assigned to a new supervising PI, a new Section 4 (4A, 4B, or 4C as appropriate) for that individual should be submitted to the FSAP.

Note: Only laboratorians, animal care staff, and unescorted visitors require a supervising PI.

To update a name, title, or supervising PI submit the following documentation:

- ☐ Request stating the name of the individual to be updated and update to be made.
- ☐ Manually or digitally signed and dated Section 4 for the individual which includes the updated information.
  - Section 4A – Laboratorians and Animal Care Staff
  - Section 4B – Support Staff
  - Section 4C – Unescorted Visitors

Additional Information

- A name change does not affect an individual's DOJ Number. Individuals who change their name should continue to use the same DOJ number for any future FD-961 or APHIS/CDC Form 1 submissions.

Update to PI Name

To update a PI's name, submit the following documentation:

- ☐ Request stating the current name and the updated name of the PI.
- ☐ If the PI is assigned staff at the entity, an updated and manually or digitally signed Section 4A and/or Section 4C as appropriate with the supervising PI column updated.
    - If a previously submitted Section 4A or 4C listed "ALL PI(s)" in the supervising PI column, then no Section 4 update for those individuals is required.
- ☐ Updated Section 7 with Section 7A and all headers, including attachments as applicable, updated.

Additional Information
• A name change does not affect the DOJ Number assigned to an individual. Individuals who change their name should continue to use the same DOJ number for any future FD-961 or APHIS/CDC Form 1 submissions.

Update to RO, ARO or Owner/Controller Name or Contact Information

Entities must ensure that the FSAP has the most up-to-date contact information for the RO and each ARO. This contact information is used to communicate directly with the RO/ARO and to send SA Grams (important program updates and other information). Contact information includes mailing address, phone numbers, fax numbers and email addresses.

To update RO or ARO contact information, submit the following documentation:

- ☐ Request stating the RO/ARO information to be updated.
- ☐ Complete Section 1A with updated information.

If the RO, ARO, or Owner/Controller name has changed, submit the following documentation:

- ☐ Request stating the RO, ARO, or Owner/Controller information to be updated.
- ☐ Complete Section 1A with updated information.
- ☐ Manually or digitally signed Section 1B.

Additional Information

- Since all communication between a registering individual or entity and the FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1A information changes, it must be immediately reported to the FSAP. Verbal change requests cannot be accepted.
- A name change does not affect the DOJ Number assigned to an individual. Individuals who change their name should continue to use the same DOJ Number for any future FD-961 or APHIS/CDC Form 1 submissions.

Update to an Individual's Access to Tier 1 Agents/Toxin

Each individual who will have access, or the ability to access, Tier 1 agents must indicate this by checking the Tier 1 access box. Several circumstances may require updating an individual's Tier 1 access status including, but not limited to, the following:

- Change in work assignment
- Addition or removal of select agent/toxin
- Addition or removal of suite/room
- Personnel pre-access suitability assessment or ongoing suitability monitoring decisions

Note: A change in Tier 1 access does not add or remove an individual from the entity's registration.

To update Tier 1 access for an RO, ARO, or Owner/Controller, submit the following documentation:

- ☐ Request stating the RO/ARO information to be updated.
- ☐ Complete Section 1A with updated Tier 1 status information.
- ☐ Manually or digitally signed Section 1B.

To update Tier 1 access for Laboratorians, Animal Care Staff, Support Staff or Unescorted Visitors, submit the following documentation:

- ☐ Request stating the name of the individual to be updated.
- ☐ Manually or digitally signed and dated Section 4 for the individual which includes the updated Tier 1 access information.
  - Section 4A – Laboratorians and Animal Care Staff
  - Section 4B – Support Staff
  - Section 4C – Unescorted Visitors

To update Tier 1 access for a Principal Investigator, submit the following documentation:

- ☐ Request stating the name of the PI to be updated.
- ☐ Updated Section 7A which includes the updated Tier 1 access information.

Select Agent/Toxin Amendments

Addition of Select Agent/Toxin

The biosafety level of the laboratory where the select agent/toxin will be used should be consistent with the BMBL guidelines. An inspection may be required prior to approval.

To add a select agent/toxin, submit the following documentation:

Note: If you are adding a Tier 1 agent for the first time, see Addition of Tier 1 Select Agent/Toxin below:

- ☐ Request specifying all changes.
- ☐ A comprehensive Section 3 that lists all the select agents/toxins for which the entity wants to be registered.
    - Check the "check if possessed" box only if you currently possess the select agent/toxin.
- ☐ Complete Section 7A listing all agents and locations for each PI that is affected by this change for the first submission only.
    - A partial Section 7A will be submitted for subsequent amendment submission.
- ☐ Complete Section 7C that includes all pending and approved select agents/toxins for each PI that is affected by this change.
    - New Section 7 Attachments may be required based on work with the new select agent/toxin.

Note: If you are adding SARS-CoV to the registration, submission of the entity's occupational health plan is required. See Recommendation of Guidelines for Medical Surveillance of Laboratory Personnel Working with SARS-CoV.

Addition of Tier 1 Select Agent/Toxin

To add a Tier 1 select agent/toxin at an entity not currently registered for Tier 1 select agents/toxins, submit the following documentation:

- ☐ Request specifying all changes.
- ☐ Section 1 (as applicable) to indicate Tier 1 access
- ☐ A comprehensive Section 3 that lists all the select agent/toxin for which the entity wants to be registered.
    - Check the "check if possessed" box only if you currently possess the select agent/toxin.
- ☐ Partial Section 4A, Section 4B, and Section 4C (as applicable) to indicate Tier 1 access.

- ☐ Complete Section 5A (as applicable) that includes additional security features for the building where Tier 1 select agents/toxins will be used or stored and information on the entity's personnel suitability program.
- ☐ Complete Section 5B that includes information on the entity's occupational health program.
- ☐ Complete Section 6A that includes security information specific to the suite/room where Tier 1 select agents/toxins will be used or stored.
- ☐ Complete Section 7A listing all agents and locations for each PI that is affected by this change for the first submission only.
    - A partial Section 7A will be submitted for subsequent amendment submission.
- ☐ Complete Section 7C that includes all pending and approved select agents/toxins for each PI that is affected by this change.
    - New Section 7 Attachments may be required based on work with the new select agent/toxin.
- ☐ Security plan
- ☐ Occupational Health Plan

Note: Depending on the agent(s)/toxin added and the scope of work, an inspection may be required before final amendment approval

- If a suite/room will be added for the new select agents/toxins, see Addition of a Suite/Room.

Additional Information
• The addition of a select agent or toxin requires that written plans, as applicable, are commensurate with the risk of the agent or toxin given its intended use. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted in accordance with the requirements of the Select Agent Regulations. • For additional requirements for Tier 1 select agents and toxins, refer to sections 11(f), 12(d), 14(e), and 15(b) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331). • Reconstructed 1918 Influenza Virus requires special consideration and/or approval. Contact your designated FSAP representative prior to your amendment submission.

Update Possession Status of Select Agents/Toxins

To update the possession status of a select agent/toxin, submit the following documentation:

- ☐ Request specifying all changes.
- ☐ Partial Section 3 that lists only the select agent/toxin to be updated.
  - Check the "check if possessed" box only if you currently possess the select agent/toxin.
- ☐ Upon possession, updated Section 7B for each affected PI.

Note: The registration is to be updated **within 7 days** of a change in the entity's possession status of a select agent or toxin.

Removal of Select Agent/Toxin from the Entity

To remove a select agent/toxin from the entity, submit the following documentation:

- ☐ Request specifying the select agent/toxin to be removed.
- ☐ Disposition of select agent/toxin
  - Verification of inventory audit.
    - Destroyed – Provide documentation of destruction (e.g., autoclave records and statement signed by witness)
    - Transferred – Provide the APHIS/CDC Form 2 transfer number from when select agents/toxins were transferred to a different registered entity (ex. CEA123456).
- ☐ If the entity is removing a select toxin from its registration, but will continue to possess the select toxin under the regulated aggregate amount,
  - Statement and/or records showing that the amount of toxin possessed by the registered PI is under the regulated aggregate amount.
  - Statement of how the entity will ensure that each PI's select toxin inventory remains below the regulated aggregate amount.
- ☐ Section 3 with all select agents/toxins for which the entity will remain registered.
- ☐ Complete Section 7A that removes the requested select agent/toxin for each PI that is affected by this change.
- ☐ Complete Section 7C that removes the requested select agent/toxin for each PI that is affected by this change.

Note: If Tier 1 status of entity personnel is affected by the removal of an agent, see Update to an Individual's Access to Tier 1 Agents/Toxins

Additional Information

- An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.
- Entities must conduct inventory audits of all affected select agents and toxins in long-term storage per section 11(e) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) when any of the following occur:
  (1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;
  (2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or
  (3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.
  For additional information on inventory audits, refer to the Security Guidance for Select Agent or Toxin Facilities.

Removal of Select Agent/Toxin from a PI (but not the Entity)

To remove a select agent/toxin from a PI, submit the following documentation:

- ☐ Request specifying the select agent/toxin to be removed.
- ☐ Disposition of select agent/toxin
  - Verification of inventory audit
    - Destroyed – Provide documentation of destruction (e.g. autoclave records and statement signed by witness).
    - Transferred – Provide documentation consistent with your intra-entity transfer protocols (e.g., chain-of-custody) or APHIS/CDC Form 2 transfer number (ex. CEA 123456) for transfer outside the entity.
- ☐ If the entity is removing a select toxin from its registration, but will continue to possess the select toxin under the regulated aggregate amount,
  - Statement and/or records showing that the amount of toxin possessed by the registered PI is under the regulated aggregate amount.
  - Statement of how the entity will ensure that each PI's select toxin inventory remains below the regulated aggregate amount.
- ☐ Complete Section 7A that removes the requested select agent/toxin for this PI.
- ☐ Complete Section 7C that removes the requested select agent/toxin for this PI.

Note: If Tier 1 status of entity personnel is affected by the removal of an agent, see Update to an Individual's Access to Tier 1 Agents/Toxins

Additional Information

- An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.
- Entities must conduct inventory audits of all affected select agents and toxins in long-term storage per section 11(e) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) when any of the following occur:
- (1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;
  (2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or
  (3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.
  For additional information on inventory audits, refer to the Security Guidance for Select Agent or Toxin Facilities.

Addition of New Work

The addition of new work may require an inspection prior to approval.
To add new work, submit the following documentation:

- ☐ Request specifying the work to be added.
- ☐ Complete Section 7C that includes all pending and approved work for each PI that is affected by this change.
  - New Section 7 Attachments may be required based on the new work/change in objectives of work.
- ☐ Request for approval of any proposed restricted experiments (section 13 of the regulations) or exclusions (section 3(d) and 3(e) of the regulations). Attachment B will capture information about restricted experiments.
- ☐ If adding a new suite/room, see Addition of a Suite/Room.
- ☐ If adding a new PI, see Addition or Reactivation of a PI.
- ☐ If adding a new select agent/toxin, see Addition of Select Agent/Toxin.

Additional Information

- The addition of new work with a select agent or toxin requires that written plans, as applicable, are commensurate with the risk of the agent or toxin given its intended use. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Select Agent Regulations.
- If a restricted experiment is included in Section 7C, Question 1 (objectives of work) and/or Attachment B, you may receive a request for additional information from the FSAP.
- Certain objectives of work need specific FSAP approval. 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. For example:
  - Reconstructed replication competent forms of the 1918 pandemic influenza virus.
  - Experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, even if the drug or chemical resistance is temporary. Note: Chemical resistance applies to plant pathogens.
  - Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.
- Work with a select agent or toxin at a biosafety level lower than that recommended by the current edition of the BMBL or other nationally recognized guidance requires special consideration.

Removal of Work

To remove work, submit the following documentation:

- ☐ Request specifying all changes.
- ☐ Complete Section 7C that removes the requested select agent/toxin work for each PI that is affected by this change.
  - Removal of work may require updating Section 7 Attachments.
- ☐ If removing a suite/room, see Removal of Suite/Room.
- ☐ If removing a PI, see Removal of a PI.
- ☐ If removing a select agent/toxin, see Removal of Select Agent/Toxin from the Entity.

If removal of work leads to storage only conditions, submit the following documentation:

- ☐ Request specifying all changes.
- ☐ Complete Section 7A that updates biosafety level(s) to storage.
- ☐ Complete Section 7C that updates the work objective to storage only.

  Note: Attachments A-G are not required for entities registering for storage only.
- ☐ If removing a suite/room, see Removal of Suite/Room.
- ☐ If removing a PI, see Removal of a PI.
- ☐ If removing a select agent/toxin, see Removal of Select Agent/Toxin from the Entity.

Strain Update

Updated strain information should be 1) maintained on a real time basis, 2) submitted quarterly if strain related changes in your entity's inventory have occurred or 3) submitted annually if no strain related changes have occurred in your entity's inventory since the last submission.

- ☐ Request specifying all changes.
- ☐ Updated Section 7B for each PI that is affected by this change.
- ☐ For additional information about designating strains or serotypes, see Strain or Serotype Designations.
- ☐ If the entity is adding a select agent/toxin, see Addition of a Select Agent/Toxin.
- ☐ If the entity is removing a select agent/toxin, see Removal of a Select Agent/Toxin.

Facility Amendments

Addition of a Suite/Room

The addition of a new suite/room may require an inspection prior to the approval of the amendment. Each suite/room must be assigned a PI and at least one select agent/toxin on Section 7A.

To add a suite/room, submit the following documentation:

- ☐ Request specifying suite/room to be added.
- ☐ Complete Section 5 (as applicable) with any updated information regarding entity-wide physical security, biosafety/biocontainment, and entry requirements for FSAP inspectors.
- ☐ Complete Section 6 for the suite/room.
- ☐ Floor plan as detailed in Section 6B and an expanded floor plan showing the suite/room relative to the building layout.
- ☐ Complete Section 7A listing all agents and locations for each PI that is affected by this change for the first submission only.
    - A partial Section 7A will be submitted for subsequent amendment submission.
    - The biosafety level of the suite/room should be consistent with BMBL containment recommendations for the select agent/toxin listed and work described.
- ☐ Complete Section 7C if amendment involves the addition of a BSL-3Ag or BSL-4 suite/room or if any change to Section 7C is required.
- ☐ If suite/room will be operated at BSL4/ABSL4 safety level, Attachment G.
- ☐ If work objectives for the PI(s) affected by this change will increase in scope, see Addition of New Work.
- ☐ If adding a new PI, see Addition or Reactivation of a PI.
- ☐ If adding a new select agent/toxin, see Addition of Select Agent/Toxin.

To add storage designation to a registered laboratory, submit the following documentation:

- ☐ Request specifying suite/room to be updated.
- ☐ A partial Section 7A that lists only the requested suite/room and storage additions for each PI that is affected by this change.

Additional Information
• The addition of a new suite or room requires that written plans, as applicable, are site-specific to include the additional location. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the

Additional Information
Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

Removal of Suite/Room

It is important for entities to consider how the removal of a suite/room may affect other aspects of their registration (e.g., the room to be removed is the only registered location for a select agent/toxin or a PI) and submit updates to other sections of APHIS/CDC Form1 as needed.

To remove a suite/room, submit the following documentation:

- ☐ Request specifying the suite/room to be removed.
- ☐ Documentation that effective decontamination appropriate to the use of the suite/room has been performed. If you believe decontamination is not necessary, provide a risk assessment and/or contact your designated FSAP representative.
- ☐ Complete Section 7A that removes the requested suite/room for each PI that is affected by this change.
- ☐ If removal of suite/room removes a select agent/toxin, see Removal of Select Agent/Toxin from the Entity.

  Note: If a select agent/toxin is being transferred to a different PI at your entity (intra-entity transfer) and this PI is not registered for the select agent/toxin, an updated Section 7 adding this select agent/toxin will need to be submitted and approved before the receiving PI takes possession of the select agent/toxin.
- ☐ If removal of suite/room removes a PI, see Removal of a PI.
- ☐ If removal of suite/room will also remove work, see Removal of Work.
- ☐ If personnel are being removed, see Removal of Laboratorians, Animal Care Staff, Support Staff, and Unescorted Visitors, Removal of RO, ARO, or Owner/Controller or Removal of a PI, as appropriate.

Update to Building and Suite/Room Specific Security

Entities should periodically review the information contained in this section and notify the FSAP of any changes. Updates to Section 6A may be required. For example:

- Addition of security lights or guards
- Addition of biometric system
- Addition of intrusion detection system
- Addition of pass-through autoclave
- Removal of locks

To update building and suite/room specific security, submit the following documentation:

☐ Request stating the building and suite/room security information to be updated.

☐ Complete Section 6A with updated information.

Update to Suite/Room Physical Information

Entities should periodically review the information contained in this section and notify the FSAP of any changes. Updates to Section 6B may be required. For example:

- Addition or removal of a sink, eyewash or BSC
- Changes to the HVAC system

To update suite/room physical information, submit the following documentation:

☐ Request stating the suite/room physical information to be updated.

☐ Complete Section 6B with updated information.

Other Amendments

Entity Name or Address Changes

A change of address, including a change of physical address, may be requested as an amendment and must include a detailed explanation.

To change the entity name or address, submit the following documentation:

- ☐ Request specifying changes.
- ☐ Complete Section 1A.

  Note: Section 1A denotes the physical location at which the entity is registered to possess select agents and/or toxins. The physical address will display on the entity's certificate of registration and is normally not changed unless there are extenuating circumstances such as roads which are renamed, addresses being changed by the post office, or a change in physical location by the entity.

  Note: The entity's mailing address to which all official correspondence will be sent should be provided in the address field under RO Information.
- ☐ Complete Section 1B with signatures for the RO and all AROs.
- ☐ Any change in the physical location of the entity will most likely require new Sections 5A, 5C, 6 and 7 as well as revision of entity-specific biosafety, security, and incident response plans, and an inspection.

Additional Information

- Since all communication between a registering individual or entity and the FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1A information changes, it must be immediately reported to the FSAP. Verbal change requests cannot be accepted.

Update to Entity Institutional Mission, Function and/or Size

Entities should periodically review the information contained in this section and notify the FSAP of any substantive changes.

To update an entity abstract, submit the following documentation:

- ☐ Request stating the entity abstract information to be updated.
- ☐ Complete Section 1C with updated information.

Update to Entity Wide Security and Incident Response

Updates to Section 5A may be required. For example:

- Recent break-in
- Threats or protests at the entity
- Changes to electronic access security
- Addition of a lock box for select agents/toxins

To update entity wide security and incident response, submit the following documentation:

☐ Request stating the entity wide security information to be updated.

☐ Complete Section 5A with updated information.

Additional Information

- Changes to entity wide security and/or incident response require that written plans, as applicable, are site-specific and in accordance with the entity's risk assessments. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Select Agent Regulations.

Update to Entity-Wide Biosafety/Biocontainment

Updates to Section 5B may be required. For example:

- Significant changes to the entity's biosafety program.
- Addition of Tier 1 select agents requiring individuals with access to be enrolled in an occupational health program.

To update entity wide biosafety/biocontainment, submit the following documentation:

☐ Request stating the biosafety/biocontainment information to be updated.

☐ Complete Section 5B with updated information.

Update to Entity Entry Requirements for Federal Select Agent Program Inspectors

Entities should periodically review the information contained in this section and notify the FSAP of any changes. Updates to Section 5C may be required. For example:

- Addition of new work, suite/room, or select agent/toxin
- Update to vaccination requirement for entry into registered suite/room

To update entry requirements, submit the following documentation:

☐ Request stating the entry requirements to be updated.

☐ Complete Section 5C with updated information.

Note: This section should only be updated when an entity adds or removes work or makes a policy change. It should not be updated to reflect changes in entry requirements based on when work is active or inactive.

Withdrawal Requests

Amendment Withdrawal

To withdraw an amendment, submit the following documentation:

☐ Request stating wish to withdraw the amendment. Include the amendment number and the changes originally requested.

Note: An amendment adding an individual cannot be withdrawn. Instead, submit an update to the amendment adding the individual that requests removal of the individual.

Registration Withdrawal

To withdraw from the Federal Select Agent Program, submit the following documentation:

- ☐ Request stating wish to withdraw registration, the reason for withdrawal, and the disposition of agents/toxins.
- ☐ Disposition of select agent(s) and/or toxin(s).
  - Destroyed – Provide documentation of destruction (e.g., autoclave records and statement signed by witness).
  - Transferred – Provide the APHIS/CDC Form 2 transfer number from when select agents/toxins were transferred to a different registered entity (ex. CEA123456).
- ☐ Documentation that effective decontamination appropriate to the use of the suite(s)/room(s) must be provided. If you believe decontamination is not necessary, provide a risk assessment and/or contact your designated FSAP representative.
- ☐ If the entity was registered for and possessed select toxin(s) and will now operate with select toxin(s) below the regulated aggregate amount,
  - Statement and/or records showing that the amount of toxin(s) possessed by the registered PI(s) is under the regulated aggregate amount.
  - Statement of how the entity will ensure that each PI's select toxin inventory remains below the regulated aggregate amount.

Additional Information

- An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.

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.

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

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – The Centers for Disease Control and Prevention and the National Institutes of Health publication 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 ascending 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 and the public health and 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 and 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 – Safe methods, facilities and equipment for managing infectious materials in the laboratory environment where they are being handled or maintained.

Department of Justice (DOJ) Number or Unique Identifying Number (UIN) – number provided to the Responsible Official by the FSAP 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.

Effluents – Effluents are 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.
* Effluent decontamination is required for maximum containment facilities performing work at BSL4, ABSL4, and BSL3Ag.For propagative work performed at BSL3with 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.

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 joint management of Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agricultural Select Agent Program of the Select Agent Regulations.

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 entity 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 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 7C, Question 1 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).

N95 respirator – A particulate filtering face piece respirator that filters at least 95% of airborne particles 0.3 microns and larger, but is not resistant to oil, and will not filter out volatile chemicals or

other substances for which it is not designed to serve as a protective device. A N95 can be used to provide respiratory protection when working with biological agents. See also “N100”.

N100 respirator – A particulate filtering face piece respirator that filters at least 99.97% of airborne particles 0.3 microns and larger, but is not resistant to oil, and will not filter out volatile chemicals or other substances for which it is not designed to serve as a protective device. A N100 can be used to provide respiratory protection when working with biological agents.

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.

Powered Air Purifying Respirators (**PAPR)** – PAPRs use a motorized air source to filter and clean ambient air before it is delivered to the user, usually through a full head covering (hood). PAPR systems can use many different filters such as HEPA, vapor protection, activated charcoal, or simple particulate filtration. A PAPR with HEPA filtration can be used to provide respiratory protection when working with biological agents.

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.

Personal Protective Equipment (PPE) – Any protective clothing, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or 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.

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).

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".

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.

To be Acquired (TBA) – TBA is used in Section 7B for each select agent, toxin or regulated nucleic acid for which the entity is registered but does not currently possess. Also see "TBD".

To be Determined (TBD) – TBD is used in Section 7B if there are defined strains of the agent but the entity does not have strain information for that agent (e.g., diagnostic samples that were not identified to the strain level). Also see "TBA".

Tier 1 Select Agents and Toxins – A subset of select agents and toxins designated in the Select Agent Regulations as "Tier 1" because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties or deleterious effects on the economy, critical infrastructure, or public confidence. This list can be found in the instructions for Section 3 in this document and at SelectAgents.gov.

Change History

Version	Date	Summary of Changes
1.0	06/24/2013	Initial release. These instructions replace the existing Form 1 Guidance Document.
1.1	12/9/13	Second release. Updated section 1A; Section 6A, Q4; Section 6B, Q1; Section 6B, Q16; Section 7C, Q9; Attachment A, Q3; and Amendment Reference table in New Application section. In Amendment section, updated Addition of a Select Agent/Toxin, Addition of a Tier 1 Select Agent/Toxin, and Addition of a Suite/Room
1.2	9/8/2014	Third release. Updated APHIS phone number; clarified initial, update, and renewal for type of submittal; updated appropriate sections to include the policy for work with registered toxin below the permissible amount; updated language regarding chimeric viruses; adding link to training requirements; updated Sections 3,

Version	Date	Summary of Changes
		5A, 6B, 7A to require complete 7A for first submittal on newly revised form, 7B, 7C, Attachments A, B, and C. In Amendment section, updated use of electronic signatures; requirements for submission of the following amendment types: Addition of a Select Agent, Addition of a Tier 1 Select Agent, Addition of a suite/room, Addition of New Work; included instructions for moving from work to storage only conditions; updated requirements for the addition of a BSL-3Ag or BSL-4 suite/room, added definition for effluent.
1.3	6/4/15	Fourth release. Updated sections 1, 3, 4, 5, 6, 7 and Attachments B & C. Amendment section regarding addition of SARS, removal of agent and addition of work.
1.4	12/17/15	Fifth release. Clarify when section 4 and 7C is needed, provide additional guidance for validation of effluent decontamination systems, added use of electronic signatures.
1.5	5/20/2016	Sixth release. Update instructions for Section 2; clarify when email request for amendment change is allowed; update requirements for entity withdrawal; add note to Amendment section regarding addition of a Tier 1 SAT; updated floor plan instructions in Section 6B.
1.6	1/18/17	Seventh release. Added statement that pdf or excel version of Sections 4A, 4B, 4C, and 7B can be used; clarified note about effluent decontamination requirements in Section 6B and definitions. Added new agent *Bacillus cereus* Biovar *anthracis.* Updated toxin permissible amounts.