FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576

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 and Response Act of 2002" (Public Law 107-188; 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 severe 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, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 1) 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 regulation (42 CFR 73, 9 CFR 121, and 7 CFR 331) to register with either APHIS or CDC 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 select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

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 (7 CFR 331, 9 CFR 121, and 42 CFR 73), 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.

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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 APHIS or CDC 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 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 other changes to this application.

REGISTRATION

Entities wishing to register must submit an application to APHIS or CDC for review:

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/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an entity must submit the application package to APHIS or CDC, but not both.

Before you complete this application, please read these documents carefully to determine whether your entity is required to register. Please review the exemptions and exclusions requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73.

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 APHIS or CDC at the addresses listed above

The entity should also perform a facility risk assessment (see 42 CFR 73.11-12, 9 CFR 121.11-12, and 7 CFR 331.11-12) 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 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, or if the application is incomplete, the entity will not be registered. APHIS or CDC will inform the entity of

[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.

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. Currently, there is no fee for registration for select agents and toxins.

CONTENTS OF THIS APPLICATION PACKAGE

1. Application overview and instructions for registration of entity
2. Forms to be completed by applicants

NOTE: This guidance document and form are also available at http://www.cdc.gov/od/sap or http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

INSTRUCTIONS FOR REGISTRATION OF ENTITY

Forms to be completed by all applicants:

(1) Section 1- Entity, RO, and alternate RO information. If more than one alternate RO has been identified, additional Section 1 and 2 should be completed, as appropriate.

(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 is 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 4A - 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 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.

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		LaboratorySafety 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

(5) Section 4B - All RO's should complete this section by providing 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 Table 4A or it will delay processing the application. The name (including the 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 Form FD-961 submitted to CJIS for each individual. 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 (APHIS or CDC). The first and last name of each individual should correspond exactly to the information submitted to the Attorney General. NOTE: Table 4B relates to the Principal Investigator (PI) who is accountable for the work listed on the Table 4A. The "supervising principal investigator" field on Table 4B refers to the individual who is supervising all activities associated with select agents and toxins in the specified rooms. Thus, the PI listed in Table 4B may not be the direct supervisor of the individual. For example, facilities, support and administrative personnel have superiors they report to, but the "supervising PI" listed in Table 4B refers to the person whose work is registered with the APHIS or CDC.

Submitting security risk assessment (SRA) information. A notification will be given to the entity with the unique Department of Justice (DOJ) identifying number for each individual listed on the Table 4B or amended 4B. The RO should then forward to each individual their unique DOJ identifying number. The individual should complete the FBI form (FD-961), including their unique identifying number in block 17. The individual should follow all of the FBI instructions (http://www.fbi.gov/hq/cjisd/takingfps.html) for submitting fingerprints and then mail the FD-961 form and fingerprint cards as one package directly to the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS). 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 (Section 4B). 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 is not his immediate supervisor, her name should be listed because she is responsible for the agent in this laboratory.

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
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

(6) Section 5A and 5B - All RO's should complete these sections for *each* of the principal investigators and each laboratory at their institution. Complete Sections 5C through 5G as appropriate for the agents in use for each principal investigator.

(7) 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 for each principal investigator.

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.
- 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. 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 73.3(e)(1) and 42 CFR 73.4(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*.

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 and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

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 and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

HOW TO DESIGNATE A DIFFERENT OR ALTERNATE RO

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 HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part. 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, and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

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 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-24, Atlanta, Georgia 30333.

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FORM APPROVED
OMB NO. 0579-0213
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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 8½" 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 APHIS or CDC. 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*) APHIS# CDC#	Date

Legal name of entity

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

Type of entity: ☐ Academic (Private) ☐ Academic (State) ☐ Government ☐ Commercial (Profit) ☐ Private (Non-Profit)

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

(CDC Adobe Acrobat 5.0 Electronic Version, 4/2005)

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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 7 CFR 331, 9 CFR 121, and 42 CFR 73 is equipped and capable of safely and securely handling the agent(s) and will use or transfer these agents solely for purposes authorized by 7 CFR 331, 9 CFR 121, and 42 CFR 73.

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 7 CFR 331, 9 CFR 121, and 42 CFR 73 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)

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Date:_____

SECTION 3 – SELECT AGENTS USED, POSSESSED, 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). Items that are exempt from registration should not be listed on this form.

HHS SELECT AGENTS AND TOXINS

- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ *Coccidioides posadasii*
- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ Ebola viruses
- ☐ 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

OVERLAP SELECT AGENTS AND TOXINS

- ☐ *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
- ☐ *Francisella tularensis*
- ☐ Hendra virus
- ☐ Nipah Virus
- ☐ Rift Valley fever virus
- ☐ Venezuelan equine encephalitis virus
- ☐ Botulinum neurotoxin
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxin
- ☐ T-2 toxin

USDA SELECT AGENTS AND TOXINS

- ☐ African swine fever virus
- ☐ African horse sickness virus
- ☐ Akabane 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
- ☐ Japanese encephalitis virus
- ☐ Lumpy skin disease virus
- ☐ Malignant catarrhal fever (Alcelaphine herpesvirus type 1)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Newcastle disease virus (velogenic)
- ☐ Peste Des Petits Ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

USDA PLANT PATHOGENS

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

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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. For each Principal Investigator (or Chief Scientist) and laboratory or storage room list each select agent or toxin by type (viable, genomic material, small animal, etc.) on a separate line. Failure to complete this table in detail will delay processing of your application.

Agent/Toxin name	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												
	☐	☐	☐	☐	☐	☐	☐						
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*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

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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 and toxins at the entity. The information provided in this section must correspond to that presented in Section 3 and 4A or it will delay processing the application. The name (including the 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 Form FD-961 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). 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)	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 and toxins 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: _____

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