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

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

Unless exempted from the requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73, an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by APHIS or CDC. To apply for a certificate of registration, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS or CDC based on the type of select agent or toxin they may possess, use, or transfer. For HHS agents, the Responsible Official (RO) should submit this form to CDC. For USDA agents, the RO should submit this form to APHIS. For HHS/USDA overlap agents, the RO may submit this form to APHIS or CDC, but not both:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

A listing of select agents and toxins is available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap. Before you complete this application, please review the exemption and exclusion requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73 to determine whether your entity is required to register. Allow at least 8 weeks for processing. Submission of an incomplete application will result in a significant delay in processing the application. Currently, there is no fee for registration for select agents and toxins. The registration is valid for a period up to three years. All entities will be subject to inspection during the three-year registration period.

PURPOSE

The purpose of this form is to provide a method for entities to register to possess, use, or transfer select agents and toxins as described in 7 CFR 331.7, 9 CFR 121.7, and 42 CFR 73.7. The information requested in this form includes: facility information; a list of select agents or toxins to be possessed, used, or transferred by the entity; a list of individual who will have access to select agents and toxins; characterization of the select agents and toxins and additional laboratory information.

INSTRUCTIONS

(A) Designating a RO and alternate RO

The entity is required by the regulations to assign a Responsible Official (RO). The RO must have the authority and responsibility to act on behalf of the entity, ensure compliance with the requirements of 7 CFR 331, 9 CFR 121, and 42 CFR 73, and must be approved based on a security risk assessment (SRA) by the Attorney General (Public Act 212(e)(3)). The purpose of the RO is to provide an established point of contact for the entity if APHIS or CDC has questions concerning the application or other matters related to the entity registration. The RO should consult with others (e.g., engineering support services, principal investigators, biosafety officers) as necessary to obtain the information required for this application prior to submitting the form to APHIS or CDC.

An entity may also designate an alternate RO in cases where extended absences or other circumstances warrant acting for the RO in his or her absence. The alternate RO must meet all of the qualifications for a RO. We recommend that the RO and alternate RO are biosafety officers or senior management officials of the entity, or both. Although we understand that some entities have limited staff, we recommend that the RO not be an individual actually using, working with, or transferring or receiving the select agents and toxins to minimize potential conflicts of interest.

To designate a different RO or an alternate RO, the current RO must mail, fax, or email to the same agency that you filed your original application with (APHIS or CDC) a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit completed Sections 1 and 2.

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 a SRA by the Attorney General and who meets the requirements of the regulations. The owner of the entity must mail, fax, or email to the appropriate agency a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit Sections 1 and 2.

(B) Completing Application

1. Submission of an incomplete or illegible application will result in a significant delay in processing the application.
2. Section 1 – Entity Information
   a. Indicate in Section 1 if the submission is for a "new registration" or an "amendment to an existing registration."
   b. Section 1A should contain information regarding the physical location of the entity.
   c. Section 1B should contain information regarding the RO.
   d. Section 1C should contain information regarding the alternate RO information. If more than one alternate RO has been identified, additional sections 1C and 2 should be completed, as appropriate.
   e. If the entity was previously registered with APHIS or CDC, section 1D should be completed.
3. Section 2 – Certification and Signature form. This section must be completed and signed by the RO and all alternate RO(s) for the entity.
4. Section 3 – Entity Summary. Complete section to indicate each select agent (genus and species) or toxin which is currently in possession at the entity. Include all select agents and toxins not currently in possession but which the entity plans to possess in the future. Record the building and room number where the select agents will be used or stored for each Principal Investigator (Chief Scientist) who will be using and storing the select agents and toxins. Do not include toxins that the entity will never possess above the excluded amount. The Principal Investigator listed should be that individual who has responsibility over the use and disposition of the select agents and toxins.
5. Section 4 – Entity's Personnel Information. Complete this section by providing the information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access (possession or the ability to gain possession) to select agents and toxins at the entity. If multiple pages are submitted, the RO only needs to sign the last page indicating that the listed individuals who will have access to select agents and toxins have received the appropriate training.
   a. The name and the date of birth for individuals listed on this table should be identical to that given on the FBI form (FD-961) submitted to the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS) for each individual.
   b. The individuals who have been identified as RO, ARO, owners of the entity, and Principal Investigator (PI) should be listed as that for their job title. For example, the RO would be listed as the "Responsible Official" for the job title.
   c. The "Principal Investigator" field for this section refers to the individual who is supervising all activities associated with the select agents and toxins. If individual(s) will be supervised by all PIs at your entity, indicate "all" under the "Principal Investigator" column. This column should be left blank only for the RO, ARO, PI, and owner/controller of the entity.
   d. Amending Section 4:
      1) To request an individual to be added to Section 4, submit an amended Section 4 with the individual's information added to the same agency that you filed your original application with (APHIS or CDC). For submitting the SRA information to CJIS:
         a) Once the entity has submitted an amended Section 4 listing new persons requiring an SRA, the RO receives the individual's unique Department of Justice (DOJ) identifying number from APHIS or CDC and forwards to the individual to complete the SRA information (FD-961 form and fingerprint cards). After the receipt of the DOJ identifier number by APHIS or CDC, the RO should include this number for the individual on all future correspondence or Section 4 submissions.
         b) The individual should complete the FD-961 form including their unique DOJ identifying number in the "Unique Identifier Number" block and follows the FBI instructions (http://www.fbi.gov/hq/cjisd/takingfps.html) for submitting fingerprints. The FD-961 form and fingerprint cards should be mailed as one package directly to CJIS, not to APHIS or CDC. Specific guidance on the process is available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html, http://www.cdc.gov/od/sap, or http://www.fbi.gov/terrorinfo/bioterrorfd961.htm.
      2) To request individual's access to be terminated, submit the Section 4 with the individual's information lined through or removed include a cover letter indicating the reason for termination of the individual's access to the same agency that you filed your original application with (APHIS or CDC).

Example: John Johnson will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2 in Dr. Jane Doe's laboratory. Although Dr. Jane Doe may not be his immediate supervisor, her name should be listed because she is responsible for the select agent in this laboratory.

Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mmddyr)	Job Title	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)
Doe	Jane	C-JD-0000	1/1/61	Principal Investigator	
Johnson	John	A-JJ-0001	1/2/60	Laboratorian	Doe

6. Section 5 – Select Agent Requirements. Complete section to indicate that your entity has the implemented plans or procedures to ensure compliance with the requirements of 7 CFR 331, 9 CFR 121, and 42 CFR 73. A Section 5 should be completed for each PI identified in Section 3.
   a. Section 5A must be completed to describe the security measures put in place at your entity to ensure compliance with Section 11 of the regulations. Informational documents have been developed to assist in the development and implementation of the written security plan. The referenced documents are available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.
   b. Section 5B must be completed to explain the biosafety and incident responses procedures put in place at your entity to ensure compliance with Sections 12 and 14 of the regulations.
   c. Section 5C must be completed to describe the training procedures put in place at your entity to ensure compliance with Section 15 of the regulations.
   d. Section 5D must be completed to detail how your entity ensures records and databases are accurate and maintained to ensure compliance with Section 17 of the regulations.

7. Section 6 – Biosafety and Laboratory Information on Select Agents and Toxins. Complete this section for *each* PI at the entity. Complete only sections as appropriate for the select agents and toxins in use under the control of each PI.
   a. For Section 6A, the following information must be listed on a separate line for each laboratory safety level: the select agent or toxin; the strain designation of the select agent or toxin, the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each PI (or Chief Scientist). The PI is the one 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. If your entity has delegated more than one person as the PI, the RO should designate one individual as the primary person and the additional individuals should be listed in question #2 in Section 6B. For all select agents and toxins that are not currently in possession but which the entity plans to possess in the future, please indicate "TBA" in the strain designation column to note that the agent or toxin is to be acquired.
      1) The strain designation for the select agent and toxin should be listed if known. For the purposes of this form 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. Resistance to specific antibiotics is a feature of certain strains of bacteria. For select agents that have been genetically modified such as introduction of an antibiotic resistant gene, you would note that in the strain designation column. In addition, you would need to provide information regarding these experiments in Section 6D. If your entity does not perform strain designation, then you would list "N/A" for this column.
      2) The entity should perform a facility risk assessment for each agent possessed (*see* 7 CFR 331.11-12, 9 CFR 121.11-12, and 42 CFR 73.11-12) that is based on the requirements for handling the agent to ensure that the facility meets those requirements. All entities using select agents and toxins should base their facility risk assessments on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant DNA* (NIH Guidelines), 29 CFR 1910.1450, or other required assessment materials. The facility risk assessment based on the requirements for the type of activities conducted with each select agent and toxin in each of the rooms should be listed in the "Laboratory Safety Level" column. The resources/references used for the facility risk assessment must be described in question #39 in Section 6G.
      3) For entities only **storing** and not actively working with select agents or toxins, do not complete "laboratory area" column.

Example: An entity needs to register one PI (e.g., Dr. Jane Doe will be working with the Ames strain of *Bacillus anthracis* and experiments that involve the introduction of plasmids containing kanamycin resistance cassettes used as selectable markers in *Yersinia pestis* in Bldg 1, Room 100 at BSL-3. Dr. Doe is storing *Bacillus anthracis* (strain unknown) in hopes of a future grant). Storage of the select agents will be in the same locations where the work will be conducted.

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	1	100	1	100	BSL3	Doe
Bacillus anthracis	N/A			1	100	BSL3	Doe
Yersinia pestis	Kanamycin resistance	1	100	1	100	BSL3	Doe

b. Complete sections 6B-6F to describe the work for each select agent or toxin listed in Section 6A under the control of the PI including a description of the methodologies or laboratory procedures that will be used. For example, if the research involves experiments introducing an antibiotic resistant gene into a select agent and then performing aerosol challenges in mice, you would need to describe this research by completing sections 6B, 6D, and 6E. If no work is being performed on each select agent or toxin listed in Section 6A, then indicate "storage only" for Question #1 and skip to Section 6G.

c. Complete Section 6G for each laboratory under a different biosafety level listed in Section 6A where select agents or toxins are used or stored.
   1) For any laboratory that is not operational, indicate "No" for question #37 and note this on the floor plan including the anticipated certification or commission date of the laboratory.
   2) For question #39, indicate which references or resources was used to perform a facility risk assessment that is based on the requirements for handling that agent to ensure that the facility meets those requirements.

d. Complete 6H and 6I for any work that will be performed in a laboratory considered a "BSL-3 Ag," BSL-4" or "ABSL-4" laboratory.

(C) Submitting application to APHIS or CDC

1. To apply for a certificate of registration that covers only HHS select agents or toxins, an entity must submit the application package to CDC.
2. To apply for a certificate of registration that covers only USDA select agents or toxins, an entity must submit the application package to APHIS.
3. To apply for a certificate of registration that does not cover only HHS select agents or toxins (i.e., covers at least one overlap select agent and toxin, or covers any combination of HHS select agents and toxins and USDA select agents and toxins), an entity must submit the application package to APHIS or CDC, but not both.

(D) Amending certification of registration

The RO or his or her alternate RO are also responsible for notifying APHIS or CDC of any changes to the registration, such as modifications to authorized laboratory personnel, changes in currently registered laboratories, additional new laboratories that require registration, or any other changes to the information provided in this application. Prior to any change, the RO must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application and forwarding it to APHIS or CDC for approval.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 718-2000. This guidance document and form along with information on the referenced documents are available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.

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

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2011

Read all instructions carefully before completing the application. Answer all items completely and type or print in ink. Failure to complete this application in detail will delay processing of your application. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

SECTION 1 – ENTITY INFORMATION (TO BE COMPLETED BY RO)

This application is: ☐ A new registration ☐ An amendment to an existing registration ☐ Update to Amendment #: _____

SECTION 1A– ENTITY INFORMATION

Entity registration number (e.g., A00000000-0000):		Date:	
Entity name:			
Address (NOT a post office box):	City:	State:	Zip Code:
Type of entity: ☐ Academic (Private) ☐ Academic (State) ☐ Commercial (Profit) ☐ Government (Federal) ☐ Government (State/Local) ☐ Private (Non-Profit)			

SECTION 1B– RESPONSIBLE OFFICIAL INFORMATION

Name of Responsible Official:	Last Name:	First Name:	Middle Name:
Emergency Telephone #:	Title of Responsible Official (e.g., biosafety officer):		
Business Telephone #:	Business FAX #:	Business E-mail address:	
Business Address (NOT a post office box):	City:	State:	Zip Code:

SECTION 1C – ALTERNATE RESPONSIBLE OFFICIAL INFORMATION

Name of Alternate Responsible Official:	Last Name:	First Name:	Middle Name:
Emergency Telephone #:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone #:	Business FAX #:	Business E-mail address:	
Business Address (NOT a post office box):	City:	State:	Zip Code:
Name of Alternate Responsible Official:	Last Name:	First Name:	Middle Name:
Emergency Telephone #:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone #:	Business FAX #:	Business E-mail address:	
Business Address (NOT a post office box):	City:	State:	Zip Code:

SECTION 1D – REGISTRATION HISTORY

Has this entity previously been registered with the Select Agent Program? Yes No
if yes, then provide Select Agent Program registration number and expiration date:

SECTION 2 – CERTIFICATION AND SIGNATURE
(TO BE COMPLETED BY RO AND ALTERNATE RO'S)

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official(s) for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is, to the best of my knowledge, accurate and truthful. The institution/organization listed above meets the requirements specified in 42 CFR Part 73 and/or 7 CFR Part 331 and/or 9 CFR Part 121, is equipped and capable of safely and securely handling the agent(s), and will use or transfer these agents solely for purposes authorized by 42 CFR Part 73 and/or 7 CFR Part 331 and/or 9 CFR Part 121.

I understand that submission of a false statement and/or failure to comply with the provisions of the applicable regulations (7 CFR Part 331 and/or 9 CFR Part 121 and/or 42 CFR Part 73) may result in the immediate revocation of this entity's registration, a civil penalty of up to $500,000 for each violation, and a criminal penalty and/or imprisonment up to five years for each violation. (7 USC 8401; 18 USC 175, 175B, 1001, 3559, 3571; 42 USC 262a).

Responsible Official Signature	Date	Responsible Official Name (typed or printed)
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name (typed or printed)
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name (typed or printed)

This application is: ☐ A new registration ☐ An amendment to an existing registration ☐ Update to Amendment #: _____	Date
Entity name:	Entity registration number (e.g., A00000000-0000):

SECTION 3 – ENTITY SUMMARY
(TO BE COMPLETED BY RO)

Provide the following information on a **separate line** for each select agent or toxin and the building and room number(s) where each select agent or toxin will be used/stored for each PI (or Chief Scientist). Select agents or toxins that are exempt or excluded from registration should not be listed on this form. For information on completing this section, refer to page 2 of the guidance document. A listing of select agents and toxins is available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.

Select Agent/Toxin	Laboratory Area		Principal Investigator
	Bldg	Room	

This application is: ☐ A new registration ☐ An amendment to an existing registration ☐ Update to Amendment #: _____	Date
Entity name:	Entity registration number (e.g., A00000000-0000):

SECTION 4 – ENTITY'S PERSONNEL INFORMATION
(TO BE COMPLETED BY RO)

Provide the information in the following table (Last Name, First Name, DOJ Unique Identifier Number, Date of Birth, Job Title, PI) for each individual employed by the entity that has access to the select agents and toxins. The RO, ARO, owners of the entity, and PI should be listed as that instead of their official institution title. (Example, The RO would be listed as "RO" not biosafety officer in the Job Title column.) Each person should list the PI who controls the use of the select agents and toxins that the person will work with. If the person will work with all PIs the term "All" should be listed in the PI column. The name and the date of birth for individuals listed on this table should be identical to that given on the FD-961 Form submitted to CJIS for each individual. To request additions to, or deletions from, this list of individuals submit this Section to the agency that you filed your original application with (APHIS or CDC). If multiple pages are submitted, the RO will only need to sign the last page. For additional information on completing this section, refer to page 2 (B)(5) of the application instructions.

Last Name	First Name	DOJ Unique Identifier Number	Date of Birth (mmddyr)	Job Title	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)

I certify that information and training on safety and security for working with select agents and toxins has been provided to the individuals listed above who will have access to select agents and toxins.

RO/ARO Signature:_____ Date: _____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

SECTION 5 – ENTITY'S SELECT AGENT REQUIREMENTS (TO BE COMPLETED BY RO)

This section should be completed by the RO during the initial request for a certificate registration and any time there is a change in the entity's procedures noted in Section 5. For information on completing this section, refer to page 3 (B)(6) of the guidance document.

SECTION 5A – SECURITY

1. Each laboratory has a site-specific written security plan: ☐ Yes ☐ No
   a. Plan designed according to a site-specific risk assessment and provides graded protection in accordance with the risk of select agent or toxin: ☐ Yes ☐ No
   b. Plan contains all information as required by the Select Agent Regulations: ☐ Yes ☐ No
   c. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No
   d. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No
2. Physical Security (check all that apply):
   a. Means to limit access to buildings with select agents and toxins:
      ☐ Guard station at the building entrance
      ☐ Locks
      ☐ Card access system
      ☐ Biometric system
      ☐ Intrusion detection system
      ☐ Other (describe): _____
   b. Means to limit access to rooms with select agents and toxins:
      ☐ Locks
      ☐ Card access system
      ☐ Biometric system
      ☐ Intrusion detection system
      ☐ Other (describe): _____
   c. Means to limit access to select agents and toxins inside the room:
      ☐ Locked incubators, refrigerators, freezers, etc.
      ☐ Locked box inside incubators, refrigerators, freezers, etc.
      ☐ Biometric system
      ☐ Card access system
      ☐ Intrusion detection system
      ☐ Other (describe): _____
   d. Means to monitor access to areas where select agents and toxins are used or stored:
      ☐ Electronic logs of access
      ☐ Manual sign in logs
      ☐ Video camera surveillance
      ☐ Other (describe): _____
   e. Access to select agents and toxins is restricted to individuals that have access approval from the APHIS Administrator or HHS Secretary: ☐ Yes ☐ No
   f. Are individuals, not approved for access from the APHIS Administrator or HHS Secretary, allowed access to an area with select agents and toxins without escort by approved individual? ☐ Yes ☐ No
   g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No
3. Suspicious packages are inspected prior to entry or removal from an area where select agents and toxins are used or stored: ☐ Yes ☐ No
4. Select agents and toxins are transferred within the entity (intra-entity transfers): ☐ Yes ☐ No
   a. Intra-entity transfer is only under the supervision of an individual with access approval from APHIS Administrator or HHS Secretary: ☐ Yes ☐ No
   b. Chain-of-custody documents are used for intra-entity transfers: ☐ Yes ☐ No

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

5. Select agents and toxins are transferred from an individual approved to have access to select agents and toxins directly to a licensed commercial courier services or from a licensed commercial courier service: ☐ Yes ☐ No

Note: The transfer must be from the approved person to the courier or vice versa not between the courier and the shipping area.

SECTION 5B – BIOSAFETY AND INCIDENT RESPONSE

6. Each laboratory has a written agent-specific, site-specific biosafety plan: ☐ Yes ☐ No
   a. The plan is commensurate with the risk of the select agent and toxin and contains all information as required by the Select Agent Regulations: ☐ Yes ☐ No
   b. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No
   c. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No
7. Personal protective equipment (PPE) recommended for the agents and the work performed is required: ☐ Yes ☐ No
8. A medical surveillance system is in place for personnel using the select agents and toxins: ☐ Yes ☐ No
9. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the Responsible Official: ☐ Yes ☐ No
10. There are policies for the handling of sharps: ☐ Yes ☐ No
11. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents and toxins at this facility? ☐ Yes ☐ No ☐ N/A

    If yes, has the IBC approved the work proposed in this application: ☐ Yes ☐No

    If no, please attach an explanation.
12. The facility has been inspected by USDA, HHS, CLIA, DoE, DoD or others: ☐ Yes ☐No

    If yes, please add attachment listing inspection organization/agency name and date of last inspection.
13. Each laboratory has a written incident response plan: ☐ Yes ☐ No
    a. The plan is commensurate with the hazards of the select agent and toxin and contains all information required by the Select Agent Regulations: ☐ Yes ☐ No
    b. The plan is reviewed annually and revised as necessary: ☐ Yes ☐ No
    c. Drills or exercises are conducted to validate or test the effectiveness of the plan: ☐ Yes ☐ No

SECTION 5C – TRAINING

14. Training:
    a. Security and biosafety training is provided prior to individual's access to areas where select agents and toxins are handled or stored: ☐ Yes ☐ No
    b. Training addresses the needs of the individual, the work being performed, and risks posed by select agents and toxins: ☐ Yes ☐ No
    c. Refresher training is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____
    d. Written records of individuals trained are maintained: ☐ Yes ☐ No
    e. Personnel are required to demonstrate proficiency in laboratory procedures prior to working with select agents and toxins: ☐ Yes ☐ No
    f. Provide a brief description of what is included in the training program:
       - ☐ Biosafety: _____
       - ☐ Incident Response: _____
       - ☐ Security: _____
       - ☐ Other: _____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

g. Describe the means used to verify that individuals understood the training (add additional sheets as necessary):

_____

_____

SECTION 5D – RECORDS AND INFORMATION SYSTEMS CONTROL

15. Records specified in Section 17 of the Select Agent Regulations are maintained and current: ☐ Yes ☐ No

16. Provide a brief explanation of the system in place that ensures records and databases are accurate, their authenticity may be verified, and explains any discrepancies:

_____

_____

17. Describe the means to control access to manual records that would allow for access to select agents and toxins (check all that apply):
    - ☐ Locks
    - ☐ Locked filing cabinet, drawer, cabinet, etc.
    - ☐ Card access system
    - ☐ Other: _____

18. Describe the means to control access to electronic records and database that would allow access to select agents and toxins (check all that apply):
    - ☐ Locks
    - ☐ Card access system
    - ☐ Password protected
    - ☐ Firewall protection
    - ☐ Antivirus protection
    - ☐ Other: _____
    - ☐ Network System [inter/intranet]
    - ☐ Not connected to a network (stand alone system)

    _____

19. Name(s) of Individual(s) responsible for inventory of select agent(s) and toxin(s): _____

    a. Inventory record is reconciled: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

    b. Inventory tracking includes the following information (list): _____

    _____

    _____

This application is: ☐A new registration ☐An amendment to an existing registration ☐ Update to Amendment #: _____	Date
Entity name:	Entity registration number (e.g., A00000000-0000):

SECTION 6 – BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS AND TOXINS

Make additional copies of this section of the form as needed for *each* PI at your entity. Each PI should complete the appropriate section for laboratories under his/her control where select agents are used or stored. For information on completing this section, refer to page 3 (B)(7) of the guidance document.

SECTION 6A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

Provide the following information on a **separate line** for each laboratory safety level: the select agent or toxin; the strain designation of the select agent or toxin, the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each PI (or Chief Scientist). For entities only **storing** and not actively working with select agents or toxins, do not complete "laboratory area" column. For information on completing this section, refer to page 3 (B)(7) of the guidance document.

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**		

*Biosafety Level 2=BSL2 Animal Biosafety Level 2=ABSL2 rDNA BSL2=NIHBL2 rDNA Large Animal BSL2=NIH BL2N rDNA Large Scale BSL2=NIH BL2-LS
Biosafety Level 3=BSL3 Animal Biosafety Level 3=ABSL3 rDNA BSL3=NIHBL3 rDNA Large Animal BSL3=NIH BL3N rDNA Large Scale BSL3=NIH BL3-LS
Biosafety Level 4=BSL4 Animal Biosafety Level 4=ABSL4 rDNA BSL4=NIHBL4 rDNA Large Animal BSL4=NIH BL4N rDNA Large Scale BSL4=NIH BL4-LS
Plant=BSL2 Biosafety Level 3 Agriculture=BSL3ag Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL

Plant=BSL3

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

SECTION 6B – TO BE COMPLETED FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH SELECT AGENTS/TOXINS

1. Provide the objectives of the work for each select agent or toxin listed in Section 6A, including a description of the methodologies or laboratory procedures that will be used. Each PI should also complete each sub-section as appropriate for this work. If no work is being performed on select agent or toxin, indicate storage only. For information on completing this section, refer to page 4 of the guidance document. Attach additional sheets if needed:

   _____

   _____

   _____

   _____

   _____

2. Additional PIs performing the same objective of work: ☐ Yes ☐ No

   If yes, list: _____

3. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 10^5 cfu/ml). If select agent will not be propagated, then indicate "no propagation of agent". Attach additional sheets if needed:
   a. Agent/Toxin: _____ Maximum Quantities: _____
   b. Agent/Toxin: _____ Maximum Quantities: _____
   c. Agent/Toxin: _____ Maximum Quantities: _____
   d. Agent/Toxin: _____ Maximum Quantities: _____

4. All cultures, stock and other regulated wastes are decontaminated before removal from the containment area: ☐ Yes ☐ No
   If yes, describe method:
   ☐ Autoclaved (temperature, time, and psi):_____
   ☐ Chemical (disinfectant, concentration, and time): _____
   ☐ Irradiation: _____
   ☐ Other:_____

SECTION 6C –WORK WITH TOXINS

5. Will work be performed with toxins or with agents that produce regulated amounts of toxins? ☐ Yes ☐ No
   If yes, complete questions 6 – 10.

6. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

7. The toxin is produced by viable agent at the entity: ☐ Yes ☐ No
   If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

8. Dilution procedures and other manipulations of the concentrated toxins are performed: ☐ Yes ☐ No
   a. If yes, conducted in: ☐ Fume hood ☐ Biological safety cabinet
   b. If a fume hood or biosafety cabinet is used, certification is conducted:
      ☐ Annually ☐ Biannually ☐ Other (describe): _____
   c. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

9. A hazard sign is posted on the door when toxins are in use: ☐ Yes ☐ No

10. All cultures, stock and other regulated wastes are decontaminated before removal from the containment area: ☐ Yes ☐ No
    If yes, describe method:
    ☐ Autoclaved (temperature, time, and psi):_____
    ☐ Chemical (disinfectant, concentration, and time): _____
    ☐ Irradiation: _____
    ☐ Other:_____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

SECTION 6D –WORK WITH GENETIC ELEMENTS, RECOMBINANT NUCLEIC ACIDS, OR RECOMBINANT ORGANISMS

11. Will work be performed with genetic elements, ☐ Yes ☐ No
    recombinant nucleic acids, ☐ Yes ☐ No
    recombinant organisms, or ☐ Yes ☐ No
    antibiotic resistant select agents? ☐ Yes ☐ No
    If yes, complete questions 12 – 16.

12. Will you be possessing, using or transferring the following:
    a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No
    b. 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. ☐ Yes ☐ No
       2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No
    c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

13. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____

14. Give an estimate of range of length of recombinant DNA to be used: _____

15. Are you intending to conduct experiments that introduce antibiotic resistance markers/traits into select agents/toxins: ☐ Yes ☐ No

    If yes, provide the agent/toxin and antibiotic being used:
    a. Select Agent/Toxin: _____ Antibiotic: _____
    b. Select Agent/Toxin: _____ Antibiotic: _____
    c. Select Agent/Toxin: _____ Antibiotic: _____

16. Will experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight: ☐ Yes ☐ No

    If yes, list toxin and provide a brief description of the restricted experiment: _____

    _____

    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 APHIS Administrator and HHS Secretary.

SECTION 6E – WORK WITH ANIMALS

17. Will work be performed with animals? ☐ Yes ☐ No
    If yes, complete questions 18 – 22.

18. Provide the agent/toxin and animal being used:
    a. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____
    b. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____
    c. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____

19. How are animal waste and animal carcasses treated prior to disposal (e.g., carcasses, sewage, bedding, etc.) by an approved method:
    ☐ Not treated
    ☐ Autoclaved (temperature, time, and psi):_____
    ☐ Chemical (disinfectant, concentration, and time): _____
    ☐ Irradiation: _____
    ☐ Other:_____

20. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No

    If yes, the proposed work with select agents and toxins in animals has been approved by the IACUC: ☐ Yes ☐ No

21. The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC): ☐ Yes ☐ No
    If yes, give accreditation date: _____

22. Is there a system in place for recording the number of animals received and the number of animals disposed of and are the records reviewed frequently? ☐ Yes ☐ No

    If yes, please describe: _____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

SECTION 6F – WORK WITH PLANTS

23. Will work be performed with plants? ☐ Yes ☐ No
    If yes, complete questions 24 – 36.

24. Provide the agent/toxin and plant being used:
    a. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____
    b. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____
    c. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____

25. Work will be done in a glass or greenhouse: ☐ Yes ☐ No
    If yes, provide a description of the glass or greenhouse:
    ☐ Laminated Glass ☐ Tempered Glass ☐ Polycarbonate ☐ Other (*describe*): _____

26. Structure is reinforced: ☐ Yes ☐ No

27. Floor is concrete: ☐ Yes ☐ No

28. Vents into facility: ☐ Yes ☐ No

29. Floor drains: ☐ Yes ☐ No

30. Waste water collection and treatment, prior to release into sanitary sewer system: ☐ Yes ☐ No

31. Greenhouse HVAC supply and exhaust:
    a. Negative air pressure is maintained inside greenhouse: ☐ Yes ☐ No
    b. Greenhouse exhaust air is re-circulated to other areas of the facility: ☐ Yes ☐ No
       If yes, HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

32. Vectors present: ☐ Yes ☐ No
    If yes, vectors are restricted to cages: ☐ Yes ☐ No

33. Work will be done in growth chambers: ☐ Yes ☐ No
    a. If yes, the growth chamber is integrated into the laboratory building structure: ☐ Yes ☐ No
    b. If yes, the growth chamber is stand alone: ☐ Yes ☐ No
    c. Manufacture name:_____ Model number: _____

34. Growth chamber has floor drains: ☐ Yes ☐ No
    If yes, waste water is collected and treated prior to release into sanitary sewer system: ☐ Yes ☐ No

35. Growth chamber HVAC supply and exhaust:
    a. Negative air pressure is maintained inside the growth chamber: ☐ Yes ☐ No
    b. Growth chamber exhaust air is re-circulated to other areas of the facility: ☐ Yes ☐ No
       If yes, HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

36. Plant waste is treated prior to disposal (e.g., soil, plant material, etc.) by an approved method:
    ☐ Not treated
    ☐ Autoclaved (temperature, time, and psi):_____
    ☐ Chemical (disinfectant, concentration, and time): _____
    ☐ Irradiation: _____
    ☐ Other:_____

SECTION 6G –LABORATORY INFORMATION

This section should be completed for each laboratory safety level listed in Section 6A under the control of the PI.

37. Laboratory(ies) is/are currently operational: ☐ Yes ☐ No
    If no, indicate on floor plan which laboratory/laboratories are not operational and the date of anticipated certification/commission of laboratory.

38. Include a floor plan for each laboratory under the control of the PI where select agents or toxins listed in Section 6A are to be used or stored (for all laboratory safety levels). Floor plan(s) for all laboratory safety levels include: entry into laboratory and locations of equipment (e.g., sink, eyewash, biological safety cabinets (BSC), fume hoods, freezer, refrigerator, incubator, centrifuges, autoclave, and incinerator), HVAC supply and exhaust, and cage washing area (if applicable).

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

39. A facility risk assessment was performed to determine biosafety level: ☐ Yes ☐ No
    a. If yes, what was the determination:

    ☐ BSL2 ☐ BSL3 ☐ BSL4 ☐ ABSL2 ☐ ABSL3 ☐ BSL3 Ag ☐ ABSL4

    ☐ Other: _____

    b. List the resources/references used: _____

    _____

40. Define certification period for BSC located in laboratory: ☐ Annual ☐ Biannual ☐ Other (explain):_____
41. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
42. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
43. Laboratory is separated from open and unrestricted areas: ☐ Yes ☐ No
44. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
45. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
46. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

SECTION 6H – BSL3 AG LABORATORIES

47. Will work with animals be performed in BSL-3 Ag Laboratory? ☐ Yes ☐ No
    If yes, complete questions 48 – 59.
48. Describe where infected animals will be housed during and after experiments:

    _____

    _____

49. Personnel assigned to work with infected animals work in pairs: ☐ Yes ☐ No
50. Aerosol experiments are conducted in this BSL-3 Ag laboratory: ☐ Yes ☐ No
51. There is a mandatory daily inspection of the containment parameters for the BSL-3 Ag laboratory area(s) and critical life support systems: ☐ Yes ☐ No
52. Supplies, material and equipment enter BSL-3 Ag space only through an airlock, fumigation chamber, and interlocked and double-door autoclave or shower. ☐ Yes ☐ No
53. All walls are constructed slab-to-slab and walls, floors, and ceilings of the BSL-3 Ag laboratory rooms are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of contained agents and to allow gaseous fumigations for biological decontamination: ☐ Yes ☐ No
54. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No
55. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No
56. Differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No
57. There is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s): ☐ Yes ☐ No
    If yes, all HEPA filters are tested and certified annually: ☐ Yes ☐ No
58. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No
59. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No
    If yes, describe method utilized for decontamination of BSL-3 Ag area(s):

    _____

    _____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory Safety Level:_____

SECTION 6I – BSL4/ABSL4 LABORATORIES

60. Will work be performed in BSL-4/ABSL-4 Laboratory? ☐ Yes ☐ No
    If yes, complete questions 61 – 70.

61. There is a mandatory daily inspection of the containment parameters for the BSL-4 laboratory area(s) and critical life support systems: ☐ Yes ☐ No

62. Walls, floors, and ceilings of the BSL-4 laboratory rooms are sealed. All penetrations into the laboratory are sealed: ☐ Yes ☐ No

63. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No

64. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No

65. Differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No

66. There is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s): ☐ Yes ☐ No
    If yes, all HEPA filters are tested and certified annually: ☐ Yes ☐ No

67. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No

68. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No
    If yes, describe method utilized for decontamination of BSL-4 area(s):
    _____
    _____

69. Will work be performed in a protective suit: ☐ Yes ☐ No
    a. A breathing air system is provided with redundant compressors, backup storage tanks, HEPA filtration protection, and alarm monitoring in the event of failure: ☐ Yes ☐ No
    b. All penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed: ☐ Yes ☐ No
    c. Daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins: ☐ Yes ☐ No
    d. If a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration: ☐ Yes ☐ No
    e. Liquid and gas services to the suit area(s) are protected by backflow devices: ☐ Yes ☐ No

70. Will work with animals be performed in ABSL-4 laboratory: ☐ Yes ☐ No
    a. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or protective suit laboratories: ☐ Yes ☐ No
    b. Aerosol experiments are conducted in this ABSL-4 laboratory: ☐ Yes ☐ No
    c. Describe how animals are housed under ABSL-4 conditions (add additional sheets as necessary):
    _____
    _____
    d. Personnel assigned to work with infected animals work in pairs: ☐ Yes ☐ No

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Public reporting burden: Public reporting burden of this collection of information for the requirements of this application request is estimated to be 3.75 hours. An agency may not conduct, nor is an individual required to respond to, information collection unless a current valid OMB control number has been issued. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, ATTN: PRA (0920-0576), MS D-74, Atlanta, Georgia 30333.

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