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| Revision: 5.0 | Subject: Biohazard Permit Application Process | |

To ensure compliance with the Laboratory Biosafety Guidelines (Public Health Agency of Canada), and/or the Containment Standards for Veterinary Facilities (Canadian Food Inspection Agency), and/or the Tri-Council Policy Statement and/or the conditions of other granting agencies, a Queen's University Biohazard Permit is required for all research and teaching activities which involve the use, manipulation and storage of biohazardous material (including, but not limited to, viruses, bacteria, fungi, parasites, recombinant DNA, biological toxins, prions and other micro-organisms/genetic systems, and human and animal tissues, cells, blood and body fluids), and which are:

1. supervised or conducted by employees or members of the University, or
2. conducted on University premises, or in a building or location administered by or under the control of the University, or
3. supported by funds provided by or through the University

An application for a Queen's Biohazard Permit is a two-stage process. The first stage is the review and approval of the research or teaching activity. The second stage is the inspection and approval of the laboratory or facility where the work will be conducted.

An approved permit is valid for a maximum of four years, authorizes usage of and protocols involving only those biohazardous materials listed in the permit, and requires annual renewal for each of the three years following the first year. A new application is required after three renewals.

Application Process

1. To obtain a biohazard permit, complete the Biohazard Permit Application form, available on the Environmental Health & Safety (EH&S) website. The application consists of two parts, a fillable form and a separate summary.
2. Complete the relevant sections of the fillable part of the application. The required information must be printed or typed legibly on the application form and appended pages as required.
3. A summary statement is needed to show that you are fulfilling the requirements of the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) that each laboratory perform a detailed risk assessment to determine the biohazard containment level for both facilities and operational practices for the biohazardous agents in use. **Attach to this application a summary of your biohazard risk assessment describing the biohazard risks of the material, the risks associated with the techniques or procedures that will be used to manipulate it, and the**



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methods employed to mitigate these risks. This must be completed for the application to be approved. A carefully written one to three page document should generally be sufficient to summarize the required risk assessment. **The following guidance is provided:**

Indicate the Risk Group to which you think the biological agent/material should be assigned. If available, you can support this classification by providing an accepted Risk Group classification and documentation such as a relevant MSDS, and/or product information from a commercial source (ATCC/Company of Origin) for each biohazardous agent listed in the application.

Canadian MSDS's can be reviewed at: <http://www.phac-aspc.gc.ca/msds-ftss/>
 ATCC information can be obtained from <https://absa.org/>. The Association for Biosafety and Biosafety Security (ABSA) summary of Risk Group classifications from a number of countries: <https://my.absa.org/tiki-index.php?page=Riskgroups>

If a risk group has not been published for the biological agent/material, then indicate the group to which you think it should be assigned and provide a rationale. Factors influencing the assignment to a risk group include: pathogenicity/virulence, infectious dose, mode of transmission, transmissibility, environmental stability, host range, endemicity, vectors if applicable (e.g. mosquitoes for malaria), recombinants, and availability of prophylactic and therapeutic treatments.

For each infectious agent in use, provide a description of the host range, and indicate whether (how) the agent is attenuated. If applicable, for example for viral vectors, indicate whether (and how) the agent is attenuated or rendered replication defective and any other safety features that have been engineered into the agent or system (including the packaging cells) to reduce the probability of generating replication competent virus. If recombinant plasmids, viruses, cell lines or organisms are in use or created, describe the biology of the transgene(s) (if any) and indicate whether it poses any potential or known biohazardous threat.

If recombinant organisms are in use or created, list them, and indicate whether they pose any additional or known biohazardous threat beyond that of the non-recombinant or parental strain.

Because the **procedures employed during manipulation of a particular organism may alter the containment requirements** from that suggested by the risk group to which it has been assigned, please ensure that sufficient information is provided in the summary to allow the committee to determine the containment level required for each biohazardous material being used in your project. The information should be organized in a project-based format if the application contains multiple projects that may or may not be funded by different sources. The committee requires information concerning purpose, experimental/manipulation procedures, techniques for containment and handling,



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transport, storage, and disposal. Please indicate how you will ensure that the material is inactivated prior to leaving containment.

Indicate what laboratory specific **training** in handling of biohazardous material is provided.

4. Submit the completed Biohazard Permit Application to the Department of Environmental Health & Safety. The application will be reviewed by the Biosafety Officer, and then by Biohazard Committee at the next scheduled meeting. A list of meeting dates and corresponding application submissions deadlines is available on the EH&S website.

In order for an application to be reviewed by the Biosafety Officer, amended if required, and subsequently reviewed by the Biohazard Committee, it must be submitted by the deadline, which is four weeks before the next scheduled meeting. Failure to meet the application deadline will result in the application being deferred to the next meeting.

5. Once approved by the Biohazard Committee, a Biohazard Permit, conditional on an inspection of the laboratories or facilities where the research or teaching activity will be conducted, will be issued to the Principal Investigator. The covering letter containing information related to granting agency, grant number and title of the approved project will be copied to the Office of Research Services.
6. A copy of the Biohazard Permit and the original copy of the application will be placed on file in the Department of Environmental Health & Safety.

Laboratory/Facility Inspection:

The issuance of a Biohazard Permit is conditional on an inspection of the laboratories or facilities where the research or teaching activity will be conducted. Inspections will be conducted by members of the Biohazards Committee using the Public Health Agency of Canada Laboratory Biosafety Guidelines (3rd Edition), and/or the Containment Standards for Veterinary Facilities (Canadian Food Inspection Agency).

Failure to have the laboratory or facility inspected before work with the biohazardous material begins will result in the suspension or revoking of the Biohazard Permit, and the Queen's Office of Research Services will be notified.



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When approval to use or possess biohazardous material is granted and the laboratory or facilities listed in the application has a current inspection record on file, then no further action is necessary and the research or teaching activities can proceed.

Conditions of Approval:

The approval granted by the issuance of a biohazard permit is **limited** to those materials, personnel, and facilities specifically stated in the biohazard permit.

Biohazard Permit Amendments:

Changes to the approved biohazard permit must be communicated to the Biohazard Committee through the Biosafety Officer in the Department of Environmental Health & Safety. Amendments may be reviewed and approved by the Biosafety Officer prior to the meeting of the Committee, unless the amendments are considered “significant” as described below. Such changes may be made to existing approvals using the amendment form available on the EH&S website.

The following changes can be made with the amendment form:

- Addition and/or deletion of research project titles.
- Changes in approved laboratory space (new laboratory space is subject to an inspection to approve the space).
- Addition and/or deletion of biohazardous material, if it is similar in nature/type to the material listed on the permit. For example, the addition of a cell line that has a similar containment requirement and risk profile to those cell lines listed on the permit.
- Addition of personnel

A “significant amendment” would include new biohazardous material that differs in type from that already approved (e.g. mammalian or insect cell lines when only bacteria had been previously approved); or material that requires a containment level higher than the current permit stipulates; and/or significant changes to experimental protocols and/or procedures. A “significant” amendment requires the use of the Biohazard Permit Application form and will be reviewed by the Biohazard Committee.



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The request to amend a biohazard permit must include assurance that the new protocols do not differ in the type or level of associated risk than those previously approved. Safety procedures different from those previously approved should not be required. (e.g. if the risk of a procedure is the generation of aerosols of a level 2 organism that requires the use of a Biological Safety Cabinet, and if this type of risk and the use of a Biological Safety Cabinet has already been approved, then continue using the amendment form; otherwise use the Biohazard Permit Application form for what is considered a significant amendment).

In order to delete authorized personnel from the permit, an e-mail should be sent to the Department of Environmental Health & Safety (safety@post.queensu.ca).

In the event that the Public Health Agency of Canada and/or the CFIA impose additional operational or containment conditions in an importation permit issued to a Principal Investigator, the issued biohazard permit must be amended to include the new conditions (use the amendment form).

A copy of the approved amendment form will be sent to the Principal Investigator and the Office of Research Services. The approved amendment form will be placed on file in the Department of Environmental Health & Safety.

Biohazard Permit Annual Renewal:

Every Biohazard Permit must be renewed on an annual basis. A notification to renew a biohazard permit will be sent by the Department of Environmental Health & Safety.

Renewals can be submitted using the Biohazard Permit Renewal form available on the EH&S website. Renewal forms will be reviewed and may be approved by the Biosafety Officer. Prior to approving the renewal, the Biosafety Officer will check that issues raised due to annual laboratory inspections have been addressed and that applicable training or refresher training are up-to-date for all personnel. If there are changes in the permit (other than personnel and project title) then a Biohazard Amendment Application form or a Biohazard Permit Application form must be submitted.

An approved permit is valid for a maximum of four years and requires annual renewal for each of the three years following the first year. After three renewals, the Principal Investigator must complete and submit a new application for review and approval, if the project is still in progress.

Biohazard Permit Cancellation



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If a project that involves the use of biohazardous material is terminated, it is the responsibility of the Principal Investigator to inform the Biohazard Committee through the Department of Environmental Health & Safety. The approved Biohazard Permit will then be cancelled.

Suspension and/or Revocation of Biohazard Permits:

The Department of Environmental Health & Safety and the Biohazard Committee reserve the right to suspend and/or revoke Biohazard Permits should the Principal Investigator be found engaging in activities not specified in or contrary to the approved protocol. All such activities relating to the research will be suspended as will access to research funds until such time the Biohazard Permit is reinstated or reissued. The Queen's Office of Research will be notified of such situations.

Information and Enquires:

For further information regarding Biohazard Permits, contact the University Biosafety Officer at ext. 77077 or by e-mail at Shelagh.Mirski@queensu.ca

Revision History

- Revision 1.0: February 2006 – Draft
- Revision 2.0: April 2006 – Initial Release
- Revision 3.0: July 2006 – Revision
- Revision 4.0: July 2006 – Revision
- Revision 5.0: April 2007 – Revision