Guidance Document for Completion of APHIS/CDC Form 1

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

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

If you are a registered entity and are submitting an amendment to your registration, please see the Guidance Document for the Submission of Registration Amendments of APHIS/CDC Form 1 to determine the submission requirements for the particular type(s) of amendment(s) you are requesting.

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Section 1 – Entity Information

Since all communication between a registering individual or entity and APHIS/CDC are completed through the Responsible Official (RO) or alternate RO (ARO), it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1 information changes, you must immediately report the change(s) to APHIS/CDC by submitting an update using the current Office of Management and Budget approved APHIS/CDC Form 1. Verbal change requests cannot be accepted.

This application is:

- Please check "A new registration."
  - This header information must be repeated in Sections 1, 3 and 4

Note: Once your entity is registered, the instructions for completing "An amendment to an existing registration" or an "Update to Amendment #" can be found in the Guidance Document for the Submission of Registration Amendments of APHIS/CDC Form 1.

Section 1A – Entity Information

Entity registration number:

- Leave this field blank. A registration number is assigned to an entity after Federal Select Agent Program has approved an initial application or a subsequent renewal of an existing registration.

Date:

- Enter the date that the document is being submitted to Federal Select Agent Program.
  - This date must be repeated in the header for Sections 1, 3, 4, 5, and 6.

Entity name:

- Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- Please do not abbreviate the organization name.

Address:

- Please provide the complete physical business address of the entity listed in the *Entity Name* field.
  - The address in Section 1A is not the mailing address to which official correspondence will be sent, the physical address of the entity should be listed. The mailing address(es) is/are entered in Sections 1B and 1C.
- Do not provide a P.O. Box address.
- Zip Code – please provide only the five digit zip code.

Type of entity:

- Please 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 who owns or controls such entity. For entities other than these, a security risk assessment for the entity must be performed and the entity must identify an individual(s) deemed to own or control the entity.

  - **Academic (Private)** – a university that is run without the control of any government entity. This entity would need to identify 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 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.
  - **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 would need to 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 would need to 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.

Section 1B – Responsible Official Information

Please refer to the definition below when specifying an RO:

RO – the individual designated by an entity with the authority and control to ensure compliance with the select agent regulations.

Name of Responsible Official:

- Please provide the full name of the RO.
  - For the purposes of completing the APHIS/CDC Form 1, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
  - The RO's last name and first name must be identical to that provided on the FD-961 Form submitted to the Federal Bureau of Investigation, Criminal Justice Information Services Division (CJIS).

Emergency Telephone #:

The purpose of this emergency contact number is to provide Federal Select Agent Program an emergency contact number for the RO. Generally, this represents an after-hours emergency number, whether that is a cell phone or a home phone is at your discretion. The phone number will only be used in emergency situations (e.g., natural disasters) when Federal Select Agent Program is unable to reach the RO at his/her designated business telephone number.

- Please provide the direct dial 10-digit emergency telephone number (i.e., after-hours number) for the RO; include an extension, if required.

Title of RO:

- Please provide the institutional job title of the RO. This title may be different from the Job Title listed in Section 4.

Business Telephone #:

- Please provide the direct dial 10-digit business telephone number for the RO; include an extension, if required.

Business FAX #:

- Please provide the 10-digit facsimile number for the RO.
  - All official fax correspondence is sent to the fax number specified for the RO.

Business E-mail address:

- Please provide the business e-mail address for the RO.
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net).

Business address:

- Please provide a complete mailing address for the RO.
  - All official hardcopy correspondence will be sent to the mailing address specified for the RO.

- This address may be different from the address listed in Section 1A.

- Do not provide a P.O. Box address.
- Zip Code – please provide only the five digit zip code.

Section 1C – Alternate Responsible Official Information

Please refer to the definition below when specifying AROs:

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 RO. (*Multiple AROs may be specified*.)

Note: If your entity wishes to designate more than two AROs, please use the Microsoft Word version of Sections 1 and 2 available at http://www.selectagents.gov/RegistrationForm.html .

Name of Alternate Responsible Official:

- Please provide the full name of the ARO(s).
  - For the purposes of completing the APHIS/CDC Form 1, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
  - The ARO's last name and first name must be identical to that provided on the FD-961 Form submitted to CJIS.

Emergency Telephone #:

The purpose of this emergency contact number is to provide Federal Select Agent Program an emergency contact number for the ARO(s). Generally, this represents an after-hours emergency number, whether that is a cell phone or a home phone is at your discretion. The phone number will only be used in emergency situations (e.g., natural disasters) when Federal Select Agent Program is unable to reach the ARO(s) at his/her designated business telephone number.

- Please provide the direct dial 10-digit emergency telephone number (i.e., after-hours number) for the ARO(s); include an extension, if required.

Title of ARO:

- Please provide the institutional job title of the ARO. This title may be different from the Job Title listed in Section 4.

Business Telephone #:

- Please provide the direct dial 10-digit business telephone number for the ARO(s); include an extension, if required.

Business FAX #:

- Please provide the 10-digit facsimile number for the ARO(s).
  - All official fax correspondence is sent to the fax number specified for the RO.

Business E-mail address:

- Please provide the business e-mail address for the ARO(s).
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net).

Business address:

- Please provide a complete mailing address for the ARO(s).
  - All official hardcopy correspondence will be sent to the mailing address specified for the RO.
  - This address may be different from the address listed in Sections 1A and 1B.
- Do not provide a P.O. Box address.
- Zip Code – please provide only the five digit zip code.

Section 1D – Registration History

- Please indicate if the entity has been previously registered with the Federal Select Agent Program by selecting “Yes” or “No” as appropriate.
- If “Yes” is selected, please indicate any previous registration numbers and registration and/or expiration dates if known.

Section 2 – Certification and Signature

RO/ARO Signatures and Dates:

- Submit signatures and date signed from the RO and all AROs.

Section 3 - Entity Summary

Complete the Select Agent/Toxin column of the table to indicate each select agent (genus and species) or toxin (above the aggregate regulated amount (http://www.selectagents.gov/Permissible%20Toxin%20Amounts.html) that the entity wishes to register on a separate line. A Microsoft Excel version of Section 3 is available at http://www.selectagents.gov/RegistrationForm.html. This version can be helpful for entities registering for numerous select agents and toxins. For assistance in using the spreadsheet version, a help document is also provided.

Notes: a) An entity is not authorized to possess, use and/or transfer select agents and toxins without an approved registration from the Federal Select Agent Program (FSAP).

b) Entities must register for the possession, use, or transfer of select agents and toxins, including regulated genomic material (i.e. +strand RNA viruses and some dsDNA viruses) and recombinant construct(s) that encode for the functional form of select toxins as defined in Section 3(c) of 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331.

c) An entity should consider the current edition of the Biosafety in Microbiological and Biomedical Laboratories (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.

d) 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, any select agent or toxin is subject to the entirety of the select agent regulations (42 CFR 73.3 and 73.4, 7 CFR 331.3 and 331.4, and 9 CFR 121.3 and 121.4). The current list of select agent exclusions can be viewed at http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html

Header Completion:

This header information should match that which was entered in Section 1 and 1A.

- **This application is** - Check “A new registration.”
- **Date** - Enter the date that the document is being submitted to Federal Select Agent Program.
- **Entity name** - Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- **Entity registration Number -** Leave this field blank. A registration number is assigned to an entity after Federal Select Agent Program has approved an initial application or a subsequent renewal of an existing registration.

Select Agent/Toxin:

- List only one select agent or toxin per row
- 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 – Central European Tick-borne encephalitis virus
Genomic material – Far Eastern Tick-borne encephalitis virus
Genomic material - Kyasanur Forest disease virus
Genomic material - Omsk Hemorrhagic Fever virus
Genomic material – Russian Spring and Summer encephalitis virus
Genomic material - Cercopithecine Herpesvirus 1 (Herpes B virus)
Genomic material – Eastern Equine Encephalitis virus
Recombinant nucleic acids encoding Abrin
Recombinant nucleic acids encoding Botulinum neurotoxin
Recombinant nucleic acids encoding Clostridium perfringens epsilon toxin
Recombinant nucleic acids encoding Conotoxins
Recombinant nucleic acids encoding Diacetoxyscirpenol
Recombinant nucleic acids encoding Ricin
Recombinant nucleic acids encoding Saxitoxin
Recombinant nucleic acids encoding Shiga-like ribosome inactivating proteins
Recombinant nucleic acids encoding Shigatoxin
Recombinant nucleic acids encoding Staphylococcal enterotoxins
Recombinant nucleic acids encoding T-2 toxin
Recombinant nucleic acids encoding Tetrodotoxin
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 - Japanese Encephalitis virus
Genomic material - Swine Vesicular Disease virus
Genomic material - Malignant Catarrhal fever virus (Alcephaline Herpesvirus Type 1)

- Do not list any biological agents or toxins that are not on the current, approved Select Agent/Toxin List.

Note: You do not have to complete the *Laboratory Area Bldg*, *Laboratory Area Room*, or *Principal Investigator* columns. The information in these columns is captured in other sections of the form. Therefore, to decrease the burden of entering duplicate data and to help ensure data consistency throughout all sections of APHIS/CDC Form 1 we do not require these columns to be completed in Section 3. However, if you do choose to complete these columns, enter all laboratory areas where work occurs for each agent. Do not include storage only rooms. In addition, complete the Principal Investigator column for each agent.

Section 4 – Entity's Personnel Information

Complete this section by providing the information for the RO, ARO(s), owner(s)/controller(s) of the entity, as well as each person who is authorized to have access to select agents and toxins at the entity. 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 § 331.10(b), 9 CFR § 121.10(b), 42 CFR § 73.10(b)]. A Microsoft Excel version of Section 4 is available at http://www.selectagents.gov/RegistrationForm.html. This version can be very helpful for entities registering numerous personnel. For assistance in using the spreadsheet version, a help document is also provided.

Note: If multiple pages are submitted, the RO only needs to sign the last page.

Header Completion:

This header information should match that which was entered in Section 1 and 1A.

- **This application is** - Check "A new registration."
- **Date** - Enter the date that the document is being submitted to Federal Select Agent Program.
- **Entity name** - Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- **Entity registration Number** - Leave this field blank. A registration number is assigned to an entity after Federal Select Agent Program has approved an initial application or a subsequent renewal of an existing registration.

Last Name/First Name:

- Please provide the last name and first name for all individuals to be authorized to have access (or the ability to gain access) to select agents or toxins.
    - The last name and first name must be identical to that provided on the FD-961 Form submitted to CJIS.

DOJ Unique Identifier Number:

- The DOJ Number field should be left blank for new applications. This number will be assigned by Federal Select Agent Program after a review of the initial application and will be communicated to the entity for use in completion of the FD-961 Form submitted to CJIS for each individual.

  Note: Once provided by Federal Select Agent Program, the DOJ number should be listed for the individual on subsequent Section 4 submissions.

Date of Birth:

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

Job Title:

When completing the Job Title section for all individuals, please use *only* the following titles. Do not include your institutional job titles or codes.

Note: An individual may have multiple job titles if they perform more than one of the following roles at the entity: RO, ARO, Owner/Controller or Principal Investigator.

- **RO** – the individual designated by an entity with the authority and control to ensure compliance with the select agent regulations.
- **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 RO.
- **Owner/Controller** – 1) an individual who owns 50 percent or more of the entity 2) a holder or owner of 50 percent or more of the entity's voting stock 3) 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 are all considered to be someone who owns or controls the entity.

  Note: Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity. For entities other than these, a security risk assessment for the entity must be performed and *the entity must identify an individual(s) deemed to own or control the entity*. An individual will be deemed to own or control an entity under the following conditions:

  - For a private institution of higher education, an individual will be deemed to own or control the entity 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 with access to the select agents or toxins possessed, used, or transferred by the entity.
  - For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

a) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

b) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

- **Principal Investigator (PI)** – the individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.
- **Laboratorian** – an individual who performs the work listed in Section 6B, Item #1 and/or directly handles select agents or toxins.
- **Support Staff: (*specific role*)** – an individual who provides an indirect service in support of the direct work with select agents or toxins, does not directly handle or work with select agents/toxins, but could potentially gain access to select agents/toxins.

  Examples (Select the role which best describes the individuals main work activities):

Support Staff: IT	Support Staff: Animal Care
Support Staff: Security	Support Staff: Maintenance
Support Staff: Administrative	Support Staff: Janitorial
Support Staff: Shipping/Receiving	Support Staff: Other

- **Visitor** – an individual who has access approval at a registered entity other than yours and will temporarily work with and/or receive select agent/toxin training at your registered entity. More detailed information for visitors can be found on the NSAR website located at http://www.selectagents.gov/FAQ_SecurityRiskAssessments.html#sec1q5 under the Visiting Scientist section.

Principal Investigator:

- For each individual listed on the Section 4 table (except RO, ARO, Owner/Controller, PI), you must list the supervising 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 or supports more than one PI, list all of these PIs in the PI column for that individual.
- If the person will work with or support all PIs, the term "All PIs" should be listed in the PI column for that individual.

Example for Completing the Section 4 Table:

This section is intended to provide an example on how to complete the Section 4 Table for the most common application conditions.

- **Example:** An entity has 1 individual who will be working directly with select agents or toxins under the direct supervision of John Smith, who performs the roles of both PI and ARO. The entity also has 2 individuals who perform support work, including maintenance and upkeep of laboratory areas for PI John Smith but do not directly work with select agent or toxin.

SECTION 4 – ENTITY'S PERSONNEL INFORMATION					
Last Name	**First Name**	**DOJ Unique Identifier Number**	**Date of Birth (mm/dd/yyyy)**	**Job Title**	**Principal Investigator**
Jones	Mary		01/01/1970	Responsible Official	
Johnson	Bill		02/02/1980	Owner/ Controller	
Smith	John		07/01/1966	ARO/Principal Investigator	
Taylor	John		03/03/1985	Laboratorian	John Smith
Williams	Sue		01/01/1975	Support Staff: Maintenance	John Smith
Anderson	James		02/02/1979	Support Staff: Maintenance	John Smith

Section 5 – Entity's Select Agent Requirements

This section must be completed by the RO during the initial request for a certificate of registration and resubmitted as an amendment any time there is a change in the entity's procedures noted in Section 5 for any or all PIs.

- Section 5 indicates that your entity and its PIs have implemented plans and procedures to ensure compliance with the requirements of Select Agent Regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

Header Completion:

Section 5 is intended to capture security, safety and other information for registered rooms. If all information applies to multiple rooms, these rooms, as well as their corresponding safety levels, may be listed on one Section 5. If Section 5 information is different, separate Section 5s, using appropriate header information, will need to be submitted.

- **Principal Investigator –** List the name of the PI or PIs that this Section 5 applies to. Using "All PIs" in this field is acceptable if the information in all parts of Section 5 applies to all PIs at your entity.
- **Date –** Enter the date that the document is being submitted to Federal Select Agent Program.
- **Laboratory building/Laboratory room number(s) –** List the building and room numbers that this Section 5 applies to. Listing multiple buildings and rooms in this field is acceptable if the information in all parts of Section 5 applies to all of the buildings and rooms listed.
- **Laboratory safety level –** List all laboratory safety levels listed on the Section 6A for the room(s) listed in the Laboratory building/Laboratory room number(s) field above. Example: BSL2, BSL3, NIHBL3, ABSL3.

Section 5A - Security

This section is used to assess the overall security precautions and procedures in place at an entity. Section 5A must be completed to ensure compliance with 7 CFR Part 331.11, 9 CFR Part 121.11, and 42 CFR Part 73.11. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 1, Security Plan:

- If you have a written security plan in place, check "Yes." Otherwise, check "No." The security plan must be 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 Federal Select Agent website under Resources for the Security Guidance Document, available at http://www.selectagents.gov/SecurityRelatedInformation.html.

Question 2, Physical Security:

a. This question is asked from the perspective of an individual entering the laboratory building from the outside. Check all that applies as you walk into the building, and is outside of the laboratory or room which houses the select agents or toxins.

b. This is the outer door(s) to the laboratory or storage area. Check each feature which applies to all access points, including emergency exits.

c. Within the laboratory or storage area, check any additional security features.

d. Check any measures used to monitor and record access to laboratories and/or storage rooms.

e. If access to select agents and toxins is restricted to individuals that have access approval from the APHIS Administrator or HHS Secretary, check "Yes." Otherwise, check "No." Access to select agents or toxins should only be granted to those individuals with access approval from the APHIS Administrator or HHS Secretary.

f. If access to select agents and toxins is allowed to individuals without an escort that do not have access approval from the APHIS Administrator or HHS Secretary, check "Yes." Otherwise, check "No." Access to select agents or toxins should only be granted to those individuals with access approval from the APHIS Administrator or HHS Secretary.

g. If the laboratory is secured when no one is present during regular working hours, check "Yes." Otherwise, check "No."

Question 3, Suspicious Packages:

- If suspicious packages are inspected prior to entry or removal from an area where select agents and toxins are used or stored, check "Yes." Otherwise, check "No." Suspicious packages must be inspected prior to entry or removal from an area where select agents and toxins are used or stored.

Question 4, Intra-entity Transfers:

- Inventories can be controlled by distinct PIs or shared. Transfers between PIs with distinct inventories are intra-entity transfers; transfers between PIs that share an inventory do not require documentation. Transfers between individuals working for PIs do not require an intra-entity transfer. If intra-entity transfer is only under the supervision of an individual with access approval from the APHIS Administrator or HHS Secretary, check "Yes." Otherwise, check "No." Entities must establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator

    a. If chain-of-custody documents are used for intra-entity transfer, check "Yes." Otherwise, check "No." Entities must establish a protocol for intra-entity

transfers that include chain-of-custody documents and provisions for safeguarding against theft, loss, or release.

Question 5, Commercial Courier Transfers:

- If select agents and toxins are transferred directly to or from a licensed commercial courier service only by an individual approved to have access to select agents or toxins, check "Yes." Otherwise, check "No." For additional information on transferring select agents or toxins, please visit http://www.selectagents.gov/resources/Form_2_Transfer_Questions_For_FAQ_(final).pdf

Section 5B – Biosafety and Incident Response

This section is used to assess the overall biosafety and incident response precautions and procedures in place. Section 5B must be completed to acknowledge compliance with Sections 12 and 14 of Select Agent Regulations. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 6, Biosafety Plan:

- If the entity has developed and implemented a written agent-specific, site-specific biosafety plan, check "Yes." If a written biosafety plan has not been developed and implemented check "No." The entity must develop and implement an agent-specific, site-specific plan that meets the requirements of Section 12 of Select Agent Regulations. In developing a biosafety 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.
    a. If the biosafety plan is commensurate with the risk of the select agent and toxin and contains all information required by the APHIS and CDC Select Agent Regulations, check "Yes." Otherwise, check "No." The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.
    b. If the biosafety plan is reviewed annually and revised as necessary, check "Yes." Otherwise, check "No." The biosafety plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. The review must occur at least annually.
    c. If drills or exercises are conducted to validate or test of the effectiveness of the biosafety plan, check "Yes." Otherwise, check "No." Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the

biosafety plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

Question 7, Personal Protective Equipment (PPE):

- If appropriate PPE is required for the select agents and/or toxins and the work performed, check "Yes." Otherwise, check "No."
    - A biological risk assessment performed by the entity may be requested by the Federal Select Agent Program if the entity has determined that no or inadequate PPE is required for the work performed with the select agent(s) or toxin(s).

Question 8, Medical Surveillance:

- If a medical surveillance system is in place (e.g., a system for reporting and documenting laboratory accidents, procedures in place in the event of an exposure and potential Laboratory Associated Infections, immunizations offered to at-risk personnel and collection/storage of serum samples) check "Yes." Otherwise, check "No."

Question 9, Spills and Accidents:

- If spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the RO, check "Yes." Otherwise, check "No." An individual or entity must immediately notify the Federal Select Agent Program upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area.

Question 10, 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 the BMBL, check "Yes." Otherwise, check "No."

Question 11, Institutional Biosafety Committee:

- If an Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents and toxins at your facility, check "Yes." If an IBC does review protocols prior to initiating work and has reviewed the work proposed in this application, check "Yes." If the IBC has yet to approve the work in the current application, check "No" and provide as an attachment the estimated date for when the IBC will review the proposed work or provide an explanation as to why the IBC did not approve the proposed work with select agents or toxins. If an IBC does not review and approve the work proposed in this application, check "No." If the proposed work does not require formal IBC review as stipulated by NIH guidelines and/or the entity has not designated an IBC, check "N/A."

Question 12, Other Inspections:

- If the facility has been inspected by U.S. Department of Agriculture (USDA), Department of Health and Human Services (HHS), Clinical Laboratory Improvement Amendments (CLIA), Department of Energy (DoE), Department of Defense (DoD), or any other inspecting agencies, check "Yes." Attach additional page(s) with the inspecting agencies and date/year inspected. Please note that inspections conducted by the Federal Select Agent Program are not required to be reported here. If the facility has not been inspected by an agency other than the Federal Select Agent Program, check "No."

Question 13, Incident response Plan:

- If the facility has developed and implemented a written incident response plan, check "Yes." Otherwise, check "No." The entity must develop and implement an incident response plan that meets 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 http://www.selectagents.gov.

  a. If the incident response plan is commensurate with the hazards of the select agent and toxins and contains all information required by the Select Agent Regulations, check "Yes." Otherwise, check "No." 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.

  b. If the incident response plan is reviewed annually and revised as necessary, check "Yes." Otherwise, check "No." The incident response plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. The review must occur at least annually.

  c. If drills or exercises are conducted to validate or test of the effectiveness of the incident response plan, check "Yes." Otherwise, check "No." Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the incident response plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

Section 5C – Training

This section is used to assess the overall training procedures in place. Section 5C must be completed to acknowledge compliance with Section 15 of the Select Agent Regulations. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 14, Training:

a. If security and biosafety training are provided to individuals prior to accessing areas where select agents and toxins are handled or stored, check "Yes." Otherwise, check "No." An entity must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access.

b. If the training addresses the needs of the individual, the work being performed, and risks posed by the select agents and toxins, check "Yes." Otherwise, check "No." 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.

c. Indicate the frequency of refresher training provided by checking annually, biannually, or other and specifying the frequency. Refresher training must be provided at least annually.

d. If written records of individuals trained are maintained, check "Yes." Otherwise, check "No." 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.

e. If personnel are required to demonstrate proficiency in laboratory procedures prior to working with select agents and toxins, check "Yes." Otherwise, check "No" and provide as an attachment the means the entity uses to assess an individual's ability to work with select agents and toxins.

f. Provide a brief description of what is included in the training program for the following topic areas:

   - Biosafety (e.g., risks posed by agents, waste disposal practices, medical surveillance, PPE usage)
   - Incident response (e.g., emergency contact information, exit routes and safe distances, exit procedures during an emergency)
   - Security (e.g., physical security, inventory control, information systems control)
   - Other training provided

g. Briefly describe the means used to verify that individuals understood the training (e.g., graded quiz, signed statement of understanding). If additional space is needed, attach additional sheets as necessary.

Section 5D – Records and Information Systems Control

This section is used to assess the overall records and information systems controls in place. Section 5D must be completed to acknowledge compliance with Section 17 of the Select Agent Regulations. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 15, Record Keeping:

- If all records specified in Section 17 of the Select Agent Regulations are maintained and current, check "Yes." Otherwise, check "No."

Question 16, Records Accuracy:

- In the space provided, briefly describe the system(s) in place to ensure records and databases are accurate, their authenticity is verified, and explain any discrepancies (e.g., describe the method of inventory tracking and maintenance of other select agent documents, how often records [such as access logs, inventory records] are reviewed and by whom, and how discrepancies are documented).

Question 17, Records Security:

- Check all that applies to describe the means used to control access to manual records that would allow for access to select agents and toxins. If the method(s) used to control access to manual records that would allow for access to select agents and toxins is not adequately described by the available selections, check "Other" and provide a brief description of the security measure(s) in place.

Question 18, Electronic Records Security:

- Check all that apply to describe the means used to control access to electronic records and databases that would allow for access to select agents and toxins. If the methods used to control access to electronic records and databases that would allow for access to select agents and toxins is not adequately described by the available selections, check "Other" and provide a brief description of the security measure(s) in place.

Question 19, Inventory Records:

- List the name(s) of the individual(s) responsible for conducting inventory reconciliation of select agents and toxins.
    a. If inventory reconciliation is conducted annually or biannually, check the appropriate box. If reconciliation occurs at a frequency other than annually or

biannually, check “Other” and specify the frequency (e.g., weekly, monthly, quarterly).

b. List the information captured for select agent and toxin inventory tracking. Please note that the inventory tracking requirements found under Section (a)(1) and (2) of the Select Agent Regulations must be met to ensure compliance.

Section 6 – Biosafety and Laboratory Information on Select Agents and Toxins

Complete each subsection as appropriate for the select agents and toxins, including regulated genomic material and recombinant nucleic acids that encode for the functional form of select toxin(s), in use or stored under the control of each PI listed on Section 4. Complete a separate Section 6 as needed for each PI at your entity. Detailed information on completing each subsection is provided below.

Section 6A – To be Completed by All Entities for each Principal Investigator

A Microsoft Excel version of Section 6A is available at http://www.selectagents.gov/RegistrationForm.html. This version can be very helpful for entities registering numerous select agents and toxins, PI’s, buildings, and/or rooms. For assistance in using the spreadsheet version, a help document is also provided.

Header Completion:

This header information should match that which was entered in Section 1 and 1A.

- **This application is** - Check “A new registration.”
- **Date** - Enter the date that the document is being submitted to Federal Select Agent Program.
- **Entity name** - Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM).
- **Entity registration Number** - Leave this field blank. A registration number is assigned to an entity after Federal Select Agent Program has approved an initial application or a subsequent renewal of an existing registration.

Select Agent /Toxin:

- List only one select agent or toxin per row
- 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 – Central European Tick-borne encephalitis virus
Genomic material – Far Eastern Tick-borne encephalitis virus
Genomic material - Kyasanur Forest disease virus
Genomic material - Omsk Hemorrhagic Fever virus
Genomic material – Russian Spring and Summer encephalitis virus
Genomic material - Cercopithecine Herpesvirus 1 (Herpes B virus)
Genomic material – Eastern Equine Encephalitis virus
Recombinant nucleic acids encoding Abrin
Recombinant nucleic acids encoding Botulinum neurotoxin
Recombinant nucleic acids encoding Clostridium perfringens epsilon toxin
Recombinant nucleic acids encoding Conotoxins
Recombinant nucleic acids encoding Diacetoxyscirpenol
Recombinant nucleic acids encoding Ricin
Recombinant nucleic acids encoding Saxitoxin
Recombinant nucleic acids encoding Shiga-like ribosome inactivating proteins
Recombinant nucleic acids encoding Shigatoxin
Recombinant nucleic acids encoding Staphylococcal enterotoxins
Recombinant nucleic acids encoding T-2 toxin
Recombinant nucleic acids encoding Tetrodotoxin
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 - Japanese Encephalitis virus
Genomic material - Swine Vesicular Disease virus
Genomic material - Malignant Catarrhal fever virus (Alcephaline Herpesvirus Type 1)

- Do not list any biological agents or toxins that are not on the current, approved Select Agent/Toxin List

Note: For more detailed guidance regarding the application of the current select agent regulations to those who create and use synthetic genomic products please refer to the document titled "Synthetic Genomics" available at http://www.selectagents.gov/SyntheticGenomics.html.

Strain Designation:

- New applications will always use "To be Acquired" (TBA) for the strain designations. Additionally, those entities registering for agents they do not currently possess should enter "TBA" in the strain column next to that agent. If the strain is unknown or undetermined to date, please enter "N/A" in the strain column.
- For currently registered entities that are completing a renewal application, list the strain designation(s) for all select agent(s) and toxin(s) listed only if known.
    - Do not list strains excluded from the select agent regulations. If you have questions, contact either APHIS or the CDC.
    - For the purposes of the APHIS/CDC Form 1, a strain is defined as a group of organisms of the same species, sharing certain hereditary characteristics not typical of the entire species but minor enough not to warrant classification as a separate 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 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 phenotype 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. *xyz*K237A Cm^R), if characterized. Additional information for the introduction of antimicrobial resistance must be provided regarding these experiments in Section 6D.
            - 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.Δ*xyz*::zeo Δ*abc*::kan; B.m. .Δ*xyz*::zeo

(pBHR2*abc*::kan)). Additional information regarding these experiments should be described in Sections 6B and 6D.

- **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 Section 6D.
    - Recombinant 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 Sections 6B and 6D.
- 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 nucleic acids that encode for the functional form(s) of select agent 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 DNA containing genes for the biosynthesis of select toxins or subunits of those toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight as defined in 42 CFR 73.13(b)(2) must be described in Section 6D.
- **Note:** Genetic modification of select agents or toxins should be designated in the strain table and described in Sections 6B and 6D. 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".

- As defined in section 3(c) of 42 C.F.R Part 73, 9 C.F.R Part 121, and 7 C.F.R Part 33, regulated select agent viral nucleic acids, recombinant nucleic acids encoding select toxins, and genetically modified select agents should be indicated in Section 6D and include explanatory information regarding these experiments. Sufficient information should be included such that the Federal Select Agent Program can evaluate the safety and security considerations associated with recombinant nucleic acids or genetic modification of select agents and toxins. Please 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.** Please note, at any time the Federal Select Agent Program 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.
- **Note:** If your entity does not perform identification to the strain level, then you would list "N/A" for this column. For select agents and toxins that have not been acquired by the entity, enter "TBA" in this column.
- **Note:** Do not list strains excluded from the select agent regulations. If you have questions, contact either APHIS or the CDC.

There are two options for initially providing strain designation information to the Federal Select Agent Program. (See the "Guidance Document for the Submission of Registration Amendments of APHIS/CDC Form 1" for instructions on submitting updates to your entity's strain related inventory.) Language may need to be revised if the amendment document is a separate document.

Option 1: Complete Attachment

- List "see attached" in the strain designation column and provide all strain information to Federal Select Agent Program using the form located at http://www.selectagents.gov/RegistrationForm.html.
- Note: This method may be preferable for entities with a large number of strains.

Option 2: Complete 6A Table

- Complete Section 6A to include all strain designations and all building/room/PI combinations.

Laboratory Area:

- Complete this column for any buildings and rooms that will be used for manipulation of select agents and toxins. Leave blank if storage only.
- Enter only one building for each row entry on the Section 6A table.
- It is acceptable to enter more than one room in a single row entry on the Section 6A table.
- If space will be registered as a suite, provide the suite designation in the room column. At the end of the Section 6A in an available space, list the rooms that comprise the suite, or provide an attachment which lists the rooms that comprise the suite.

Storage Area:

- Complete this column for any buildings and rooms that will be used to store select agents and toxins.
- Enter only one building for each row entry on the Section 6A table.
- It is acceptable to enter more than one room in a single row entry on the Section 6A table.
- For buildings/rooms that are only used for storing and not actively working with select agents or toxins, leave the "Laboratory Area" column blank and enter either "storage" or the appropriate laboratory safety level in the "Laboratory Safety Level" column.
- For rooms that are used only for decontamination/destruction purposes (e.g., irradiator room, autoclave room, "cook tank" room, incinerator room, etc.).
  a) do not complete the "Laboratory Area" column,
  b) enter the building and room designation in the "Storage Area" column, and
  c) enter the appropriate room description in the "Laboratory Safety Level" column (e.g., irradiator, autoclave, incinerator, cook tank, etc.).

  Notes: a) For decontamination/destruction rooms, you do not need to list strain information since the select agents and toxins will be destroyed.

  b) Decontamination/destruction 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.

Laboratory Safety Level:

- Selecting from the safety levels listed at the bottom of the Section 6A table; list the laboratory safety level for each select agent or toxin and building/room combination listed in the Section 6A table.
  - Indicate all safety levels that pertain to each laboratory area. For example, a single laboratory room may operate at (1) the BSL3 safety level for propagation of a select agent, (2) the NIHBL3 safety level for recombinant DNA work performed using a select agent, and (3) the ABSL3 safety level for select agent animal studies where inoculated animals are housed in the laboratory.
  - List "storage only" for storage only areas.

- It is acceptable to enter additional laboratory safety levels on a single row providing that the containment level is identical (e.g., BSL3/ABSL3/NIHBL3, or BSL2/ABSL2)

  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) recommendations in the current edition of the BMBL for each laboratory area.

Principal Investigator:

For the purpose of the APHIS/CDC Form 1, a PI is defined as the one individual who is designated by the entity to direct a project or program and who is responsible for the scientific and technical direction of that project or program.

- It is acceptable to enter multiple PIs on a single row providing that they work and/or store with the same agent in the same space.
- The "All PIs" designation can be used if all PI's on the registration will be using these rooms and select agents/toxins. This designation can also be used for registered common areas (e.g., storage rooms, irradiator rooms, decontamination rooms, incinerator rooms, etc.).

Examples for Completing the Section 6A Table:

- **Example 1:** An entity is requesting to work with *Bacillus anthracis* and *Yersinia pestis* in Building A. Within Building A, rooms 101 and 102 will be operated at BSL3 as well as used for storage and room 103 will be used for storage only. PIs Jane Smith and Matt Wilson will both access all storage and laboratory spaces in Building A.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Bacillus anthracis	TBA	A	101,102	A	101,102	BSL3	Jane Smith, Matt Wilson
Bacillus anthracis	TBA			A	103	Storage	Jane Smith, Matt Wilson
Yersinia pestis	TBA	A	101,102	A	101,102	BSL3	Jane Smith, Matt Wilson
Yersinia pestis	TBA			A	103	Storage	Jane Smith, Matt Wilson

- **Example 2:** An entity is requesting to work with Eastern Equine Encephalitis virus (EEEV) and regulated EEEV genomic material in Building B. Within Building B, rooms 201 and 202 will be operated at BSL3 as well as used for storage and room 203 will be used for storage only. Room 204 will be operated at BSL2 for work with EEEV genomic material, as well as used for storage. PIs Jane Smith and Matt Wilson will both access all storage and laboratory spaces in Building B.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Eastern Equine Encephalitis virus	NJ60	B	201,202	B	201,202	BSL3	Jane Smith, Matt Wilson
Eastern Equine Encephalitis virus	NJ60			B	203	Storage	Jane Smith, Matt Wilson
Genomic material-Eastern Equine Encephalitis virus	NJ60	B	204	B	204	BSL2	Jane Smith, Matt Wilson

- **Example 3:** 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.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Botulinum neurotoxins	BoNT/A1	C	301	C	303	BSL2	Jane Smith
Recombinant nucleic acids encoding botulinum neurotoxins	A1 (BoNTA-LC+H(n), BoNTA-LC+Belt)	C	301	C	303	NIHBL2	Jane Smith

- **Example 4:** An entity is requesting to work with *Bacillus anthracis* and *Yersinia pestis* in Building A. Within Building A, room 101 will be operated at BSL3 for work with *Bacillus anthracis* under the direction of PI Jane Smith and room 102 will be operated at BSL3 for *Yersinia pestis* work under the direction of Matt Wilson. Both *Bacillus anthracis* and *Yersinia pestis* will be stored in room 103 in a locked freezer.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Bacillus anthracis	Ames	A	101	A	103	BSL3	Jane Smith
Yersinia pestis	N/A	A	102	A	103	BSL3	Matt Wilson

- **Example 5:** An entity is requesting to work with Avian Influenza virus (Highly Pathogenic) in Building B. Within Building B, rooms 101, 102, 103, 104 and 105 will be used for both laboratory and storage. Additionally, room 106 will be used for laboratory work only. Jane Smith will direct all activities.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Avian Influenza virus (Highly Pathogenic)	A/Goose/Guangdong/1/96(H5N1) A/Vietnam/1203/2004 (H5N1)	B	101,102, 103, 104, 105,106	B	101,102, 103, 104, 105	BSL3Ag	Jane Smith

- **Example 6:** An entity is requesting to work with *Brucella abortus* in Building C. Within Building C, Suite 200 will be used for both laboratory and storage. Suite 200 consists of rooms 201, 202, 203 and 204. Since Suite 200 is not yet approved for registration, the strain designation of "TBA" is used. Jane Smith will direct all activities.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Brucella abortus	TBA	C	Suite 200	C	Suite 200	BSL3	Jane Smith

* Building C, Suite 200 = Rooms 201, 202, 203 and 204.

Other Examples for Completing the Section 6A Table:

Many factors may influence the size and complexity of an entity's Section 6A table. Entities with a large number of agents, PI's, rooms and/or safety levels may not be able to easily complete the Section 6A table as in examples 1-3 above. The below examples are intended to provide additional information with respect to how Federal Select Agent Program interprets Section 6A submissions.

- **Example 7:** Entity submits the Section 6A table below.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Burkholderia pseudomallei	K96243	A	101, 102, 103	A	101, 102	BSL3	Jane Smith

Federal Select Agent Program Interpretation of Example 4 Section 6A table – PI Jane Smith oversees work with *Burkholderia pseudomallei* in Building A, rooms 101, 102 and 103. Of these rooms, 101 and 102 are used for both laboratory work and storage for the agent while room 103 is only used as a laboratory. Labs 101 and 102 and 103 are all operated at BSL3.

- **Example 8:** Entity submits the Section 6A table below.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		
Bacillus anthracis	Ames	A	101, 102, 103, 104	A	104	BSL3	Jane Smith
Bacillus anthracis	Ames			A	105	Storage	Jane Smith
Yersinia pestis	N/A			A	104	Storage	Matt Wilson

Federal Select Agent Program Interpretation of Example 5 Section 6A table – PI Jane Smith oversees work on *Bacillus anthracis* in Building A, rooms 101, 102, 103, 104 and 105. Of these rooms, 101, 102 and 103 are used for laboratory work only, room 104 is used for both laboratory and storage space and room 105 is used for storage only. Rooms 101, 102, 103 and 104 are all operated at BSL3. Additionally, Matt Wilson oversees work on *Yersinia pestis* which is currently storage only in room 104.

Section 6B – To be Completed for each Principal Investigator Working With Select Agents/Toxins

This section is used to describe the work each PI will perform. One or more Sections 6B-6I may need to be submitted. Separate Section 6B-I are recommended for work conducted at different containment levels as work objectives, biosafety practices and laboratory information may be different. For work conducted at two or more safety levels, Section 6B-I packet(s) may be submitted by PI for each safety level (e.g., one Section 6B-I at BSL2, one Section 6B-I at BSL3/ABSL3, and one Section 6B-I at BSL4).

Complete subsections 6B-6I by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Header Completion:

Sections 6B-I are intended to capture a PI's work in laboratories and storage rooms, by safety level (ex. ABLS3, BSL3, NIHBL3). If multiple PIs perform the exact same work in the same rooms, multiple PIs may be listed in the header or the additional PIs may be listed in 6B question 2.

- **Principal Investigator** – List the names of the PI this Section 6B-I applies to. Using "All PIs" in this field is acceptable if all PIs will perform the same work.
- **Date –** Enter the date that the document is being submitted to the Federal Select Agent Program.
- **Laboratory building/Laboratory room number(s)** – List the building and room numbers that this Section 6B-I applies to. Listing multiple buildings and rooms in this

field is acceptable if the information in all subsequent sections applies to all of the buildings and rooms listed.

- **Laboratory safety level** – List all laboratory safety levels listed on the Section 6A for the room(s) listed in the Laboratory building/Laboratory room number(s) field above. For storage only rooms, enter "Storage only."

  Example: BSL3, NIHBL3, ABSL3.

Question 1, Objective of Work:

- For each PI listed in Section 6A, provide the statement of work to include all select agents and toxins under the control of the PI for the work performed in the room number(s) indicated in the header. The statement should indicate any *in vitro* and/or *in vivo* assays used for research and/or identification of the select agents/functional toxins listed in Section 6A for these rooms to include a description of the methodologies and laboratory procedures, including propagation, isolation, concentration, purification, and/or detection procedures and including arthropod work as applicable. If applicable:
  - Indicate equipment used that may produce infectious aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer, sonicator, bead beater) with infectious select agents/functional toxins.
  - Indicate recombinant or genetic modification of select agents/toxins.
  - Indicate introduction of antimicrobial resistance genes/markers to select agents.
  - Attach additional pages as needed.
- If no manipulation of select agents or toxins will occur, indicate "storage only."

Question 2, Additional PIs:

- If there are additional PIs at your entity that are performing identical work with the same agents listed in Section 6B Question 1, please check "Yes" and list their full name(s), otherwise check "No."

  Note: If additional PI names are listed for this question, only the primary PI needs to be included in the Section 6B-I header.

Question 3, Maximum Quantities:

- For each select agent listed in Section 6A, 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." For each select toxin listed in Section 6A, estimate the maximum quantity of functional toxins held by the PI at any one time. If select toxins are produced by a viable agent at the entity, please indicate maximum quantities in Section 6C, Question 7. Additional sheets may be attached if necessary.

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/toxins listed in Section 6A for each PI must be provided.

Example 1: PI John Smith propagates *Bacillus anthracis* and *Xanthomonas oryzae*, receives botulinum neurotoxin from a commercial vendor, and stores highly pathogenic avian influenza virus isolates (but does not propagate the virus).

Agent/Toxin	Maximum Quantities
Bacillus anthracis	200 petri dishes, 10 x 100 ml/10^6 cfu/ml
Botulinum neurotoxins	25 mg
Highly pathogenic avian influenza virus	No propagation of agent
Xanthomonas oryzae	50 mL flask

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/Toxin	Maximum Quantities
All agents	No propagation of agents

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

Agent/Toxin	Maximum Quantities
Bacillus anthracis	2 plates/specimen
Francisella tularensis	2 plates/specimen
Yersinia pestis	2 plates/specimen
Brucella abortus	2 plates/specimen
Brucella melitensis	2 plates/specimen
Brucella suis	2 plates/specimen
Ricin	500 mg

Question 4, Decontamination:

- If all cultures, stocks, and other regulated waste (e.g., disposable PPE, contaminated sharps) are decontaminated before removal from the entity, check yes. If decontamination does not occur prior to removal of waste from the entity, check no. If yes was indicated, check the box next to the applicable method(s) used for the decontamination of cultures, stocks, and other regulated waste. If waste is autoclaved, include the temperature, time and psi of the cycle. If chemical disinfection is used, indicate the type of disinfectant, the concentration, and the exposure 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 means of decontamination, describe the method used.

Section 6C – Work With Toxins

This section is used to assess any work with toxins which may be performed at the entity. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 5, Work with Regulated Toxins:

- If work is performed with a select toxin and/or with agents that will be used to produce **regulated amounts** of toxin, check "Yes." Otherwise, check "No."
    - 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) shown below:

HHS Toxins	Amount
Abrin	100 mg
Botulinum neurotoxin	0.5 mg
Clostridium perfringens epsilon toxin	100 mg
Conotoxins	100 mg
Diacetoxyscirpenol	1,000 mg
Ricin	100 mg
Saxitoxin	100 mg
Shiga-like ribosome inactivating proteins	100 mg
Shigatoxin	100 mg
Staphylococcal enterotoxins	5 mg
T-2 toxin	1,000 mg
Tetrodotoxin	100 mg

Note: HHS toxins may be **exempted** from these requirements as defined in 42 CFR 73.5.

- The Federal requirements to register with the select agent program apply at any time the aggregate amount of a select toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor exceeds the aggregate amounts specified above. An entity must register the PI(s) that will

possess, use or transfer a select toxin in quantities greater than the excluded aggregate amount.

- All work with the select toxin under the control of the registered PI, including work with excluded quantities of toxin, must be in compliance with the select agent regulations, such as the registration of all laboratory and storage rooms, maintenance of inventory records, and development of a chemical hygiene plan.
- For animal work, once an animal has been injected with or exposed to (for example, by inhalation, dermal absorption, or ingestion) a select toxin, the animal would not be considered a "select toxin" and would not need to be housed in a registered space. However, until the select toxin is injected into or exposed to the animal, the select toxin would be regulated under the Select Agent Regulations. This would include storage or use of the material (e.g., injection or exposure procedure). If select toxin is stored or used in the same area as the injected or exposed animal, the space will need to be listed on the entity's approved certificate of registration. The room where the injection or exposure procedures occur may be assessed using laboratory biosafety level criteria instead of animal biosafety level criteria.
- For Botulinum neurotoxins, if the toxin preparation contains Botulinum neurotoxin producing strains of Clostridium, the animals will need to be treated as a select agent.
- If the proposed work will involve the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight, Section 6D must also be completed and will require approval by the Federal Select Agent Program. Further, recombinant 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 of any length that have a deleterious biological effect lethal for vertebrates at an LD50 < 100 ng/kg body weight. Lack of biological effect should not be assumed. Experimental data from a recognized biological model (either *in vivo* or *in vitro*) of toxin activity must be submitted to the Federal Select Agent Program for consideration before subunits of regulated toxin genes can be excluded from regulation.

- If yes, complete questions 6-10.

Question 6, Chemical Hygiene Plan:

- If you have a Chemical Hygiene Plan (CHP) that is both site-specific and toxin-specific, check “Yes.” Otherwise, check “No.” The CHP must be reviewed annually and revised as necessary.
- Entities that distribute select toxins are additionally required to have a hazard communication plan that addresses the safety and security considerations of other federal agencies (e.g., Department of Transportation).

Question 7, Toxin Production:

- If you intend to purify select toxin from natural sources or produce select toxin by in vitro culture and/or recombinant gene expression systems, check "Yes." If yes, please describe briefly the methodology used and the expected amounts of select toxin to be produced over a given time period. For example, suitable statements could include, but are not limited to: "Full-length toxin gene is present in a plasmid expression vector, and viable toxin is produced in vitro using commercially available in vitro transcription and translation kits in 1-10 microgram amounts monthly", "Full-length toxin gene is present in a bacterial plasmid expression vector, and transformed bacteria are used to produce viable toxin weekly in microgram to milligram quantities", or "Viable botulinum neurotoxin is produced by *Clostridium botulinum* vegetative forms without modification of the natural production pathways." If you possess a finite amount of select toxin (ordered from a commercial entity or received from a collaborator), check "No."

Question 8, Toxin Dilution/Manipulation:

- If dilution procedures and other manipulations of concentrated toxins are performed, check "Yes." Otherwise, check "No." If "Yes" is checked, you must complete questions 8a-c.

  a. Indicate whether dilution procedures and other manipulations of concentrated toxins are performed in a fume hood and/or biological safety cabinet by checking all that apply.

  b. If a fume hood or biological safety cabinet is used for dilution procedures and other manipulations of concentrated toxins, indicate the frequency at which the fume hood and/or biological safety cabinet is certified by checking "Annually" or "Biannually" (every six months). Check "Other" to indicate certification periods other than Annual or Biannual. Include an explanation for certifications performed less often than annually.

  c. If dilution procedures and other manipulations of concentrated toxins are conducted with two knowledgeable people present, check "Yes." Otherwise, check "No."

Question 9, Hazard Sign:

- If "Toxins in Use – Authorized Personnel Only" signs are posted at all times when toxins are being manipulated, check "Yes." Otherwise, check "No." Select toxin regulations require additional BMBL-recommended signage for biological laboratories approved to work with toxins.

Question 10, Decontamination:

- If all cultures, stocks, and other regulated waste (e.g., disposable PPE, contaminated sharps) are decontaminated before removal from the entity, check "Yes." Otherwise, check "No." If yes was indicated, check the box next to the applicable method(s) used for the decontamination of cultures, stocks, and other regulated waste. If waste is autoclaved, include the temperature, time and psi of the cycle. If chemical disinfection is used, indicate the type of disinfectant, the concentration, and the exposure 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 means of decontamination, describe the method used.

Section 6D – Work With Genetic Elements, Recombinant Nucleic Acids, or Recombinant Organisms

This section is used to assess any work that a PI may perform with genetic elements, recombinant nucleic acids or recombinant organisms. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Further description(s) of the proposed work may be requested by the Federal Select Agent Program prior to approval. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Note: All products of a restricted experiment as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13 are also restricted and require review by the Federal Select Agent Program before transfer or use. If this applies to your application, contact the Federal Select Agent Program.

Question 11, Work with Genetic Elements/Recombinant Nucleic Acids/Recombinant Organisms/Antibiotic Resistant Select Agents:

- Per Federal Select Agent Program policy: Recombinant organisms are defined as select agents that have been genetically modified by recombinant technology. Construction of chimeric organisms that contain any genes from a select agent or functional subunits of a select toxin should be submitted for Federal Select Agent Program review. If work will be performed with recombinant organisms, check "Yes". Otherwise, check "No".
- Per Federal Select Agent Program policy: Genetic elements are defined as any molecule or segment of DNA or RNA that carries genetic information. If work will be performed with genetic elements, check "Yes." Otherwise, check "No."
- Per Federal Select Agent Program policy: Recombinant nucleic acids are defined per NIH guidelines, such that recombinant DNA molecules are: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
    - If work will be performed with recombinant nucleic acids as defined above, check "Yes." Otherwise, check "No."
- Per Federal Select Agent Program policy: Recombinant organisms are defined as select agents that have been genetically modified by recombinant technology. Construction of chimeric organisms that contain any genes from a select agent or functional subunits of a select toxin should be submitted for Federal Select Agent

Program review. If work will be performed with recombinant organisms, check "Yes". Otherwise, check "No".

- If work will be performed with antimicrobial resistant select agents, check "Yes." Otherwise, check "No."
- If yes is checked for any item above, complete questions 12-16.

Question 12, Possession/Use/Transfer:

a. If the entity will possess, use or transfer nucleic acids that can produce infectious forms of any select agent virus, check "Yes." Otherwise, check "No."

Note: Positive strand RNA viruses and certain double stranded DNA viruses that utilize host polymerases contain nucleic acids that can produce infectious virions (or particles). Examples of select agent viruses that meet this criterion, and would therefore be regulated, are shown in the table below. For additional guidance, please refer to http://www.selectagents.gov/resources/Applicability%20of%20the%20Select%20Agents%20Regulations%20to%20Issues%20of%20Synthetic%20Genomics.pdf

HHS Agents	Overlap Agents	USDA Agents
Cercopithecine Herpesvirus 1 (Herpes B virus) Tickborne encephalitis complex viruses: o Central European Tick-borne encephalitis o Far Eastern Tickborne encephalitis o Russian Spring and Summer encephalitis o Kyasanur Forest Disease o Omsk Hemorrhagic Fever Eastern Equine Encephalitis virus (EEE)	Venezuelan Equine Encephalitis virus (VEE)	Classical Swine Fever virus Foot-And-Mouth Disease virus Japanese Encephalitis virus Swine Vesicular Disease virus Malignant Catarrhal fever virus (Alcephaline Herpesvirus Type 1)

b. If the entity will possess, use or transfer recombinant nucleic acids that encode for the **functional form(s) of any select toxins** if the nucleic acids:

1) can be expressed *in vivo* or *in vitro*, check "Yes." Otherwise, check "No."

2) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*, check "Yes." Otherwise, check "No."

Note: Recombinant 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 of any length that have a deleterious biological effect lethal for vertebrates at an LD50 < 100 ng/kg body weight.. 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 Federal Select Agent Program for consideration before subunits of regulated toxin genes can be excluded from regulation.

c. If the entity will possess, use or transfer select agent viruses, bacteria, fungi, and toxins that have been genetically modified, check "Yes." Otherwise, check "No."

Question 13, Recombinant Constructs/Expression Control Elements:

- Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes, if known.
- Attach additional pages and/or maps of the recombinant construct, cloning/expression vector.

Question 14, Length of Recombinant DNA:

- If recombinant constructs are described in Question 13, provide an estimate of the range of length of recombinant DNA used (e.g., 300 bp, 2-4 kb).

Question 15, Antibiotic Resistance Markers/Traits:

- If the proposed work will introduce antimicrobial resistance markers/traits into select agents/toxins, check "Yes." Otherwise, check "No."
- If yes, indicate the proposed agents and antibiotic (e.g., *Francisella tularensis*, ampicillin). Additionally, the fourth part of Question 11 should also be checked "Yes."

  Notes: a) The deliberate transfer of a drug resistance trait to select agents, including those used for transient transformation(s), must be noted here.

  b) An individual or entity may not conduct a restricted experiment as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13 unless approved by the Federal Select Agent Program.

Question 16, Recombinant Toxin Synthesis:

- If the proposed work will involve the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight, check "Yes." Otherwise, check "No."

  Note: Recombinant 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 of any length that have a deleterious biological effect lethal for vertebrates at an LD50 < 100 ng/kg body weight. 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 Federal Select Agent Program for consideration before subunits of regulated toxin genes can be excluded from regulation.

- If "Yes" is checked, list the toxin and provide a brief description of the proposed experiments, including any proposed animal studies as applicable. Attach additional pages as needed. Additionally, the second part of Question 11 and Question 12(b) should also be checked "Yes."

  Note: An individual or entity may not conduct a restricted experiment as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13 unless approved by the Federal Select Agent Program.

Section 6E – Work With Animals

This section is used to assess any work which may be performed with animals at an entity. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 17, Work With Animals:

- Check "Yes" if you will work with any live animals. Otherwise, check "No." If "Yes" is checked, complete questions 18 - 22.

Question 18, Animals and Routes of Administration:

- List each select agent to be used in animals, provide the species of animal (genus & species name, as well as common name) and any and all routes of administration of the agent. See the example below:

Select Agent	Species of Animal	Route(s) of Administration
Lassa fever virus	*Mus musculus* (ICR mouse)	IC, IP, IM
Bluetongue virus (exotic)	*Bos taurus* (Black Angus beef cattle)	IP, IM, ID

Notes: a) Use attachment if needed.

b) The form does not support italicization of genus and species names.

c) Use the following abbreviations: AE = Aerosol, IC = Intracranial, IN = Intranasal, 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, or any other uncommon routes of administration.

Question 19, Animal Waste and Carcasses:

- Please describe the waste stream of the laboratory as it relates to animal work, including any items that are not accounted for in other areas of this form (e.g., scalpels, forceps, syringes and needles). Check multiple boxes if multiple methods apply. For example, if you autoclave and then incinerate, describe your autoclave protocol including time, temperature, and pressure, and check the incineration box as well.
- Please describe the policies and procedures in place that prevent personnel or environmental exposure if you transport contaminated (untreated or minimally treated) waste outside of its place of generation before decontamination. For example, if you transport animal waste to an offsite incinerator, or transport waste from a "hot" area of the laboratory through a "grey" area of the laboratory to an autoclave, please describe the procedures that dictate the conditions of that transport in detail so the Federal Select Agent Program can evaluate safety and security concerns that may arise from such transport.

- If you take any tissues or blood samples from infected or control animals, please describe how they are stored and/or manipulated, including where and by whom. For example, blood or tissue samples from infected animals are still select agents. Therefore, they must be stored and manipulated in registered space by approved individuals until an adequate disinfection procedure has inactivated the agent's ability to infect living organisms as well as its nucleic acid's ability to generate infectious agents if applicable. Please describe the procedures and methods in detail.

Question 20, IACUC:

- Check "Yes" if the entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity. Otherwise, check "No."

  Note: Some corporate or private entities do not have these committees, so please check "No" if an IACUC does not review proposed animal work.

- Check "Yes" if the proposed work with select agents and toxins in animals has been approved by the entity IACUC. Otherwise, check "No."

Question 21, AAALAC:

- Check "Yes" if the laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Otherwise, check "No."

  Note: Some corporate or private entities do not seek this accreditation, please check "No" if the entity is not AAALAC accredited.

- If "Yes" is checked, please provide the date of accreditation.

Question 22, Animal Tracking:

- Check "Yes" if there is there a system in place for recording the number of animals received and the number of animals disposed of and the records for these activities reviewed frequently. Otherwise, check "No."
- If "Yes" is checked, describe the method used to track and account for animals from the time they enter the registered space and are exposed to the select agent until final disposition. Include sufficient detail such that a person unfamiliar with your specific system can understand the concepts and check-points that exist in the system. For example, "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", etc. Additionally, indicate if unique animal identifiers such as ear tags or brands are used. Also include the frequency of reconciliation of records (daily counts checked against inventory database, etc.).

  Note: Animals exposed to select toxins are not subject to select agent regulations. The exposure and waste associated with the exposure is regulated but the animal is not. Please refer to the "Animals injected with or exposed to a select toxin" information available at http://www.selectagents.gov/SA_Gram.html for more details.

Section 6F – Work With Plants

This section is used to assess any work with plants that may be performed at an entity. Multiple, complete Section 6s 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 applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 23, Work With Plants:

- Check "Yes" if work will be performed with plants. Otherwise, check "No." If "Yes" is checked, you must complete questions 24-36.

Question 24, Plants and Routes of Administration:

- List each select agent to be used in plants, provide the species of plant (genus & species name, as well as common name) and any and all routes of administration of the agent. See the example below:

Select Agent	Species of Plants	Route(s) of Administration
Xanthomonas oryzae	Rice	Leaf wound
Synchytrium endobioticum	Potato	Soil/roots
Peronosclerospora philippinensis	Maize	Leaf

Note: The form does not support italicization of genus and species names

Question 25, Work in Glass or Greenhouse:

- Check "Yes" if Work will be done in a glass or greenhouse. Otherwise, check "No."
- If "Yes" is checked, provide a description of the glass or greenhouse by checking all that apply.

Question 26, Structure:

- Check "Yes" if the structure where work with plants will be performed is reinforced. Otherwise, check "No."

Question 27, Floor:

- Check "Yes" if the floor is concrete where work with plants will be performed. Otherwise, check "No."

Question 28, Vents:

- Check "Yes" if the space where work with plants will be performed vents into the facility. Otherwise, check "No."

Question 29, Floor Drains:

- Check “Yes” if the space where work with plants will be performed has floor drains. Otherwise, check “No.”

Question 30, Waste Collection and Treatment:

- Check “Yes” if waste water is collected and treated prior to release into the sanitary sewer system. Otherwise, check “No.”

Question 31, Greenhouse HVAC Supply/Exhaust:

- Please describe the greenhouse HVAC supply and exhaust parameters by completing Question 31a-b.
  a. Check “Yes” if negative air pressure is maintained inside the greenhouse. Otherwise, check “No.”
  b. Check “Yes” if greenhouse exhaust air is re-circulated to other areas of the facility. Otherwise, check “No.” If “Yes” is checked, please indicate if HEPA filtration of all exhaust air is in place by checking either “Yes” or “No.”

Question 32, Vectors:

- Check “Yes” if vectors are present. Otherwise, check “No.”
- If “Yes” is checked, please indicate if vectors are restricted to cages by checking either “Yes” or “No.”

Question 33, Growth Chambers:

- Check “Yes” if work will be done in growth chambers. Otherwise, check “No.” If “Yes” is checked, you must complete Questions 33a-c.
  a. Check “Yes” if the growth chamber is integrated into the laboratory building structure. Otherwise, check “No.”
  b. Check “Yes” if the growth chamber is stand alone. Otherwise, check “No.”
  c. Provide the manufacture name and model number of the growth chamber(s).

Question 34, Growth Chamber Floor Drains:

- Check “Yes” if the growth chamber has floor drains. Otherwise, check “No.”
- If “Yes” is checked, please indicate if waste water is collected and treated prior to release into the sanitary sewer system by checking either “Yes” or “No.”

Question 35, Growth Chamber HVAC Supply/Exhaust:

- Please describe the growth chamber HVAC supply and exhaust parameters by completing Question 35a-b.
  c. Check “Yes” if negative air pressure is maintained inside the growth chamber. Otherwise, check “No.”

d. Check “Yes” if growth chamber exhaust air is re-circulated to other areas of the facility. Otherwise, check “No.” If “Yes” is checked, please indicate if HEPA filtration of all exhaust air is in place by checking either “Yes” or “No.”

Question 36, Plant Waste Treatment:

- Please describe the treatment of plant waste prior to disposal by checking all that apply and providing a brief description of the treatment method(s).

Section 6G – Laboratory Information

This section is used to assess the laboratory space where select agents and/or toxins will be used. Complete this section by checking either “Yes” or “No” for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Notes: a) If the rooms listed in the Section 6B-I header are storage only and no laboratory work will be performed in these areas, complete Questions 38 and 39 only.

b) Please refer the “Policy on BMBL 5th edition Laboratory Facilities (Secondary Barriers) Standards” information available at http://www.selectagents.gov/SA_Gram.html for more detailed information regarding Select Agent Program registered facility policies.

- For any laboratory that is not operational, indicate “No” and note this on the floor plan (Question 38), and include the anticipated date the laboratory will become operational. For all operational laboratories, check “Yes.”

Question 38, Floor Plan:

- Submit floor plans, both specific for the room and an expanded floor plan, showing the room relative to the building layout. Designate entry and exit access points, including emergency exit doors. Indicate if there is a door or just a doorway without a door. Any doors no longer in use and blocked by temporary measures should be indicated. Permanently sealed doors do not need to be indicated on the floor plan.
  - Indicate the location of all key pads or other electronic devices used to access the laboratory.
  - Indicate all surveillance cameras used to monitor registered select agent rooms and access points.
- Any large equipment and its location should be indicated on the floor plan. Large equipment may include the following: BSCs, fume hoods, clean workstations, freezers, refrigerators, incubators, centrifuges, autoclaves, incinerators, fermenters, and shakers. Particularly include any equipment that is specially ventilated or connects directly to the building exhaust system.

Note: If an autoclave is used for decontamination of waste and is located in a different part of the building or another building, indicate its location on a separate floor plan.

- All plumbing fixtures, such as sinks, eyewashes, drench showers, open floor drains, and cage washing areas in the laboratory should be indicated on the floor plan.

  Note: If cage washing area used is located in a different part of the building or another building, indicate its location a separate floor plan

- HVAC supply and exhaust venting systems should be indicated on the floor plan. You may use the following symbols:
  -  to indicate supply air
  -  to indicate exhaust air
- Include other items such as ultraviolet (UV) decontamination boxes, room decontamination ports, pass-through boxes and dunk tanks.

Question 39, Facility Risk Assessment:

Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a Laboratory Acquired Infection (LAI), and the probable consequences of such an infection.

- If you performed a biological risk assessment to determine the appropriate biosafety level for the select agent/toxin and the work performed, check "Yes." Otherwise, check "No."

a. Check all applicable biosafety levels.
   - These biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards associated with the select agents or toxins used and for the laboratory function and activity.

   Note: The biosafety level checked is for the laboratory or storage area(s) listed in the Section 6B-I header.

b. Indicate which references or resources were used to perform the risk assessment.
   - If performing recombinant DNA work, check "Other" and indicate the appropriate biosafety level as shown on the bottom of Section 6A (e.g., NIHBL3).
   - In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory should be considered together.
   - The objective of physical containment is to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms containing recombinant DNA molecules.

Question 40, Biological Safety Cabinets (BSC) Certification:

A properly certified and operational BSC is an effective engineering control that may be used in concert with the appropriate practices, procedures and other administrative controls to further reduce the risk of exposure to potentially infectious microorganisms.

- Indicate the frequency at which the BSC is certified by checking "Annual" or "Biannual" (every six months). Check "Other" to indicate certification periods other than Annual or Biannual. Include an explanation for BSC certifications performed less often than annual.
    - The operational integrity of a BSC must be validated before it is placed into service and after it has been repaired or relocated. Moving a BSC may break the HEPA filter seals or otherwise damage the filters or the cabinet.
    - Each BSC should be tested and certified at least annually to ensure continued, proper operation when appropriate practices and procedures are followed.

Question 41, Laboratory Exhaust:

- If the air from the laboratory is exhausted to any other part of the building or facility, check "Yes." Otherwise, check "No."

Notes: a) BSL3, ABSL3, BSL4 and ABSL4 laboratory exhaust air must not re-circulate to any other areas of the building or facility.

b) There are no specific requirements for ventilation systems in a BSL2 laboratory. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.

Question 42, Laboratory Air Pressure:

- Check "Yes" if the laboratory is maintained at negative air pressure to provide directional air into the laboratory. If not, check "No".
    - For BSL3/ABSL3/BSL4/ABSL4 laboratories, the supply and exhaust components of the ventilation system must be designed to maintain the laboratory at negative pressure to surrounding areas and provide differential pressure or directional airflow, as appropriate, between adjacent areas within the laboratory.

Question 43, Laboratory Separation:

- If the laboratory is separated from areas that are open to unrestricted traffic flow within the building or facility, such as public passageways, check "Yes." Otherwise, check "No".
    - Access to BSL3 laboratories should be through two self-closing doors. A clothing change room (anteroom) may be included.

Question 44, Visual Air Direction System:

- If laboratory personnel are able to monitor and verify directional airflow before entering and during use of the laboratory, check "Yes." Otherwise, check "No." The visual monitoring device must be provided at the laboratory entry, such as magnehelic or digital gauge, Baulin-Tube ®, Tell-Tale, etc.

Question 45, Exhaust System Alarm:

- If the laboratory is equipped with a visual or audible alarm system to alert laboratory personnel of exhaust system failure, check "Yes." Otherwise, check "No."

  Note: An audible alarm should be considered to notify personnel of air flow disruption.

Question 46, Exhaust HEPA Filtration:

- If HEPA filtration of the laboratory exhaust air is in place, check "Yes." Otherwise, check "No."

Section 6H – 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 applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 47, BSL3 AG Work:

- Check "Yes" if work with animals will be performed in a BSL3Ag laboratory. Otherwise, check "No." If "Yes" is checked, you must complete questions 48-59.

Question 48, Infected Animal Housing:

- Describe where infected animals will be housed during and after experiments.
  - Include in the description what specific type of pen equipment is used, such as portable panels, metal fencing with posts embedded in concrete floor, or elevated open cages. Also address whether biobubbles are used and how, are animals contained directly on the floor, what bedding material is used if any, and how many animals held in each room. Describe any restraint devices used such as stanchions, chutes with head catch, halters, ropes or leads, and collars.

Question 49, Two-Person Rule:

- Check "Yes" if personnel assigned to work with infected animals work in pairs. Otherwise, check "No."
  - Work with larger species such as cattle, swine, bison, deer, horses, sheep, and goats increase the risk of injury to the animal caretaker or laboratory worker

when attempting to handle or move animals, inoculate with infectious agents, applying restraint or conducting routine animal care activities such as removal of waste and bedding, feed and watering. It is recommended that personnel work in pairs or implement a system to be able to alert individuals outside of the containment area when injuries occur to an employee.

Question 50, Aerosol Experiments:

- Check "Yes" if aerosol experiments are conducted in this BSL3Ag laboratory. Otherwise, check "No."
  - For high level bio-containment facilities include two HEPA filters arranged in series or with consideration of parallel system on the exhaust side serving high-risk areas where large amounts of aerosols containing BSL3Ag agents could be expected (e.g. animal rooms, contaminated corridors, necropsy areas, carcass disposal facilities, etc.) based on risk assessment.
  - Central vacuum filtration systems are not recommended. If, however, there is a central filtration vacuum system, it must not serve areas outside of the BSL3Ag laboratory. Two in-line HEPA filters must be placed near each end point. Filters must be installed to permit in-place decontamination and replacement.
  - When leaving the animal space that contain large volumes of aerosols containing highly infectious agents require showering out.

Question 51, Daily Inspections:

- Check "Yes" if a mandatory daily inspection of the containment parameters for the BSL3Ag laboratory area(s) and critical life support systems is performed. Otherwise, check "No."
  - Daily inspections of essential containment and life support systems must be completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.
  - Daily inspections should address the status of all necessary variables for laboratory and facilities support functions, as well as provide a clear "NO ENTRY" cut off for personnel to assess whether the daily condition is optimal for entry.

Question 52, Supply/Material Entry:

- Check "Yes" if supplies, material and equipment enter BSL3 Ag space only through an airlock, fumigation chamber, and interlocked and double-door autoclave or shower. Otherwise, check "No."
  - Pass through double-door autoclaves should be situated through an exterior wall of the containment area with the autoclave forming an airtight seal with the barrier wall with the bulk of the autoclave outside of the containment space.
  - Gas sterilizer, pass-through liquid dunk-tank, or cold gas decontamination chamber must be provided for safe removal of materials and equipment that are steam or temperature sensitive.

- Disposable material must be decontaminated through autoclaving or other verifiable decontamination method followed by incineration or other approved means.

Question 53, Wall/Penetration Seals:

- Check "Yes" if all walls are constructed slab-to-slab and walls, floors, and ceilings of the BSL3Ag laboratory rooms are sealed. Checking "Yes" also indicates that all penetrations into the laboratory are sealed airtight to prevent escape of contained agents and to allow gaseous fumigations for biological decontamination. Otherwise, check "No."
  - BSL3Ag containment spaces must be designed, constructed and verified as a primary containment barrier. Primary containment must provide a shower with change rooms within the BSL3Ag animal rooms and a secondary shower with change rooms prior to leaving the facility.
  - For BSL3Ag rooms, walls, floors, and ceiling of the room must be constructed to form a sealed internal box to provide for primary containment of the select agent and facilitate decontamination. Floors must be monolithic, sealed and covered. All penetrations in the internal wall of the room and inner change room must be sealed.
  - Doors serving as primary containment barriers to BSL3Ag space must be sealed and tested as airtight via pressure decay test.
  - Doors must be interlocked when serving airlocks and/or anterooms. Airlock doors must have air inflated or compressible gaskets. Compressed air lines to air inflated gaskets must be provided with HEPA filters and check valves.
  - Windows must be break-resistant and sealed.

Question 54, Bench Top Construction:

- Check "Yes" if all bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontamination chemicals. Otherwise, check "No."
  - If provided, for BSL3Ag laboratories, cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination. Sharp edges and corners should be avoided.

Question 55, Laboratory Furniture:

- Check "Yes" if all laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated. Otherwise, check "No."
  - Should be kept to a minimum. If provided, laboratory furniture, including casework should be isolated from animal pen areas.

- Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination. Chairs and other furniture must be covered with a non-porous material that can be easily decontaminated.

Question 56, Air Flow Monitoring:

- Check "Yes" if differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure. Otherwise, check "No."
  - An alarm system should be considered to notify personnel of ventilation and HVAC system failure. Audible alarms are acceptable as long as they are not installed within the animal rooms. A visual indicator inside the animal rooms that is tied into the alarm system should be considered. All alarm devices must register/report to a central monitoring station or similar remote location.
  - The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters. A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified prior to entry.
  - Directional air flow within the BSL3Ag containment spaces moves from areas of least hazard potential towards areas of greatest hazard potential.
  - A visible means of displaying pressure differentials is provided.

Question 57, Supply/Exhaust HEPA Filtration:

- Check "Yes" if there is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s). Otherwise, check "No."
  - Air handling systems must provide 100% outside conditioned air to the BSL3Ag containment spaces.
  - Supply and exhaust systems must be dedicated, single pass, directional, and pressure gradient ventilation systems serving BSL3Ag containment areas.
  - Ductwork serving BSL3Ag containment spaces must be air tight and pressure tested via pressure decay test.
  - Supply and exhaust air to and from each containment space is HEPA filtered. HEPA filters must have a minimum efficiency rating of 99.9997%. Biological pre-filters for each HEPA filter application must have a minimum efficiency rating of 80%-90%.
  - HEPA filters must be installed on all atmospheric vents serving plumbing, central or local vacuum systems and on return lines of compressed gas air systems.

Question 58, Communication Systems:

- Check "Yes" if appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer). Otherwise, check "No."
    - Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and emergency access or egress must be developed and implemented.

Question 59, Drains:

- Check "Yes" if all drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system. Otherwise, check "No."
- If "Yes" is checked, describe the method(s) utilized for decontamination of liquid waste from the BSL3Ag area(s).
    - Liquid effluents from BSL3Ag areas must be collected and decontaminated in a central liquid waste sterilization system before disposal into the sanitary system.
    - Drains, if present, in the laboratory floor must be connected directly to the liquid waste decontamination system. Sewer vents and other service lines must be protected by HEPA filtration and have protection against insect and animal intrusion.
    - Liquid effluent from showers, sinks, floor drains, and other sources within the laboratory be decontaminated, if needed, by a proven method.
    - Services and plumbing that penetrates the laboratory walls, floors, or ceiling must be installed to ensure no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices.

Section 6l – BSL4/ABSL4 Laboratories

This section is used to assess any work that may be performed in BSL4 or ABSL4 laboratories at an entity. Complete this section by checking either "Yes" or "No" for all applicable questions and entering additional information when prompted. Additional guidance is provided for some questions below although if further information or guidance is required; please visit http://www.selectagents.gov or contact the CDC at (404) 718-2000 / lrsat@cdc.gov or APHIS at (301) 851-3300, Option 1 / ASAP@aphis.usda.gov.

Question 60, BSL4/ABSL4 Work:

- Check "Yes" if work will be performed in a BSL4/ABSL4 laboratory. Otherwise, check "No." If "Yes" is checked, you must complete questions 61-70.

Question 61, Daily Inspections:

- Check "Yes" if a mandatory daily inspection of the containment parameters for the BSL4 laboratory area(s) and critical life support systems is performed. Otherwise, check "No."
    - Daily inspections of essential containment and life support systems must be completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.
    - Daily inspections should address the status of all necessary variables for laboratory and facilities support functions, as well as provide a clear "NO ENTRY" cut off for personnel to assess whether the daily condition is optimal for entry.

Question 62, Wall/Penetration Seals:

- Check "Yes" if all walls, floors, ceilings, and penetrations into the BSL4 laboratory room are sealed. Otherwise, check "No."
    - For BSL4 cabinet laboratories, walls, floors, and ceiling of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. Floors must be monolithic, sealed and covered. All penetrations in the internal shell of the laboratory and inner change room must be sealed. Openings around doors into the cabinet room and inner change room must be minimized and capable of being sealed to facilitate decontamination. Windows must be break-resistant and sealed.
    - For BSL4 suit laboratories, walls, floors, and ceiling of the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. Floors must be monolithic, sealed and covered. All penetrations in the internal shell of the laboratory, suit storage room and inner change room must be sealed. Windows must be break-resistant and sealed.

Question 63, Bench Top Construction:

- Check "Yes" if all bench tops are seamless and are a sealed surface that is impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontamination chemicals. Otherwise, check "No."
    - For BSL4 laboratories, cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment must be accessible for cleaning and decontamination. Sharp edges and corners should be avoided.

Question 64, Laboratory Furniture:

- Check "Yes" if all laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated. Otherwise, check "No."
    - Laboratory furniture must be of simple construction, capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and

equipment must be accessible for cleaning and decontamination. Chairs and other furniture must be covered with a non-porous material that can be easily decontaminated. For BSL4 suit laboratories, sharp edges and corners should be avoided. Equipment to be placed in the Class III cabinet should also be free of sharp edges or other surfaces that may damage or puncture the cabinet gloves.

Question 65, Air Flow Monitoring:

- Check "Yes" if differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure. Otherwise, check "No."
    - The ventilation system must be monitored and alarmed to indicate malfunction or deviation from design parameters. A visual monitoring device must be installed near the clean change room so proper differential pressures within the laboratory may be verified prior to entry.

Question 66, Supply/Exhaust HEPA Filtration:

- Check "Yes" if there is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s). Otherwise, check "No."
    - A dedicated non-recirculating ventilation system must be provided. Only laboratories with the same HVAC requirements (i.e., other BSL4 labs, ABSL4, BSL3-Ag labs) may share ventilation systems if gas-tight dampers and HEPA filters isolate each individual laboratory system.
    - For BSL4 cabinet laboratories, supply air to and exhaust air from the cabinet rooms, inner change rooms and fumigation/decontamination chambers must pass through HEPA filter(s). The air exhaust discharge must be located away from occupied spaces and building air intakes.
    - For BSL4 suit laboratories, supply air to the laboratory, including the decontamination shower, must pass through a HEPA filter. All exhaust air from the suit laboratory, decontamination shower and fumigation or decontamination chambers must pass through two HEPA filters, in series, before discharge to the outside. The exhaust air discharge must be located away from occupied spaces and air intakes.
- If all HEPA filters are tested and certified annually, check "Yes." Otherwise, check "No."
    - For BSL4 cabinet laboratories, all HEPA filters should be located as near as practicable to the cabinet and laboratory in order to minimize the length of potentially contaminated ductwork. All HEPA filters must be tested and certified annually.
    - For BSL4 suit laboratories, all HEPA filters must be located as near as practicable to the laboratory in order to minimize the length of potentially contaminated ductwork. All HEPA filters must be tested and certified annually.
    - The HEPA filter housings should be designed to allow for *in situ* decontamination and validation of the filter prior to removal. The design of the

HEPA filter housing must have gas-tight isolation dampers, decontamination ports, and ability to scan each filter assembly for leaks.

Question 67, Communication Systems:

- Check "Yes" if appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer). Otherwise, check "No."
    - Appropriate communication systems must be provided between the laboratory and the outside (e.g., voice, fax, and computer). Provisions for emergency communication and emergency access or egress must be developed and implemented.

Question 68, Drains:

- Check "Yes" if all drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system. Otherwise, check "No."
    - Liquid effluents from chemical showers, cabinet room/suit laboratory sinks, floor drains, autoclave chambers, and other sources within the cabinet room must be decontaminated by a proven method, preferably heat treatment, before being discharged to the sanitary sewer.
    - Decontamination of all liquid wastes must be documented. The decontamination process for liquid wastes must be validated physically and biologically. Biological validation must be performed annually or more often if required by institutional policy.
    - Effluents from personal body showers and toilets may be discharged to the sanitary sewer without treatment.
- If "Yes" is checked, describe the method(s) utilized for decontamination of liquid waste from the BSL4 area(s).
    - In your description, please comment on the treatment of liquid waste prior to leaving the containment area. Describe what parameters were considered for effluent decontamination treatment tank run conditions and how effective kill was verified.

Question 69, Work in a Protective Suit:

- Check "Yes" if work will be performed in a protective suit. Otherwise, check "No." If "Yes" is checked, you must complete questions 69a-e.

a. Check "Yes" if a breathing air system is provided with redundant compressors, backup storage tanks, HEPA filtration protection, and alarm monitoring in the event of failure. Otherwise, check "No."
    - All personnel who enter the BSL4 laboratory must wear a positive pressure suit supplied with HEPA filtered breathing air. The breathing air systems must have redundant compressors, failure alarms and emergency backup.

- An automatically activated emergency power source must be provided, at a minimum, for the laboratory exhaust system, life support systems, alarms, lighting, entry and exit controls, BSCs, and door gaskets.
- Monitoring and control systems for air supply, exhaust, life support, alarms, entry and exit controls, and security systems should be on an uninterruptable power supply (UPS).

b. Check "Yes" if all penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed. Otherwise, check "No."

- Walls, floors, and ceiling to the laboratory must be constructed to form a sealed internal shell to facilitate fumigation and prohibit animal and insect intrusion. Floors must be monolithic, sealed and covered. All penetrations in the internal shell of the laboratory, suit storage room and inner change room must be sealed. Windows must be break-resistant and sealed.

c. Check "Yes" if daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins. Otherwise, check "No."

- Daily inspections of essential containment and life support systems must be completed and documented before laboratory work is initiated to ensure that the laboratory is operating according to established parameters.
- Daily inspections should address the status of all necessary variables for laboratory and facilities support functions, as well as provide a clear "NO ENTRY" cut off for personnel to assess whether the daily condition is optimal for entry.

d. Check "Yes" if a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration. Otherwise, check "No."

- Central vacuum systems are not recommended. If, however, there is a central vacuum system, it must not serve areas outside the BSL4 laboratory. Two in-line HEPA filters must be placed near each use point. Filters must be installed to permit in-place decontamination and replacement.

e. Check "Yes" if liquid and gas services to the suit area(s) are protected by backflow devices. Otherwise, check "No."

- Services and plumbing that penetrate the laboratory walls, floors, or ceiling must be installed to ensure that no backflow from the laboratory occurs. These penetrations must be fitted with two (in series) backflow prevention devices. Consideration should be given to locating these devices outside of containment.

Question 70, Work with Animals:

- Check “Yes” if work with animals will be performed in an ABSL4 laboratory. Otherwise, check “No.” If “Yes” is checked, you must complete questions 70a-d.

a. Check “Yes” if specific procedures have been developed for handling animals under ABSL4 conditions in the Class III cabinet or protective suit laboratories. Otherwise, check “No.”

b. Check “Yes” if aerosol experiments are conducted in this ABSL4 laboratory. Otherwise, check “No.”

c. Describe how animals are housed under ABSL4 conditions (add additional sheets as necessary).

d. Check “Yes” if personnel assigned to work with infected animals work in pairs. Otherwise, check “No.”

Amendment Submission Overview

This Guidance Document is intended to provide reference information to registered entities in order to aid in the submission and timely approval of registration amendments. Please note that additional information, other than specifically outlined in this document, may be requested by the Federal Select Agent Program (either Animal and Plant Health Inspection Service Select Agent Program or Centers for Disease Control and Prevention Division of Select Agents and Toxins (DSAT).

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 Federal Select Agent Program. In some cases, an Amendment Update will be requested by Federal Select Agent Program in order to obtain clarification and or additional information for an existing, *pending* amendment.

Amendment Submission Process and Documentation Requirements

This guidance document is intended to provide a list of all documentation that Federal Select Agent Program will need to process the most frequent registration changes addressed within. In addition, amendment submission guidelines and communication from Federal Select Agent Program for registration amendments is described.

Amendment submissions from a registered entity may or may not require the submission of amended pages or sections of the APHIS/CDC Form 1. For example, some minor changes to the registration, such as the removal of a laboratorian, require only an official request from a Responsible Official (RO) or an Alternate Responsible Official (ARO) in the RO's absence. Major changes, such as the addition of new agents or laboratory room(s), will likely require updated Sections 3, 5 or 6.

Submit the required documentation to your designated representative at Federal Select Agent Program. For amendments submitted to DSAT, a faxed confirmation receipt with the assigned amendment number will be provided. Further communications with Federal Select Agent Program regarding this request should include the assigned amendment number.

In some cases, an Amendment Update will be requested by Federal Select Agent Program in order to obtain clarification and or additional information for an existing, *pending* amendment.

The amendment will be processed for approval following the submission of sufficient documentation and/or pending satisfactory closure of an inspection. The entity will receive notification from Federal Select Agent Program once the amendment has been approved.

If you have any questions on the amendment process, on these examples or any other amendments, contact your designated representative at Federal Select Agent Program.

Separate Amendment Requests to Help APHIS/CDC Approve Amendments in a Timely Manner

An amendment will not be approved until appropriate documentation for all requested changes is sufficient. For example, if an entity submits a single amendment request to add a new laboratory building as well as modify their objectives of work for an existing select agent or toxin, final approval may not be granted to update the objectives of work until the new laboratory building has been inspected and the inspection report has been closed. An entity can help the Federal Select Agent Program process requests by separating disparate changes into separate amendments.

Example: A registered entity is adding two new laboratory rooms (Rooms A and B) to their registration so that they may perform additional work with a select agent or toxin. 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.

Federal Select Agent Program Concurrence Requirements

An amendment to the registration which concerns an agent not regulated by your lead agency will require concurrence from the non-lead agency. You may be required to submit additional documentation. Federal Select Agent Program will initiate the concurrence process. All correspondence will be directed through your designated Federal Select Agent Program representative. Amendments of this type may require additional time for processing and review.

Note: Please send your amendment documentation only once. For example, if you email your amendment documentation to your designated representative, please do not fax a duplicate copy.

Amendment Cover Letters

General Information

All amendments and amendment updates submitted to Federal Select Agent Program should contain a cover letter which details the changes to be made and must be signed by the Responsible Official or an Alternate Responsible Official in the RO's absence. Cover letters should be written on company letterhead or have other characteristics which clearly indicate the origin of the request. Registered entities are also urged to use their Federal Select Agent Program Application Number (ex. CDC050555) within the cover letter in order to help Federal Select Agent Program route documents efficiently.

- Federal Select Agent Program encourages entities to communicate any amendments or amendment updates via email to their designated representative. Emails from designated representatives at entities (ex. Administrative Staff) will be accepted as long as there is an attached cover letter signed by the RO or ARO.

- Electronic versions (.doc, .xlsx, .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 Form1 sections must have the required signatures. Digital/Electronic signatures are not accepted at this time.

- An email may be substituted for a cover letter provided it includes all info required in the cover letter and is sent from the email address on file for the RO or ARO.

- Cover letters should be as descriptive as possible. **Cover letters which do not clearly explain the changes to be made to your registration or conflict with the forms submitted may result in delayed approval of your amendment request and require the submission of additional documentation. Any changes made to your APHIS/CDC Form1 must be requested in the cover letter.**

Examples of Cover Letter Language

Cover letter language should be as descriptive as possible and reference the relevant sections of the APHIS/CDC Form1 which are attached. 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, see attached Section 4.

- Please designate Mike Smith (C-MS-000000) as a new ARO. Mike Smith is currently security risk assessment approval (SRA) approved at our entity and has an assigned role of laboratorian. Updated Sections 1 and 2 as well as a Section 4 with a title change for Mr. Smith is attached.

- Please remove rooms 101, 102, 103 and 104 from Principal Investigator (PI) Jones. These rooms will continue to be utilized by the other PI(s) and should not be removed from our overall registration. See the attached Sections 5 and 6 which remove rooms 101, 102, 103 and 104 from PI Jones and lists only those rooms for which he continues to use for select agent and/or toxin work and/or storage.

- Please remove BSL3 rooms 205, 206, and 208 from our registration. All select agents have been reconciled and transferred to long-term storage in BSL3 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 Michael Williams (C-MW-000000) from our registration. PI Williams has accepted a position at another university, effective date January 1, 2012. All select agents used by PI Williams have been reconciled and custody transferred to his co-PI Johnson according to our intra-entity transfer policies. See the attached Sections 5 and 6 for PI Johnson and chain of custody documentation.

- Please remove *Bacillus anthracis* from our registration. All *B. anthracis* stocks and working samples possessed by the entity were reconciled and autoclaved, and witnessed by the RO and PI Smith. See the attached Section 3 and documentation of the autoclave records and witness signatures.

- Please add *Bacillus anthracis* to our registration. Attached is documentation delineating facility improvements to achieve BSL3 standards as well as updated Sections 3, 5 and 6.

- Please add *Bacillus anthracis* to our registration. Attached is a request to perform restricted experiments with *Bacillus anthracis* as well as updated Sections 3, 5 and 6. The new statement of work delineates the proposed restricted methods.

- We have conducted a quarterly review of our inventory and would like to update our strain table on file with Federal Select Agent Program. See the attached Approved APHIS/CDC strain table.

Amendment Reference Table

Amendment type	Cover Letter/Notes	Section 1	Section 2	Section 3	Section 4	Section 5A-D	Section 6A	Section 6B-I
Adding or Reactivating Laboratorians, Support Staff, Owners or Corporate Officers	State changes (name, job). Requires SRA approval				Update			
Removal of Personnel (excluding PI, RO, ARO)	State reason for removal							
Addition of RO or ARO	State changes. Requires SRA approval	Update	Update		Update			
Adding or Reactivating a PI	Requires SRA approval and (a)			Update if PI/room captured	Update	Update for new PI	Update for new PI	Update for new PI
Removing a PI	State disposition of agents and reason for removal of PI and (a)			Update if PI/room captured	Update	Update if needed	Update	Update if needed
Addition of Room(s)	(a), (b)			Update if PI/room captured		Update	Update	Update including 6G and floor plan
Removal of Room(s)	State disposition of agents, decon of space and (a)			Update if PI/room captured		Update if needed	Update	Update if needed
Addition of Agents and/or Toxins	Consider BSLevel of agent/space and (a), (c)			Update			Update	Update
Removal of Agents or Toxins	State disposition of agent/toxin and (a)			Update			Update	
Addition of Work Removal of Work	(a), (b), (c)							Update
Updates to Names or Titles on Section 4	Explanation of changes				Update			

(a) APHIS concurrence for USDA select agents only (b) May require inspection (c) May require Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) approval

Administrative Amendments

Contact Information for RO or ARO

Entities must ensure that Federal Select Agent Program has the most up-to-date contact information for the RO and all ARO's. Federal Select Agent Program uses this contact information to communicate directly with the RO/ARO as well as to send SA Grams. Contact information includes the mailing address, phone numbers, fax numbers and email addresses.

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

- ☐ Cover letter stating the RO/ARO(s) information to be updated
- ☐ Complete Section 1 – Entity Information with updated information
- ☐ **If the RO or ARO(s) name has changed**, submit a signed and dated Section 4 – Entity's Personnel Information for the RO/ARO(s) which includes the updated information.
  - Complete name of each individual.
  - DOJ # for each individual listed.
  - Date of birth.
  - The individual must be listed as an RO or ARO in the Job Title column.
  - The Principal Investigator column must be left blank for this individual.

Additional Information

- **Since all communication between a registering individual or an entity and the Federal Select Agent Program is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1 information changes, you must immediately report the change(s) to Federal Select Agent Program by submitting an update using the currently Office of Management and Budget (OMB) approved APHIS/CDC Form 1. Verbal change requests cannot be accepted.**

- **A name change does not affect the DOJ Number assigned to an individual. Individuals that change their name should continue to use the same DOJ Number for any future FD-961 form or Section 4 submissions.**

Entity Name or Address Changes

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

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

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ Complete Section 1 – Entity Information.

  Notes: a) Section 1A denotes the physical location at which the entity is registered to possess select agents and/or toxins. The Section 1A 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 or addresses being changed by the post office.

  b) The entities *mailing address* to which all official correspondence will be sent should be annotated in the address field in Section 1B (RO Information). The information entered in Section 1B (address, phone, fax) will appear on all letterhead which pertains to the entity in question, and all future changes to the desired primary contact information should be updated within this section and **not** within Section 1A (Entity Information).
- ☐ Complete Section 2 – Certification and Signature with signatures from the RO and all AROs.
- ☐ Any change in the physical location of the entity will require new Section 5 – Entity's Select Agent Requirements and Section 6 – Biosafety and Laboratory Information on Select Agents and Toxins.

Additional Information

- **Since all communication between a registering individual or an entity and the Federal Select Agent Program is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1 information changes, you must immediately report the change(s) to the Federal Select Agent Program by submitting an update using the current OMB approved APHIS/CDC Form 1. Verbal change requests cannot be accepted.**

Amendment Withdrawal

An amendment adding a person cannot be withdrawn. Instead, request an update to that amendment which requests the deactivation of the individual(s) being withdrawn

To withdrawal a submitted amendment, submit the following documentation:

- ☐ Cover Letter (must specifically request withdrawal of amendment, include amendment number, state changes originally requested, and be signed by RO/ARO)

Registration Withdrawal

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

- ☐ Cover Letter (must request withdrawal of registration, state disposition of agents/toxins, and be signed by RO)
- ☐ Disposition of agent(s) and or toxin(s)
  - 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 a Form 2 for transfer outside the entity.
- ☐ Documentation that effective decontamination appropriate to the use of the room(s) must be provided. If you believe decontamination is not necessary, please provide a risk assessment and/or contact your designated DSAT/APHIS representative.
- ☐ If the entity is registered for and possessed toxin(s) and will now be operating with toxin(s) under the aggregate amount,
  - Statement/records showing the amount of toxin(s) possessed by the registered PI(s) are under the regulated amount.
  - Statement of how the entity will ensure that each PI's inventory remains below the regulated amount.

Additional Information

- **Select agents or toxins transferred to another registered entity require an approved APHIS/CDC Form 2 prior to the transfer.**

Personnel Amendments

Adding Individuals – General Information

When submitting an amendment to add new individuals to your registration, you need only to submit documentation for *those specific individuals being added*. In order to validate your personnel records against those maintained by Federal Select Agent Program, you should periodically (ex. quarterly) request a comprehensive DOJ list for your entity. The DOJ List will list the individuals, their DOJ number, their current SRA status as well as their SRA expiration date.

- The first and last name submitted for each individual should match that which is entered in Block 4 on their respective FD-961 form.
- Upon receipt of your request, a DOJ Number will be provided for each individual to enter in Block 11 on their respective FD-961 form. The DOJ numbers for all individuals added within an amendment will be sent in a DOJ Number Assignment Letter to the Responsible Official.
- SRA Approval must be granted for every individual added within the amendment before the amendment is approved. However, individual access to select agents or toxins is granted according to the SRA Approval Letters (not DOJ Number Assignment Letters) which are sent directly to the RO for each approved individual.
- Once assigned at an entity, an individual's DOJ number will not change.

Adding or Reactivating Laboratorians, Support Staff, Owners or Corporate Officers

An individual will be deemed to own or control an entity under the following conditions:

(i) For a private institution of higher education, an individual will be deemed to own or control the entity 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 with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

(B) 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.

To add or reactivate non-visiting Laboratorians, Support Staff, Owners or Corporate Officers, submit the following documentation:

- ☐ Cover letter stating the name(s) of the individual(s) to be added or reactivated.
- ☐ Signed and dated Section 4 – Entity's Personnel Information with the individual(s) being added or reactivated.
  - Complete name of each individual.
  - DOJ Number - This field will be left blank for new additions
    - For reactivations enter the previously assigned DOJ number.
  - Date of birth
  - Job title for each person
    - For a list of all approved titles, see the application instructions.
  - Supervising PI(s) for each person listed.

Additional Information
▪ **Once an individual is SRA approved, his/her DOJ number must be included on Section 4 (e.g., if updating the individual's job title)** ▪ **An individual is deactivated upon the request to remove the individual from Section 4. In the event that an individual requires access approval in the future, the entity may request to reactivate the individual. Reactivated individuals will keep their original DOJ Number and this number must be included in Section 4.**

References:
Section 4 examples in the Application Instructions

Removal of Personnel (excluding PI, RO, ARO)

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

☐ Cover letter stating the name(s) of the individual(s) to be removed as well as the reason for removal.

Note: If the individual to be removed was added in an amendment which is not yet approved, the request to remove the individual from the Section 4 must be submitted as an update to the pending amendment.

Note: The Owner/Controller cannot be removed without appointing a replacement.

Additional Information

- **Do not include the names of removed individuals on future Section 4 submissions.**
- **Once the individual is removed, the individual will be deactivated from the entity's registration. If the individual requires access approval in the future, the individual may be reactivated and added to Section 4 at that time see the Adding or Reactivating Laboratorians, Support Staff, Owners or Corporate Officers section.**

Addition of Visiting Personnel

Visitors are defined as those individuals with SRA approval at a registered entity (Home Entity) who wish to visit another registered entity (Host Entity). Although each individual added, whether they are a visitor or not, is assigned a unique DOJ number at each entity to which they are added, visitors are not required to and should not use this DOJ number to complete another FD-961. In order to add a visitor to your registration, additional information is needed beyond that which is submitted for routine additions of personnel.

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

- ☐ Cover letter stating the name(s) of the individual(s) to be added as a visitor.
- ☐ Signed letter from the RO of the individual(s) Home Entity which includes the following:
  - Affirmation that the individual(s) will be visiting the entity
  - Name of the individual(s)
  - Date of birth of the individual(s)
  - DOJ Number of the individual(s) at their Home Entity.
  - SRA Approval date of the individual(s) at their Home Entity.
- ☐ Signed and dated Section 4 – Entity's Personnel Information for the individuals(s) being added as a visitor.
  - Complete name of each individual.
  - The DOJ # from the Home Entity for each person listed.
  - Date of birth.
  - Enter "visitor" for the job title.
  - Supervising PI(s) for each person listed.

Additional Information

- **Upon receipt of your request, DOJ numbers will be provided for each visitor listed. Visitors are NOT required to submit an FD-961 form using this DOJ Number.**
- **Once the visit is complete, a request to remove the individual should be submitted. See the Removal of Individuals section for further information.**

References:
Security Risk Assessments Frequently Asked Questions

Adding or Reactivating a PI

All PI must have at least one agent or toxin and at least one room listed on the Section 6A.

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

- ☐ Cover letter stating the name(s) of the PI(s) to be added or reactivated.
- ☐ Signed and dated Section 4 – Entity's Personnel Information for the PI(s) being added or reactivated.
  - Complete name of each individual.
  - DOJ Number - This field will be left blank for new additions.
    - For reactivations enter the previously assigned DOJ number.
  - Date of birth
  - The Job Title will be PI
  - The Supervising PI field will be left blank for PI(s).
  - The Section 4 should include any staff assigned to this PI.
- ☐ Complete Section 5 – Entity's Select Agent Requirements for each new PI
  - The use of "ALL PI(s) and ALL Laboratories" is acceptable when the information pertains to all rooms and PI(s) and separate Section 5's would not be required in this case.
- ☐ Complete Section 6A – To be Completed by All Entities for each Principal Investigator for each new PI
  - The location of where the agent will be used and/or stored must be currently registered rooms. If adding new rooms, see Addition of Room(s).
  - The agents assigned to the PI must match the approved Section 3. If adding new agents, see Addition of Agents and/or Toxins.
  - Complete listing of agents to be used and/or stored by the PI must be provided. List the strain designation(s) for all select agent(s) and toxins(s) only if known, otherwise, list N/A. For additional information regarding strain information, please see Strain Designation:
  - The 6A must indicate where (building and room designation) the agent/toxin is used and stored.
  - The biosafety level of the room(s) should be consistent with Biosafety in Microbiological and Biomedical Laboratories (BMBL) containment recommendations for the agents listed. If the agent/toxin is storage only, use "Storage Only" for biological safety level (BSL).

    Note: Multi-room suites can be assigned multiple biosafety levels within the same numeric level (e.g., BSL3, NIHBL3, ABSL3).
  - The new PI's name must be included in the PI column.

☐ Complete Section 6B-6I

- The PI/room/biosafety header at the top of the page must be completed and should be consistent with Sections 3 and 6A.
- The use of "ALL PIs and ALL Laboratories" is acceptable when the information pertains to all rooms and PIs and separate Sections 6B-6I would not be required in this case.

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 42 CFR 73.1. PIs independently control inventory and can supervise laboratorians.**
- **A *Curriculum Vitae* for the PI may be requested.**

References:
Example for Completing the Section 4 Table:
Examples for Completing the Section 6A Table:

Removing a PI

The removal of a PI requires additional documentation to account for the disposition of any affected 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 specific agent, room or laboratorian) and submit updates to other Sections of APHIS/CDC Form1 as needed.

To remove a PI, submit the following documentation:

- ☐ Cover letter stating the name(s) of the individual(s) to be removed as well as the reason for removal.

  Note: If the individual to be removed was added in an amendment which is not yet approved, the request to remove the individual from the Section 4 must be submitted as an update to the pending amendment.
- ☐ If the PI leaving is also an RO or ARO, see the Removal of RO or ARO section.
- ☐ Disposition of agent(s) and or toxin(s)
  - 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 a APHIS/CDC Form 2 for transfer outside the entity.
- ☐ If the entity is removing toxin(s) from the registration and will possess the toxin(s) under the aggregate amount,
  - Statement/records showing the amount of toxin(s) possessed by the registered PI(s) are under the regulated amount.
  - Statement of how the entity will ensure that each PI's inventory remains below the regulated amount.
- ☐ If the removed PI is assigned staff at the entity, an updated signed Section 4 – Entity's Personnel Information with the PI removed and assigning a different PI to his/her staff must be submitted.
  - If the PI was only listed as "ALL PI(s)", an updated Section 4 will not be required.
- ☐ If the removed PI is assigned rooms at the entity, an updated Section 6A – To be Completed by All Entities for each Principal Investigator with the PI removed and assigning a different PI to his/her rooms must be submitted.
  - If the PI was only listed as "ALL PI(s)" an updated Section 6A will not be required.
  - If rooms are to be removed, see Removal of Room(s).

Additional Information
▪ **Agents, rooms, laboratorians and support staff must have a designated PI.** ▪ **Agents transferred to another registered entity require an approved APHIS/CDC Form 2 prior to the transfer.** ▪ **Federal Select Agent Program may request a comprehensive Section 4 or 6A at any time.**

References:
Example for Completing the Section 4 Table:

Addition of RO or ARO

A new RO cannot self-appoint (i.e., a currently registered ARO cannot sign paperwork requesting to be RO). Ideally, 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 from the entity. ARO(s) must be designated by the current RO. RO is the individual designated by an entity with the authority and control to ensure compliance with the Select Agent regulations in this part. ARO must have the authority and control to ensure compliance with the regulations when acting as the RO during the individual's absence.

To add RO or ARO, submit the following documentation:

- ☐ Cover letter stating the name(s) of the individual(s) to be added.
- ☐ Complete Section 1 – Entity Information (including the newly appointed official).
- ☐ Complete Section 2 – Certification and Signature signed by the RO and all ARO(s) (including the newly appointed official).
- ☐ Signed and dated Section 4 – Entity's Personnel Information for the individuals(s) being added or reactivated.
    - Complete name of each individual.
    - DOJ Number - This field will be left blank for new additions
    - Date of birth
    - The Job Title will be either RO or ARO.
    - The Supervising PI field will be left blank for RO and ARO(s)

Additional Information

- **Since all communication between a registering individual or an entity and Federal Select Agent Program is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 1 information changes, you must immediately report the change(s) to Federal Select Agent Program by submitting an update using the current OMB approved APHIS/CDC Form 1. Verbal change requests cannot be accepted.**
- **A *Curriculum Vitae* for the RO or ARO may be requested.**
- **It is recommended that an entity have at least one ARO to ensure continuity of operations.**

References:
Example for Completing the Section 4 Table:

Removal of RO or ARO

An RO or Owner/Controller cannot be removed without appointing a replacement.

Ideally, 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 from the entity. Removal of AROs does not require a replacement although it is recommended.

To remove an RO or ARO, submit the following documentation:

- ☐ Cover letter stating the name(s) of the RO or ARO to be removed as well as the reason for removal.

  Note: If the individual to be removed was added in an amendment which is not yet approved, the request to remove the individual from the Section 4 must be submitted as an update to the pending amendment.
- ☐ If RO/ARO leaving is also a PI, see Removing a PI.
- ☐ Complete Section 1 – Entity Information without the removed individual.
- ☐ Complete Section 2 – Certification and Signature signed by the RO and all remaining ARO(s).

Additional Information

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

Updates to Names or Titles on Section 4

In the event that an individual changes their name or title, a new Section 4 for that individual should be submitted to the Federal Select Agent Program.

To update names or titles, submit the following documentation:

- ☐ Cover letter stating the name(s) of the individual(s) to be updated
- ☐ If the individual changing their name or title is an RO or ARO, see Contact Information for RO or ARO.
- ☐ If the individual changing their name or title is a PI, see Updates to PI Names.
- ☐ Signed and dated Section 4 – Entity's Personnel Information for the individuals(s) being updated which includes the updated information.
  - Complete name of each individual.
  - DOJ # for each individual listed.
  - Date of birth
  - Job title for each person
    - For a list of all approved titles, see Job Title:
  - Supervising PI(s) for each person listed.

Additional Information
▪ **A name change does not affect the DOJ Number assigned to an individual. Individuals that change their name should continue to use the same DOJ Number for any future FD-961 form and/or Section 4 submissions.**

References:
Example for Completing the Section 4 Table:

Updates to PI Names

In the event that an individual changes their name or title, a new Section 4 for that individual should be submitted to the Federal Select Agent Program. For those individuals who are designated as PIs, Sections 5 and 6 will also need to be updated.

To update existing PI information, submit the following documentation:

- ☐ Cover letter stating the name(s) of the PI(s) to be updated
- ☐ If the updated PI is assigned staff at the entity, an updated signed Section 4 – Entity's Personnel Information with the supervising PI column updated.
  - If the PI was listed as "ALL PI(s)" in the supervising PI column, only the PI's entry must be updated.
- ☐ Signed and dated Section 4 – Entity's Personnel Information for the PI(s) being updated which includes the updated information.
  - Complete name of the PI
  - DOJ # for each individual listed.
  - Date of birth
  - The individual must be listed as a PI in the Job Title column.
  - The Supervising PI column must be left blank.
- ☐ Complete Section 5 – Entity's Select Agent Requirements with the PI's updated name in the header.
  - If the PI was only listed as "ALL PI(s)", an updated Section 5 will not be required.
- ☐ Complete Section 6B – To be Completed for each Principal Investigator Working With Select Agents/Toxins with the PI's updated name in all applicable tables.
  - If the PI was only listed as "ALL PI(s)", an updated Section 6A will not be required.
- ☐ Complete Sections 6B - I with the PI's updated name in the header.
  - If the PI was only listed as "ALL PI(s)", an updated Section 6B-6I will not be required.

Additional Information
▪ **A name change does not affect the DOJ Number assigned to an individual. Individuals that change their name should continue to use the same DOJ Number for any future FD-961 form or Section 4 submissions.**

References:
Example for Completing the Section 4 Table:
Examples for Completing the Section 6A Table:

Select Agent/Toxin Amendments

Addition of Agents and/or Toxins

Please consider the BMBL containment recommendations for the agent. The biosafety level of the laboratory where the agent will be used should be consistent with the BMBL guidelines. An inspection may be required prior to approval.

Reconstructed 1918 Influenza Virus requires special consideration and/or ISATTAC approval. Please contact the Centers for Disease Control, Division of Select Agents and Toxins (DSAT), prior to your amendment submission.

To add agents or toxins, submit the following documentation:

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ Complete Section 3 - Entity Summary.
  - All agents that the entity is currently approved for and requests to be registered for must be included, whether or not the entity actually has acquired the agent, including regulated genomic material (i.e. +strand RNA viruses and some dsDNA viruses) and recombinant nucleic acids that encode for the functional form of select toxins as defined in Section 3(c) of 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331. For additional information regarding genomic material and recombinant nucleic acids see the *Application Instructions*.
  - Only one agent can be listed per line.
  - **Note: It is recommend that only the agents/toxins are listed and that entities do not complete the Laboratory Area and Principal Investigator sections.**
- ☐ Complete Section 6A – To be Completed by All Entities for each Principal Investigator.
  - Complete listing of agents must be provided. List the strain designation(s) for all select agent(s) and toxins(s) only if known, otherwise, list N/A. Strains may be listed on the 6A, included as an attachment, or inventory may be provided for strain designation. If agent is to be acquired, indicate "TBA." For additional information regarding strain information please see the *Application Instructions*.
  - The agents listed must be included on the Section 3.
  - The location where the agent will be used and/or stored must be currently registered room(s). If adding new room(s), see Addition of Room(s).
  - The biosafety level of the agent should be consistent with BMBL containment recommendations for the agent. If the agent/toxin will only be stored, use "Storage Only" in the laboratory safety column. For additional information regarding the completion of the laboratory area, storage area, laboratory safety level columns, please see Laboratory Area:, Storage Area: and Laboratory Safety Level:.
  - The PI(s) that will use or store the select agent(s) or toxin(s) must be listed in the PI column.

☐ Complete Sections 6B – 6I

- The PI/room(s)/laboratory safety levels in the header must be consistent with Section 6A.
- Update Objectives of Work (Section 6B, Question 1) to include work performed with new agent.
- The maximum quantity propagated must be listed in Section 6B, Question 3 for the new agent.
    - 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."

References:
Examples for Completing the Section 6A Table:

Removal of Agents or Toxins

To remove agents or toxins, submit the following documentation:

- ☐ Cover Letter (must specify the agents and/or toxins to be removed and be signed by RO/ARO)
- ☐ Disposition of agent(s) and or toxin(s)
  - 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 for transfer outside the entity.
- ☐ If the entity is removing toxin(s) from the registration and will possess the toxin(s) under the aggregate amount,
  - Statement/records showing the amount of toxin(s) possessed by the registered PI(s) are under the regulated amount.
  - Statement of how the entity will ensure that each PI's inventory remains below the regulated amount.
- ☐ Complete Section 3 - Entity Summary.
  - All agents that the entity is currently approved for and requests to be registered for must be included, whether or not the entity actually has acquired the agent, including regulated genomic material (i.e. +strand RNA viruses and some dsDNA viruses) and recombinant nucleic acids that encode for the functional form of select toxins as defined in Section 3(c) of 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331. For additional regarding genomic material and recombinant nucleic acids see the *Application Instructions.*
  - Only one agent can be listed per line.
    Note: It is recommend that only the agents/toxins are listed and that entities do not complete the Laboratory Area and PI sections.
- ☐ Complete Section 6A – To be Completed by All Entities for each Principal Investigator.
  - Complete listing of the remaining agents must be provided. List the strain designation(s) for all select agent(s) and toxins(s) only if known, otherwise, list N/A. Strains may be listed on the 6A, included as an attachment, or inventory may be provided for strain designation. If agent is to be acquired, indicate "TBA." For additional information regarding strain information please see the *Application Instructions.*
  - The remaining agents listed must be included on the Section 3.

☐ Complete Section 6B – 6I
- The PI/room(s)/laboratory safety levels in the header must be consistent with Section 6A.
- Update Objectives of Work (Section 6B, Question 1) to reflect the absence of the removed agents.
- Update Sections 6D – 6F to reflect the absence of the removed agents.

Additional Information

- **Agents transferred to another registered entity require an approved APHIS/CDC Form 2 prior to the transfer.**
- **Federal Select Agent Program may request a comprehensive Section 4 or 6A at any time. [7 CFR Part 331.17(c), 9 CFR Part 121.17(c), and 42 CFR Part 73.17(c)]**

Addition of Work

The addition of work may require an inspection prior to approval.

To add work, submit the following documentation:

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ If adding new room(s), PIs or agents, see the *Addition or Removal of Room(s)*, *Addition of a Principal Investigator* or *Additions of Agents or Toxins* sections.
- ☐ Update Question 1, Objective of Work:.
  - Updated Objectives of Work (this may be provided as an attachment).
- ☐ Update applicable parts of the Section 6C-I
  - Toxin work – Section 6C
  - Recombinant work – Section 6D
  - Animal work – Section 6E
  - Plant work – Section 6F
  - BSL3 AG – Section 6H
  - BSL4/ABSL4 – Section 6I

  Note: The biosafety level should be consistent with the agents/toxins and the PI/room(s)/biosafety level must be consistent with Section 6A.
- ☐ Approval for any restricted experiments (Section 13 of the regulations) or exclusions (Section 3(d) and 3(e) of the regulations).

Additional Information

- **The Objectives of Work, Section 6B, Question 1, or any yes answers to the questions in Section 6D may indicate performance of restricted experiments. In these instances, you may receive a request for additional information letter from Federal Select Agent Program.**

- **Objectives of work with any of the following need to be approved:**
  - **Reconstructed replication competent forms of 1918.**
  - **Recombinant organisms (bacteria, rickettsia) containing antibiotic resistance even if antibiotic resistance is temporary.**
  - **Recombinant forms of active toxin or functional subunits of regulated toxins.**
  - **Work with organisms at a biosafety level lower than what is recommended.**
    - **Genetically modified or chimeric viruses (e.g., half of Venezuelan Equine Encephalitis virus joined with half of Western Equine Encephalitis virus).**

References:
Examples for Completing the Section 6A Table:

Removal of Work

In some cases, removal of work requires an inspection prior to approval.

To remove work, submit the following documentation:

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ If removing room(s), PIs or agents, see the Removal of Room(s), Removing a PI, or Removal of Agents or Toxins *Removal of Room(s)*, *Removal of a Principal Investigator* sections.
- ☐ Update Question 1, Objective of Work:.
  - Updated Objectives of Work (this may be provided as an attachment).
- ☐ Update applicable parts of the Section 6C-I
  - Toxin work – Section 6C
  - Recombinant work – Section 6D
  - Animal work – Section 6E
  - Plant work – Section 6F
  - BSL3 AG – Section 6H
  - BSL4/ABSL-4 – Section 6I

References:
Examples for Completing the Section 6A Table:

Inventory Updates

Internal location changes that do not involve the addition of new rooms, transfers, or possessed strain updates.

Note: If an entity is adding or removing an agent or toxin, please see Addition of Agents and/or Toxins.

☐ Cover Letter (must specify all changes and be signed by RO/ARO)
☐ There are two options for providing strain designation information to Federal Select Agent Program.

Option 1: Complete Attachment

- Updated strain table.

Note: This method may be preferable for entities with a large number of strains.

Option 2: Complete 6A Table

- Complete Section 6A to include all strain designations and all bldg/room/PI combinations.

☐ Internal location changes require a complete Section 6A – To be Completed by All Entities for each Principal Investigator. A complete Section 6A should include:

- Complete listing of agents must be provided. List the strain designation(s) for all select agent(s) and toxins(s) only if known, otherwise, list N/A. Strains may be listed on the 6A, included as an attachment, or inventory may be provided for strain designation. If agent is to be acquired, indicate "T*BA." For additional information regarding strain information,* see Strain Designation:.
- The location where the agent will be used and/or stored must be currently registered room(s). If adding new room(s), see Addition of Room(s).
- The biosafety level of the agent should be consistent with BMBL containment recommendations for the agent. If the agent/toxin will only be stored, use "Storage Only" in the laboratory safety column. For additional information regarding the completion of the laboratory area, storage area, laboratory safety level columns, please see Laboratory Area:, Storage Area:, and Laboratory Safety Level:.
- The PI(s) that will use or store the select agent(s) or toxin(s) must be listed in the PI column.

Additional Information

- **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 3) or submitted annually if no strain related changes have occurred in your entity's inventory since the last submission. 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.**

References:
Example for Completing the Section 4 Table:
Examples for Completing the Section 6A Table:

Facility Amendments

Addition of Room(s)

The addition of new room(s) may require an inspection prior to the approval of the amendment. All room(s) must have at least one agent or toxin and at least one PI on the Section 6A.

To add room(s), submit the following documentation:

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ Complete Section 5 – Entity's Select Agent Requirements for each room.

  Note: Entities can use the designation *ALL laboratories* in the header as long as the information pertains to all rooms on registration.
- ☐ Complete Section 6A – To be Completed by All Entities for each Principal Investigator.
  - If rooms are only assigned to a single PI or a group of PIs performing related work, it is acceptable to submit a Section 6A specific to that PI or group of PIs that includes all the registration information for that PI or group of PIs.
  - If rooms will be used by multiple PIs performing different work, a comprehensive Section 6A for the entity must be submitted.
  - Complete listing of agents to be used and/or stored in the new room(s) must be provided. List the strain designation(s) for all select agent(s) and toxins(s) only if known, otherwise, list N/A. Strain designations may be listed on the 6A or included as an attachment. If agent is to be acquired, indicate "TBA." For additional information regarding strain information see Strain Designation:.
  - The agents listed must match the approved Section 3. (If entity is adding agents, see Addition of Agents and/or Toxins.
  - The 6A must indicate where the agent/toxin is used and stored (building and room designation).
  - The biosafety level of the room(s) should be consistent with BMBL containment recommendations for the agents listed. If the agent/toxin is storage only, use "Storage Only" for BSL.
  - The Principal Investigator(s) that will use or store select agents or toxins in the new room(s) must be listed in the PI column.

  Note: Multi-room suites can be assigned multiple biosafety levels within the same numeric level (e.g., BSL3, NIHBL3, ABSL3).
- ☐ Complete Sections 6B – 6I
  - The PI/room/biosafety level in the header must be consistent with Section 6A table information.
  - The new room(s) must be listed at the top of each page along with the PI or PI group and biosafety level(s)

- If Toxin work – Complete Section 6C – Work With Toxins
- If Recombinant work – Complete Section 6D – Work With Genetic Elements, Recombinant Nucleic Acids, or Recombinant Organisms
- If Animal work – Complete Section 6E – Work With Animals
- If Plant work – Complete Section 6F – Work With Plants
- Laboratory information, Complete Section 6G – Laboratory Information
- If BSL3 AG – Complete Section 6H – BSL3 AG Laboratories
- If BSL4/ABSL4 – Complete Section 6I – BSL4/ABSL4 Laboratories

☐ Floor plans, both specific for the room(s) as described in 6G, Question 37 and an expanded floor plan showing the room(s) relative to the building layout.

References:
Examples for Completing the Section 6A Table:

Removal of Room(s)

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

To remove room(s), submit the following documentation:

- ☐ Cover Letter (must specify all changes and be signed by RO/ARO)
- ☐ Documentation that effective decontamination appropriate to the use of the room(s) must be provided. If you believe decontamination is not necessary, please provide a risk assessment and/or contact your designated representative.
- ☐ Disposition of agents and PIs must be provided.
  - PIs/Agents cannot remain on the registration without a room designation.

  Note: If removal of room(s) also removes agents or PIs, see the *Addition or Removal of Agents/Toxins* section and the *Addition or Removal of a Principal Investigator* section.
- ☐ Complete Section 5 – Entity's Select Agent Requirements with the updated rooms in the header.
  - If the room was only listed as "ALL Laboratories", an updated Section 5 will not be required.
- ☐ Complete Section 6A – To be Completed by All Entities for each Principal Investigator with the rooms removed from the tables.
  - If rooms are only assigned to a single PI or a group of PIs performing related work, it is acceptable to submit a Section 6A specific to that PI or group of PIs that includes all the registration information for that PI or group of PIs.
  - If rooms will be used by multiple PIs performing different work, a comprehensive Section 6A for the entity must be submitted.
- ☐ Complete Sections 6B-6I with the rooms removed from the headers
  - If the room was only listed as "ALL Laboratories", an updated Section 6B-6I will not be required.

Additional Information
▪ **Federal Select Agent Program may request a comprehensive Section 4 or 6A at any time.**