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 12/31/2008

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 (telephone: 404-718-2000, facsimile: 404-718-2096, or e-mail: lrsat@cdc.gov). For USDA agents, the RO should submit this form to APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov). For HHS/USDA overlap agents, the RO may submit this form to APHIS or CDC, but not both. A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html. 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.

The entity should also perform a facility risk assessment (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 that 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. If information supplied in the application package indicates that the entity is properly equipped and capable of handling select agents and toxins, APHIS or CDC may issue a registration certificate to the entity. The registration is valid for a period up to three years. All entities will be subject to inspection during the three-year registration period.

If an entity's application fails to document that the entity is properly equipped and capable of work with select agents and toxins, or if the application is incomplete, the entity will not be registered. APHIS or CDC will inform the entity of problems with the application by contacting the designated RO. Upon resolution of the problem, the entity may again seek registration. 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.

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 RO to assume responsibility for providing application information to APHIS or CDC. 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 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.

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 or fax 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 completed Sections 1 and 2.

In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of this part. The owner of the entity must mail or fax 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. Complete section 1 regarding entity, RO, and alternate RO information.
   b. If more than one alternate RO has been identified, additional sections 1C and 2 should be completed, as appropriate.
   c. 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 institution.
4. Section 3 – Select Agents and Toxins, Possessed, Used, or Transferred by Entity. Complete section to indicate each select agent or toxin which is currently in possession, use or in storage at the entity, or those agents that are anticipated in the near future (e.g., within 6 months).
5. Section 4A – Biosafety and Laboratory Information on Select Agents and Toxins.
   a. The following information must be listed on a separate line for each laboratory safety level: the select agent(s) or toxin(s); the type of work with each select agent or toxin (e.g., viable, genomic material, recombinant DNA, use in animals, or large scale), the building and room number(s) where select agent(s) or toxin(s) will be used and stored for each Principal Investigator (or Chief Scientist).
   b. 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.

Example 1. An entity needs to register one principal investigator (e.g., Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; large scale production of *Bacillus anthracis* in Bldg A, Room 5 at BSL3; and *Bacillus anthracis* in mice in Bldg B, Room 200 at ABSL2). Storage of the select agents will be in the same locations where the work will be conducted.

EXAMPLE 1												
Select agent/Toxin name	**Viable**	**Genomic material**	**Recombinant DNA**	**Animal**	**Large Scale**	**Toxin**	**Laboratory Area**		**Storage Area**		**Laboratory Safety Level**	**Principal Investigator**
							Bldg	**Room**	**Bldg**	**Room**		
Bacillus anthracis	X						A	2	A	2	BSL2	Dr. Jane Doe
Bacillus anthracis	X				X		A	5	A	5	BSL3	Dr. Jane Doe
Bacillus anthracis	X			X			B	200	B	200	ABSL2	Dr. Jane Doe

Example 2. An entity needs to register three principal investigators (e.g., Dr. John Smith will be working with recombinant Ebola in Bldg 15, Room 100 at NIHBL-4; Dr. Mary Johnson will be working with botulinum toxins in Bldg 3A, Room 1000 under 29 CFR 1910.1450 conditions; and Dr. Tony Small will be working with viable *Francisella tularensis* in Bldg 4, Room 300 at BSL3 and viable *Brucella melitensis* in the same room). Storage of the agents will be in the same locations where the work will be conducted.

EXAMPLE 2												
Select agent/Toxin name	**Viable**	**Genomic material**	**Recombinant DNA**	**Animal**	**Large Scale**	**Toxin**	**Laboratory Area**		**Storage Area**		**Laboratory Safety Level**	**Principal Investigator**
							Bldg	**Room**	**Bldg**	**Room**		
Ebola virus			X				15	100	15	100	NIHBL4	Dr. John Smith
Botulinum toxin						X	3A	1000	3A	1000	29 CFR	Dr. Mary Johnson
Francisella tularensis	X						4	300	4	300	BSL3	Dr. Tony Small
Brucella melitensis	X						4	300	4	300	BSL3	Dr. Tony Small

6. Section 4B – Authorized Personnel Working with Select Agents and Toxins. 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 to select agents and toxins at the entity.
   a. The name (including middle initial), the date of birth and address, (including zip code) 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. The first and last name of each individual should correspond exactly to the information submitted to CJIS.
   b. The "Principal Investigator" (PI) field on Table 4B refers to the individual who is supervising all activities associated with select agents and toxins in the specified rooms. Therefore, the PI listed in Table 4B must be a PI listed on Table 4A. This column should be left blank only for the RO, ARO, PI, and owner/controller of the entity.
   c. Amending Section 4B:
      1) To request additions to Section 4B, submit an amended Section 4B with the individual's information added to the same agency that you filed your original application with (APHIS or CDC).
      2) To request deletions to Section 4B, submit the Section 4B with the individual's information lined through or removed (if removed, include a cover letter indicating which individual's information was removed) to the same agency that you filed your original application with (APHIS or CDC). If the individual's access to select agents or toxins is terminated by the entity, the RO must submit the reason for termination along with the amended Section 4B.
   d. Submitting security risk assessment (SRA) information to CJIS:
      1) Once the entity has submitted an amended Section 4B 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).
      2) The individual should complete the FD-961 form including their unique DOJ identifying number in block 15 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.cdc.gov/od/sap, http://www.aphis.usda.gov/programs/ag_selectagent/index.html, or http://www.fbi.gov/terrorinfo/bioterrorfd961.htm.

Example 3. 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	Middle Initial	Date of Birth	Home Address (No P.O. boxes)	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)	Select Agent(s)/ Toxin(s)	Laboratory Building	Laboratory Room	Job Title
Doe	Jane	A.	1/1/61	123 Street City, ST 01234		*Bacillus anthracis*	A	2	Principal Investigator
Johnson	John	D.	1/2/60	456 Lane City, ST 01234	Doe	*Bacillus anthracis*	A	2	Laboratorian

7. Section 5 – Principal Investigator and Laboratory Information. Complete this section for *each* principal investigator and each laboratory at the entity. Complete only sections as appropriate for the select agents and toxins in use for each principal investigator. If statement does not apply to the laboratory, check "N/A" box (if box is not available, write "N/A" beside statement).

(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.

FACILITY RISK ASSESSMENTS AND SAFETY LEVELS: REQUIREMENTS FOR HANDLING SELECT AGENTS

All entities using select agents 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.

- Laboratories working with viable select agent viruses, bacteria, or fungi should base their facility risk assessments on the BMBL. Use the BMBL to determine the appropriate Biosafety Level (BSL) for the various types of work to be conducted with each of the select agents.
- Laboratories working with recombinant DNA or regulated genetic elements should base their facility risk assessment on the *NIH Guidelines* to determine the recommended Biosafety Level (BSL) for the type of work to be conducted with each of the select agents. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins should meet the requirements of 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*. Additional guidance regarding toxin may be found in the BMBL. If the entity is also working with viable select agent toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and *NIH Guidelines* in addition to 29 CFR 1910.1450.
- Distributors of toxins in which the toxins are only handled in sealed containers should meet the requirements of 29 CFR 1910.1200, *Hazard Communication*.

ADDITIONAL REFERENCE MATERIALS:

(1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available on the internet at http://www.cdc.gov/od/sap. An errata sheet for the most current edition of the BMBL is available at the internet website: http://www.cdc.gov/od/sap.

(2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines*). The *NIH Guidelines* are available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

(3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory.* Available on the Internet at http://www.osha.gov or from the U.S. Government Printing Office (phone 202-512-1800).

(4) 29 CFR 1200 - *Hazard Communication.* Available on the Internet at http://www.osha.gov or from the U.S. Government Printing Office (phone 202-512-1800).

(5) Additional information and clarification is available at http://www.cdc.gov/od/sap and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on the APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or the CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 718-2000.

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FORM APPROVED
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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

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

SECTION 1 – ENTITY INFORMATION (TO BE COMPLETED BY ALL RO'S)			
This application is: ☐ A new registration ☐ An amendment to an existing registration			
SECTION 1A– ENTITY INFORMATION			
Entity registration number (e.g., A00000000-0000):		Date:	
Legal name of entity:			
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:
Date of birth:	Title of Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
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:
Date of birth:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
Business Address (NOT a post office box):	City:	State:	Zip Code:
Name of Alternate Responsible Official:	Last Name:	First Name:	Middle Name:
Date of birth:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
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 ALL RO'S AND ALTERNATE RO'S)

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official 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 C.F.R. Part 73 and/or 7 C.F.R. Part 331 and/or 9 C.F.R. 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 C.F.R. Part 73 and/or 7 C.F.R. Part 331 and/or 9 C.F.R. Part 121.

I understand that submission of a false statement and/or failure to comply with the provisions of the applicable regulations (7 C.F.R. Part 331 and/or 9 C.F.R. Part 121 and/or 42 C.F.R. 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 U.S.C. 8401; 18 U.S.C. 175, 175B, 1001, 3559, 3571; 42 U.S.C. 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)

Date:_____

SECTION 3 – SELECT AGENTS AND TOXINS POSSESSED, USED, OR TRANSFERRED BY ENTITY
(TO BE COMPLETED BY ALL RO'S)

Indicate each select agent or toxin that your entity intends to register by placing an "X" in the box for each agent or toxin (check one or more as appropriate). 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.

HHS SELECT AGENTS AND TOXINS

- ☐ Abrin
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ *Coccidioides posadasii*
- ☐ Conotoxins
- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ Diacetoxyscirpenol
- ☐ Ebola virus
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- ☐ Ricin
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ South American Haemorrhagic Fever viruses
  - ☐ Flexal
  - ☐ Guanarito
  - ☐ Junin
  - ☐ Machupo
  - ☐ Sabia
- ☐ Tetrodotoxin
- ☐ Tick-borne encephalitis complex (flavi) viruses
  - ☐ Central European Tick-borne encephalitis
  - ☐ Far Eastern Tick-borne encephalitis
  - ☐ Kyasanur Forest disease
  - ☐ Omsk Hemorrhagic Fever
  - ☐ Russian Spring and Summer encephalitis
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*

OVERLAP SELECT AGENTS AND TOXINS

- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxins
- ☐ Botulinum neurotoxin producing species of *Clostridium*
- ☐ *Brucella abortus*
- ☐ *Brucella melitensis*
- ☐ *Brucella suis*
- ☐ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- ☐ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ *Coccidioides immitis*
- ☐ *Coxiella burnetii*
- ☐ Eastern Equine Encephalitis virus
- ☐ *Francisella tularensis*
- ☐ Hendra virus
- ☐ Nipah virus
- ☐ Rift Valley fever virus
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxins
- ☐ T-2 toxin
- ☐ Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

- ☐ African horse sickness virus
- ☐ African swine fever virus
- ☐ Akabane virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Bluetongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot-and-mouth disease virus
- ☐ Goat pox virus
- ☐ Japanese encephalitis virus
- ☐ Lumpy skin disease virus
- ☐ Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides Capri* (contagious caprine pleuropneumonia)
- ☐ *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia)
- ☐ Newcastle disease virus (velogenic)
- ☐ Peste des petits ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

- ☐ *Candidatus* Liberobacter africanus
- ☐ *Candidatus* Liberobacter asiaticus
- ☐ *Peronosclerospora philippinensis*
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae* pv. *oryzicola*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

SECTION 4 – SELECT AGENT AND TOXIN INFORMATION
(TO BE COMPLETED BY ALL RO'S)

SECTION 4A. BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS AND TOXINS

Provide the following information on a **separate line** for each laboratory safety level: the select agent or toxin; the type of work with each select agent or toxin (e.g., viable, genomic material, recombinant DNA, use in animals, or large scale), the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each Principal Investigator (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 2 of the guidance document.

Select agent/Toxin name	Viable	Genomic Material	Recombinant DNA	Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
							Bldg	Room	Bldg	Room		
	INDICATE WITH AN "X" FOR EACH SELECT AGENT/TOXIN AS APPROPRIATE											

*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

Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL

I certify that the select agents and toxins listed are categorized commensurate with the risk of the select agent or toxin and its intended use, and the biosafety and containment procedures are sufficient to contain the select agent or toxin.

Responsible Official/Alternate Responsible Official Signature:_____ Date: _____

This application is: ☐ A new registration ☐ An amendment to an existing registration	Date
Legal name of entity:	Entity registration number (e.g., A00000000-0000):

SECTION 4B – AUTHORIZED PERSONNEL WORKING WITH SELECT AGENTS AND TOXINS
(TO BE COMPLETED BY ALL RO'S)

Provide the following information for the Responsible Official (RO), Alternate Responsible Official (ARO), owners of the entity, as well as *each* person who is authorized to have access to select agents and toxins at the entity. If the person listed is identified to own or control the entity, indicate "Y" in the "Owner/Controller" column. The name (including middle initial) and the date of birth and address (including zip code) 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 page to the agency that you filed your original application (APHIS or CDC). For information on completing this section, refer to page 3 of the guidance document.

Last Name	First Name	Middle Initial	Date of Birth (mmddyr)	Home Address (No P.O. boxes)	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)	Select Agent(s)/Toxin(s)	Laboratory Building	Laboratory Room	Job Title	Owner/ Controller (Y/N)

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.

Responsible Official/Alternate Responsible Official Signature:_____ Date: _____

Principal investigator: _____ Date: _____
Laboratory building: _____ Laboratory room number(s): _____ Laboratory safety level:_____

SECTION 5 – LABORATORY INFORMATION
(COMPLETED BY EACH PRINCIPAL INVESTIGATOR AND APPROVED BY THE RO)

Provide the following information for each principal investigator (PI) working with select agents and toxins at your entity. Make additional copies of this section of the form as needed. Each principal investigator should complete Section 5 as appropriate for *each* laboratory room where select agents and toxins are used or stored. For information on completing this section, refer to page 3 of the guidance document.

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

1. Name of individual responsible for the laboratory (e.g., principal investigator): _____
2. Provide the following information for each select agent(s) and toxin(s) worked with or stored in the laboratory building(s) and room(s):

SELECT AGENT/TOXIN NAME	STRAIN DESIGNATION	DATE ACQUIRED (list N/A if not acquired)	ADDRESS OF FACILITY FROM WHICH THE SELECT AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable)	FACILITY AGENT I.D. (Include any identification used to identify agent unique to laboratory)	SOURCE OF ISOLATE			UNIQUE CHARACTERISTICS	REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.)
					Clinical	Environmental	Other (explain)		

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

SECTION 5B – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (OBJECTIVES OF WORK)

Make additional copies of this section of the form as needed for *each* laboratory room for each principal investigator at your entity. Each principal investigator should complete questions 1 through 101, as appropriate for *each* laboratory where select agents are used or stored. If all laboratories with the same biosafety level under the control of one principal investigator meet the same criteria, then list all laboratory rooms and submit only one form. Include a floor plan for each laboratory where select agents or toxins are to be used or stored.

1. Provide the objectives of the work for each select agent or toxin listed on Table 4A, including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live select agents and recombinant DNA. If no work is being performed on select agent or toxin, indicate storage only. Attach additional sheets if needed:

   _____

   _____

   _____

   _____

   _____

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

   _____

3. Additional Principal investigators performing the same objective of work: ☐ Yes ☐ No

   If yes, list: _____

   _____

SECTION 5C – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (FACILITY)

Include a floor plan for each laboratory where select agents or toxins are to be used or stored (for all laboratory safety levels).

4. Laboratory is currently operational: ☐ Yes ☐ No

   If no, date of anticipated completion of laboratory: _____

5. Floor plan(s) for all laboratory safety levels include:

   a. Entry into laboratory: ☐ Yes ☐ No
   b. Sink locations: ☐ Yes ☐ No
   c. Eyewash locations: ☐ Yes ☐ No
   d. Biological safety cabinet (BSC) locations: ☐ Yes ☐ No
   e. Fume hood locations: ☐ Yes ☐ No
   f. HVAC supply and exhaust locations: ☐ Yes ☐ No
   g. Freezer/refrigerator locations: ☐ Yes ☐ No
   h. Other large equipment locations (incubators, centrifuges, etc): ☐ Yes ☐ No
   i. Autoclave location (if applicable): ☐ Yes ☐ No ☐ N/A
   j. Incinerator location (if applicable): ☐ Yes ☐ No ☐ N/A
   k. Cage washing area (if applicable): ☐ Yes ☐ No ☐ N/A

   NOTE: For BSL-4 or ABSL-4 facility questions, complete Section 5P and all other applicable sections.

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

SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL2 LABORATORY(IES)

6. Will work be performed in BSL2 laboratory(ies)? ☐ Yes ☐ No
   If yes, complete questions 7 – 8.
7. Provide a description of the HVAC system (*check all that are appropriate*):
   - ☐ Single-pass ☐ Re-circulated
   - ☐ Dedicated exhaust ☐ Shared exhaust
   - ☐ Constant air volume ☐ Variable air volume
   - ☐ Redundant exhaust fans
   - ☐ Emergency power back-up
8. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
   a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III
      Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III ☐ N/A
   b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
      BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
   c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____

SECTION 5E – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL3 LABORATORY(IES)

9. Will work be performed in BSL3 laboratory(ies)? ☐ Yes ☐ No
   If yes, complete questions 10 – 20.
10. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up
11. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
12. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
13. Each laboratory room has a hands-free sink: ☐ Yes ☐ No
14. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No
15. 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:_____

16. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
17. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
18. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
19. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
20. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

SECTION 5F – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN ABSL2 LABORATORY(IES)

21. Will work be performed in ABSL2 laboratory(ies)? ☐ Yes ☐ No
    If yes, complete questions 22 – 31.
22. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up
23. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
24. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
25. Animal laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
26. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
27. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
28. There is an autoclave in the laboratory: ☐ Yes ☐ No
29. The location of cage washing area is included on floor plan: ☐ Yes ☐ No
    If yes, cage washing is: ☐ Manual ☐ With a mechanical cage washer
30. Each animal room where infected animals are kept contains a hand-washing sink: ☐ Yes ☐ No
31. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

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

SECTION 5G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN ABSL3 LABORATORY(IES)

32. Will work be performed in ABSL3 laboratory(ies)? ☐ Yes ☐ No
    If yes, complete questions 33 – 46.
33. Provide a description of the HVAC system (*check all that are appropriate*):
    - ☐ Single-pass ☐ Re-circulated
    - ☐ Dedicated exhaust ☐ Shared exhaust
    - ☐ Constant air volume ☐ Variable air volume
    - ☐ Redundant exhaust fans
    - ☐ Emergency power back-up
34. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):
    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III
       Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III ☐ N/A
    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
       BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A
    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
35. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
36. Entry into the animal lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
37. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
38. Each animal room contains a hands-free hand washing sink: ☐ Yes ☐ No
39. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
40. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
41. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☐ No
42. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
43. HEPA filtration of all exhaust air is present: ☐ Yes ☐ No
44. There is an autoclave in the laboratory: ☐ Yes ☐ No
45. The location of cage washing area is included on floor plan: ☐ Yes ☐ No
    If yes, cage washing is: ☐ Manual ☐ With a mechanical cage washer
46. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

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

SECTION 5H – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (SECURITY)

47. 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

48. Physical Security (check all 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? ☐ Yes ☐ No

    1) If yes, are these individuals allowed into the area escorted? ☐ Yes ☐ No

    2) If no, explain: _____

    g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

49. Suspicious packages are inspected prior to entry or removal from an area where select agents and toxins are used or stored: ☐ Yes ☐ No

50. 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

51. Select agents and toxins are transferred from a laboratory to a shipping area and vice versa only under the supervision of an individual with access approval from APHIS Administrator or HHS Secretary: ☐ Yes ☐ No

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

SECTION 5I – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (BIOSAFETY AND INCIDENT RESPONSE)

52. 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

53. Appropriate personal protective equipment (PPE) is used: ☐ Yes ☐ No ☐ N/A

54. A medical surveillance system is in place for personnel using the select agents and toxins: ☐ Yes ☐ No ☐ N/A

55. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported: ☐ Yes ☐ No

56. A sharps policy is in place for this laboratory: ☐ Yes ☐ No

57. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents and toxins at this facility? ☐ Yes ☐ No

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

58. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☐No

    If yes, then give agency name and date of last inspection(s): _____

59. 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 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

SECTION 5J – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (TRAINING)

60. 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 kept: ☐ Yes ☐ No

    e. Personnel 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: _____

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

    _____

    _____

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

SECTION 5K – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (RECORDS AND INFORMATION SYSTEMS CONTROL)

61. Complete records are maintained as required by the Select Agent Regulations: ☐ Yes ☐ No

62. 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:

_____

_____

63. Describe the means to control access to records and databases that would allow for access to select agents and toxins:
    - ☐ Locks
    - ☐ Locked filing cabinet, drawer, cabinet, etc.
    - ☐ Secured electronic database (e.g., password protected, "stand alone PC")
    - ☐ Card access system
    - ☐ Other: _____

    a. Are these records and databases located on any computer on a network? ☐ Yes ☐ No

    If yes, provide a brief explanation of the systems in place to prevent unauthorized access to select agents and toxins (e.g., password protected, firewall protection)? _____

    _____

64. 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): _____

    _____

    _____

SECTION 5L – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS

65. Will work be performed with toxins or with agents that produce regulated amounts of toxins? ☐ Yes ☐ No
    If yes, complete questions 66 – 71.

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

67. Maximum quantity of each toxin under the control of the principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, at a given time:

    a. Toxin: _____ Aggregate amount of Toxin: _____

    b. Toxin: _____ Aggregate amount of Toxin: _____

    c. Toxin: _____ Aggregate amount of Toxin: _____

68. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

69. The toxin is produced by viable agent at the entity: ☐ Yes ☐ No

    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

70. 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

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

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

SECTION 5M – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH GENETIC ELEMENTS, RECOMBINANT NUCLEIC ACIDS, OR RECOMBINANT ORGANISMS

72. Will work be performed with genetic elements, ☐ Yes ☐ No
recombinant nucleic acids, ☐ Yes ☐ No
or recombinant organisms? ☐ Yes ☐ No

If yes, complete questions 73 – 77.

73. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No

74. 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

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

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

77. Are you intending to conduct the following restricted experiments as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13? ☐ Yes ☐ No

a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture: ☐ Yes ☐ No

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

_____

b. 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, provide a brief description of the restricted experiment: _____

_____

Note: An individual or entity may not conduct a restricted experiment with select agents and toxins unless approved by the APHIS Administrator and HHS Secretary.

SECTION 5N – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH ANIMALS

78. Will work be performed with animals? ☐ Yes ☐ No
If yes, complete questions 79 – 84.

79. List species of animals that will be used: _____

80. Describe route of administration of select agent or toxin:_____

81. Animal waste is 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:_____

82. Carcasses of animals are disposed of on site: ☐ Yes ☐ No

a. If yes, provide method of disposal of treated carcasses:

☐ Incineration ☐ Rendering ☐ Chemical decomposition ☐ Other (*describe*): _____

b. If no, describe:_____

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

83. 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

84. The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC): ☐ Yes ☐ No

    If yes, give accreditation date: _____

SECTION 5O – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH PLANTS

85. Will work be performed with plants? ☐ Yes ☐ No
    If yes, complete questions 86 – 93.

86. 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 ☐ Lexan ☐ Other (*describe*): _____

87. Structure is reinforced: ☐ Yes ☐ No

88. Floor is concrete: ☐ Yes ☐ No

89. Vents in facility: ☐ Yes ☐ No

90. Waste water collection and treatment: ☐ Yes ☐ No

91. Greenhouse HVAC supply and exhaust:

    a. Negative air pressure is maintained inside greenhouse: ☐ Yes ☐ No

    b. Greenhouse exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No

        If yes, HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

    c. Provide a description of the HVAC system (*check all that are appropriate*):

        ☐ Single-pass ☐ Re-circulated

        ☐ Dedicated exhaust ☐ Shared exhaust

        ☐ Constant air volume ☐ Variable air volume

        ☐ Redundant exhaust fans

        ☐ Emergency power back-up

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

93. 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:_____

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

SECTION 5P – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING IN BSL4/ABSL4 LABORATORIES

94. Will work be performed in BSL4/ABSL4 Laboratory? ☐ Yes ☐ No
    a. If yes, complete questions 95 – 101.

    b. Activities conducted under BSL-4/ABSL4 laboratory (check all that apply):
    ☐ Research ☐ Small animal
    ☐ Diagnostic ☐ Large animal
    ☐ Large scale production ☐Recombinant DNA
    ☐ Other (give description):_____

95. What type of BSL-4 laboratories are you registering?
    ☐ Stand alone Class III cabinet laboratory (complete question 99)
    ☐ Protective suit laboratory (complete question 100)
    ☐ Protective suit laboratory with associated Class III cabinet (complete questions 99 and 100)
    ☐ ABSL-4 Stand alone Class III cabinet laboratory (complete questions 99 and 101)
    ☐ ABSL-4 Protective suit laboratory (complete questions 100 and 101)
    ☐ ABSL-4 Protective suit laboratory with associated Class III cabinet (complete all questions)

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96. Provide a description of the HVAC system (*check all that are appropriate*):

    ☐ Single-pass ☐ Re-circulated

    ☐ Dedicated exhaust ☐ Shared exhaust

    ☐ Constant air volume ☐ Variable air volume

    ☐ Redundant exhaust fans

    ☐ Emergency power back-up

97. Provide information on the biological safety cabinets (BSC) in use (For more than one cabinet, provide class and how BSC is connected to HVAC system. Attach additional sheets if needed):

    a. Class of cabinet #1: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III

    Class of cabinet #2: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III ☐ N/A

    b. BSC #1 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating

    BSC #2 connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating ☐ N/A

    c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____

98. Provide safety information for the BSL-4 laboratory facility(ies) you are registering by answering the questions in this section. Use separate sheets if necessary.

    a. A specific BSL-4 facility operations manual has been prepared: ☐ Yes ☐ No

    b. All standard BSL-4 microbiological practices are followed: ☐ Yes ☐ No

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

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

    e. A visual pressure differential monitoring system is provided at the clean change room for laboratory personnel to verify directional air before entry into the BSL-4 laboratory: ☐ Yes ☐ No

    f. Differential pressures/directional airflow between adjacent areas is monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No

    g. Double HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet exhaust air is in place: ☐ Yes ☐ No

    h. Single HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet supply air is in place: ☐ Yes ☐ No

i. Describe method utilized for decontamination of BSL-4 area(s):
_____
_____

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99. Entities registering a stand alone Class III cabinet laboratory must complete the following information:

a. Inner and outer change rooms are separated by a shower for personnel entering and leaving the cabinet room: ☐ Yes ☐ No

b. There is a double-door (pass-through) autoclave, dunk tank, fumigation chamber, or ventilated anteroom for passing materials, supplies, or equipment into or out of the cabinet room: ☐ Yes ☐ No

c. Walls, floors, and ceilings of the cabinet room(s) are sealed and all penetrations into the cabinet room(s) are sealed: ☐ Yes ☐ No

d. Floors are seamless and coved: ☐ Yes ☐ No

e. 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

f. Sewer vents and other service lines contain HEPA filters: ☐ Yes ☐ No

g. 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

h. 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

i. If a central vacuum system is present, it serves only the cabinet room(s) and is HEPA filter protected, and liquid and gas services to the cabinet room are protected by backflow prevention devices: ☐ Yes ☐ No

j. Any windows are break resistant and sealed: ☐ Yes ☐ No

k. Double-door autoclaves are provided for decontamination of materials removed from the Class III cabinet and the cabinet room. These autoclaves are interlocked so that the outside door can only be opened after the sterilization cycle is complete: ☐ Yes ☐ No

l. Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods are provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from both the Class III biological safety cabinet(s) and the cabinet room(s): ☐ Yes ☐ No

m. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

n. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians of exhaust system failure: ☐ Yes ☐ No

o. There is HEPA filtration of all supply and exhaust air from the cabinet room(s), inner change room(s), and anteroom(s): ☐ Yes ☐ No

p. The Class III cabinet is directly connected to the exhaust system with HEPA filtration on the supply and double HEPA filtration on the exhaust: ☐ Yes ☐ No

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

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100. Entities registering a protective suit laboratory must complete the following information:

a. Entry into the area(s) where work is performed with BSL-4 select agents [suit room(s)] is through a series of changing and decontamination areas separated by airtight doors: ☐ Yes ☐ No

b. Inner and outer change rooms are separated by a personal shower: ☐ Yes ☐ No

c. A chemical shower is provided for decontaminating the outer surface of the protective suit: ☐ Yes ☐ No

d. 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

e. All penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed: ☐ Yes ☐ No

f. Daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins: ☐ Yes ☐ No

g. A double-door, interlocked autoclave is provided for decontaminating waste materials removed from the suit area(s): ☐ Yes ☐ No

h. A dunk tank, fumigation chamber, or ventilated airlock to pass materials, supplies, or equipment into or out of the suit area(s): ☐ Yes ☐ No

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

j. 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

k. If a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration: ☐ Yes ☐ No

l. Liquid and gas services to the suit area(s) are protected by backflow devices: ☐ Yes ☐ No

m. Inner and outer doors to chemical showers and airlocks are interlocked to prevent both doors from being opened at the same time: ☐ Yes ☐ No

n. Any windows are break resistant and sealed: ☐ Yes ☐ No

o. All drains in the suit area(s), chemical shower(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No

p. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians in the event of exhaust system failure: ☐ Yes ☐ No

q. Redundant exhaust fans are installed: ☐ Yes ☐ No

r. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

s. HVAC supply to the suit area(s), chemical shower(s), and airlock(s) is HEPA filtered: ☐ Yes ☐ No

t. HVAC exhaust from the suit area(s), chemical shower(s), and airlock(s) is double HEPA filtered with the HEPA filters in series: ☐ Yes ☐ No

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

v. Emergency lighting and emergency communications systems are provided for the BSL-4 areas: ☐ Yes ☐ No

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101. Entities registering an ABSL-4 laboratory must complete the following information:

a. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or protective suit laboratories being registered: ☐ 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.

Penalties: Knowingly providing false statements on any part of this form or its attachments will subject the offender to fines of up to $250,000 ($500,000 for organizations), imprisonment for up to 5 years or both (18 USC Section 1001). Failure to maintain records constitutes a 1 year misdemeanor (42 USC Section 271).

APHIS/CDC FORM 1 (12/31/2008)