UNIVERSITY OF TORONTO

Biosafety Office Use Only
Permit #
Permit Level:
Expiry Date:

BIOSAFETY PERMIT APPLICATION (LEVEL 1 OR 2)

To meet the requirements of The University of Toronto Biosafety Program, a Biosafety Permit must be approved by the Biosafety Office prior to acquiring (purchasing, importing) or conducting work with biological agents. Any proposed changes to the biological agents or the nature of the work must be submitted to the Biosafety Office for approval through an amendment. The Office must be notified by email immediately when there are changes to locations or personnel.

THE BIOSAFETY PERMIT COVERAGE IS LIMITED TO THE INFORMATION DISCLOSED HEREIN.

PLEASE TYPE

A – Principal Investigator

Department | UTORid

Mailing Address

Email

Phone (Office) | Phone (Lab) | Phone (Emerg.)

Primary Affiliation: ○ University of Toronto ○ Other (please specify)

B – Principal Lab Contact

Department | UTORid (if available)

Mailing Address

Email

Phone (Office) | Phone (Lab) | Phone (Emerg.)

C – Application Type	○ **New**	○ **Renewal**		
Permit Type	○ **Research**	○ **Facility**	○ **Teaching**	○ **Storage**
D – Permit Level	○ **Level 1**	○ **Level 2**		

E – Project Title(s) and Funding Sponsor/Granting Agency Name(s)

Project Title					
Funding Agency		Fund/Grant #		Dates Held	
Project Title					
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If space is insufficient, please use Appendix I

F – Project Locations (Including rooms used for storage only, shared equipment rooms, etc.)

Building	**Room No.**	**Room Use** (*e.g.* tissue culture, cold room)	**Containment Level (1 or 2)**

If space is insufficient, please use Appendix II

G – I) Please list all Biological Safety Cabinets (BSCs) to be used and provide the following information:

Make	Class	Type	Building	Room

G – II) BSC(s):

Please attach a copy of report(s) on testing and certification performed within the last 12 months.

H – Lab Personnel

1) All personnel working in the lab must complete EHS601 Laboratory Biosafety and EHS101 WHMIS and Lab Safety, and their respective annual refreshers.
2) Personnel must also complete work-specific courses as applicable to their research. For a full list please refer to the EHS Training Matrix for Lab Personnel.
3) Personnel must complete in-lab training on specifics of their research and training on emergency response procedures.

Name	UTORid	Position	Start Date

If space is insufficient, please use Appendix III

I – Animal and/or Radioisotope Usage in Conjunction with Biological Agents

Please select all that apply from below.

Animal Use

☐ None. No animal work will be conducted in conjunction with biological agents.

☐ Approval Pending. Animal Use Protocol Form submitted for review.

☐ Approved. Please provide the relevant Animal Use Protocol Number(s): _____

☐ Non-primate mammals ☐ Other animals

Radiation Use

☐ None. No radiation will be used in conjunction with biological agents.

☐ Approval Pending. Permit Application submitted for review.

☐ Approved. Please provide the IRPC Permit Number(s): _____

☐ Radioisotope ☐ Irradiator ☐ X-ray ☐ Laser

J – Other Permits and Approvals

Indicate if any other approvals or permits are required for the listed project(s). ○ **YES** ○ **NO**

E.g. REB, CFIA Import permits. If yes selected, submit copies with your application package.

K-I – Biological Agent(s): Check all applicable bioagent categories including for material in use and stored.

See instructions in Appendix IV and Appendix IVA for further information on biological agents that is required in this permit application.

☐ Human tissues and cells	☐ Human blood and blood fractions	☐ Human body fluids
☐ Primary human cell cultures	☐ Established human cell lines	
☐ Animal tissues and cells	☐ Animal blood and blood fractions	☐ Animal body fluids
☐ Primary animal cell cultures	☐ Established animal cell lines	
☐ Bacteria	☐ Parasites	☐ Fungi
☐ Viruses (replication competent)	☐ Non-replicating viral vectors	☐ Recombinant DNA/RNA
☐ Microbial toxins	☐ Other (specify): _____	

K-II – Biological Agents In Use

Please specify the biological agents, toxins and materials that are currently being used in the project(s). Biological agents and materials that are currently **not being used**, but are stored in the laboratory, should be listed separately in Appendix VI.

Descriptive (Full) Name including species	**Scientific Name and Special Features**	**Risk Group** (from ePATHogen or ATCC website)
e.g., Escherichia coli	e.g., DH5-alpha (cloning strain)	e.g., 1
e.g., highly transfectable derivative of human embryonic kidney cells	e.g., 293T (express the transforming region of human adenovirus type 5 and the SV40 large T antigen)	e.g., 2
e.g., human cervical epithelial cell line	e.g., HeLa (express human papilloma virus 18)	e.g., 2
e.g., lentiviral vector particles	e.g., HIV-based vector with no coding sequences for HIV proteins	e.g., 2

If space is insufficient, please use Appendix V.

Microbial Toxins as per PHAC HPTA Schedule 1	**Maximum Quantity (mg)**

K-III – Assessment on the Potential for Dual-Use

Use the Assessment on the Potential for Dual-Use subform provided in the application package.

M – Medical Surveillance

Medical Surveillance is the process of evaluating the health of workers as it relates to their potential exposure in the laboratory to biohazardous agents, monitoring the result of an exposure, and arranging for and monitoring pre- and post-exposure prophylaxis where applicable. Please answer the following questions with respect to all biological agents listed on the permit.

1. Is medical surveillance, immunoprophylaxis and/or vaccine available/indicated for any of the biological agents or biological toxins listed on this permit?

- ◯ Yes
- ◯ No

2. Does your research involve biological agents or biological toxins with pre- and post-exposure prophylaxis (e.g., SARS CoV-2, HIV, Human T-lymphotropic virus (HTLV), Hepatitis A, Hepatitis B, Hepatitis C, Listeria, Mycobacterium tuberculosis, Q-fever (Coxiella), Rubella, Toxoplasma, Diptheria, Vaccinia and/or Varicella)?

- ◯ Yes
- ◯ No

3. Does your research involve animals other than purpose-bred laboratory rodents, that might pose a risk of zoonotic pathogens.

- ◯ Yes
- ◯ No

4. Does your research involve human or non-human primate organs, tissues, whole blood, blood products and/or body fluid.

- ◯ Yes
- ◯ No

5. I have made all current lab members aware of the Workplace Screening Tool for Pregnant Workers, and have instructed them to consult with U of T Occupational Health at ehs.occhealth@utoronto.ca upon completing the form. I will ensure that all future incoming lab members receive the same information and guidance.

- ◯ Yes
- ◯ No

6. Have you informed all individuals in the lab, that if they are or become immunocompromised, they must consult with Occupational Health at U of T at ehs.occhealth@utoronto.ca.

- ◯ Yes
- ◯ No

N – Declarations

All researchers and their respective Departmental Chair/Faculty Dean or official designate must sign below.

As the **Principal Investigator** on this project, I declare that I am familiar with the contents of the **University of Toronto Biosafety program**, and that the above describes my research program, insofar as this includes the use of hazardous biological agents and materials, in its entirety. As the legally responsible individual I will ensure that all research and/or teaching conducted under my direction in the above laboratories and by the personnel listed, conforms to the standards set out in the **Biosafety Guidelines at the University of Toronto**, *as well as* provincial, federal and international policies and regulations that govern research involving biological agents. Any major deviation from the project, as originally approved, will be submitted to the biosafety office for review and approval by the Biosafety Review Committee prior to its implementation.

Name of Principal Investigator	Signature	Date

As the **Departmental Chair/Faculty Dean**, I am aware of the proposed activity. My administrative unit will follow guidelines and procedures which ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research with biological agents.

Name of Chair/Dean (or designate)	Signature	Date

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	Signature	Date
Subject Matter Expert (if applicable)		
University Biosafety Committee Veterinary Reviewer (if applicable)		
University Local Biosafety Committee Member		
University Local Biosafety Committee Chair		
University Biosafety Officer		

Conditions and/or Comments:

APPENDICES

APPENDIX I

E – Project Title(s) and Funding Sponsor/Granting Agency Name(s)

Project Name ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Name ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

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Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

APPENDIX II

F – Project Locations (including rooms used for storage only, shared equipment rooms, etc.)

Building	**Room No.**	**Room Use** (*e.g.* tissue culture, cold room)	**Containment Level (1 or 2)**

APPENDIX III

H – Lab Personnel

Name	UTORid	Position	Start Date

APPENDIX IV

Research Activities involving Biological Agents

Please use a WORD document to briefly outline the procedures which involve the use of biological agents including procedures involving animals used in conjunction with biological agents for each project. For work involving viral vectors, follow instructions in Appendix VIA.

Instructions for Appendix IV

1) See guidelines provided by EHS for Appendix IV
2) Use a WORD document to outline the goal(s) and overview of the procedures used for each project and submit along with your permit application package.
3) Provide sufficient detail so that the Local Biosafety Committee reviewer can understand and evaluate the work without having to resort to external sources.
4) For protocols that are not widely used, include a reference.

APPENDIX IVA

Research Activities involving Viral Vectors

Use the Viral Vectors subform (provided in the application package) to describe details of the viral vectors employed.

Fill one subform for each vector system used.

APPENDIX V

Materials in Use (continued from section K-II)

List the biological agents and/or materials currently used in the project(s). If additional space is required, please submit as an excel document.

Descriptive (Full) Name including species	Scientific Name	Risk Group (from ePATHogen or ATCC website)
e.g., Escherichia coli	e.g., DH5-alpha (cloning strain)	e.g., 1
e.g., highly transfectable derivative of human embryonic kidney cells	e.g., 293T (express the transforming region of human adenovirus type 5 and the SV40 large T antigen)	e.g., 2
e.g., human cervical epithelial cell line	e.g., HeLa (express human papilloma virus 18)	e.g., 2
e.g., lentiviral vector particles	e.g., HIV-based vector with no coding sequences for HIV proteins	e.g., 2

APPENDIX VI

Stored Materials

List the biological agents and/or materials stored and **not** currently used in the project(s).

Descriptive (Full) Name including species	Scientific Name	Risk Group (from ePATHogen or ATCC website)
e.g., Escherichia coli	e.g., DH5-alpha (cloning strain)	e.g., 1
e.g., highly transfectable derivative of human embryonic kidney cells	e.g., 293T (express the transforming region of human adenovirus type 5 and the SV40 large T antigen)	e.g., 2
e.g., human cervical epithelial cell line	e.g., HeLa (express human papilloma virus 18)	e.g., 2
e.g., lentiviral vector particles	e.g., HIV-based vector with no coding sequences for HIV proteins	e.g., 2

APPENDIX VII

Provisions for VIABLE human pathogens

It is important for people working with pathogens to be aware of symptoms of infection so that should they become infected, appropriate action can be taken. The information requested in the boxes refers to that for humans. EHS suggests using PSDS, CDC, or Public Health Ontario.

Please list the following criteria for pathogenic risk group 2 agents listed in **Section K-II:**

	Infectious Agent 1	**Infectious Agent 2**	**Infectious Agent 3**	**Infectious Agent 4**	**Infectious Agent 5**
Name of Biological Agent					
Mode of Transmission					
Incubation Period					
Period of Communicability					
Infectious Dose					
Typical Presenting Symptoms					
Mode of Decontamination					
Emergency Response					