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

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE XX/XX/XXXX

Section 1A – Entity Information				
This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal			Date:	
ENTITY INFORMATION				
Entity Application Number (e.g., CDC030001):				
Current Registration Number (e.g., A00000000-0000):				
Entity Name:				
Physical Address (NOT a post office box):		City:	State:	Zip Code:
Additional Physical Address(es):				
Type of Entity: <input type="checkbox"/> Academic (Private) <input type="checkbox"/> Academic (State) <input type="checkbox"/> Commercial (Profit)				
<input type="checkbox"/> Government (Federal) <input type="checkbox"/> Government (State/Local) <input type="checkbox"/> 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 <input type="checkbox"/>	
Business Telephone #:	Business Fax #:	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 <input type="checkbox"/>	
Business Telephone #:	Business Fax #:	Emergency Telephone #:		
Mailing Address (NOT a post office box):		City:	State:	Zip Code:
Last Name:	First Name:	DOJ Number:	Date of Birth:	
Business E-mail Address:	Title (e.g., Biosafety Officer):		Tier 1 Access <input type="checkbox"/>	
Business Telephone #:	Business Fax #:	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 <input type="checkbox"/>		
Last Name:	First Name:			
DOJ Number:	Date of Birth:	Tier 1 Access <input type="checkbox"/>		
This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal			Date:	
Entity Name:				Date:

Section 1B – Certification of Responsibility

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
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal		
Entity Name:		Date:

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.

This submission is: <input type="checkbox"/> A new registration			<input type="checkbox"/> An update to an existing registration			<input type="checkbox"/> A renewal		
Entity Name:						Date:		

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] (**initial each line**):

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.

This submission is: <input type="checkbox"/> A new registration			<input type="checkbox"/> An update to an existing registration			<input type="checkbox"/> A renewal		
Entity Name:						Date:		

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)

- Government owned
- Entity owned
- Other _____
- Rented/leased
- Shared with another entity or 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
 - Hurricane
 - Tornado
 - Other _____
 - Earthquake (as defined by USGS)
 - Wildfire
 - Tsunami
- 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 _____

This submission is: <input type="checkbox"/> A new registration	<input type="checkbox"/> An update to an existing registration	<input type="checkbox"/> A renewal
Entity Name:		Date:

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 Yes No

- facility (remote log in, work from home)?
- 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)? 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 _____

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Entity Name:		Date:

Section 5B – Entity-Wide Biosafety/Biocontainment

- 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.

- Laboratory personnel must demonstrate proficiency in laboratory procedures prior to working with select agents and/or toxins. Yes No
- Appropriate Personal Protective Equipment (PPE) for the select agent and/or toxin and the work performed is required. Yes No
- Individuals with access to Tier 1 select agent and/or toxin are enrolled in an occupational health program. Yes No
- Laboratory personnel with access to non Tier 1 select agent and/or toxin are enrolled in an occupational health program as appropriate. Yes No
- There are policies for the safe handling of sharps. Yes No
- There is a spill protocol in place appropriate to the select agent and/or toxin risk. Yes No
- There is an effective, integrated pest management program in place. Yes No

This submission is: <input type="checkbox"/> A new registration	An update to an existing registration	A renewal
Entity Name:	Date:	

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.

This submission is: A new registration An update to an existing registration A renewal

Entity Name:

Date:

Building/Suite or Room:

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
 - Biometric system
 - Other _____
 - None
 - Card access system
 - Card access system w/ PIN
 - Guards

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
 - Card access system
 - Card access system with PIN
 - Biometric System
 - Intrusion detection system
 - a. What triggers the alarm? _____
 - b. Is the alarm contracted to an outside company? Yes No
 - c. Who does the alarm notify? _____
 - d. Are any emergency exits equipped with the same kind of intrusion detection system as the customary entrances? Yes No
 - Video surveillance
 - a. Does the video surveillance observe select agent and/or toxin work? Yes No
 - b. Does the video surveillance observe select agent and/or toxin storage? Yes No
 - c. Does the video surveillance observe access to the registered room? Yes No
 - d. Is the video monitored by security personnel? Yes No
 - e. Is the video reviewed by laboratory personnel? Yes No
 - Other _____
 - None

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal		
Entity Name:	Date:	
Building/Suite or Room:		

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):
- | | | | |
|---------------------------------|----------------------------------|------------------------------------|-------------------------------|
| <input type="checkbox"/> BSL2 | <input type="checkbox"/> NIHBL2 | <input type="checkbox"/> NIHBL2-LS | <input type="checkbox"/> ACL3 |
| <input type="checkbox"/> BSL3 | <input type="checkbox"/> NIHBL3 | <input type="checkbox"/> NIHBL3-LS | <input type="checkbox"/> ACL4 |
| <input type="checkbox"/> BSL4 | <input type="checkbox"/> NIHBL4 | <input type="checkbox"/> NIHBL4-LS | |
| <input type="checkbox"/> ABSL2 | <input type="checkbox"/> NIHBL2N | | |
| <input type="checkbox"/> ABSL3 | <input type="checkbox"/> NIHBL3N | | |
| <input type="checkbox"/> BSL3Ag | <input type="checkbox"/> NIHBL4N | | |
| <input type="checkbox"/> 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 <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. A sink is present in the laboratory for hand washing. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| If yes, the hand washing sink is hands-free or automatically operated. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. An eyewash station is readily available. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 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 <input type="checkbox"/> | No <input type="checkbox"/> |
| If yes, | | |
| a. Are the liquid effluents from the containment shower areas similarly treated for sterility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| b. Is the effluent decontamination system validated monthly with a bio-indicator? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

If BSL3Ag, BSL4 or ABSL4 is selected, proceed to Section 7.

- | | | |
|--|------------------------------|-----------------------------|
| 6. Access to the laboratory is through two self-closing doors. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| If yes, door(s) from the anteroom open inward to the laboratory? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal		
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Entity Name:	Date:
--------------	-------

Building/Suite or Room:	
-------------------------	--

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 <input type="checkbox"/> | No <input type="checkbox"/> |
| 8. | The laboratory is designed such that under failure conditions the airflow will not be reversed. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 9. | Laboratory design and operational parameters are re-verified at least annually. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 10. | A visual monitoring device, which confirms directional airflow, is provided at the laboratory entry. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 11. | Laboratory exhaust is not re-circulated to other areas of the building. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 12. | Exhaust air is HEPA filtered. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | a. If yes, the HEPA filter housing has decontamination and test ports. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | 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 <input type="checkbox"/> | No <input type="checkbox"/> |
| | b. If no, exhaust air is dispersed away from occupied areas and building air intake locations. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 13. | Emergency shower is readily available. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 14. | Floor drains are present. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 15. | Sink traps and any floor drains are filled with water and/or appropriate liquid to prevent the migration of vermin and gases. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 16. | Mechanical cage washer is present. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | If yes, cage washer has a final rinse temperature of at least 180°F. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 17. | The laboratory has a shower-out capability with a change room. | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

This submission is: <input type="checkbox"/> A new registration	<input type="checkbox"/> An update to an existing registration	<input type="checkbox"/> A renewal
Entity Name:		Date:

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 <input type="checkbox"/>

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	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

Suite Legend: (If Applicable)	Suite A = Rooms 1, 2, 3, 4
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This submission is: <input type="checkbox"/> A new registration	<input type="checkbox"/> An update to an existing registration	<input type="checkbox"/> A renewal
Entity Name:		Date:

PI(s):	
--------	--

Section 7B – Strain or Serotype Designation Information

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

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal		
Entity Name:		Date:
PI(s):		

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”. Attach additional sheets as needed.

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 10⁵ cfu/ml). If select agent will not be propagated, indicate “no propagation of agent”. Attach additional sheets if needed.

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). Attach additional sheets if needed.

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

This submission is: <input type="checkbox"/> A new registration <input type="checkbox"/> An update to an existing registration <input type="checkbox"/> A renewal		
Entity Name:		Date:
PI(s):		

Section 7C – Description of Work (Continued)

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:

- 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. BSL3Ag laboratory? Yes No
If yes, complete Attachment F – BSL3Ag Laboratories

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

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Entity Name:						Date:		
PI(s):			Laboratory Safety Level:					

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. Add additional sheets as needed.

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. Yes No
 If yes, describe method:
 - Autoclaved
 - Chemical (disinfectant, concentration, and time) _____
 - Incineration
 - Other _____

7. Dilution procedures and other manipulations of concentrated select toxins are performed. Yes No
 If yes, conducted in:
 - 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

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Entity Name:						Date:		

PI(s):		Laboratory Safety Level:
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Attachment A –Work with Toxins (Continued)

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
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.**

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Entity Name:						Date:		
PI(s):				Laboratory Safety Level:				

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 LD₅₀ < 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 LD₅₀ < 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 resistance, increased host range, enhanced transmissibility, infectivity, environmental stability) in select agents or toxins? Yes No

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Entity Name:						Date:		
PI(s):						Laboratory Safety Level:		

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

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.

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Entity Name:		Date:
PI(s):		Laboratory Safety Level:

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. Describe the waste stream:

a. Are animal carcasses, cages, and waste (e.g., sewage, bedding) treated prior to disposal by an approved method? (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. Waste Handling Procedures

- Waste decontaminated inside the containment area (e.g., pass-through autoclave loaded within the animal facility).
- Waste outside of the containment area for decontamination. Describe when and how waste is treated before transport out of the containment area. Add additional sheets as needed.

4. Describe any inactivation (e.g., formalin fixation, lysis of cells for nucleic acid extraction, irradiation) of samples collected from infected animals that will be manipulated at a lower biosafety level. Include concentration or dosage and contact/exposure time, as applicable. Add additional sheets as needed.

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

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Entity Name:		Date:
PI(s):		Laboratory Safety Level:

Attachment C – Work with Animals (Continued)

6. The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Yes No
 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. Add additional sheets as needed.

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

9. Are experimentally infected animals 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).

Species	Animal Housing

11. Describe how animals will be euthanized. Add additional sheets as needed.

12. Are animals euthanized? Yes No
 If no, explain.

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

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Entity Name:		Date:
PI(s):	Laboratory Safety Level:	

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
- 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: Yes No
 - 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: Yes No
 - Concrete
 - Tile or other floor covering
 - Dirt or gravel

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Entity Name:						Date:		
PI(s):						Laboratory Safety Level:		

Attachment D – Work with Plants (Continued)

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
- f. Structure is reinforced. Yes No
- g. Floor is constructed of:
- Concrete
- Tile or other floor covering
- Dirt or gravel
- h. Manufacturer name _____ Model number _____
- i. Access to growth chamber is controlled (e.g., lock and key, card access system, biometrics). Yes No
- j. 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.**

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Entity Name:		Date:
PI(s):		Laboratory Safety Level:

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. Yes No
 If yes, complete questions 3-16.

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. Add additional sheets as needed.

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. Add additional sheets as needed.
-

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

This submission is: A new registration An update to an existing registration A renewal

Entity Name: _____ Date: _____

PI(s):		Laboratory Safety Level:
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Attachment E – Work with Arthropods (Continued)

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. Add additional sheets as necessary.

9. Arthropods are prevented from release into suite/room. Yes No
 If yes, do procedures include protocol for accidental escape? Yes No

10. Experimentally infected arthropods are housed and manipulated in a suite/room such that accidental contact and release is prevented. 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

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Entity Name:				Date:
PI(s):				

Attachment F – BSL3Ag Laboratories (Continued)

9. Humane restraining devices are provided in large animal rooms. Yes No
If yes, describe. Add additional sheets as needed.

10. Necropsy rooms are sized and equipped to accommodate large animals. Yes No
If yes, describe. Add additional sheets as needed.

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Entity Name:						Date:		
PI(s):								

Attachment G – BSL4/ABSL4 Laboratories (Continued)

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.