FORM APPROVED
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GUIDANCE DOCUMENT FOR APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

This application package is for entities required to register to possess, use, or transfer select agents under Public Law 104-132 and its implementing regulation (42 CFR 73 - *Select Biological Agents and Toxins*; 7 CFR 331 - *Possession, Use, and Transfer of Biological Agents and Toxins*; and 9 CFR 121- *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins*). An entity[1] is required by law (42 CFR 73.15, 9 CFR 121, and 7 CFR 331) to register with either CDC or APHIS if they wish to use, possess, or transfer select agents or toxins. The entity should assign a Responsible Official (RO) to assume responsibility for providing application information to the appropriate agency. The agency that the RO should contact is determined by the type of select agent or toxin that they possess. For HHS agents, the RO should contact CDC (telephone: 404-498-2255; facsimile 404-498-2265). For HHS/USDA overlap agents, the RO should contact either APHIS or the CDC. For USDA agents, the RO should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA animal agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppq/permits.

RESPONSIBLE OFFICIAL

The regulation requires that a RO of the entity be identified, that the entity has facilities meeting the requirements to work safely with select agent(s), that only authorized personnel have access to select agents, and that registered entities keep records of select agents transferred to and from their facilities. The RO must be approved based on a security risk assessment by The Attorney General (Public Act 212(e)(3)), be familiar with the regulations (42 CFR 73, 7 CFR 331, and 9 CFR 121), and have the authority and responsibility to ensure that the requirements of the appropriate regulations are met.

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.

[1] Entity as defined by HHS/CDC and USDA/APHIS means any government agency (Federal, State, or local), university, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

The purpose of the RO and alternate RO is to ensure management oversight of the implementation of the select agent regulations and to provide an established point of contact for the entity. He or she is the designated individual responsible for all activities relating to the handling or transfer of select agents under the regulation. The RO and alternate RO must review and sign the Certification form (Section 2), and will be the person(s) contacted if CDC or APHIS have questions concerning the application or other matters related to the regulation. The RO or alternate RO should consult with others (e.g., engineering support services, principal investigators) as necessary to obtain the information required for this application. The RO or his or her alternate RO are also responsible for notifying CDC or APHIS 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 other changes to this application.

REGISTRATION

Entities wishing to register must submit an application to CDC or APHIS for review. Attachments to this application package include 42 CFR 73, 7 CFR 331, and 9 CFR 121. Before you complete this application please read these documents carefully to determine whether your entity is required to register. Note that there are some exemptions to the registration requirement (see 42 CFR 73.6). The entity should also perform a facility risk assessment (see 42 CFR 73.10-12, 9 CFR 121.12, and 7 CFR 331.11) that is based on the requirements for handling that agent to ensure that the facility meets those requirements. If information supplied in the application package indicates that the entity is properly equipped and capable of handling and transferring select agents, CDC or APHIS 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, or if the application is incomplete, the entity will not be registered. CDC or APHIS 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. Send all supporting documentation on 8½" by 11" paper in black and white, not color.

Registration and transfer documents shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.

CONTENTS OF THIS APPLICATION PACKAGE

1. Application overview and instructions for registration of entity
2. Forms to be completed by applicants
3. Attachments (attachments include the regulation and several clarification documents. All applicants should review these before completing the application forms)
   a. 42 CFR Part 73. *Select Biological Agents and Toxins*; Interim Final Rule. Federal Register, December 13, 2002.
   b. 9 CFR Part 121 - *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins*. Federal Register, December 13, 2002
   c. 7 CFR 331 – *Possession of Select Agents*. Federal Register, December 13, 2002
   d. Application for permit to: Import or transport controlled material or organisms or vectors (VS form 16-3)
   e. Additional Information for cell cultures and their products (VS form 16-7)
   f. Guidance document for report of transfer of select agents and toxins and EA-101

Please note that this application has been revised. This guidance document and form are also available at http://www.cdc.gov/od/sap or http://www.aphis.usda.gov/vs/ncie/bta.html.

INSTRUCTIONS FOR REGISTRATION OF ENTITY

Forms to be completed by all applicants

(1) Section 1- Entity, RO, and alternate RO information.

(2) Section 2 - Certification and Signature form. This form must be signed by the RO and the alternate RO for the institution.

(3) Section 3 - Indicate each select agent or toxin which are currently in possession, use or in storage at the entity, or those that you anticipate working with in the near future (e.g., within 6 months).

(4) Section 4 - Laboratory and biosafety information summary for the entity (Section 4A) and information on personnel requiring access must be completed (Section 4B). For each of the select agents the entity plans to use, list the following information on a separate line: the select agent(s); the characteristics of each select agent (e.g., viable, genomic, recombinant material, use in small or large animals, or large scale), the building and room number(s) where select agent(s) will be used and stored, and, the facility risk assessment based on the requirements for the type of activities conducted in each of the rooms. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

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 small mammals in Bldg B, Room 200 at ABSL2). Storage of the agents will be in the same locations where the work will be conducted.

AGENTS/ACTIVITIES TO BE CONDUCTED AT THE ENTITY														
	Facility Agent ID	Viable	Genomic material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
									Bldg	Room	Bldg	Room		
SELECT AGENT	**INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE**													
Bacillus anthracis		X							A	2	A	2	BSL2	Dr. Jane Doe
Bacillus anthracis							X		A	5	A	5	BSL3	Dr. Jane Doe
Bacillus anthracis					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 NIHBSL-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.

AGENTS/ACTIVITIES TO BE CONDUCTED AT THE ENTITY														
	Facility Agent ID	Viable	Genomic material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
									Bldg	Room	Bldg	Room		
SELECT AGENT	**INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE**													
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

*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 Appendix I

(5) Section 5A and 5B– All RO's should complete these sections for *each* of the principal investigators at their institution. Complete Sections 5C through 5G as appropriate for the agents in use.
(6) Section 6 is to be completed by all entities that have biosafety level 4 or animal biosafety level 4 laboratories. Sections 6A and 6B – All RO's should complete these sections for *each* of the principal investigators at their institution. Complete Sections 6C through 6F as appropriate for the agents in use.

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 live 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 you have listed in Section 5A.
- Laboratories working with recombinant DNA or genetic elements should base their facility 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 you have listed in Section 4. 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*, and the toxin guidelines contained in Appendix I of the BMBL. If the entity is also working with intact select toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and/or *NIH Guidelines* in addition to 29 CFR 1910.1450. Certain conditions may exclude select agent toxins from the requirements of this regulation (see 42 CFR 73.4(e)(1) and 42 CFR 73.5(e)(1)).
- Distributors of toxins in which the toxins are only handled in sealed containers should meet the requirements 29 CFR 1910.1200, *Hazard Communication*.

FOR HHS SELECT AGENTS, SEND COMPLETED FORMS TO CDC:
Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Road, NE
Mail Stop E-79
Atlanta, GA 30333

FOR USDA SELECT AGENTS, SEND COMPLETED FORMS TO APHIS:
Agricultural Select Agent Program
4700 River Road, Unit 2
Mailstop 22, Cubicle 1A07
Riverdale, MD 20737

FOR HHS/USDA OVERLAP AGENTS, SEND COMPLETED FORMS TO:
Either CDC or APHIS at the addresses listed above

ADDITIONAL MATERIALS YOU MAY NEED:
(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, http://www.aphis.usda.gov/vs/ncie/bta.html, and http://www.aphis.usda.gov/ppq/permits.

HOW TO AMEND YOUR REGISTRATION

To add, delete or change information on your registration, complete the relevant portion of the registration application package and return to the appropriate agency. These forms are available on the internet at http://www.cdc.gov/od/sap, http://www.aphis.usda.gov/vs/ncie/bta.html and http://www.aphis.usda.gov/ppq/permits.

HOW TO DESIGNATE A DIFFERENT OR ALTERNATE RO

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 Sections 1 and 2. The alternate RO must meet all of the qualifications for a RO. See additional details outlined in the section above entitled *Responsible Official*.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact CDC at (404) 498-2255 or APHIS at (301) 734-5960. It is also permissible to photocopy the originals contained in this application package if additional copies are needed. This application and guidance document is also available on the CDC Web site at http://www.cdc.gov, http://www.aphis.usda.gov/vs/ncie/bta.html and http://www.aphis.usda.gov/ppq/permits.

HOW THE INFORMATION IN THIS APPLICATION PACKAGE WILL BE USED

Each section of the application package is designed to obtain specific information required under 42 CFR 73, 7 CFR 331, and 9 CFR 121.

PUBLIC REPORTING BURDEN

The public reporting burden of this collection of information for the requirements of this application request is estimated to be 225 minutes. 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-24, Atlanta, Georgia 30333.

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APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Read all instructions carefully before completing the application. Answer all items completely. Type or print in ink on 81/2" by 11" paper. All documentation must be in black and white, not color. The application must be signed or it will not be processed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For HHS/USDA overlap agents submit the form to either CDC or APHIS. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

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

Before completing the application, read all instructions carefully. Give complete answers to all items. Type or print in ink.

This application is: ☐ A new registration ☐ A renewal of an existing registration ☐ An amendment to an existing registration

Current entity registration number(s) (*if applying for amendment or renewal*)	Date

Legal name of entity

Address (NOT a post office box)	City	State	Zip Code

Type of entity: ☐ Academic ☐ Government ☐ Commercial ☐ Private ☐ Other (please explain):

Name of Responsible Official (RO):	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

Name of Alternate Responsible Official (ARO):	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

Has this laboratory previously been registered with the CDC Select Agent Program under 42 CFR 72.6? ? Yes ? No
if yes, then provide CDC Select Agent Program registration number and expiration date:

Has this laboratory previously been registered with the USDA Select Agent Program? ? Yes ? No
If yes, then provide USDA 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 CFR 73, 9 CFR 121, and 7 CFR 331 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 73, 9 CFR 121, and 7 CFR 331.

I understand that a false statement on any part of this agreement or failure to comply with the provisions of the applicable regulations may result in the immediate revocation of this entity's registration as described in 42 CFR 73, 9 CFR 121, and 7 CFR 331 and could result in a civil fine of up to $500,000 for each violation, or if criminally prosecuted a criminal fine or imprisonment for up to five years, or both for each violation. (7 U.S.C. 8401; 18 U.S.C. 175, 175b, 1001, 3559, 3571; 42 U.S.C. 264, 271).

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

Date:_____

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

Indicate each select agent or toxin in use or storage at your entity by placing an "X" in the box for each agent or toxin possessed by your entity (check one or more categories as appropriate). Items that are exempt from registration should not be listed on this form.

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ *Coccidioides posadasii*
- ☐ Ebola viruses
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*
- South American haemorrhagic fever viruses
  - ☐ Junin
  - ☐ Machupo
  - ☐ Sabia
  - ☐ Flexal
  - ☐ Guanarito
- Tick-borne encephalitis complex (flavi) viruses
  - ☐ Central European tick-borne encephalitis
  - ☐ Far Eastern tick-borne encephalitis
  - ☐ Russian spring and summer encephalitis
  - ☐ Kyasanur forest disease
  - ☐ Omsk hemorrhagic fever
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*
- ☐ Abrin
- ☐ Conotoxins
- ☐ Diacetoxyscirpenol
- ☐ Ricin
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

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

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- ☐ Akabane virus
- ☐ African swine fever virus
- ☐ African horse sickness virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Blue tongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot and mouth disease virus
- ☐ Goat pox virus
- ☐ Lumpy skin disease virus
- ☐ Japanese encephalitis virus
- ☐ Malignant catarrhal fever virus (Exotic)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum* / M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Newcastle disease virus (VVND)
- ☐ Peste Des Petits Ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

- ☐ *Liberobacter africanus*
- ☐ *Liberobacter asiaticus*
- ☐ *Peronosclerospora philippinensis*
- ☐ *Phakopsora pachyrhizi*
- ☐ Plum Pox Potyvirus
- ☐ *Ralstonia solanacearum* race 3, biovar 2**?**
- ☐ *Schlerophthora rayssiae* var *zeae***?**
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

Date:_____

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

SECTION 4A. BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS

All applicants must complete this table. Each select agent used at different risk levels should be listed separately for each laboratory. Failure to complete this table in detail will delay processing of your application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

Agent/Toxin name	Facility Agent I.D.	Viable	Genomic Material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
									Bldg	Room	Bldg	Room		
		INDICATE WITH AN "X" FOR EACH AGENT 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 Appendix I

Registration number (if applicable) _____

SECTION 4B – AUTHORIZED PERSONNEL WORKING WITH SELECT AGENTS

Provide the following information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access to select agents in the institution. The information provided in this section must correspond to that presented in Section 3 and 4A or it will delay processing the application. To request additions to or deletions from this list of individuals, submit this page to the same agency that you filed your original application with (CDC or APHIS). The first and last name of each individual should correspond exactly to the information submitted to the Attorney General.

Last Name	First Name	Middle Initial	Date of Birth	Home Address (No P.O. boxes)	Supervising Principal Investigator (PI's, RO's, and owners leave this column blank)	Agent(s)/Toxins	Laboratory Building	Laboratory Room	Job Title

I certify that the individuals listed above have a legitimate need for access to select agents in the laboratories listed above, and that each individual has the training and skills to safely work with these agents or toxins.

RO Signature:_____ Date: _____

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

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

Provide the following information for each laboratory working with select agents at the institution. Make additional copies of this section of the form as needed for each principal investigator at your entity. Each principal investigator should complete questions 3 through 77, as appropriate for *each* laboratory room where select agents are used or stored. Incomplete answers will delay processing the application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

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

Include a current resume or Curriculum Vitae from the principal investigator.

1. Name of individual responsible for the laboratory (e.g., principal investigator): _____ _____

2. Provide the following information for each agent(s) worked with or stored in the laboratory building(s) and room(s) specified in section 4B:

AGENT/TOXIN NAME	STRAIN DESIGNATION	DATE ACQUIRED	ADDRESS OF FACILITY FROM WHICH THE AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable)	FACILITY AGENT I.D.	SOURCE OF ISOLATE			UNIQUE DIAGNOSTIC CHARACTERISTICS	REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.)	HOST RANGE (i.e., man and birds)
					Clinical	Environmental	Other (explain)			

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

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 3 through 77, 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 agents or toxins are to be used or stored (for all biosafety levels).

3. Floor plan(s) include:
   - a. Sink locations ☐ Yes ☐ No
   - b. Eyewash locations ☐ Yes ☐ No
   - c. Biological safety cabinet (BSC) locations ☐ Yes ☐ No
   - d. Fume hood locations ☐ Yes ☐ No
   - e. HVAC supply and exhaust locations ☐ Yes ☐ No
   - f. Freezer/refrigerator locations ☐ Yes ☐ No
   - g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No
4. Provide a description of the HVAC system (*check all that are appropriate*):
   - a. ☐ Single-pass ☐ Re-circulated
   - b. ☐ Dedicated exhaust ☐ Shared exhaust
   - c. ☐ Constant air volume ☐ Variable air volume
   - d. ☐ Redundant exhaust fans
   - e. ☐ Emergency power back-up
5. Provide information on the biological safety cabinets in use (attach additional sheets if needed):
   - a. Class of cabinet: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   - b. Biological safety cabinet connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
   - c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
   - d. Does user verify air inflow during BSC use? ☐ Yes ☐ No

6. **NOTE**: If your entity has a BSL-4 or ABSL-4 laboratory, then skip to Section 6 and complete Sections 6A and 6B, and any other sections that are applicable to your entity.

7. BSL-3 laboratory registration must answer the following:
   - a. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
   - b. Each laboratory room has a hands-free sink: ☐ Yes ☐ No
   - c. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No
   - d. There is an autoclave or other verified or approved method for decontamination within the laboratory: ☐ Yes ☐ No
   - e. If no autoclave in the BSL-3 laboratory, describe waste handling protocols to be used by the laboratory personnel:
     _____
     _____
   - f. Laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
   - g. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
   - h. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
   - i. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
   - j. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

8. ABSL-2 laboratory registration must answer the following:
   a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
   b. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
   c. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
   d. There is an autoclave in the laboratory: ☐ Yes ☐ No
   e. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
   f. Cage washing is: ☐ Manual ☐ With a mechanical cage washer
   g. The cage washing area is shown on attached floor plan: ☐ Yes ☐ No
   h. Each animal room where infected animals are kept contains a hand-washing sink: ☐ Yes ☐ No
   i. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

9. ABSL-3 laboratory registration must include the following:
   a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
   b. Entry into the animal lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
   c. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
   d. Each animal room contains a hands-free hand washing sink: ☐ Yes ☐ No
   e. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
   f. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
   g. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☐ No
   h. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
   i. HEPA filtration of all exhaust air is present: ☐ Yes ☐ No
   j. There is an autoclave in the laboratory: ☐ Yes ☐ No
   k. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No
   l. Cage washing area is shown on the floor plans: ☐ Yes ☐ No
   m. Animal waste treated (carcasses, sewage, bedding, etc.) before disposal ☐ Yes ☐ No
      If yes describe treatment method: _____
   n. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

10. Appropriate personal protective equipment is used: ☐ Yes ☐ No
11. Vacuum lines contain HEPA filters: ? Yes ? No ? No vacuum lines are used
12. Each laboratory using select agents has an agent-specific, site-specific biosafety manual: ☐ Yes ☐ No
13. A medical surveillance system is in place for laboratory personnel using select agents: ☐ Yes ☐ No
14. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No
15. A sharps policy is in place for this laboratory (or laboratories): ☐ Yes ☐ No
16. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No
17. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this entity? ☐ Yes ☐No
    a. If yes, has IBC approved the work proposed in this application: ? Yes ? No
    b. The entity has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ? Yes ? No

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

18. Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), 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 agents and recombinant DNA:

_____

_____

_____

_____

_____

_____

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

19. Training:

a. Site specific security and safety training is provided to individuals with access to areas where select agents are handled or stored: ☐ Yes ☐ No

b. Is provided prior to individuals beginning to work with select agents: ☐ Yes ☐ No

c. 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: ☐ Yes ☐ No

f. Provide a brief description of what is included in the training program:

_____

_____

20. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

_____

_____

a. Individual responsible for inventory of select agent(s):

_____

b. How often is the inventory record reconciled?

_____

c. How is access to the inventory log limited?

_____

d. Inventory tracking includes the following information (list):

_____

_____

_____

21. There is a site-specific security plan for each of the laboratories listed above in Section 5A (number 2): ☐ Yes ☐ No

a. Building with select agents has self-closing doors: ☐ Yes ☐ No

b. Means to limit access to buildings with laboratories with select agents:
☐ Guard station at the entity entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory building
☐ Other (describe): _____

_____

c. Means to limit access to laboratories with select agents once inside the building:
☐ Door to laboratory is locked

☐ Guard station at the building entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory

☐ Other (describe): _____

d. Means to limit access to select agents once inside the laboratory:
☐ Locked incubators, refrigerators, freezers, etc.
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

e. Means to limit access to select agents in storage:
☐ Storage area door locked
☐ Lock boxes
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

f. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
☐ Electronic logs of card access system entries are reviewed for unusual activity
☐ Manual sign in and out logs are kept and monitored

☐ Video camera surveillance
☐ Other (describe): _____

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

h. Number of people with access:
_____

i. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain:_____

j. Non-laboratory personnel (visitors, including janitorial and entity maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

k. Provide additional details regarding how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons:
_____
_____

SECTION 5C –TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH INFECTIOUS AGENTS

22. Provide an estimate of the maximum quantities (e.g., number of petri dishes or flasks) and concentration of organisms grown at a given time: _____

23. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No

a. If yes, describe method:_____

SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH RECOMBINANT DNA

24. The entity has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No

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

26. Will you be possessing, using or transferring the following:

a. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication. ☐ Yes ☐ No

b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*. ☐ Yes ☐ No

c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

27. Are you intending to conduct the following experiments:

a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms 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

b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD_{50} < 100 ng/kg body weight. ☐ Yes ☐ No

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

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

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

30. List species of small animals that will be used: _____

31. Describe route of infection: _____

32. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.):

a. If yes, describe method: _____

33. 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

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

34. The institution is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give accreditation date: _____

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

35. List species of large animals that will be used: _____

36. Describe route of infection: _____

37. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐ Yes ☐ No

38. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

a. If yes, give method: _____

39. Carcass of animals are disposed of on site: ☐ Yes ☐ No

40. 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

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

41. The institution is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give accreditation date: _____

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

42. A Chemical hygiene plan is available for the entity using toxins: ☐ Yes ☐ No

43. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

44. Form of toxins used: ☐ Liquid ☐ Lyophilized

45. The toxin is produced by live 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): _____

46. Dilution procedures and other manipulations of the concentrated toxins are:

    a. Conducted in ☐ Fume hood ☐ Biological safety cabinet

        1) If a fume hood is used, certification of the hood is conducted:
        ☐ Annually ☐ Biannually ☐ Other (describe): _____

    b. Conducted with two knowledgeable people present: ☐ Yes ☐ No

    c. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

SECTION 6A – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

NOTE: All entities must also complete Section 5A, Questions 1 and 2, above (CDC Form 0.1319/APHIS Form 2040)

47. All entities must answer the following questions for each BSL-4 laboratory:

    a. Activities conducted under BSL-4 containment (check all that apply):

    ☐ Research ☐ Diagnostic ☐ Large scale production ☐ Small animal ☐ Large animal

    ☐ Recombinant DNA ☐ Other (give description):_____

    b. How many separate BSL-4 laboratories are you registering for select agent work?

    ☐ 1 laboratory ☐ 2 laboratories ☐ 3 or more laboratories

    c. Are these laboratories currently registered with the CDC Select Agent Program? ☐ Yes ☐ No

    d. Are these laboratories currently registered with the APHIS? ☐ Yes ☐ No

    e. Are these BSL-4 laboratories currently operational (presently conducting BSL-4 work)? ☐ Yes ☐ No

    f. What type of BSL-4 laboratory (ies) are you registering?

    ☐ Protective suit laboratory ☐ Stand alone Class III cabinet laboratory

    ☐ Protective suit laboratory with associated Class III cabinet

48. Include a floor plan for each BSL-4 laboratory, Class III cabinet laboratory, or ABSL-4 laboratory where select agents are to be used or stored.

    Floor plan(s) must include:

    a. Sink locations ☐ Yes ☐ No

    b. Eyewash locations ☐ Yes ☐ No

    c. Laboratory furniture locations (including bench work) ☐ Yes ☐ No

    d. Biosafety cabinet (BSC) locations ☐ Yes ☐ No

    e. Fume hood locations ☐ Yes ☐ No

    f. HVAC supply and exhaust locations ☐ Yes ☐ No

    g. Freezer/refrigerator locations (include LN2 storage) ☐ Yes ☐ No

    h. Other large equipment locations (e.g., incubators, centrifuges) ☐ Yes ☐ No

49. Provide information on the biosafety cabinets in use (attach additional sheets if needed):

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

    b. Biosafety cabinet connection to the HVAC system: ☐ Hard ducted ☐ Thimble ☐ Re-circulating

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

50. Provide a description of the BSL-4 HVAC system (*check all that are appropriate*):

a. ☐ Single-pass

b. ☐ Dedicated exhaust

c. ☐ Constant air volume ☐ Variable air volume

d. ☐ Redundant exhaust fans

e. ☐ Emergency power back-up

51. Provide general facility and 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. BSL-4 laboratory design and operational procedures are documented and re-verified annually: ☐ Yes ☐ No

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

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

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

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

f. The HVAC system is dedicated and is not re-circulated: ☐ Yes ☐ No

g. There is a visual and auditory alarm system provided to alert facility workers to system malfunctions and/or failures of containment parameters: ☐ Yes ☐ No

h. Entry to the laboratory is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

i. Each protective suit or cabinet laboratory room has a hands-free sink: ☐ Yes ☐ No

j. There is a double door autoclave for decontamination of materials from the suit lab and/or the Class III cabinet and cabinet room: ☐ Yes ☐ No

k. 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

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

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

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

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

_____

_____

p. Inactivation of organisms and materials removed from BSL-4 containment is accomplished by what method?

☐ Irradiation ☐ Chemical disinfection ☐ Autoclaving ☐ Other

Describe:_____

_____

q. Inactivation of materials removed from BSL-4 containment is verified: ☐ Yes ☐ No

Describe:_____

Facilities registering a laboratory containing a Class III cabinet, must answer question 52. Facilities wishing to register protective suit laboratories and suit laboratories with associated Class III cabinets must also answer question 53.

52. Entities registering a **stand alone Class III Cabinet laboratory registration** must verify the following items:

    a. Entry to the laboratory housing the Class III cabinet is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

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

    c. 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

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

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

    f. 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

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

    h. 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

    i. 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

    j. A hands-free sink is located in the cabinet room(s) near the door and in the inner and outer change rooms: ☐ Yes ☐ No

    k. 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

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

    m. 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

    n. 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

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

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

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

    r. 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

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

53. Entities registering a **protective suit laboratory or a protective suit laboratory with associated Class III cabinet registration** must verify the following items (**suit laboratories with associated Class III cabinets must also answer question 52**):

    a. Entry into the area(s) where work is performed with BSL-4 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. A hands-free sink is located in the suit area(s): ☐ Yes ☐ No

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

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

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

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

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

q. 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

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

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

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

u. 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

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

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

---

54. Entities registering an **ABSL-4 laboratory** must provide the following information. Entities registering a **stand alone Class III cabinet** for housing animals infected with biosafety level 4 agents, or other ABSL-4 use must complete **question 52** above. Entities registering a **protective suit laboratory** housing animals infected with Biosafety level 4 agents must complete **question 53**:

a. List animal models in use for ABSL-4 experiments: _____

_____

b. ABSL-4 Laboratory Room(s) designations: _____

c. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or Protective suit laboratory(ies) being registered: ☐ Yes ☐ No

d. All appropriate special policies and procedures are approved by the Institutional Animal Care and Use Committee: ☐ Yes ☐ No

e. Are aerosol experiments conducted in this ABSL-4 laboratory (ies): ☐ Yes ☐ No

f. Describe how are animals housed under ABSL-4 conditions:

_____

_____

g. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No

h. Cage washing area is shown on the floor plans: ☐ Yes ☐ No

i. Animal waste is sterilized (carcasses, sewage, bedding, etc.) before disposal ☐ Yes ☐ No

Describe treatment method: _____

j. Method of disposal of treated carcasses? ☐ Incineration ☐ Rendering ☐ Chemical decomposition

☐ Other (*describe*): _____

k. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

l. Appropriate personal protective equipment is used: ☐ Yes ☐ No

m. Personnel assigned to work with infected animals work in pairs: ☐ Yes ☐ No

---

55. Vacuum lines contain HEPA filters: ☐ Yes ☐ No ☐ No vacuum lines are used

56. A medical surveillance system is in place for laboratory personnel using select agents: ☐ Yes ☐ No

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

58. A sharps policy is in place for this laboratory (or laboratories): ☐ Yes ☐ No

59. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

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

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

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

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

61. Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), 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 agents and recombinant DNA: _____

_____
_____
_____
_____
_____

SECTION 6B – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES (TRAINING AND SECURITY)

62. Training:

a. Site-specific security training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

b. Site-specific safety training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

c. A biosafety manual has been prepared that indicates special hazards associated with the BSL-4 agents in use and laboratory personnel are required to read and follow these practices and procedures: ☐ Yes ☐ No

d. Training is provided to laboratory personnel prior to beginning work with BSL-4 select agents: ☐ Yes ☐ No

e. Training is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

f. Written records of individuals trained are kept: ☐ Yes ☐ No

g. Personnel are required to demonstrate proficiency in laboratory procedures prior to working with BSL-4 select agents: ☐ Yes ☐ No

h. Please provide a brief description of the individual training program for BSL-4 laboratory personnel (attach additional sheets if necessary):

_____

_____

_____

_____

63. Security: Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

_____

_____

_____

_____

_____

a. All viable BSL-4 agents are stored within the BSL-4 containment area: ☐ Yes ☐ No

b. Storage areas within BSL-4 containment are under surveillance: ☐ Yes ☐ No

c. Individual responsible for inventory of select agent(s): _____

d. How often is the inventory record reconciled? _____

e. How is access to the inventory log limited? _____

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

_____

_____

64. There is a site-specific security plan for each of the BSL-4 laboratories listed above: ☐ Yes ☐ No

a. Only persons whose presence in the BSL-4 laboratory facility or individual laboratory rooms is required for program or support purposes are authorized to enter: ☐ Yes ☐ No

b. Access is to the laboratory is controlled by secure, locked doors: ☐ Yes ☐ No

c. A signature log book indicating date and time of entry and exit of all personnel to and from the BSL-4 containment area is maintained: ☐ Yes ☐ No

d. Indicate means of limiting access to buildings with BSL-4 laboratories using select agents:
☐ Guard station at the entity entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory building Other (describe):
_____

e. Indicate means of limiting access to select agents once inside the building:
☐ Door to laboratory is locked
☐ Guard station at the building entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory
Other (describe): _____

f. Means to limit access to select agents once inside the laboratory:
☐ Locked incubators, refrigerators, freezers, etc.
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

g. Means to limit access to select agents in storage:
☐ Storage area door locked
☐ Lock boxes
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

h. Means to monitor unauthorized entry into the BSl-4 laboratory where select agents are used or stored:
☐ Electronic logs of card access system entries are reviewed for unusual activity
☐ Manual sign in and out logs are kept and monitored

☐ Camera surveillance (e.g., CCTV)
☐ Other (describe): _____

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

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

k. Total number of personnel with access to BSL-4 area during operations: _____

l. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

If yes, please explain: _____

n. Describe how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons:

_____

_____

SECTION 6C – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH INFECTIOUS AGENTS

65. Provide an estimate of the maximum quantities (e.g., number of petri dishes or flasks) and concentration of organisms grown at any given time: _____

a. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved sterilization method: ☐ Yes ☐ No

If yes, describe method: _____

SECTION 6D – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH RECOMBINANT DNA

66. This laboratory meets NIH guidelines for research involving recombinant DNA molecules: ☐ Yes ☐ No

67. Will you possess, use or transfer the following:

a. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication. ☐ Yes ☐ No

b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*. ☐ Yes ☐ No

c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

68. Do you intend to conduct the following experiments:

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

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

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

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

SECTION 6E – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH SMALL ANIMALS

71. List species of small animals that will be used: _____

72. Describe route of infection: _____

73. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

    If yes, describe method: _____

74. 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

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

    b. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

    c. If yes, give inspection date: _____

SECTION 6F – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH LARGE ANIMALS

75. List species of large animals that will be used: _____

    a. Describe route of infection: _____

    b. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐ Yes ☐ No

    c. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

    If yes, give method: _____

76. Carcass of animals are disposed on site: ☐ Yes ☐ No

    a. 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 in small animals has been approved by the IACUC: ☐ Yes ☐ No

77. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

Attachments

Attachment 1. 42 CFR Part 73. Select Biological Agents and Toxins; Final Rule. Federal Register, December 13, 2002.

Attachment 2. 9 CFR Part 121 - Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins. Federal Register, December 13, 2002.

Attachment 3. 7 CFR 331 – Possession of Select Agents. Federal Register, December 13, 2002.

Attachment 4. APHIS application for permit to import or transport controlled material or organisms or vectors (VS form 16-3). (see pdf attachment)

Attachment 5. Additional Information for cell cultures and their products (VS form 16-7). (see pdf attachment)

Attachment 6. Guidance document for report of transfer of select agents and toxins and EA-101

The purpose of the CDC EA-101 form is to provide a method for the documentation of the transfer of a select agent. An EA-101 form must be completed for each transfer of a select agent. A copy of each EA-101 must be kept by the responsible official (RO) for three years.

Prior to transferring a select agent
Before a select agent is transferred, both the sender (transferor) and recipient (requestor) facilities must be registered with the CDC or APHIS. The agency that the Responsible Official (RO) should contact is determined by the type of select agent or toxin involved in the transfer. For HHS agents, the RO should contact CDC by facsimile (404-498-2265). For USDA agents, the RO should contact APHIS (for animal agents and toxins, telephone: 301-734-3277; facsimile: 301-734-3652). For HHS/USDA overlap agents, the RO should contact either APHIS or CDC. For plant agents and toxins the RO should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA animal agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppq/permits.

The recipient fills out blocks 1 and 2 of the EA-101 form and submits it to the sender. The sender's responsible official (RO) must FAX the form to CDC (FAX: 404-498-2265) or APHIS (FAX: 301-734-3652) to verify that the requesting entity: (1) retains a valid, current registration for the select agent being requested; (2) the person requesting the select agent is an employee of the requesting entity, and has been given Department of Justice clearance as an authorized individual to receive the select agent material to be transferred; and, (3) that the proposed use of the agent by the recipient is correctly indicated on CDC Form EA-101. CDC or APHIS will FAX back the form with a confirmation if the transfer information is approved. If the sender has a suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the sender should consult with the CDC.

Transfer:
(a) Shipment of the select agent to the recipient
The sender should ship the material to the receiver only after the sender has received a verification number from CDC or APHIS regarding the information in blocks 1 and 2 of the EA-101. The sender fills out Section 4, including the date the agent was shipped. Select agents must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, and 49 CFR 100-180) and international (IATA) regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents being shipped.
(b) Transmittal of the EA-101 form to the CDC or APHIS
The RO from the recipient's entity must fill out Section 4 of the EA-101 form with the date received and FAX the form back to both the Sender's RO and the CDC or APHIS. The recipient is required to provide a completed paper copy or facsimile transmission of the EA-101 form within 2 business days to the Sender RO and the CDC or APHIS.

Destruction or depletion of a select agent

When a select agent from a transfer is depleted or destroyed, the RO of the entity must complete the appropriate information in Block 4 of the Form. A copy or FAX of the EA-101 form must be sent to the CDC or APHIS.

Recipient RO	**Sender RO**
1. Completes agent description (Block 1)	
2. Completes recipient information (Block 2)	
3. Faxes form EA-101 and registration certificate to sender	
	4. Completes sender information (Block 3)
	5. Faxes form EA-101 to CDC or APHIS for verification number
	6. After receipt of approval by CDC or APHIS, sender completes shipping information (Block 4), except for date received
	7. Oversees packaging and shipment of agent to recipient. Sends shipment.
8. Receives agent	
9. Recipient RO completes Block 4 (i.e., date select agent material received and confirms that what was listed on packing inventory has been received) and provides paper copy or faxes form EA-101 to both CDC or APHIS and the sender within 2 business days of receipt.	
10. Retains paper record for 3 yr, or retains record 3 yr after agent consumed or destroyed, whichever is longer	10. Retains paper record for 3 yr, or retains record 3 yr after agent consumed or destroyed, whichever is longer