



# **Biosafety Plan Guide**

2017

Safety Resources

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## About This Guide

The *Biosafety Plan Guide* is intended to provide instructions for new or existing permit holders on the development of their biosafety plan. The biosafety plan is a single document that acts as a specific biosafety manual for that permit holder. The Biosafety Plan is based on the current *Canadian Biosafety Standard (2nd Ed.)* and the *Canadian Biosafety Handbook (2nd Ed.)*.

The guide is also intended to act as a companion document to the following forms and procedures:

- *New Biosafety Permit Application Form*;
- *New Biosafety Permit Application Procedure*;
- *Biosafety Permit Amendment Form*; and
- *Biosafety Permit Amendment Procedure*.

The Biosafety Plan will be reviewed by the Biosafety Group and the Biosafety Protocol Approval Committee (BPAC) for completeness against program, facility, operational, and regulatory requirements.

## How to Use this Guide

This guide provides the applicant or the current permit holder with further information on requirements relating to each specific element required in the *New Biosafety Permit Application Form* or *Biosafety Permit Amendment Form*, and the *Biosafety Plan template*.

The plan element will be confirmed through a site visit by Safety Resources and/or the Biosafety Group as part of the permit application/amendment review and approval process.

Additional reference information and specific requirements related to the plan element are provided throughout the guide and in the reference section at the end of the guide.

For further information, or assistance completing the *New Biosafety Permit Application Form*, the *Biosafety Permit Amendment Form*, and/or preparing a biosafety plan contact Tara Donovan, Biosafety and Environmental Officer at 306-966-8190 (tara.donovan@usask.ca), or Andrea Smida, Biosafety Officer at 306-966-8496 (andrea.smida@usask.ca).

## 1 Contact Information

Create a list of the primary and secondary contacts; include their full names (first and last) and 24 hour contact numbers of who can be contacted if an emergency has occurred within the permitted laboratory outside of normal working business hours.

Include the contact phone for Protective Services (306-966-5555) as they respond to any emergency or incidents that occur on campus.

**Resources:** A “24 Hour Contact Information” template is available on the Safety Resources website, <http://safetyresources.usask.ca/>.

**Other Requirements:** Emergency contact information must be posted in an area that is highly visible upon entry into laboratory areas.

**Complete Section 1 of Biosafety Plan Template.**

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## 2 Summary of Program/Research Intent

Provide a brief description in lay-man terms of the research initiatives that will be conducted under the biosafety permit, which includes a summary of the procedures involved, an outline of objectives, experimental approach, and significance of the expected results.

Refer to the following examples in **Table 1**.

Table 1: Examples of research initiatives – single versus multiple-type research projects.

<p><u>Example #1: Single project</u></p> <p>Low levels of <i>Lactobacillus subtilis</i> exposure can provide protection of newborns against respiratory syncytial virus (RSSV). This study will expose <i>Lactobacillus subtilis</i> neonatal mice to see if there is a protective factor from RSSV. The neonatal mice will be exposed to different levels of <i>Lactobacillus subtilis</i> and blood samples will be collected to assess the immunogenic response against RSSV as measured by the ELISA assay.</p> <p><u>Example #2- Multi-Type project:</u></p> <p><b>Objective #1:</b> To compare vaccinated and non-vaccinated swine when naturally exposed to porcine respiratory virus (PRV).</p> <p>Methods Used:</p> <ul style="list-style-type: none"><li>• Use tissue culture methods and real-time polymerase chain reaction (PCR) on tracheal mucus samples obtained from the swine to measure target protein production.</li></ul>
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- Use real-time PCR and tissue culture methods to determine what percentage of swine who become infected with PRV; and
- Use of immune-histo techniques to compare the proportion of and days to disease development between vaccinated and non-vaccinated heifers as determined by ultrasonography and tracheal glycoproteins.

**Objective #2:** To develop a vaccine against the bovine epidemic diarrhea virus (BEDV) by identifying the various virulent and variant strains found in North America, and determining if the variant strain can be used as a vaccine.

Methods used:

- Collecting various strains of BEDV across North America, including Canada and the USA;
- Using cell culture to propagate the BEDV, this will be confirmed by immunofluorescence assays and electron microscopy;
- Using real time polymerase chain reaction (PCR) to identify the genetic differences between BEDV strains; and
- Validate the use of real time PCR process for identifying the genetic differences.

Ensure to provide a list of all relevant references, including published scientific papers, and any other relevant documents.

**Complete Section 2 of the *Biosafety Plan Template*.**

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### 3 Biological Assessment and Inventory

Develop an up to date inventory of all biological/biohazardous materials in your possession, which will be handled, used, produced, and/or stored under the biosafety permit.

Refer to **Table 2** in **Section 3** of the *Biosafety Plan template* to list the inventory of the biological/biohazardous material and document the risk group, containment level, and dual-use potential for each biological agent. The inventory should include the use, state the source/supplier of the biological material, and the concentration and the maximum quantity of the biological material to be cultured at one time.

For Security Sensitive Biological Agents (SSBA), further details will be required, contact the Biosafety Group for assistance. For the comprehensive SSBA list, refer to: <http://www.phac-aspc.gc.ca/lab-bio/regul/ssba-abcse-eng.php> .

#### **Biological Risk Group and Containment Level Classification**

If the risk group and containment level is known and has been identified through other external sources, include references and any available technical information in the biosafety plan. Use the following references to identify the risk group and containment level:

- Public Health Agency of Canada (PHAC) – Pathogen Safety Data Sheets \*  
<http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>
- Human Pathogens and Toxins Act, Schedules 1 through 5 \*  
(<http://laws.justice.gc.ca/eng/acts/H-5.67/>)
  - Schedule 1 – Toxins
  - (<http://laws.justice.gc.ca/eng/acts/H-5.67/page-9.html#h-23>) Schedule 2 - Risk Group 2 Human Pathogens  
(<http://laws.justice.gc.ca/eng/acts/H-5.67/page-10.html#h-24>)
  - Schedule 3 - Risk Group 3 Human Pathogens  
(<http://laws.justice.gc.ca/eng/acts/H-5.67/page-11.html#h-25>)
  - Schedule 4 - Risk Group 2 Human Pathogens  
(<http://laws.justice.gc.ca/eng/acts/H-5.67/page-12.html#h-26>)
  - Schedule 5 - Prohibited Human Pathogens and Toxins  
(<http://laws.justice.gc.ca/eng/acts/H-5.67/page-13.html#h-27>)
- Risk Group Classification for Infectious Agents, American Biological Safety Association \* (ABSA) <https://my.absa.org/Riskgroups>
- Biological Safety in Microbiological and Biomedical Laboratories, Centres for Disease Control, NIH (5<sup>th</sup> Ed., 2009)  
<http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf>
- Disease Agent Information, Canadian Food Inspection Agency (CFIA)  
<http://www.inspection.gc.ca/animals/biohazard-containment-and-safety/pathogen-imports/disease-agents/eng/1312495508549/1312497560331>

\* Most common references used.

If unknown, the risk group and required containment level for each biohazardous material must be determined. A summary of the biological risk group and containment level assessment process that is to be followed is presented in **Figure 1**.

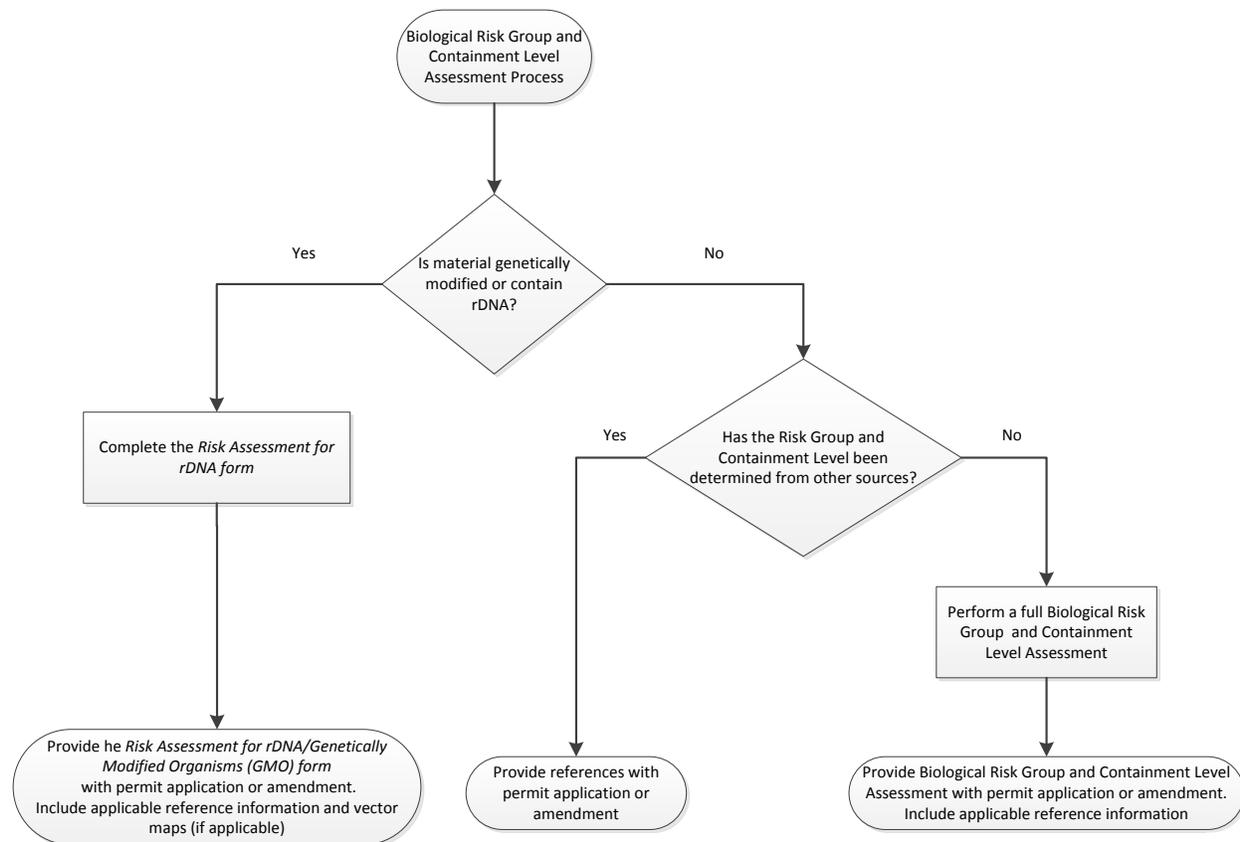


Figure 1: Biological risk group and containment level assessment process.

If the risk group and containment level is unknown or has not been determined, a full risk assessment must be conducted by completing the *Biological Risk Group and Containment Level Assessment Template*. Include any reference material, technical information (e.g. product/technical data sheets), and/or related journal articles for each organism, biological material, or biohazardous material in the Biosafety Plan.

If the biological and/or biohazardous material is genetically modified or contains rDNA, the applicant must complete the *Risk Assessment for rDNA/Genetically Modified Organisms (GMO) form*. Include any relevant literature/references, technical information (e.g. product/technical data sheets), and/or related journal articles for each organism, biological material, or biohazardous material in the biosafety plan. If the risk group of the source or recipient of the rDNA/GMO is not known, conduct a full risk group assessment.

#### Dual-use Potential Assessment

Dual-use potential is defined as the “qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism)” (*Canadian Biosafety Standard, 2<sup>nd</sup> Ed., 2015*; *World Health Organization: Dual Use Research Concern (DURC)*, <http://www.who.int/csr/durc/en/>; National Institutes of Health Biosecurity and Dual Use Research Concern, (<https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research>).

Once the RG has been determined for each biological material, an assessment must be done to help identify any dual-use potential of the material. To conduct an assessment, use the flow chart shown in **Figure 2**. If a dual-use potential has been identified, consult with the Biosafety Group to ensure proper processes are in place. Complete the Dual-use column in **Table 2** found in **Section 3** of the *Biosafety Plan Template*.

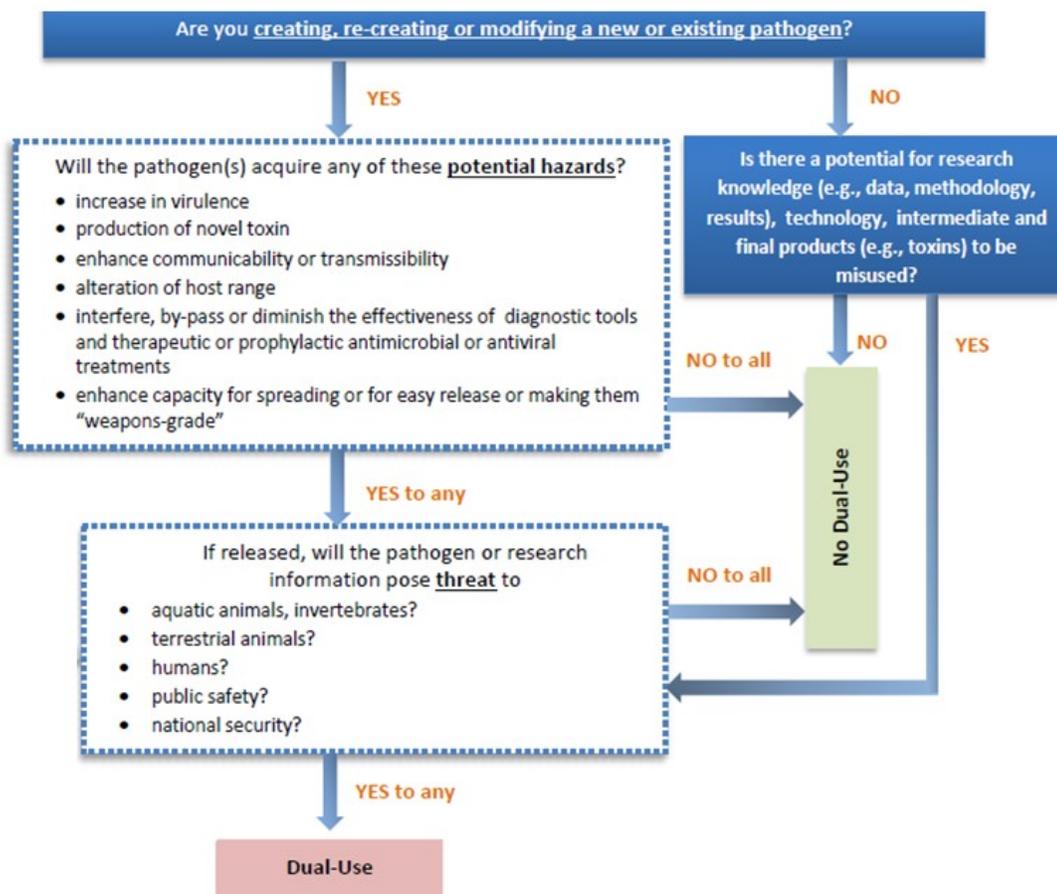


Figure 2: Identification of Dual-Use Potential for Biological Agents

**Resources:**

**Inventory:**

Refer to **Table 2** in **Section 3** of the *Biosafety Plan template* for the inventory requirements and the biological assessment.

For rDNA/GMOs:

Complete the *Risk Assessment for rDNA/Genetically Modified Materials (GMO) form*, which is available on the Safety Resources website, <http://safetyresources.usask.ca>.

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***Other Requirements:***

**Procurement and/or Transfer of Biological Materials**

It is the responsibility of the permit holder to maintain a current inventory of biological and biohazardous materials listed. Inventories should be updated whenever materials are transferred, disposed of, or inactivated. Permit holders must also verify the inventory on a regular basis and report any missing or stolen biological materials to the Biosafety Group.

For procurement or transferring materials from a campus, domestic, and/or international source(s), refer to sections 6, 7, and 8 of the U of S *Biosafety Code of Practice* at the Safety Resources website: [www.safetyresources.usask.ca](http://www.safetyresources.usask.ca) and contact the Biosafety Group.

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#### **4 Health and Safety Hazard Assessment**

To determine health and safety risks, including risks of exposure to biohazardous materials, toxins, chemicals, and other hazardous material, one must consider both the types of materials being used, and their proposed manipulations, handling, storage, and/or disposal under the research protocol or activity. Identification of the hazards associated with the activities of these materials will help to determine the physical parameters and operational procedures required for the intended work.

**Complete Tables 3, 4, and 5 in Section 4 of the *Biosafety Plan template*.**

**For Table 3 (Section 4) of the *Biosafety Plan template*:**

For each biological and/or biohazardous material, ensure the following information has been captured (e.g. list, chart, etc.):

1. Name of biological material, its risk group, and required containment level.
  2. Identify and list all procedures/techniques that will be carried out with the biological/biohazardous materials. For an example refer to **Table 2** as shown below.
  3. Identify the exposure hazards and routes of exposure (inhalation, ingestion, skin contact, injection), and any other health and safety hazards (e.g. chemical, radiological, physical) that exist for each procedure/technique. Consider the key steps in each procedure/technique when identifying health and safety hazards. For an example, refer to **Table 2** as shown below.
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4. Prioritize identified hazards according to their level of risk. In assessing risk, consider the relative severity of the hazard as well as its relative probability of occurring. Use the following priority when deciding on the appropriate preventive and protective measures for each hazard:

- 1) Eliminate the hazard;
- 2) Substitute with other materials, processes or equipment;
- 3) Use engineering controls;
- 4) Use safer work systems that increase awareness of potential hazards;
- 5) Provide administrative controls; and
- 6) Provide personal protective equipment.

Whenever possible, the hazard should be managed at the highest level possible on the priority list. For example, if the hazard cannot be eliminated entirely (priority 1), then consider substitution with other materials, processes, or equipment. If substitution is not effective at managing the hazard, then engineering controls should be established where practical. This priority approach to instituting preventive and protective measures should continue until a suitable solution is achieved. In most cases, a combination of measures will be necessary to effectively manage the hazard. When conducting preventive and protective measures, all applicable legal requirements must be met and all standards, codes, and best practices should be used to guide the process.

For an example, refer to **Table 2** as shown below.

**Table 2: List of Common Procedures Conducted in a Laboratory and a List of their Corresponding Potential Route of Exposures and Safety Mitigation Strategies**

Procedure	Potential Route of Exposure	Safety Mitigation Controls
Phlebotomy techniques on humans or animals	Inoculation	<ul style="list-style-type: none"> <li>- Wear proper PPE (lab coat, disposable gloves, safety glasses)</li> <li>- Follow U of S <i>Phlebotomy Guidelines</i></li> <li>- Use of safety engineered SHARPs</li> <li>- Use of proper SHARPs container</li> <li>- Follow specific procedural SOP</li> <li>- Use proper restraints (if required)</li> </ul>
Injecting vaccine, drugs, euthanizing agents, etc. into animals	Inoculation, inhalation	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Use of safety engineered SHARPs</li> <li>- Use of proper SHARPs container</li> <li>- Follow specific procedural SOP</li> <li>- Use proper restraints (if required)</li> <li>- Ensure proper training has been provided</li> </ul>
Conducting surgical techniques on animals	Inoculation	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> </ul>

		<ul style="list-style-type: none"> <li>- Use of safety engineered SHARPs</li> <li>- Use of proper SHARPs container</li> <li>- Follow specific procedural SOP</li> <li>- Use proper restraints (if required)</li> <li>- Ensure proper training has been received</li> </ul>
Handling human or animal tissue, including preparation, dissection, cutting	Inoculation or/and absorption through mucous membranes	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Use of safety engineered SHARPs</li> <li>- Use of proper SHARPs container</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet</li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> </ul>
Pipetting, mixing, sonicating, or vortexing human or animal blood, fluid, or tissue	Ingestion, inhalation, and/or absorption through mucous membranes	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet <u>for pipetting and mixing</u></li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> </ul>
<b>Procedure</b>	<b>Potential Route of Exposure</b>	<b>Safety Mitigation Strategy</b>
Pipetting, mixing, sonicating, or vortexing biohazardous material	Ingestion, inhalation, and/or absorption through mucous membranes	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet <u>for pipetting and mixing</u></li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> <li>- Use of appropriate disinfectant</li> </ul>
Centrifuging human or animal blood, fluid, tissue, organisms or biohazardous material	Inhalation and/or absorption through mucous membranes	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Use of a sealed rotor cup</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet to open the sealed rotor cup</li> </ul>

		<ul style="list-style-type: none"> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> </ul>
Handling tubes or other containers of human or animal blood, fluid, tissue, or other biohazardous material	Inhalation (only if Cryovial explodes, or opened outside of BSC), absorption through mucous membranes, and/or ingestion	<ul style="list-style-type: none"> <li>- For Cryovials: use thermogloves and faceshield when placing or removing vials from liquid nitrogen</li> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet</li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> </ul>
Preparing or handling human, animal or biohazardous material cell cultures	Inhalation, absorption through mucous membranes, and/or ingestion	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet</li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> <li>- Use of appropriate disinfectant</li> </ul>
Handling contaminated sharps or other biohazardous waste	Inoculation, ingestion, and/or absorption through mucous membranes	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow U of S <i>Hazardous Waste Disposal Standard</i></li> </ul>
<b>Procedure</b>	<b>Potential Route of Exposure</b>	<b>Safety Mitigation Strategy</b>
Static build up when handling powdered toxins	Inhalation	<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves)</li> <li>- Follow specific procedural SOP</li> <li>- Ensure proper training has been received</li> <li>- Use a biosafety cabinet</li> <li>- Wash hands with soap and water for 20 seconds</li> <li>- Follow good microbiological practices</li> </ul>
Cleaning spills of human or animal blood or other bodily fluids or biological hazardous material	Inhalation and/or ingestion	<ul style="list-style-type: none"> <li>- Review and be trained on building emergency response plan</li> <li>- Ensure biological spill kit is stocked</li> </ul>

		<ul style="list-style-type: none"> <li>- Wear proper PPE (safety glasses, lab coat, disposable gloves, N95 Respirator, shoe cover)</li> <li>- Conduct weekly flush tests for emergency showers and eye wash</li> </ul>
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**For Table 4 and 5 (Section 4) of the *Biosafety Plan template*:**

5. Conduct a biological material pathogenicity assessment by identifying the possible diseases, or adverse health effects associated with exposure to the organism or biohazardous materials (Refer to **Table 3** below). Include the signs and symptoms of known diseases. Include known allergies that could develop from working with the organism(s) and corresponding symptoms (Refer to the *Occupational Acquired Allergies and Sensitivities Awareness Guideline*).

The permit holder must discuss with all individuals within the laboratory about importance of individuals self-identifying if they are immunocompromised (e.g. individuals with an impaired immune system from a pre-existing medical condition, chemotherapy, immunosuppressive drugs, steroids, etc.). Having discussions with immunocompromised individuals will help identify if the individual needs to avoid working with the biohazardous material all together, get equipped with extra protection (e.g. extra PPE) when working with the material, and/or take preventative measures to protect themselves against the onset of the disease as they are more susceptible (e.g. taking antibiotics or getting vaccinated).

**Table 3: Example of how to conduct a biological material pathogenicity assessment.**

Biological Material	Route of Exposure	List Disease	Symptoms	Time Onset of Symptoms
<i>Staphylococcus aureus</i>	Ingestion	Gastroenteritis, staphylococcal food intoxication from enterotoxins	Nausea, vomiting, abdominal pain, cramps, and diarrhea	Rapid onset (acute)
	Inoculation	Infection at site of bite or needle stick	Local infections, cellulitis, tenderness, mild fever, erythema	Within 24 hours
	Inhalation	Pneumonia, meningitis,	Infection in the nasal passage	Within 5 days (if develops)

Cholera toxin (Source <i>Vibrio cholera</i> ) (LD-50: extrapolated for human – for 100 lb. (45.5 kg) is 11.4 mg iv, 25 µg oral) (Low concentration used, symptoms can show within half day to 5 days)	Ingestion	Gastroenteritis	Nausea, cramping, adnominal pain, vomiting, watery diarrhea, can be fatal due to dehydration from hours to days	Abrupt onset
	Absorption through skin	unknown	Mild Irritation	Acute
	Inoculation	unknown	Mild Irritation	Acute
Human blood, tissues, and/or bodily fluids	Inoculation (needle stick)	Blood borne pathogens (HIV, hepatitis viruses B and C, West Nile)	<u>Hepatitis:</u> Fever, Fatigue, loss of appetite, Nausea, Vomiting, Joint pain, Jaundice, abdominal pain.  <u>HIV:</u> Headache, Diarrhea, fatigue, nausea and vomiting, aching muscles  <u>West Nile Virus:</u> fever, headache, body aches, skin rash, and swollen lymph nodes. Severe symptoms and signs may include stiff neck, sleepiness, disorientation, coma, tremors, convulsions, and paralysis  Refer to Public Health Agency of Canada's Pathogen Safety Data	Hepatitis C: 2-12 weeks  Hepatitis B: 2-6 months  HIV: 2-6 weeks  West Nile: 3-14 days
	Absorption through skin and mucosal membranes			

			Sheets (Refer to PSDS)	
Live animals	Inhalation	Allergic reaction	Respiratory Tract irritation	Acute and/or chronic
	Absorption through skin and mucosal membranes	Allergic Reaction	Skin and eye irritation	Acute and chronic
Human Cell Line (HEK293T cells)	Absorption through skin and mucosal membrane s	Adenoviral component s, Blood borne pathogens (hepatitis B and C, AIDS, West Nile)	Inflammati n response, redness	Acute and chronic
	Inoculation	Adenoviral component s, Blood borne pathogens (hepatitis, AIDS, West nile)	Cause inflammati on of injection area	Acute and chronic
	Ingestion	Adenoviral component s, Blood borne pathogens (hepatitis, AIDS, West Nile, Zika Virus)	No known symptoms	Acute and chronic
Human cell line (MDA-MB-231) (ATCC HTB-26) Reference: <a href="http://www.atcc.org/products/all/HTB-26.aspx">http://www.atcc.org/products/all/HTB-26.aspx</a> )	Inoculation	Blood borne pathogens (hepatitis B and C, AIDS, West Nile, Zika Virus)	Inflammati n response, redness	Acute and chronic
		Tumors	On site of injection – inflammati on response, redness	Unknown – risk of tumor formation

6. In **Table 5** of the *Biosafety Plan Template*, identify the types of immunizations/vaccinations, medical surveillance, prophylaxis, allergy-sensitization awareness that is required for each biological material (if applicable). Individuals working with high-risk biological materials (i.e. hepatitis C virus, risk group 3 biological

materials) or are immunocompromised, are required to complete the *Medical Surveillance Form*.

**Resources:**

*The Canadian Biosafety Standards (2<sup>nd</sup> Ed., 2015) and the Canadian Biosafety Handbook (2<sup>nd</sup> Ed., 2016) provide comprehensive information on containment and operational requirements for facilities working with biohazardous materials.*

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## 5 Biosecurity Assessment

Biosecurity refers to the security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of infectious material or toxins. These concepts are inherently complementary as the implementation of good biosafety practices serves to strengthen biosecurity programs.

The development, implementation, evaluation, and maintenance of a biosecurity plan, based on a biosecurity risk assessment, is required for facilities where infectious material or toxins are handled or stored.

Document the relevant biosecurity measures utilized in the containment zone, which is outlined in **Section 5 (A)** of the *Biosafety Plan Template*.

**NOTES:**

1. The Biosafety Group may need to conduct a further assessment of the biosecurity risks involved with working with higher risk group biological materials, which is not covered in the standard hazard and biosecurity assessment. This assessment is called a *risk level analysis*, and uses the threat scenario matrix method set out by PHAC and develop a risk statement (e.g. “If [event] occurs, then the consequences could result in [negative impact]; Risk Level is [Low/Medium/High].” Refer to U of S Biosecurity Plan). This analysis is documented in **Section 5 (B)** of the *Biosafety Plan Template*.
2. For use of risk group 3 and/or Security Sensitive Biological Agents (SSBA), a detailed Biosecurity Plan will need to be developed. The plan will include an examination of possible threats and vulnerabilities, and the counter measures or mitigation strategies specific to the facility. Contact the Biosafety Group for more information and assistance.

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## 6 Work Locations

Submit a list of the locations where the organism(s), biological and biohazardous materials will be used, stored, and disposed, and include the following information:

- Building name;
- Room number;

- Containment level; and
- Type of Research (e.g. *in vitro*, *in vivo*, both, storage, teaching, animal holding, post-mortem, clinic, biowaste storage area, autoclave room, etc.).

The information about the locations can be formatted in the form of a table or simply listed.

**Other Requirements:** Work and storage locations must meet building and fire code requirements, and containment level physical and operational requirements as determined from the risk assessment information for each organism, biological or biohazardous material. Each specific location must be commissioned prior to use by the Biosafety Group or designate.

*The Canadian Biosafety Standards* (2<sup>nd</sup> Ed., 2015) provides comprehensive information on containment and operational requirements for facilities working with biohazardous materials

**Complete Table 5 and 6 in Section 6 of the *Biosafety Plan Template*.**

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## **7 Standard Operating Procedures and Element Requirements**

Under best practices, research activities should be, to the extent possible, governed by established and documented standard operating procedures (SOPs).

SOPs serve to ensure consistency and quality of work, and that health and safety hazards are adequately managed during the work activities. SOPs also serve as a training tool for faculty, staff, and students tasked with performing the work.

### **Part 1 – List of SOPs**

Provide a list of the SOPs used with the laboratory and state their location.

### **Part 2 – Required SOP Elements**

**Table 7** in **Section 7** of the *Biosafety Plan* template summarizes the required SOP elements to conduct work with biohazardous materials.

The questions asked for each required SOP elements must be addressed. The SOP elements are not inclusive and you may need to add specific procedures that are not listed in the table.

Permit applicants/holders are permitted the flexibility to organize, develop, and manage SOPs as appropriate to their facility recognizing that the key elements outlined in **Table 7** must be addressed.

Permit holders may satisfy the SOP elements outlined in **Table 7** of the *Biosafety Plan Template* by directly answering the questions in the table itself.

SOPs should also include the names of individual(s) who authored the procedure, who authorized the procedure, a unique document number and date activated, and a revision table at the beginning of the procedure to track changes made to the procedure.

SOPs can be in various formats including:

- Word document;
- Electronic file;
- Paper version;
- Procedure from an animal use protocol;
- Technical instructions from a kit; or
- Procedure from a laboratory procedure manual.

**Resources:** General SOP templates, as well as, other common SOPs are available on the Safety Resources website, <http://safetyresources.usask.ca>.

**Complete Section 7 of the *Biosafety Plan Template*.**

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## 8 References

The following is a summary of resources referenced throughout this guide document all of which are available on either the [U of S Policies website](http://policies.usask.ca) policies.usask.ca, or the [Safety Resources website](http://safetyresources.usask.ca):

- Biosafety Policy
- Biosafety Code of Practice
- New Biosafety Permit Application Procedure
- New Biosafety Permit Application Form
- Biosafety Permit Amendment Procedure
- Biosafety Permit Amendment Form
- Biosafety Plan Template
- Biological Material Risk Group and Containment Level Risk Assessment
- Risk Assessment for rDNA/Genetically Modified Organism (GMO) Form
- Chemical and Biological Inventory Template
- Procurement of Organisms and Biological Material Procedure
- Hazardous Waste Disposal Standard
- Laboratory Safety Manual
- Standard Operating Procedure Template
- Occupational Acquired Allergies and Sensitivities Awareness Guideline
- Phlebotomy Guidelines
- Monitoring Autoclave Efficacy SOP
- Compressed Gas Cylinder Safe Handling, Use, and Storage

**Other resources:**

- [Canadian Biosafety Standard \(CBS\) \(2<sup>nd</sup> Ed., 2015\)](#)
- [Canadian Biosafety Handbook \(CBH\), \(2<sup>nd</sup> Ed., 2016\)](#)
- [Public Health Agency of Canada \(PHAC\) – Pathogen Safety Data Sheets](#)
- [Human Pathogens and Toxins Act, Schedules 1 through 5](#)
  - [Schedule 1 – Toxins](#)
  - [Schedule 2 - Risk Group 2 Human Pathogens](#)
  - [Schedule 3 - Risk Group 3 Human Pathogens](#)
  - [Schedule 4 - Risk Group 4 Human Pathogens](#)
  - [Schedule 5 - Prohibited Human Pathogens and Toxins](#)
- [Disease Agent Information, Canadian Food Inspection Agency \(CFIA\)](#)
- [Containment Standards for Facilities Handling Plant Pests \(1<sup>st</sup> Ed.\)](#)
- [Containment Standards for Facilities Handling Aquatic Animal Pathogens \(1<sup>st</sup> Ed.\)](#)
- [Risk Group Classification for Infectious Agents, American Biological Safety Association \(ABSA\)](#)
- [Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, National Health Institute \(NIH\)](#)
- [Biological Safety in Microbiological and Biomedical Laboratories, Centres for Disease Control, NIH \(5<sup>th</sup> Ed., 2009\)](#)
- [Laboratory Biosafety Manual – World Health Organization \(WHO\) \(3<sup>rd</sup> Ed., 2004\)](#)
- [World Health Organization: Dual Use Research of Concern \(DURC\)](#)
- [National Institutes of Health Biosecurity and Dual Use Research Concern](#)
- [Safety Resources website](#)