# GUIDE TO COMPLETING THE LEVEL 1 AND 2 BIOSAFETY PERMIT APPLICATION

**Instructions:**

- Adhering to the instructions for filling out Appendix IV (page 3 of this document) is crucial to ensure a smooth review process and to avoid delays caused by unclear or insufficient information.
- Make sure you are using the **2025 version of the BIOSAFETY PERMIT APPLICATION FORM (Level 1 and 2),** provided in this application package.
- The application package consists of the permit application form and 2 subforms: Assessment for Potential on Dual-Use, Viral Vectors
- **Note for Mac users:** use 'Adobe Acrobat Reader for Mac' for filling out all PDF forms. Do not use Preview, which is often the set default program to open PDFs on Macs.

| Section | Information Required | Notes |
|---|---|---|
| **Section A** | PI Contact Information | • Complete all fields<br>• Emergency phone number is required for PI |
| **Section B** | Principal Lab Contact | • Complete all fields<br>• To be contacted in case of permit related questions<br>• Emergency phone number is required |
| **Section C** | Application Type<br><br>Permit Type | • New - first time applying<br>• Renewal - renewal of an existing biosafety permit<br><br>• Select as applicable |
| **Section D** | Permit Level | • Level 1 – if Risk Group 1 material is in use **and** only containment level 1 spaces are used<br>• Level 2 – if Risk Group 2 biological material is in use and/or containment level 2 spaces are used |
| **Section E** | Funding Information | • List all **current** funding **associated with the research** covered under the biosafety permit |
| **Section F** | Project Locations | • List as applicable to indicate where work is conducted and/or biological material is stored. Include shared spaces. |
| **Section G** | Biological Safety Cabinets | • List all BSCs in use (including those that are shared) |
| **Section H** | Lab Personnel | • List only the personnel who are currently using or will use biological agents or be entering containment level 1 or 2 spaces. |

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|---|---|---|
| | | • Complete all fields for each person working in the lab.<br>• Please ensure all other required training (EHS) is up-to-date all times. |
| **Section I** | Animal and Radioisotope Usage | • Select as applicable to your research activities. |
| **Section J** | Other Permits | • Other permits to attach would include ethics approvals for human studies, regulatory agency approvals, etc. |
| **Section K-I** | Biological Agent Categories | • Check all applicable bioagent categories.<br>• **NOTE:** this section and K-II MUST correspond |
| **Section K-II** | Biological Agent List | • List ALL biological agents (and biological toxins) that will be used in the projects<br>• Most risk groups can be found at https://health.canada.ca/en/epathogen. Note that EHS must follow PHAC guidance on risk group, even if this differs from other sources.<br>• **NOTE:** stored biological agents (which will not be used in the duration of the permit life) must be listed in Appendix VI<br>• **Note: Listing of HPTA exempt cell lines**<br>You do not need to list all of modified/derivative cell lines if you have the parent cell line on your permit unless you have introduced something that is regulated by CFIA (e.g., a potential animal pathogen, zoonotic pathogen or part thereof) or has the potential to alter the pathogenicity of the parent cell line in any way (e.g., introduced a toxin, altered tropism etc.). |
| **Section K-III** | Assessment on the Potential for Dual-Use | • Follow instructions for filling out the subform which is provided in the application package |
| **Section M** | Medical Surveillance | • Answer all questions |
| **Section N** | Declarations | • Please sign and date the application form<br>• Gather your Chair/Dean's signature |
| **Appendix I** | Additional Space for Section E | • Only use if you run out of room in Section E; do not repeat information already listed in section E |
| **Appendix III** | Additional Space for Section H | • Only use if you run out of room in Section H; do not repeat information already listed in section H |
| **Appendix IV** | Research Activities Involving Biological Agents<br>(excluding viral vector work) | • Submit Appendix IV as a separate Word document<br>• Provide sufficient detail so that the LBC reviewer(s) can understand and evaluate the work without having to resort to external sources.<br>• For procedures that are not widely used, include a reference<br>• Please refer to detailed guidelines on page 3 below for completing Appendix IV |

| Section | Information Required | Notes |
|---|---|---|
| **Appendix IVA** | Research Activities involving Viral Vectors | • Fill out the Viral Vectors subform provided in this application package. Fill one subform for each viral vector system used. |
| **Appendix V** | Additional Space for Section K-II – Materials in Use | • Only use if you run out of room in Section K-II; do not repeat information already listed in section K-II. |
| **Appendix VI** | Stored Biological Materials | • List ALL biological materials that are stored and not expected to be used during the permit's duration.<br>• **NOTE:** When you wish to start using any of the stored materials, you will need to submit an amendment for review and approval before the work can begin. |
| **Appendix VII** | Provisions for Viable Human Pathogens | • Fill out the subform provided in this application package.<br>• This section serves as a reference for your lab members to ensure that they know the relative risks as well as the appropriate decontamination procedures and emergency measures.<br>• For any viable **pathogenic** Risk Group 2 material, complete all rows<br>**TIPS:**<br>• Specify the concentration and contact time used for the mode of decontamination<br>• Provide references |

## Guide for Completing Appendix IV

Ensure that all biological agents listed in section K-II and Appendix V are included in the description of research activities. Please remember that the reviewers must have sufficient information to assess the risks of the research activities described and they do not have access to previous permits or amendments.

### General Information

Give brief (2-3 sentences) overview or goal of research. What are you trying to show? Test?
For each biological agent in use (similar biological agents may be grouped, e.g. cell lines, tissue, etc.):

1) Describe any potential hazard associated with organism. Is it pathogenic – what about immune-compromised individuals? What procedures are planned (can give list but no need to explain every step of the procedure). Remember to consider the potential of generating aerosols that may spread infectious agents.
2) Will it be used *in vitro*, or also *in vivo*?
3) Will you be working with large volumes?
4) Describe risk mitigation strategy which may include:
    a) Any precautions planned i.e. sharps not allowed.
    b) What physical containment level/engineering controls will be used?

c) Operational requirements, such as: specialized equipment which might include BSC, centrifuge cups with aerosol resistant lids containing O-rings etc.; appropriate PPE; medical surveillance if applicable.
d) decontamination and disposal methods.

## Additional information required for certain biological agents, in addition to the information listed above:

### Human tissues, fluids, primary cells

1) Source of samples: describe the population that the samples are from and any associated risks. Is the population generally healthy? Was the population screened? Is the population known to have pathogens for example are they all positive for HIV?
2) Have the samples been screened for blood borne pathogens? For what pathogens? If screened include certification of screening with permit application.
3) What volume will be handled? Risk increases with large volumes.

### Animal work with biological agents

1) Species
2) Source of the animals – i.e. commercial vendor, in-house, from another institution, pet-trade, wild-caught, or other – describe.
3) If wild-caught, provide geographical location
4) If from pet-trade, wild-caught or other source, list potential zoonoses

### Toxins

1) Briefly describe what you will use the toxin for/how you will use the toxin.
2) Describe deactivation and disposal procedures.

### Crispr/Cas9 systems

Crispr systems are not currently being tracked in our biosafety permits but due to possible regulatory implications we are asking researchers that are or are planning to use Crispr/Cas9 to send us answers to the following questions:

1) Target genes? - Germ lines or somatic cells?
2) Nature of insert
3) Vector?
4) Is the guide RNA and the Crispr together or separate?
5) Is the system dead ended or continuous?

If you are not yet working with Crispr/Cas9 systems, but decide to during the duration of your permit, please send an email to the ehs.biosafety@utoronto.ca informing us of the proposed work and answering the above questions.