POST THIS CERTIFICATE IN THE WORK AREA

UNIVERSITY of TORONTO

Biosafety Office Use Only
Certificate #
Containment Level:
Expiry Date:

BIOSAFETY CERTIFICATE

To meet the requirements of The University of Toronto Biosafety Program, a Biosafety Certification Form must be approved by and filed with the Biosafety office prior to purchasing, importing or conducting projects involving biohazards. Any proposed changes, e.g. personnel, biohazardous agent, location, decommissioning or changes affecting the required level of containment in authorized biohazard projects, shall be submitted to the chair of the Biosafety Committee for approval prior to implementing the changes. THE BIOSAFETY CERTIFICATE COVERAGE IS LIMITED TO THE INFORMATION DISCLOSED HEREIN.

PLEASE TYPE

A- Principal Investigator _____ Personnel No. _____

Department _____ Rank/Position _____

Mailing Address _____

Email _____

Phone (Office) _____ Phone (Lab) _____ Phone (Emerg.) _____

B- Principal Lab Contact _____ Personnel No. _____

Department _____ Rank/Position _____

Mailing Address _____

Email _____

Phone (Office) _____ Phone (Lab) _____ Phone (Emerg.) _____

C- Certificate Type ○ New ○ Renewal ○ Amendment

D- Proposed Level of Containment ○ Level 1 ○ Level 2 ○ Level 3

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

Project Title					
Funding Agency		Fund/Grant #		Dates Held	
Project Title					
Funding Agency		Fund/Grant #		Dates Held	
Project Title					
Funding Agency		Fund/Grant #		Dates Held	
Project Title					
Funding Agency		Fund/Grant #		Dates Held	
Project Title					
Funding Agency		Fund/Grant #		Dates Held	

*** If space is insufficient, please use Appendix I***

F- Project Locations

Facility/Building	Room No.	Containment Level (1-3)

*** If space is insufficient, please use Appendix II***

G- I) **Please list all Biosafety Cabinets (BSC)to be used and provide the corresponding information:**

Make	Class	Type	Building	Room

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

H. Lab Personnel: A one-day Biosafety Training Course, offered by the University of Toronto's Office of Environmental Health and Safety, is mandatory for faculty, graduate students, research technicians / technologists, research assistants / associates, postdoctoral fellows, undergraduate students and volunteers. ***Check Y if the staff member has completed the biosafety course**.*

NAME	TITLE/POSITION	PERSONNEL/STUDENT #	APPOINTMENT DATE	TRAINED YES	TRAINED NO
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○

*** If space is insufficient, please use Appendix III.***

I- Animal and/or Radiation Usage with Biological Agents. Indicate usage by marking appropriate boxes. Please use attachment provided, **Appendix IV**, to briefly outline those procedures which involve animals used in conjunction with biological agents in the project(s).

Animal Usage

○ None. No animals will be used in the identified project(s).

○ Non-human primates ○ Non-primate mammals ○ Other animals

○ Approved. Please provide the relevant Animal Research Protocol Number(s) _____

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

Radiation Usage

○ None. No radiation will be used in the identified project(s).

○ Radioisotope ○ Irradiator ○ X-ray ○ Laser

○ Approved. Please provide the UTRPA Permit Number(s) _____

○ Aprroval Pending. Permit Application submitted for review.

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

If `yes', please attach a copy of the approval or permit.
(eg. Regulatory Agency Permit, hospital or other institution's Biosafety Certificate).

K. I) Biological Agent(s). Indicate by checking the relevant boxes.

*** For activities requiring Containment Level 2 or greater, please use attachment provided, Appendix IV, to briefly outline those procedures which involve the use of biological agents.***

☐ 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 ☐ viruses ☐ fungi ☐ parasites ☐ microbial toxins
☐ recombinant DNA/RNA ☐ other (specify) _____

K. II) Please specifiy the biological agents and materials that are presently 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 V-1***

Common Name	Scientific Name /Species	Risk Group

*** If space is insufficient, please use Appendix V.***

**** For biological agents in risk group 2 or 3 that are VIABLE HUMAN PATHOGENS, please complete Appendix VI. ****

L. Immunizations.

	Y	N
1) Are the organisms VIABLE human pathogens? (Organs, tissues, blood and body fluids might contain other, unintentional harmful microbes). **If YES, proceed to question 2**.	○	○
2) Is medical surveillance, immunoprophylaxis and/or vaccine available/indicated? **If Yes, complete questions 3-5.**	○	○
3) Have ALL personnel been apprised of the hazards and appropriate precautions/preventative measures?	○	○
4) Have the lab personnel been vaccinated with the available agents?	○	○
5) Do you have a Certificate of Clearance from Occupational Health for each affected investigator?	○	○

NOTE: A ***certificate amendment*** is required for any significant changes in biohazard usage, research projects, personnel, research location, as well as **inclusion of any organism(s), previously stored, into any of the aforementioned projects**.

Researchers are responsible for removing and properly disposing of all their biological agents prior to submitting a formal request for decommissioning.

M. Declarations.

All researchers and their respective departmental Chair/Dean or 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 Manual, 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, 2007, *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 Chair for approval prior to its implementation.

Name of Principal Investigator	**Signature**	**Date**

As the **Departmental Chair/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 utilizing Biological agents.

Name of Chair/Dean (or designate)	**Signature**	**Date**

For Biosafety Office Use Only

Select: AP (Approved) , CA (Conditionally Approved) , RS (Review and Resubmit)

Local Biosafety Co-ordinator	Univeristy Biosafety Officer	University Biosafety Committee Chair or Appointee
○ AP ○ RS	○ AP ○ RS	○ AP ○ CA ○ RS
Date	Date	Date

Conditions and/or comments:

Revised January 2007

APPENDICES

APPENDIX I

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

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

Project Title ______________________________

Funding Agency ______________ Fund/Grant # ______________ Dates Held ______________

F- Project Locations

Facility/Building	Room No.	Containment Level (1-3)

APPENDIX III

H. Lab Personnel: *Check Y if the staff member has completed the biosafety course.*

NAME	TITLE/POSITION	PERSONNEL/STUDENT #	APPOINTMENT DATE	TRAINED YES	/ NO
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○
				○	○

APPENDIX IV

For Sections I and K - Protocols Used with Biohazardous Agents

Please use the space provided to briefly outline those procedures which involve the use of biological agents including those procedures involving animals used in conjunction with biological agents for each project.

Please type within space provided below

APPENDIX V- MATERIALS IN USE

List the biological agents and/or materials currently used in the project(s).

Common Name	Scientific Name /Species	Risk Group

APPENDIX V.i - STORED MATERIALS

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

Common Name	Scientific Name /Species	Risk Group

APPENDIX VI

Provisions for VIABLE human pathogens

Please list the following criteria for pathogenic risk group 2 and 3 agents indicated in **Section J:**

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

Suggested References: Control of Communicable Diseases Manual , 18th ed., David L. Heymann, APHA; MSDS/Health Canada Online; CDC.

EXPLANATORY NOTES - BIOSAFETY CERTIFICATE APPLICATION FORM

A valid UniversityofToronto Biosafety Certificate is required for all University laboratory activities which involve the use and/or manipulation of potentially hazardous biological agents and materials containing such agents. This includes work with **ANY** bacteria, viruses, fungi, parasites, prions, natural and recombinant DNA & RNA, human and animal tissues and cells, and human and animal blood and body fluids. This requirement applies to activities that are conducted on University premises or in a building or location administered by or under the control of the University, irrespective of the source of the funds used to support this activity.

Biological agents need not be overtly pathogenic; even the manipulation of biological agents which are unlikely to cause disease in healthy workers or animals requires Containment Level 1 laboratory conditions and safety practices as a minimum.

The U of T Biosafety Certificate coverage is limited to the information that is disclosed in the application form and its attachments (i.e., project titles, work locations, biological agents, and experimental procedures). Undisclosed projects and work are not covered.

Please **type** required information and fill out the Biosafety Certificate application form as completely as possible. Please bear in mind that the reviewers must perform a risk assessment and make a decision based solely on the information disclosed in the application form. Application forms that are illegible or lack the required information will be rejected and returned to the applicant, unsigned.

In general, a single application form may be completed to identify several projects requiring Containment Level 1 and Containment Level 2 laboratory conditions. However, all projects and activities that require Containment Level 3 laboratory conditions must be identified on a separate application form to clearly distinguish these from all other projects and activities that require a lower Containment Level.

Additional space is provided in the appendices if necessary for application sections: E, F, H, I & K.

A. Principal Investigator:

Only one Principal Investigator/research director's name is allowed per application form. Generally, this is the lead investigator, or the first person named in a proposal or award.

U of T Department Affiliation and Rank:

Indicate theUniversityofToronto affiliation, and the type of appointment (i.e., Full, Associate, Assistant Professor).

B. Co-PI/Principal Lab Contact:
If applicable, indicate collaborator or secondary investigator responsible for proposed research, or principal senior lab contact (director/supervisor) responsible for the ongoing daily lab activities.

C. Certificate type:
Indicate type of application enclosed.

D. Proposed Level of Containment:
Indicate the highest levels required for research project(s).

E. Project Titles and Funding:
Project titles must be clearly stated on the application form in Section E. Funding agencies must be named in full; please avoid the use of acronyms. Project titles must be matched with the name of the corresponding sponsor or granting agency funding that activity. Research proposals that have not yet been submitted to a granting agency, or which have not yet been funded, may also be identified on the application form. All sources of financial support for the identified projects and activities, whether internal or external, should be identified. Financial details are not required. Activities involving biological agents and materials that are not directly supported by grants or contracts must also be reported on aUniversityofToronto Biosafety Certificateapplication form.

F. Facilities Location:
All laboratory facilities used by the Principal Investigator and his/her group, for activities using biological agents and materials, must be listed, regardless of whether these facilities are shared with other researchers. The physical bio-containment levels and the mechanical systems, operational protocols and laboratory waste disposal facilities whose usage are proposed by the Biosafety Certificate applicant, must be surveyed in order to confirm compliance with the University of Toronto's Biosafety Policies and Procedures Manual. Submission of a Biosafety Certificate Application form implies consent for laboratory visits by the U of T Biosafety Officer.

G. Biosafety Equipment:
Biological safety cabinets are required for level 2 or greater containment laboratories. Biological safety cabinets must be tested and approved for use annually, unless otherwise noted. For each biological safety cabinet, attach a photocopy of the testing and certification report issued within the previous 12-month period. If testing has not been performed within the past year, or if the test report is more than 12 months old, please make arrangements for re-testing and indicate the scheduled retesting date on the application form. For information about this testing, please consult the U of T Biosafety Policies and Procedures Manual or the U of T Biosafety home page at:

http://www.ehs.utoronto.ca/Programs_and_Services/biosafety.htm

H. Lab Personnel:
The names of all persons, including undergraduate and summer research students, directly involved with biological agents and materials in the identified project(s) of the Principal Investigator must be listed on the application form and/or its attachments. Principal Investigators should ensure that all listed personnel attend the UniversityofToronto Biosafety Trainingcourse prior to their addition to the project(s). After the approval and issue of aUniversityofToronto Biosafety Certificate, the addition of new lab personnel must be disclosed to the Biosafety Office as soon as possible, by the Principal Investigator, in order to amend the existing Biosafety Certificate.

Course information and training dates are available on the U of T Biosafety home page at: **http://www.ehs.utoronto.ca/Programs_and_Services/biosafety.htm**

I. Identification of Animal and/or Radioactive Material Use with Biological Agents:
Indicate by marking the appropriate boxes, whether or not animals will be used in conjunction with biological agents in the identified project(s). Provide the U of T Animal Use Protocol Number(s). **Provide a brief outline** that identifies only those experimental procedures and activities that involve the use of biological agents in or with animals.
Indicate by marking the appropriate boxes, whether or not radiation / radioactive materials will be used in conjunction with biological agents in the identified project(s). Provide the UTRPA Permit Number. **Provide a brief outline** that identifies only those experimental procedures and activities that involve the use of biological agents with radioisotopes or other radiation sources, including x-rays and lasers.
Please limit outlines to less than one page per project on the attachment provided in appendix IV.

****Attaching summary pages from grant applications is not acceptable****.

J. Other Agency / Institution Approval or Permit:
If the project(s) require the approval of a regulatory agency (i.e. Public Health Agency ofCanada[formerly Health Canada], Agriculture and/orAgri-FoodCanada, Canadian Food Inspection Agency), a **photocopy** of the approval or permit must be provided. If the project(s) are in collaboration with a non-U of T facility (i.e., a hospital, institution, or other external facility), a **photocopy** of that facility's biosafety certificate or biosafety approval notification must be provided. All supplementary external approvals/permits must accompany theUniversityofToronto Biosafety Certificateapplication form.

K. Identification of Biological Agent(s):
Indicate the kinds of biological agents and materials that will be used by marking the appropriate boxes. Specify the biological agents and materials by providing the common and scientific names, and the strain identifications or alphanumeric designations, if available.

Organism Lists and Material Safety Data Sheets for some biological agents that are commonly used or are representative of a group, are available via the Public Health Agency of Canada (formerly HealthCanada) website, or via the U of T Biosafety home page. These or the ATCC website may be consulted to determine the applicable containment level(s), dependent on their risk group categorization.

Identification of human and animal tissues, cells and blood must indicate the species, whether these are primary isolates or established lines, and whether these contain, or may contain, oncogenic viruses or other biological agents.

For project work requiring level 2 or greater containment conditions, please provide **a brief outline** identifying the experimental procedures, activities and manipulations that involve the biological agents and materials used in the project(s). Please limit outlines to less than one page per project on attachment provided in appendix IV.

****Attaching summary pages from grant applications is not acceptable.****

When standard recombinant DNA / RNA techniques are used and the source of the genetic material being transferred, the vector (if any), and the recipient host are all innocuous or have low risk characteristics, then no additional details are required beyond the identification of the biological agents used. However, if there is potential for generating recombinant micro-organisms that may pose an elevated level of risk, or if any of the constituent parts pose a higher risk (i.e., requiring level 2 or greater containment conditions), then full disclosure is required and a brief outline identifying the experimental procedures and activities must be attached to the application form, for review by the Biosafety Committee.

In general, all laboratory activities involving **human** tissues, isolated cells, blood and blood fractions must be conducted at a minimum of level 2 containment conditions. In some circumstances, work with these materials may be conducted at a lower containment level. However, in such a case, the Principal Investigator must provide, with his Biosafety Certificate application form, supporting documentation justifying this request for review by the Biosafety Committee. For example, if the use of a biological safety cabinet is not possible, then all other laboratory conditions, procedures and practices should comply with all of the remaining requirements for Containment Level 2.

For organisms being stored in the laboratory, but not currently being used in the titled project(s), a separate listing should be produced on the attachment provided in appendix V-1, and submitted with the application form. **Prior to the re-introduction of these stored organisms for active usage in the laboratory, a certificate amendment must be submitted.**

For all biological agents in risk group 2 or 3 that are **viable human pathogens**, Attachment *R* must be completed and made accessible to all lab personnel directly involved with the biological agents in the identified project(s). Lab personnel should be informed about the specific criteria identified on Attachment *R* for each pathogen to which they are exposed, including its mode of transmission, incubation period, infectious dose, typical presenting symptoms, decontamination and emergency procedures.

L. Immunization:

The Principal Investigator should *encourage* personnel in her/his laboratory to obtain immunization with relevant licensed immunizing agents to provide protection against laboratory acquired infections by the biological agent(s) used in the project(s). Immunization against a biological agent will decrease, but not necessarily eliminate the risk of infection by that particular agent. **Hepatitis B immunization is strongly recommended** as a precaution for all personnel who handle or are exposed to **human** blood, blood fractions, body fluids, organs, tissues and isolated cells.

Immunoprophylaxis and information regarding the availability and the advisability of immunizing agents are available through theUniversityof Toronto Healthand Well-being Service at (416) 978-4476.

Licensed immunizing agents are available to protect persons against:

Anthrax	Lyme disease	Rabies
Botulism	Measles	Rubella
Cholera	Meningococcus	Tetanus
Diphtheria	Mumps	Tuberculosis (BCG)
Hemophilus influenzae type b	Pertussis	Typhoid
Hepatitis A	Plague	Vaccinia
Hepatitis B	Pneumococcus	Varicella
Influenza A	Polio	Yellow fever
Japanese encephalitis		

If licensed immunizing agents are AVAILABLE for use, please indicate responses by marking the appropriate boxes. Personnel should get a Certificate of Clearance from Occupational Health prior to working with any infectious agents.

M. Declaration:
By signing this declaration, the Principal Investigator acknowledges full responsibility for the project(s) and activities under her/his supervision, and agrees to maintain and operate her/his laboratory facilities in compliance with the University of Toronto's Biosafety Guidelines and Procedures Manual.

By signing this declaration, the departmental Dean/Chair acknowledges the responsibility of her/his administrative unit to follow the guidelines and procedures compliant with all relevantUniversityof Toronto Biosafety Program Guidelines.

Submission, Review and Approval:
As a precaution, it is recommended that you retain a copy of your application form and its attachments, for your own records. The completed, signed (original ink signature) application form must be submitted to the Local Biosafety Coordinator who has jurisdiction over thatUniversityofToronto building or location. The application form should then be forwarded to theUniversityofToronto Biosafety Office, 7th floor,215 Huron Street,Toronto. An electronic copy of the application form including all attachments should be sent to the Biosafety Officer.

After the application form has been fully approved and processed on R.I.S., a photocopy of the University of Toronto Biosafety Certificate application form including the attachments specifying additional project titles, personnel or lab locations, will be sent to the Principal Investigator for her/his information and records. The Biosafety Certificate number, the containment level and the expiry date will be displayed at the bottom of the front page. The signed original application including all attachments and photocopies will remain on file with the Biosafety Office.

Biosafety Certificate Validity, Expiration, Coverage and Amendments:
UniversityofToronto Biosafety Certificatesfor projects and activities requiring containment level 1 are valid for 2 calendar years from the date of approval by the University Biosafety Committee Chair. University Biosafety Certificates for projects and activities requiring level 2 or 3 containment conditions are valid for 1 year only. The U of T Biosafety Committee reserves the right to approve Biosafety Certificates `conditionally' or for a shorter period.

If the Principal Investigator intends to continue working with biological agents beyond the Certificate expiry date, then a renewal Biosafety Certificate application form must be completed and submitted for review by the U of T Biosafety Committee.

The intention to cease all projects and/or research activities must be officially submitted, by the Principal Investigator, to the Biosafety Office subsequent to suitable decontamination of the laboratory and removal of the related signs.

An approved U of T Biosafety Certificate covers only the projects, activities, work locations, biological agents and materials that are disclosed and identified on the application form and its attachments. Significant changes (i.e., use of additional biological agents and materials, additional project(s) or work locations, new personnel, animal use) must be reported to the University Biosafety Office as soon as possible, so that the current Biosafety Certificate may be amended.

A **request for an amendment** of a currentUniversityofToronto Biosafety Certificateshould be submitted to the Biosafety Committee Chair. The savable format of the application allows the PI to make amendment requests directly on the original form. The Biosafety Certificate applicant should indicate on the first page if the application is a request for an amendment. The entire Biosafety Certificate application form should then be resubmitted with the corresponding description of the requested amendment(s) to the Biosafety Office, 215 Huron Street, 7th floor, Toronto, ON, M5S 1A2; Telephone: (416) 978-4467. An electronic copy of the application form including all attachments should be sent to the Biosafety Officer.

Assistance, Information, and the World Wide Web:
TheUniversityofToronto Biosafety Programis available via the Biosafety home page at:

http://www.ehs.utoronto.ca/Programs_and_Services/biosafety.htm

This website provides hyperlinks to theUniversityofTorontoBiosafety Policies and Procedures Manual, the names and contact information of the Local Biosafety Coordinators, a link to the Public Health Agency of Canada's Material Safety Data Sheets for biological agents, and other biosafety-related information. Questions, still unanswered after consulting this website, and requests for assistance, should be directed to:

University Biosafety Officer, at (416) 978-3981, or
University Biosafety Secretary, at (416) 978-4467