Form Approved

OMB Control No. 0920-0576

Exp. Date 12/31/2018

Instructions for Using the Biosafety Plan Template

Please note that the Biosafety/Biocontainment Plan Template is not required by FSAP to be used by the entity. The purpose of this document is to facilitate creating a biosafety/biocontainment plan that meets the requirement found in section 12 of select agent regulations 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. This template is made purposely customizable to fit the specific needs of the entity.

There are resources available to assist entities in development of biosafety/biocontainment plans such as the "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)," "Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests" (Robert P. Kahn and S.B. Mathur eds., 1999; copies available upon request at lrsat@cdc.gov or AgSAS@aphis.usda.gov), and "A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes" (Patricia L. Traynor ed., 2001; copies available upon request at lrsat@cdc.gov or AgSAS@aphis.usda.gov). These resources can be used as guidance to assist in the development of the biosafety/biocontainment plan. However, entities may use other nationally recognized biosafety/biocontainment guidelines when developing and implementing a written plan.

Occupational Health Program

Section 12(d) of Part 121 and Part 73 states that "the biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program." See the Occupational Health Program guidance and information found in this template for more information. Additionally, entities registered for SARS-CoV and Reconstructed 1918 Influenza virus must also develop an occupational health program.

Review and Approval

This plan will be reviewed annually and revised, as needed. The plan will be reviewed and revised, as necessary, after any drill or exercise and after any biosafety/biocontainment incident.

I have reviewed this Biosafety/Biocontainment Plan and determined that it meets the requirements of section 12 of the select agents and toxins regulations.

_____ _____

Signature **Review Date**

_____

Print Name

REVIEW	
REVIEW DATE	SIGNATURE

Administrative Information

Location Information

Building:

Lab Room Number:

Date Biosafety Plan Prepared:

Revision History:

Key Personnel:

Principal Investigator

Name	
Primary Contact Phone Number	
Email	

(Incorporate additional entries as necessary)

Name	
Primary Contact Phone Number	
Email	

(Incorporate additional entries as necessary)

Name	
Primary Contact Phone Number	
Email	

IBC Registration (if applicable)

Document Title (**Include a copy of the IBC Registration Document in the Biosafety Plan**):

Number(s):

Date Approved:

IACUC Protocol Number (if applicable):

Containment Biosafety Level (BSL) Assigned:

☐ BSL2 ☐ ABSL2

☐ BSL3 ☐ ABSL3

☐ BSL4 ☐ ABSL4

☐ ACL 2 ☐ BSL3 Ag

☐ ACL 3 ☐ PPQ Agent

☐ ACL 4

Biological Select Agent or Toxin Information

This section should describe in detail the hazardous characteristics of each select agent and toxin listed on your registration, even if the entity does not currently possess or use that select agent or toxin. See section 12(a)(1) of the select agents and toxins regulations. Hazards should be based not only on the select agent or toxin but also on the conditions of the registered entity's space, experiments, etc.

Location Information

Select Agent or Toxin	
Status (Description of Work Being Done or Storage)	
Room Number	

Hazardous Characteristics (Note: There are dedicated websites such as Pathogen Safety Data Sheets found at http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php or BMBL to use as a reference.)

Pathogenicity/Unique traits (known resistant traits)	
Route of Infection/Primary Hazards/Special Hazards	
Sources/Specimens for Possible Infection	
Infectious Dose/Incubation Period/Communicability	
Clinical Signs of Infection/Known Symptoms	
Procedural hazards (e.g., sharps, aerosol)	

Medical Information (Note: There are dedicated websites such as Pathogen Safety Data Sheets found at http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php or BMBL to use as a reference.)

Prophylaxis	
Immunization	
Known First Aid Procedures	
Effective Disinfectants/Neutralizing Agent	

Safeguards for Protecting Against Exposure to Select Agents and Toxins

This section should describe safeguards in place with associated work practices/containment procedures to protect registered entity personnel, the public, and the environment from exposure to the select agent or toxin. See section 12(a)(2) of the select agents and toxins regulations. Safeguards should include personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards. The BMBL is considered a good reference for providing safeguards for protecting against exposure to select agents and toxins.

Standard Microbiological Practices
Special Practices
Safety Equipment (Primary Barriers and Personal Protective Equipment)
Laboratory Facilities (Secondary Barriers)

Disinfection, Decontamination or Destruction of Select Agents and Toxins

This section should describe the validated procedures for disinfection, decontamination, or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material. See section 12(a)(2) of the regulations. The procedures should include all susceptibility to disinfectants and decontamination/destructions procedures for possible spills (if applicable).

Contaminated Material Type	Validated Procedure for Disinfection, Decontamination, or Destruction
Cultures and other materials related to the propagation of select agents or toxins	
Items related to the analysis of select agents and/or toxins	
Personal Protective Equipment	
Animal caging systems and bedding/arthropod caging systems, (if applicable)	
Animal carcasses or extracted tissues and fluids (if applicable)	
Extracted plant or arthropod tissues	
Laboratory surfaces and equipment, and effluent material	
Spills	

Storage

This section should include descriptions of appropriate containers, labeling procedures, inventory procedures, and description of safe storage practices.

Emergency Notification Process

This section should describe the notification system in the event of an emergency. This section should include the contact information for the primary investigator and any other contacts that may be pertinent.

Contact	Phone Number
Principal Investigator	
Campus Police/Security	
Emergency Medical Personnel	
Other	

Animals and Plants Exposed to Select Agents and Toxins (if applicable)

Section 12 of the select agent regulations require the biosafety plan to contain biosafety and containment procedures for any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

In order to comply with these requirements, the entity should also include procedures to contend with the exposure or infection of animals or plants contained in unregistered locations not intended for select agent studies. Such areas may include:

- Areas that share equipment used in both select agent studies and non-select agent studies or general animal, and plant housing considerations.
- Areas where personnel with access to select agents, select agent infected animals or plants, or select agent contaminated materials (i.e. waste equipment) are also involved in non-select agent studies.
- Areas that could become contaminated by a release of a select agent beyond the containment boundary of a registered area.
- Areas that handle waste products prior to sterilization from select agent studies.

These provisions should extend to all unregistered areas where equipment, personnel, or release considerations apply.

Procedure:	
PI/Lead Scientist/Laboratorian:	
Animal/Plant Used:	
Select Agent/Toxin Used:	
Work Involving Plant/Animal:	
Containment method of all organic material (select agent-infected carcasses, tissues, plant biomass) until final destruction (e.g., autoclave, incineration, etc.)	
Monitoring procedure:	

Handling Select Agents and Toxins in Shared Spaces (if applicable)

Section 12(a)(4) of the select agents and toxins regulations requires the entity to describe procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins in order to prevent unintentional contamination. These procedures can include a description of:

- Decontamination of laboratory work surfaces, equipment, and all select agent and toxin waste prior to transitioning to work with non-select agents or toxins.
- How personnel are made aware of the status of any particular room or laboratory at any given time.
- Spatial and/or temporal considerations when performing tissue culture studies.
- Any concurrent work with Reconstructed 1918 Influenza virus and highly pathogenic avian influenza virus.
- Sterilization of all samples at the end of the study/experiment/procedure.

Precautions should be taken to prevent cross-contamination of viral select agents in cell cultures. Some means of preventing accidental transfer of agents between cultures can include:

- Performing all cell culture manipulations in a biosafety cabinet.
- Working with only one select agent at a time.
- Decontaminating biosafety cabinet with a surface disinfectant between select agents and toxins.
- Changing gloves when changing from one select agent to another.
- Aliquoting growth medium and other reagents so that the same vessel is not used for more than one select agent.

This section should describe the practices for working with select agents and toxins and non-select agents in the same spaces in order to prevent unintentional contamination.

Occupational Health Program (OHP)

Besides information included above, the Section 12(d) states that "the biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program." See the Occupational Health Program guidance for more detailed information. Additionally, entities registered for HPAI, SARS-CoV, and 1918 influenza virus should develop an occupational health program. See the Biosafety Guidance for more information.
If applicable, describe or refer to OHP elements for working with Tier 1 select agents and toxins. See Section VII of the BMBL for more detailed information.

Medical Assessment and Surveillance

Ensure that a competent medical authority evaluates the following information for each individual prior to access to select agents or toxins:

- Previous and ongoing medical problems
- Current medications that may impact the individual's ability to work with select agents or toxins
- Allergies
- Prior immunizations
- Necessary medical services to permit the individual to safely assume the duties of the position

Describe or refer to the procedure for periodic medical evaluations, including the point of contact:

Describe or refer to the procedure for emergency medical evaluations, including the point of contact:

Post Exposure Management

If applicable, describe or refer to the immediate/first aid actions to be taken in the event of an exposure incident.

Describe or refer to the procedure for post-exposure medical evaluations:

Describe or refer to procedures for providing post-exposure care and support for workers exposed to select agents or toxins for which effective pre- or post-exposure prophylactic measures exist.

If applicable: Describe or refer to procedures for providing post-exposure care and support for workers exposed to select agents or toxins for which effective pre- or post-exposure prophylactic measures have not been identified.

Describe or refer to procedures for when an employee reports symptoms that may have resulted from unrecognized exposure event. **Note:** An example may be to distribute medical alert cards to workers with access to select agent and toxins to validate the possibility of exposure quickly.

Hazard Communication

Describe the procedures for providing the following information to personnel with access to Tier 1 BSAT, HPAI, SARS-CoV, 1918 influenza virus, and products of restricted experiments (ex: antibiotic resistant strains):

- Risks and health hazards associated with the Tier 1 BSAT being used.
- Possible signs and symptoms of the diseases associated with the BSAT with which they work or share space with.
- Available pre- and post-exposure resources for treatment (including information on any available vaccine or prophylaxis options).
- Point of contact and what to do in an emergency.
- How to report and document all potential occupational exposures.

Reporting and Analyzing Occupational Exposure

Describe procedures for reporting all potential occupational exposures to identify contributing factors and corrective actions to be taken to mitigate the risk of recurrence.

Records Management and Retention

Describe procedure for collecting, safeguarding, and maintaining all personnel occupational health related documents and records for at least 3 years.

Modifications and Special Circumstances

Please describe any other policies of procedures relevant to your OHP that has not been covered by this form.

Drills and Exercises

Section 12(e) of the regulations states that the biosafety/biocontainment plan "must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise."

This section should describe in detail the procedures for each biosafety/biocontainment drill or exercise. You can reference Drills and Exercises Guidance and the Drills and Exercises Documentation Form for further guidance.