This submission is:	☐ A new registration	☐ An update to an existing registration	☐ A renewal	Date:
Entity Name:				

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 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.

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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]:

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)