According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0920-0576. The time required to complete the information collection for CDC ranges from 4 to 31 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Table of Contents

Sample

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

FORM APPROVED
OMB NO. 0920-0576
EXP DATE 1/31/2024

Section 1A – Entity Information			
Type of Entity: ☐ Academic (Private) ☐ Academic (State) ☐ Commercial (Profit) ☐ Government (Federal) ☐ Government (State/Local) ☐ Private (Non-Profit)			
ENTITY INFORMATION			
Entity Name:			
Physical Address (NOT a post office box):	City:	State:	Zip Code:
Additional Physical Address(es):			
Type of Entity: ☐ Academic (Private) ☐ Academic (State) ☐ Commercial (Profit) ☐ Government (Federal) ☐ Government (State/Local) ☐ Private (Non-Profit)			
RESPONSIBLE OFFICIAL INFORMATION			
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Emergency Telephone #:		
Mailing Address (NOT a post office box):	City:	State:	Zip Code:
ALTERNATE RESPONSIBLE OFFICIAL INFORMATION			
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Emergency Telephone #:		
Mailing Address (NOT a post office box):	City:	State:	Zip Code:
2nd ALTERNATE RESPONSIBLE OFFICIAL INFORMATION			
Last Name:	First Name:	DOJ Number:	Date of Birth:
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access ☐
Business Telephone #:	Emergency Telephone #:		
Mailing Address (NOT a post office box):	City:	State:	Zip Code:
OWNER / CONTROLLER INFORMATION (If Applicable)			
Last Name:	First Name:		
DOJ Number:	Date of Birth:	Tier 1 Access ☐	
2nd OWNER / CONTROLLER INFORMATION (If Applicable)			
Last Name:	First Name:		
DOJ Number:	Date of Birth:	Tier 1 Access ☐	

Section 1B – Certification of Responsibility

Sample

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

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

Responsible Official Signature	Date	Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name
2nd Alternate Responsible Official Signature	Date	2nd Alternate Responsible Official Name
3rd Alternate Responsible Official Signature	Date	3rd Alternate Responsible Official Name
4th Alternate Responsible Official Signature	Date	4th Alternate Responsible Official Name
5th Alternate Responsible Official Signature	Date	5th Alternate Responsible Official Name

Sample

Section 1C – Entity Abstract

Provide a summary of the overall institution mission, functions, and size. This information can include a general estimated number of employees, square footage of entire campus or facility, number of laboratories, overall scope of research, and any international collaborations. Specialized areas of research, education, or expertise can be highlighted. Include a brief description of the management structure of the institution related to oversight of the select agent facility/facilities. Provide a brief summary of the select agent and toxin work at the entity including mission, function, and size. Note: information specific to select agents and toxins will be required in later sections of this application.

Sample

Section 2 – Responsible Official Certification of Personnel and Facility Activities

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7 CFR 331, 9 CFR 121, and 42 CFR 73]

Security, Biosafety and Incident Response

_____ There is a written, **site-specific** security plan designed according to a **site-specific risk assessment that provides graded protection** in accordance with the risk of the select agent and/or toxin.

_____ There is a written, **agent-specific, and site-specific** biosafety plan commensurate with the risk of the select agent and/or toxin that contains sufficient information and documentation to describe the biosafety and containment procedures.

_____ There is a written, **site-specific** incident response plan commensurate with the hazards of the select agent and/or toxin that fully describe the entity's response procedures to include the theft, loss or release of a select agent and/or toxin, inventory discrepancies, security breaches, natural disasters and emergencies.

_____ The security, biosafety and incident response plans are reviewed annually and revised as necessary, including after any drill or exercise and after any incident.

_____ Laboratory specific drills or exercises are conducted at least annually to validate or test the effectiveness of the security, biosafety and incident response plans.

Training

_____ Individuals with access approval, authorized visitors, and escorted personnel are provided training on safety, security, and incident response for select agents and/or toxins, as appropriate for their role, as defined in and 7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15.

Records

_____ Complete records are maintained for at least 3 years that include but are not limited to:
an accurate, current inventory for each select agent and/or toxin possessed,
information about all entries into areas containing select agent and/or toxin, and
a current list of all individuals that have been granted access approval.

Responsible Official Duties & APHIS/CDC Program Notification

The Responsible Official will:

_____ Ensure annual inspections are conducted for each laboratory and storage area where select agent and/or toxin are stored or used to assess compliance with the requirements of the select agent regulations.

_____ Submit an amendment for any change in circumstances to the certificate of registration, including but not limited to: adding or removing individuals, addition of a suite/room prior to use or storage of select agent and/or toxin and any changes to Responsible or Alternate Responsible Official contact information.

_____ Submit an amendment describing work prior to an individual or entity conducting a restricted experiment as defined in 7 CFR Part 331.13, 9 CFR Part 121.13 or 42 CFR Part 73.13.

_____ Ensure inventory audits are conducted as defined in 7 CFR Part 331.11, 9 CFR Part 121.11 or 42 CFR Part 73.11.

Sample

Section 2 – Responsible Official Certification of Personnel and Facility Activities (Continued)

I certify that the following requirements are in effect and contain all information required by the Select Agent regulations [7 CFR 331, 9 CFR 121, and 42 CFR 73] (**initial each line**):

Responsible Official Duties & APHIS/CDC Program Notification (Continued)

The Responsible Official will:

_____ Request authorization from the Federal Select Agent Program using APHIS/CDC Form 2 prior to inter-entity transfer of a select agent and/or toxin, as put forth within Section 16 of the Select Agent regulations.

_____ Upon discovery of a theft or loss, immediately notify the Federal Select Agent Program and appropriate Federal, State, or local law enforcement agencies. Immediate notification is also required upon discovery of a release of a select agent or toxin causing occupational exposure or a release of a select agent and/or toxin outside the primary barriers of the containment area. An APHIS/CDC Form 3 must be submitted to the Federal Select Agent Program within seven calendar days upon discovery of a theft, loss, or release.

_____ Immediately report the identification of any APHIS select agent as defined in 9 CFR 121.5, or the identification of any Tier 1 select agent and/or toxin, to the Federal Select Agent Program and other appropriate authorities when required by Federal, State, or local law. Submit APHIS/CDC Form 4 for the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification within seven calendar days of identification and/or in a specimen presented for proficiency testing within 90 calendar days of receipt of the sample.

Responsible Official Signature	Date	Responsible Official Name (Typed or Printed)

Sample

Section 3 – Select Agents and Toxins

HHS Agents and Toxins (Check if possessed)	Overlap Agents and Toxins (Check if possessed)	USDA Agents and Toxins (Check if possessed)
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐
☐	☐	☐

Sample

Section 4A – Laboratorians and Animal Care Staff						
Tier 1 Access	**Last Name**	**First Name**	**DOJ Unique Identifier Number**	**Date of Birth (mm/dd/yyyy)**	**Role**	**Supervising Principal Investigator**
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						
☐						

I certify that information and training on safety, security, and incident response for working with select agents and toxins has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work being performed, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years.

RO/ARO Signature:_____ Date:_____

Sample

Section 4B – Support Staff					
Tier 1 Access	**Last Name**	**First Name**	**DOJ Unique Identifier Number**	**Date of Birth (mm/dd/yyyy)**	**Role**
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					

I certify that information and training on safety, security, and incident response for select agents and toxins, as appropriate for their role, has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work they do, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years.

RO/ARO Signature:_____ Date: _____

Section 4C – Unescorted Visitors					
For guidance and instructions on Visitors, please see www.selectagents.gov					
Tier 1 Access	**Last Name**	**First Name**	**HOME ENTITY DOJ Unique**	**Date of Birth (mm/dd/yyyy)**	**Supervising Principal Investigator**

Sample

			Identifier Number		
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					
☐					

I certify that information and training on safety, security, and incident response for working with select agents and toxins has been or will be provided to the individuals listed above before they have access to select agents and toxins. Training will address the needs of the individual, the work being performed, and risks posed by the select agents and/or toxins. Annual refresher training will be provided for these individuals. Written records and the means used to verify that the individuals understood the training will be maintained for at least three years.

RO/ARO Signature: _____ Date: _____

Sample

Section 5A – Entity-Wide Security Assessment and Incident Response							
1.	The facility is: (check all that apply)						
		☐	Government owned	☐	Rented/leased		
		☐	Entity owned	☐	Shared with another entity or		
		☐	Other _____		program		

2.	Does the entity have a security officer or other individual(s) identified to assist the RO in security matters?					Yes☐	No☐
		If yes, does the security plan contain procedures for coordination between the RO and the entity's security professionals?				Yes☐	No☐
3.	A threat assessment has been conducted:					Yes☐	No☐
	a.	Were local law enforcement or federal agencies consulted in developing the threat assessment?				Yes☐	No☐
	b.	Has there been a break-in at the entity in the last three years?				Yes☐	No☐
	c.	Have there been any direct threats against the entity or its scientists in the last three years?				Yes☐	No☐
	d.	Have there been protests at the entity in the last three years?				Yes☐	No☐
		If yes to any of the above, describe below. Add additional sheets as needed.					
4.	Insider risk assessment						
	a.	As a condition of granting unescorted access, the entity, or another organization on behalf of the entity, verifies (check all that apply):					
		☐	Educational background				
		☐	Previous work references				
		☐	Criminal history (beyond the security risk assessment approved by the Federal Select Agent Program)				
		☐	Other _____				
		☐	None				
	b.	Does the entity have policies and procedures for self and peer reporting?				Yes☐	No☐
	c.	Does the entity have additional requirements for personnel suitability to retain access to select agents or toxins?				Yes☐	No☐
5.	Natural hazards						
	a.	Is the entity located in any of the following hazard zones?					
		☐	Flood/flood zone	☐	Earthquake (as defined by USGS)		
		☐	Hurricane	☐	Wildfire		
		☐	Tornado	☐	Tsunami		
		☐	Other_____				
	b.	In the event of a natural disaster with warning, the entity will (check all that apply):					
		☐	Secure the select agent and/or toxin in place.				
		☐	Transfer the select agent and/or toxin to an alternate registered location or entity.				
		☐	Destroy the select agent and/or toxin.				
		☐	Other _____				

Sample

Section 5A – Entity-Wide Security Assessment and Incident Response (Continued)					
6.	Are there electronic records and databases that would allow access to select agent and/or toxin?			Yes ☐	No ☐
		If yes, indicate the means to control access by completing a-f below:			
	a.	Is a stand-alone (non-networked) computer employed?		Yes ☐	No ☐
	b.	Are there area external connections to systems that control security of the facility (remote log in, work from home)?		Yes ☐	No ☐
	c.	Is access to files or equipment containing select agent and/or toxin related information granted to users only when necessary to fulfill their roles and responsibilities?		Yes ☐	No ☐
	d.	Is user access modified when roles and responsibilities change or when their access to select agent and/or toxin is suspended or revoked?		Yes ☐	No ☐
	e.	Are user-based passwords employed?		Yes ☐	No ☐
	f.	Are anti-virus and anti-malware programs employed?		Yes ☐	No ☐
7.	Shipping/Receiving				
	a.	Does the entity have a centralized receiving area?		Yes ☐	No ☐
	b.	Are all personnel who ship or receive select agent and/or toxin shipments Security Risk Assessment (SRA) approved?		Yes ☐	No ☐
	c.	Are select agent and/or toxin shipments stored in a registered and secured area prior to distribution to the Principal Investigators (PIs)?		Yes ☐	No ☐
8.	Does the entity transport select agent and/or toxin outside of registered area(s)?			Yes ☐	No ☐
		If yes, does the security plan address transport of select agent and/or toxin material			
		a.	through non-registered areas?	Yes ☐	No ☐
		b.	during intra-entity transfers using chain of custody documentation?	Yes ☐	No ☐
9.	Has a response time for local law, guard force or other designated responders been determined?			Yes ☐	No ☐
10.	Is permission required to conduct select agent and/or toxin work after established work hours?			Yes ☐	No ☐
		If yes, who grants permission?			
		☐	RO/ARO		
		☐	PI		
		☐	Other _____		

Draft

Section 5B – Entity-Wide Biosafety/Biocontainment			
1.	Describe the program or expertise used to develop and implement the biosafety and biocontainment procedures described in the site-specific biosafety or biocontainment plan. Add additional sheets as needed.		
2.	Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins.	Yes☐	No☐
3.	Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required.	Yes☐	No☐
4.	Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program.	Yes☐	No☐
5.	Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate.	Yes☐	No☐
6.	There are policies for the safe handling of sharps.	Yes☐	No☐
7.	There is a spill protocol in place appropriate to the select agent and/or toxin risk.	Yes☐	No☐
8.	There is an effective, integrated pest management program in place.	Yes☐	No☐

Sample

Section 5C – Entry Requirements for Federal Select Agent Program Inspectors

1. Describe procedures for entry to the facility, such as gate location, visitor reception area, and parking for inspectors performing a site visit. Add additional sheets as needed.

2. Identification requirements:
   - ☐ Government ID
   - ☐ Other ID (describe) _____

3. Are there security clearance requirements? Yes☐ No☐
   If yes, check all that apply.
   - ☐ Exchange of security clearance documentation
     Describe _____
   - ☐ Completion of entity specific security documentation
     Describe _____

4. Is respiratory protection required? Yes☐ No☐
   a. Documentation of medical clearance for respirator use required. Yes☐ No☐
   b. List required respirators (check all that apply):
      - ☐ N95
      - ☐ N100
      - ☐ PAPR: If required, will the entity provide PAPRs? Yes☐ No☐
      - ☐ Other _____

5. List other PPE required (indicate what will be provided by the entity). Add additional sheets as needed.

6. Medical documentation required: Yes☐ No☐
   a. Immunizations Yes☐ No☐
      - ☐ Required (specify) _____
      - ☐ Recommended (specify) _____
   b. PPD skin test (e.g. for animal clearance) Yes☐ No☐
      - ☐ In past 6 months?
      - ☐ In the past 12 months?

7. Is entity specific training required? Yes☐ No☐
   If yes, provide a description (including the estimated time to complete all entry training for inspectors). Add additional sheets as needed.

8. Describe any additional entry requirements for inspectors. Add additional sheets as needed.

sample

Section 6A – Building and Suite/Room Specific Security

1.	Will this suite/room be used for Tier 1 select agent and/or toxin?					Yes ☐	No ☐
2.	Perimeter security measures outside the building (check all that apply):						
	☐	Security lighting					
	☐	Bars/security film on windows					
	☐	Exterior intrusion detection system					
	☐	Perimeter fence					
	☐	Roving guards					
	☐	Video surveillance of all access points					
	☐	Vehicle screening					
	☐	Other _____					
	☐	None					
3.	Access to building(s) or other area(s) housing the suite/room is controlled by (check all that apply):						
	☐	Lock and key	☐	Card access system			
	☐	Biometric system	☐	Card access system w/ PIN			
	☐	Other _____	☐	Guards			
	☐	None					
4.	Additional security measures present in the interior of the building where select agent and/or toxin is stored or used (check all that apply):						
	☐	Additional locked doors	☐	Biometric System			
	☐	Card access system	☐	Intrusion detection system			
	☐	Card access system with PIN					
5.	Access to suite/room where select agent and/or toxin is stored or used is controlled by (check all that apply):						
	☐	Lock and key	☐	Card access system with PIN			
	☐	Card access system	☐	Biometric System			
	☐	Other _____					
6.	Access to the storage unit(s) where select agent and/or toxin are housed is controlled by (check all that apply):						
	☐	No access control on the storage unit(s)					
	☐	Lock and key					
	☐	Card access system					
	☐	Card access system with PIN					
	☐	Biometric System					
	☐	Other _____					
7.	Is there a pass through autoclave in the suite/room?					Yes ☐	No ☐
		If yes, are the doors interlocked?				Yes ☐	No ☐
8.	Is an autoclave outside of the suite/room used for decontamination of select agent and/or toxin waste?					Yes ☐	No ☐
		If yes, distance from suite/room to autoclave _____					

Sample

9.	Is there a pass through window or box at the perimeter of the suite/room?		Yes☐	No☐
		If yes, is it secured?	Yes☐	No☐
10.	Is there a dunk tank at the perimeter of the suite/room?		Yes☐	No☐
		If yes, is it secured?	Yes☐	No☐

Sample

Section 6B – Room/Suite Physical Information

For each registered storage area, laboratory suite or room:
Include a floor plan for the suite or room where select agent and/or toxin is to be used or stored. Floor plan for each suite or room should include as applicable: points of entry and/or egress for personnel, locations of equipment [including but not limited to]: sink, eyewash, fume hood, freezer, refrigerator, floor drains, showers, incubator, centrifuge, animal caging, autoclave, Biological Safety Cabinet (BSC) including type (e.g., Class II, Type A2; Class III)], Heating Ventilation and Air Conditioning (HVAC) supply and exhaust vents, and cage washing area. A separate floor plan specifying airflow may also be requested.

For storage only area(s), proceed to Section 7.

Answer the following questions for each laboratory suite or room:

The following questions may not apply to all biosafety levels. The accompanying instructions detail which questions apply to each biosafety level according to the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL), the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules, and the American Society of Tropical Medicine and Hygiene Arthropod Containment Guidelines. If the question does not apply to the laboratory suite or room, check "No".

1. This laboratory is operated at (check all that apply):

☐ BSL2	☐ NIHBL2	☐ NIHBL2-LS	☐ ACL3
☐ BSL3	☐ NIHBL3	☐ NIHBL3-LS	☐ ACL4
☐ BSL4	☐ NIHBL4	☐ NIHBL4-LS	
☐ ABSL2	☐ NIHBL2N		
☐ ABSL3	☐ NIHBL3N		
☐ ABSL3Ag	☐ NIHBL4N		
☐ ABSL4			

List the resources/references used _____

2. BSCs and fume hoods are certified at least annually and records kept for at least three years. Yes☐ No☐

3. A sink is present in the laboratory for hand washing. Yes☐ No☐
   If yes, the hand washing sink is hands-free or automatically operated. Yes☐ No☐

4. An eyewash station is readily available. Yes☐ No☐

5. Liquid effluents originating from the laboratory are collected and heat or chemically treated for sterility prior to exiting the facility or entering a public sewage system. Yes☐ No☐
   If yes,
   a. Are the liquid effluents from the containment shower areas similarly treated for sterility? Yes☐ No☐
   b. Is the effluent decontamination system validated monthly with a bio-indicator? Yes☐ No☐

If ABSL3Ag, BSL4 or ABSL4 is selected, proceed to Section 7.

6. Access to the laboratory is through two consecutive, self-closing doors. Yes☐ No☐
   If yes, door(s) from the anteroom open inward to the laboratory? Yes☐ No☐

Sample

Section 6B – Room/Suite Physical Information (Continued)

7. The ventilation system provides sustained directional airflow by drawing air into the laboratory from "clean" areas toward "potentially contaminated" areas. Yes☐ No☐

8. The laboratory is designed such that under failure conditions the airflow will not be reversed. Yes☐ No☐

9. Laboratory design and operational parameters are re-verified at least annually. Yes☐ No☐

10. A visual monitoring device, which confirms directional airflow, is provided at the laboratory entry. Yes☐ No☐

11. Laboratory exhaust is not re-circulated to other areas of the building. Yes☐ No☐

12. Exhaust air is HEPA filtered. Yes☐ No☐
    a. If yes, the HEPA filter housing has decontamination and test ports. Yes☐ No☐
        i. If this laboratory is a suite, please list rooms with HEPA filtered exhaust : _____
        ii. HEPA filters and housings are certified at least annually. Yes☐ No☐
    b. If no, exhaust air is dispersed away from occupied areas and building air intake locations. Yes☐ No☐

13. Emergency shower is readily available. Yes☐ No☐

14. Floor drains are present. Yes☐ No☐

15. Sink traps and any floor drains are filled with water and/or appropriate liquid to prevent the migration of vermin and gases. Yes☐ No☐

16. Mechanical cage washer is present. Yes☐ No☐
    If yes, cage washer has a final rinse temperature of at least 180°F. Yes☐ No☐

17. The laboratory has a shower-out capability with a change room. Yes☐ No☐

Sample

Section 7A – Principal Investigator (PI) Information and Select Agent and Toxin Locations

A complete Section 7 must be submitted for each PI. If separate PI's would result in an identical Section 7 being completed, multiple PI's can be listed in the header.

PI	**Last Name:**	**First Name:**	**DOJ Number:**
			Date of Birth:
			Tier 1 Access ☐

Select Agent/Toxin/Regulated Nucleic Acid	**Location**		**Laboratory or Storage (Select one or both)**		**Laboratory Safety Level (Leave blank if storage only)**
	Bldg	**Suite/Room**	**Lab**	**Storage**	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

Suite Legend: (If Applicable)	Suite A = Rooms 1, 2, 3, 4

Are any of the rooms grouped as a suite? ..... Yes ☐ No ☐

If yes, list suite name and rooms in suite. _____

Section 7B – Strain or Serotype Designation Information

Sample

Select Agent/Toxin/ Regulated Nucleic Acid	Strain or Serotype Designations

Sample

Agent		
Toxin		
Regulated Nucleic Acid		

Sample

Section 7C – Description of Work

1. Provide the objectives of work for each select agent and/or toxin listed in Section 7A by agent/toxin and containment level(s), including a description of the methodologies or laboratory procedures that will be used. Include any work involving animals, arthropods or plants. Attachments A-G must be completed if

appropriate for the work described. If no work is being performed with select agent and/or toxin, indicate "storage only".

Agent/Toxin	BSL	Objective of Work

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

Agent	Maximum Quantity/Concentration

3. Provide an estimate of the maximum quantity of functional toxin held by the PI at any one time (e.g., 500 mg, 100 ml x 100 ug/ul).

Toxin	Maximum Quantity

4. Equipment that may produce infectious agent or toxin aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. Yes☐ No☐

5. Name(s) of Individual(s) responsible for inventory of select agent(s) and/or toxin(s):

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

6. Regulated nucleic acids as defined in 7 CFR 331.3, 9 CFR 121.3, 42 CFR 73.3 or 42 CFR 73.4 are held in long-term storage. Yes☐ No☐

7. All cultures, stocks and other regulated wastes are decontaminated prior to disposal. Yes☐ No☐

If yes, describe method:
- ☐ Autoclaved
- ☐ Chemical (disinfectant, concentration, and time) _____
- ☐ Incineration
- ☐ Irradiation
- ☐ Other _____

8. Written records that would allow someone the ability to gain access to select agent and/or toxin are controlled by:

Sample

☐ Lock and key
☐ Locked filing cabinet, drawer, cabinet, etc.
☐ Card access system
☐ Other _____

9. Will work be performed with:

a. agents that will be propagated and produce regulated amounts of toxins or with registered toxins at or below the regulated amount? Yes☐ No☐
If yes, complete Attachment A – Work With Toxins

b. regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms? Yes☐ No☐
If yes, complete Attachment 2 – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms

c. animals? Yes☐ No☐
If yes, complete Attachment C – Work with Animals

d. plants? Yes☐ No☐
If yes, complete Attachment D – Work with Plants

e. arthropods? Yes☐ No☐
If yes, complete Attachment E – Work with Arthropods

10. Will work be performed in:

a. ABSL3Ag laboratory? Yes☐ No☐
If yes, complete Attachment F – ABSL3Ag Laboratories

b. BSL4/ABSL4 laboratory? Yes☐ No☐
If yes, complete Attachment G – BSL4/ABSL4 Laboratories

Sample

Attachment A –Work with Toxins					
1.	A toxin-specific Chemical Hygiene Plan is available for the laboratory using select toxins.			Yes☐	No☐
2.	Select toxin manipulation or production in the laboratory includes (check all that apply):				
	☐	Dry forms			
	☐	Liquid forms			
	☐	Centrifugation			
	☐	Pressure filtration systems (e.g., chromatography)			
3.	Animals are exposed to select toxins.			Yes☐	No☐
	a.	If yes, toxin exposure procedure(s) is performed in registered laboratories.		Yes☐	No☐
	b.	If yes, complete relevant questions in **Attachment C - Work with Animals**.			
4.	Select toxin is produced by PI(s).			Yes☐	No☐
		If yes, provide a brief description of the method and an estimate of the maximum quantities during production, purification, and concentration.			
5.	A hazard sign is posted when select toxins are in use.			Yes☐	No☐
6.	All select toxins, cultures, stock, materials coming into contact with toxins, and other regulated wastes are appropriately inactivated prior to disposal. If yes, describe method:			Yes☐	No☐
		☐	Autoclaved		
		☐	Chemical (disinfectant, concentration, and time) _____		
		☐	Incineration		
		☐	Other _____		
7.	Dilution procedures and other manipulations of concentrated select toxins are performed. If yes, conducted in:			Yes☐	No☐
		☐	Fume hood		
		☐	Biological Safety Cabinet (BSC)		
		☐	Outside of a BSC or fume hood		
		☐	Work is conducted with two knowledgeable people present.		
8.	Select toxins are transferred (intra-entity transfer) to other individuals at the entity outside of the laboratory producing or receiving the toxin (check all that apply):			Yes☐	No☐
	If yes, indicate below:				
	☐	Above the aggregate amount			
	☐	Below the aggregate amount			
9.	Select toxins are transferred to other entities in quantities below the aggregate amount (inter-entity transfer).			Yes☐	No☐
10.	Select toxins are commercially distributed/shipped outside of the laboratory producing the toxin.			Yes☐	No☐
		If yes, is there a hazard communication plan?		Yes☐	No☐

SAMPLE

11.	Will work involve possession, use or transfer of recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins as defined in 42 CFR 73.3 or 42 CFR 73.13?		Yes☐	No☐
		If yes, complete **Attachment 2 – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents and Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms.**		

Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids, or Recombinant Synthetic Organisms

1.	Will work involve possession, use, or transfer of the following?			
	a.	Nucleic acids that can produce infectious forms of select agent viruses.	Yes☐	No☐
	b.	Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro.	Yes☐	No☐
	c.	Select agent viruses, bacteria, fungi or toxins that have been genetically modified.	Yes☐	No☐
2.	Will work involve the following with select agents and/or toxins:			
	a.	Introduction and/or modification of genetic elements.	Yes☐	No☐
	b.	Recombinant or synthetic nucleic acids.	Yes☐	No☐
	c.	Recombinant or synthetic organisms.	Yes☐	No☐
	d.	Reverse genetics system to produce infectious forms of select agent viruses, or any complete set of reagents that would allow rescue of infectious virus available for use by a PI at the entity.	Yes☐	No☐
3.	Will a restricted experiment be performed as defined in 42 CFR 73.13, 7 CFR 331.13 or 9 CFR 121.13?		Yes☐	No☐
	a.	If yes, please indicate the type of restricted experiment:		
		☐ The introduction of, or selection for, drug resistance trait(s) into select agent organisms.		
		List the agent(s) and the drug resistance trait(s):		
		Select Agent _____ Drug Resistance Trait _____		
		Select Agent _____ Drug Resistance Trait _____		
		Select Agent _____ Drug Resistance Trait _____		
		☐ The deliberate formation of DNA containing genes for the biosynthesis of toxin lethal for vertebrates at an LD_{50} < 100 ng/kg body weight. List toxins _____		
	b.	Has this PI received approval from the APHIS Administrator or HHS Secretary for this restricted experiment?	Yes☐	No☐
4.	Will work involve possession, use or transfer of **a product of** a restricted experiment?		Yes☐	No☐
	a.	If yes, please indicate the type of restricted experiment product:		
		☐ Drug resistance trait(s) in select agent organisms.		
		List the select agent(s) and the drug resistance trait(s) _____		
		☐ DNA containing genes for the biosynthesis of toxin lethal for vertebrates at an LD_{50} < 100 ng/kg body weight.		
		List toxin(s) _____		
	b.	Has this PI received approval from the APHIS Administrator or HHS Secretary for this product of a restricted experiment?	Yes☐	No☐
5.	Will experiments involve the acquisition of increased/restored virulence (e.g., drug		Yes☐	No☐

DRAFT

	resistance, increased host range, enhanced transmissibility, infectivity, environmental stability) in select agents or toxins?		

6. For any question 1-5 above answered "yes", provide a brief description of the work. Add additional sheets as needed.

7. An Institutional Biosafety Committee (IBC) reviews and approves protocols to perform recombinant work with select agents and toxins at this facility. Yes☐ No☐
   If yes, has the IBC approved the work described above? Yes☐ No☐
   If no, please provide an explanation. Add additional sheets as needed.

Attachment C – Work with Animals

1.	Provide the select agent/toxin and species of animal to be used:			
	Select Agent / Toxin	**Species of Animal**	**Route(s) of Administration**	
2.	Are animals exposed to select agents or toxins by the aerosol route?		Yes☐	No☐
	If yes, is the aerosol exposure equipment used within a primary containment device?		Yes☐	No☐
3.	Is the entity waste stream treated prior to disposal?			
a.	What is the method of treating carcasses? If yes, answer(check all that apply):		Yes☐	No☐
	☐ Autoclaved. Describe validation procedures that account for variables such as time and temperature of autoclave run cycles, as well as temperature and weight of carcass at initiation of autoclave cycle. Add additional sheets as needed. _____			
	☐ Chemical (disinfectant, concentration, and time) _____			
	☐ Incineration			
	☐ Tissue Digester			
	☐ Other _____			
b.	What is the method of treating infectious waste (e.g., cell cultures, infected arthropods, other biohazardous waste)?			
	☐ Incineration			
	☐ Autoclaved: Describe validation procedures that account for variables such as time and temperature of autoclave run cycles. _____			
4.	Are samples (tissue, blood, nucleic acids, etc.) from exposed or infected animals manipulated at a lower biosafety level? If yes, describe the inactivation process (e.g. formalin fixation, lysis of cells for nucleic acid extraction, irradiation) for the samples. Include concentration or dosage and contact/exposure time, as applicable.		Yes☐	No☐
5.	The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity.		Yes☐	No☐
	If yes, the proposed work with select agents and toxins in animals has been approved by the IACUC. If no, explain. Add additional sheets as needed. _____		Yes☐	No☐

6. The laboratory is accredited by the Association for Assessment and Accreditation of Yes☐ No☐

Sample

Laboratory Animal Care (AAALAC).
If yes, give most recent (re)accreditation date _____

7. There is a system in place for recording the number of animals infected, the number of animals disposed of, and the records are reviewed frequently. Yes☐ No☐

If yes, describe. _____

8. Are animals restrained for experimental manipulation? Yes ☐ No ☐
If no, explain. _____

9. Are animals intentionally or accidently infected with select agents monitored (e.g., daily checks)? Yes ☐ No ☐
If no, explain. _____

10. Describe animal housing for each species, including whether cages provide primary containment and a brief description (e.g. cage or cage rack is HEPA filtered, active or passive ventilation of the cages, non-containment caging housed within inward flow ventilated enclosure). For active ventilation caging, indicate whether or not the system is equipped to indicate operational malfunctions.

Species	Animal Housing

11. Are animals euthanized? Yes☐ No☐
If no, explain. _____

12. Will animals be necropsied? Yes☐ No☐
If yes, describe necropsy procedures. _____

13. Describe how animal carcasses are secured prior to decontamination.
☐ Locked freezers, coolers
☐ Not secured, immediately decontaminated (e.g., autoclave, tissue digester, incinerator)
☐ Other _____

Attachment D – Work with Plants

1. Provide the select agent and species of plant to be used:

Select Agent	Species of Plant	Route(s) of Inoculation

2. Plant waste is treated prior to disposal (e.g., soil, plant material, materials accompanying plants or samples) by an approved method (check all that apply): Yes☐ No☐
☐ Autoclaved
☐ Chemical (disinfectant, concentration, and time) _____
☐ Irradiation
☐ Incineration

Sample

☐ Other _____

3. Are vectors present? Yes☐ No☐
   a. Vectors are restricted to cages? Yes☐ No☐
   b. Are adjacent areas monitored to observe potential escapes? Yes☐ No☐
   c. Please describe vector species and cage mesh size _____
   d. Are vectors exposed to select agents or plants infected with select agents? Yes☐ No☐
      If yes, complete **Attachment E - Work with Arthropods**.

4. Will plants exposed to select agents be housed or manipulated in a **glass house**? Yes☐ No☐
   a. Is the glass house attached to the laboratory? Yes☐ No☐
   b. Is the glass house separated from the laboratory? Yes☐ No☐
   c. Is pest monitoring conducted within the glass house? Yes☐ No☐
   d. Are inoculated plants moved between areas such as glass house to laboratory? Yes☐ No☐
   e. Structure is reinforced. Yes☐ No☐
   f. Floor is constructed of:
      ☐ Concrete
      ☐ Tile or other floor covering
      ☐ Dirt or gravel

5. Will plants exposed to select agents be housed or manipulated in a **greenhouse**? Yes☐ No☐
   a. Is the greenhouse attached to the laboratory? Yes☐ No☐
   b. Is the greenhouse separated from the laboratory? Yes☐ No☐
   c. Is pest monitoring conducted within the greenhouse? Yes☐ No☐
   d. Are inoculated plants moved between areas such as greenhouse to laboratory? Yes☐ No☐
   e. Structure is reinforced. Yes☐ No☐
   f. Floor is constructed of:
      ☐ Concrete
      ☐ Tile or other floor covering
      ☐ Dirt or gravel

6. Will plants exposed to select agents be housed or manipulated in a **screenhouse**? Yes☐ No☐
   a. Is the screenhouse attached to the laboratory? Yes☐ No☐
   b. Is the screenhouse separated from the laboratory? Yes☐ No☐
   c. Is pest monitoring conducted within the screenhouse? Yes☐ No☐
   d. Are inoculated plants moved between areas such as screenhouse to laboratory? Yes☐ No☐
   e. If yes, provide a description of the screenhouse materials (including screen mesh size) _____
   f. Structure is reinforced. Yes☐ No☐
   g. Floor is constructed of:
      ☐ Concrete
      ☐ Tile or other floor covering
      ☐ Dirt or gravel

7. Will plants exposed to select agents be housed or manipulated in a **growth chamber**? Yes☐ No☐
   a. Is the growth chamber located in or attached to the laboratory? Yes☐ No☐
   b. Is the growth chamber separated from the laboratory? Yes☐ No☐
   c. Is pest monitoring conducted within the growth chamber? Yes☐ No☐
   d. Are inoculated plants moved between areas such as growth chamber to laboratory? Yes☐ No☐
   e. Structure is reinforced. Yes☐ No☐
   f. Floor is constructed of:
      ☐ Concrete
      ☐ Tile or other floor covering
      ☐ Dirt or gravel
   g. Manufacturer name _____
      Model number _____

Sample

h. Access to growth chamber is controlled (e.g., lock and key, card access system, biometrics). Yes☐ No☐

i. Is the growth chamber located at a reasonable distance from other growth chambers with healthy plants, insectaries and outside doors? Yes☐ No☐

8. Will work be performed with regulated nucleic acids, genetic modification of select agents or toxins, recombinant/synthetic nucleic acids or recombinant/synthetic organisms? Yes☐ No☐

If yes, complete **Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms.**

Sample

Attachment E – Work with Arthropods				
1.	Work is performed with **field-collected** arthropods in a **diagnostic capacity only** for identification of select agents.		Yes☐	No☐
2.	Work is performed to experimentally inoculate or infect arthropods (any stages) with select agents. If yes, complete questions 3-16.		Yes☐	No☐
3.	Provide the select agent and species of arthropod used:			
	Select Agent	**Species of Arthropod**		
4.	Arthropod experimental exposure route(s).			
	a.	Injected with select agent.	Yes☐	No☐
	b.	Infected with select agent via blood meal.	Yes☐	No☐
		If yes, indicate the blood meal source.		
		☐ Animal species _____		
		If vertebrate hosts are used, has the IACUC approved the work proposed in this objective of work?	Yes☐	No☐
		If yes, complete **Attachment C - Work with Animals**.		
		If no, explain. Add additional sheets as needed. _____		
		☐ Collected blood (describe type/method) _____		
	c.	Infected with select agent via insect feeding on select agent infected plants.	Yes☐	No☐
		If yes, complete **Attachment D - Work with Plants**.		
	d.	Other (Describe)_____		
5.	Provide a description of the procedures used for primary containment and any transfer(s) of infected arthropods. _____			
6.	There is a system in place for recording the number of arthropods infected and the number of arthropods disposed of, and the records are reviewed frequently.		Yes☐	No☐
	If yes, describe. _____			
7.	Arthropod containment laboratory design and operational procedures are developed and implemented in accordance with guidance found in the current edition of the Arthropod Containment Guidelines, a project of the American Committee of Medical Entomology of the American Society of Tropical Medicine and Hygiene.		Yes☐	No☐
8.	An Institutional Biosafety Committee (IBC) reviews and approves arthropod work with select agents at this facility.		Yes☐	No☐
	If yes,			
	a.	has the IBC approved the arthropod containment laboratory design and operational procedures?	Yes☐	No☐
	b.	has the IBC approved the work described in this objective of work?	Yes☐	No☐
	If no, explain. _____			
9.	Are arthropods, including those experimentally infected, housed and manipulated in a suite/room such that accidental contact and release is prevented?		Yes☐	No☐

Sample

10.	Do protocols account for accidental escape?			Yes☐	No☐
11.	Ventilation filters/barriers are installed to prevent arthropod escape.			Yes☐	No☐
12.	Floor drains are present in the laboratory.			Yes☐	No☐
		If yes, floor drains are modified to prevent accidental release of arthropods and agents.		Yes☐	No☐
13.	Suite/room plumbing is suitable to prevent arthropod escape.			Yes☐	No☐
14.	All stages of arthropods are killed before disposal.			Yes☐	No☐
15.	All wastes from the arthropod containment laboratory are treated for disposal using an approved method.			Yes☐	No☐
		If yes, describe method:			
		☐	Autoclaved		
		☐	Chemical (disinfectant, concentration, and time)_____		
		☐	Incineration		
		☐	Other _____		
16.	Animals or plants are permitted in the arthropod containment laboratory.			Yes☐	No☐
	If yes,				
	a.	are animals or plants associated with the work being performed?		Yes☐	No☐
	b.	are animals or plants accessible to escaped arthropods?		Yes☐	No☐

Sample

Attachment F – ABSL3Ag Laboratories

1. Supplies, material and equipment enter and exit ABSL3Ag areas only through an airlock, fumigation chamber, an interlocked and double-door autoclave, or shower. Yes☐ No☐

   For materials and equipment that cannot be decontaminated in the autoclave, a pass-through dunk tank, fumigation chamber, or equivalent decontamination method is available. Yes☐ No☐

2. Is a shower required when leaving the containment boundary Yes☐ No☐

3. Disposable materials are decontaminated by a verified method (check all that apply): Yes☐ No☐
   - ☐ Autoclaved
   - ☐ Chemical (disinfectant, concentration, and time) _____
   - ☐ Incineration _____
   - ☐ Other _____

4. All containment areas are designed, constructed and verified to function as a primary containment barrier. All walls are constructed slab-to-slab and walls, floors, and ceilings are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of agents and to allow fumigation for biological decontamination. Yes☐ No☐

5. Differential pressures/directional airflow are monitored and alarmed to indicate system failure. Yes☐ No☐

6. There are two HEPA filters installed in series prior to air being exhausted from the containment space. Supply air passes through ductwork with a HEPA filter and/or fast acting bioseal (i.e., bubble tight) damper that fails in the closed position. Yes☐ No☐

   If yes, all HEPA filters are certified annually. Yes☐ No☐

7. Laboratory procedure and design features include:
   a. Entrance into the facility is through an interlocking double door vestibule that separates containment areas from non-containment areas. Yes☐ No☐
   b. A clean change room outside of containment. Yes☐ No☐
   c. Doors that define a containment boundary are sealed and verified airtight through pressure decay testing. Yes☐ No☐
   d. A shower room at the non-containment/containment boundary. Yes☐ No☐
   e. A dirty change room within containment. Yes☐ No☐

8. A second shower is required at the facility access control point before donning street clothing. Yes☐ No☐

   If no, describe the alternate strategies used to satisfy the BMBL 6th edition.

9. Necropsy rooms are sized and equipped to accommodate large animals. Yes☐ No☐

   If yes, describe. Add additional sheets as needed. _____

Sample

Sample

Attachment G – BSL4/ABSL4 Laboratories

BSL4 LABORATORY

1. Will work be performed in a BSL4/ABSL4 Cabinet Laboratory? Yes☐ No☐
   If yes, complete questions 2 - 8

2. Describe the type of personal protective equipment that will be used. Add additional sheets as needed.

3. Describe the decontamination methods for materials/equipment in the Class III cabinet. Add additional sheets as needed.

4. Describe what liquid effluents are decontaminated and how they are decontaminated. Add additional sheets as needed.

5. Describe the supply and exhaust components of the ventilation system, including how the ventilation system of the Class III cabinet is manifolded to the room ventilation. Add additional sheets as needed.

6. In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow. Add additional sheets as needed.

7. Describe how differential pressures and directional airflow are monitored and analyzed. Add additional sheets as needed.

8. Describe how containment parameters are monitored daily. Add additional sheets as needed.

9. Will work be performed in a BSL4/ABSL4 Suit Laboratory? Yes☐ No☐
   If yes, complete questions 10 - 16

10. Describe the type of personal protective equipment that will be used. Add additional sheets as needed.

11. Describe what liquid effluents are decontaminated and what measures are used to do so. Add additional sheets as needed.

12. Describe the supply and exhaust components of the ventilation system, including how negative pressure is maintained and HEPA filtration of supply and exhaust air. Add additional sheets as needed.

13. In the event of a ventilation failure, describe what measures are used to prevent reversal of airflow. Add additional sheets as needed.

14. Describe how differential pressures and directional airflow are monitored and analyzed. Add additional sheets as needed.

15. In the event of a breathing air failure, describe what facility redundancies are in place. Add additional sheets as needed.

16. Describe how containment parameters are monitored daily. Add additional sheets as needed.

Sample