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OFFICE OF THE
VICE-PRESIDENT (RESEARCH)



File Ref:

Biohazards Containment Certification Report of the Biohazards Safety Committee

Required for all Applications Proposing Research involving Biohazards

Research and teaching projects involving micro-organisms known to be pathogenic to humans, plants or animals and projects involving recombinant DNA, and some genetically modified organisms, may not be undertaken unless the proposed project has been found acceptable by the Biohazards Safety Committee operating in accordance with the Health Canada *Laboratory Biosafety Guidelines*, 3rd ed., 2004. Research/teaching projects involving biohazards must be carried out under the required level of containment facilities.

The University Biohazards Safety Committee has examined the application for approval of projects involving biohazards, entitled:

submitted by: _____
Principal Investigator Department

to: (indicate granting or contracting agency, if appropriate) _____

and certifies that the proposed research/teaching project may be carried out under containment conditions meeting level _____.

This approval is subject to the following:

**This certificate is valid for two years from date of issue
and is subject to annual inspection of facilities.**

**The University grants approval for this project and certifies that it will monitor
adherence to these guidelines.**

Chair, Biohazards Safety Committee

University Representative

Date



Application for Approval of Projects Involving Biohazards

Principal Investigator: _____ **Phone No.:** _____

Title: _____ **Department:** _____

List all rooms and buildings where biohazards are to be used: _____

University Campus: _____
Fredericton Saint John

Project Title: (Attach copy of application to external funding agency, if appropriate) _____

Level of Containment: 1 2 3 4

Refer to Appendix B and/or the Health Canada *Laboratory Biosafety Guidelines* "Chapter 2" to determine required levels of containment.

Nature of Biohazard: Please state the species, cell types (bacterial, fungal, viral) parasites, plasmids, types of recombinant DNA, GMO, or other infectious agents known to be pathogenic to humans, plants or animals which will be used in this project; also indicate the supplier(s) of these materials. For recombinant DNA experiments, if moderate (Level II) or high (Level III) biological containment levels are not used, please state why.

If using any of the viruses indicated in Table 5 (page 33) of the 1980 MRC Design Operation & Maintenance Supplement to the Guidelines for Handling of Recombinant DNA Molecules & Animal Viruses & Cells, please enclose a copy of the letter of permission from Agriculture and Agri-Food Canada.

The Biohazards Safety Committee, together with the undersigned principal investigator, have examined the application for approval of the above-mentioned project, on matters relating to laboratory procedures, and certify that:

- a) the principal investigator and his collaborating staff have read and understand the *Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells* (1977) and the *Supplement* (1980) and the *Laboratory Biosafety Guidelines, 3rd ed.*, 2004; and are apprised of the nature of containment required for different types of research. **List all collaborating staff on Appendix A.**
- b) the laboratory procedures to be used comply with the safety precautions necessary for the given level of physical containment;
- c) a laboratory emergency plan has been developed and documented which is compatible with the research and acceptable to the University;
- d) containment facilities complying with the appropriate physical containment level for this research exist and are in operation;

If condition d) is not fulfilled, please indicate below the status of the facilities:

or

- e) containment facilities complying with the appropriate physical containment level for this research are being constructed;

or

- f) funds for the containment facilities complying with the appropriate physical containment level for this research are being sought.

It is understood that funds will not be released nor administered by the University until appropriate certification is received.

Principal Investigator

Date

Head of Department/Unit

Date

Submit one copy of this application to the Office of the Vice-President (Research) together with a copy of the application to external funding agency, if appropriate.

Protocol for Projects Involving Biohazards

The UNB Biohazards Safety Committee is responsible to the office of the Vice-President (Research) for ensuring all research and teaching projects involving the use of biohazards are conducted safely and in compliance with established biosafety guidelines.

Projects proposing the use of biohazards must meet the protocol for safe use, physical containment and personnel training in accordance with the Health Canada *Laboratory Biosafety Guidelines*, 3rd ed., 2004. Biohazards include plant, animal and human pathogens, some recombinant DNA and some genetically modified organisms (GMOs). Pathogens may include micro-organisms such as bacteria, viruses, fungi or parasites or other infectious agents that are known, or reasonably believed, to cause disease. The definition of a biohazard can also extend to cell cultures, isolates, diagnostic specimens or biological products (*e.g.*, blood products or live or attenuated vaccines).

Prior to commencing projects with biohazards, approval must be received from the Biohazards Safety Committee. The Health Canada, Office of Biosafety, must be consulted to determine “risk group” and containment level.

Pathogenic organisms are divided into four risk groups based upon virulence, transmissibility, pathogenicity and availability of treatment of disease. These risk groups are analogous to the required level of containment, as described in Chapters 2 and 3 of the *Guidelines*.

UNB facilities, at present, are designed to accommodate research or teaching projects requiring containment Levels 1 and 2 only. Approval to conduct research involving containment Level 3 may require additional funding for provision of the appropriate containment. UNB is not equipped for projects requiring containment Level 4.

The risk group criteria were first introduced by the World Health Organization and adopted in 1990 by Health Canada and the Medical Research Council of Canada in their publication *Laboratory Biosafety Guidelines* (available from the Safety Office) and on the web at <http://www.phac-aspc.gc.ca/>

Several factors can influence classification of pathogens into risk groups. For example:

- Work that involves mutation or frequent subculturing of a pathogen may affect the microorganism's virulence, transmissibility or pathogenicity.
- If a strain of bacteria becomes resistant to a wide range of antibiotics and the disease it causes is difficult to treat, a researcher may consider classifying it in a higher risk group.
- Treating of pathogen microorganisms by freeze drying, chemical preservation or heating

can also affect its risk group assignment and the researcher may choose to re-evaluate its classification.

Risk Group 1 (low individual and community risk)

A microorganism that is unlikely to cause disease in healthy workers or animals.

Containment Level 1

This level applies to the basic laboratory for the handling of Risk Group 1 agents. Level 1 requires no special design features beyond those suitable for a well designed and functional laboratory. Containment cabinets are not required. Work may be performed on an open bench top. Containment is achieved through the use of standard microbiology practices.

Risk Group 2 (moderate individual risk, limited community risk)

Any pathogen that can cause human or animal disease but under normal circumstances is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

Containment Level 2

In addition to the requirements of containment Level 1, the following are required:

- laboratory should be located away from public areas and general offices.
- biohazard sign with appropriate risk level must be posted on the entrance to the laboratory.
- laboratory furnishings should be constructed with impervious and readily cleanable work surfaces.
- coat hooks must be provided for laboratory coats near the exit.
- autoclave must be available in or near the laboratory.
- laboratory doors should be self-closing.
- Class I or II biological safety cabinets (refer to *Guidelines*, Chapter 3) are required for all manipulations involving the agent which may create an aerosol. The biological safety cabinet must have been tested and certified within the previous 12 months according to accepted standards.
- air from cabinets may be recirculated to the room only after passage through a high-efficiency particulate air (HEPA) filter.

Risk Group 3 (high individual risk, low community risk)

Any pathogen that usually causes serious human or animal disease or which can result in serious economic consequences, but does not ordinarily spread by casual contact from one individual to another or that can be treated by antimicrobial or antiparasitic agents.

Containment Level 3

The operational requirements for the Level 3 laboratory are substantially higher than those for Level 1 and 2 and the laboratory personnel must receive specific training in the safe handling and manipulation of the agents used in this laboratory.

Risk Group 4 (high individual risk, high community risk)

Any pathogen that usually produces very serious human or animal disease, *i.e.*, often untreatable and may be readily transmitted from one individual to another or from animal to human or vice-versa, directly or indirectly, or through casual contact.

Containment Level 4

Containment Level 4 is the highest level of containment and represents a geographically isolated unit functionally independent of other areas. This level of containment requires an air lock for entry and exit, Class III biological safety cabinets, and/or positive pressure ventilated suits, a laboratory support area, and a separate ventilation system in addition to the physical and operational requirements of Levels 1 to 3. The laboratory must be physically separated from other laboratories or consist of an isolated zone which is monolithic in construction with all penetrations to floors, walls and ceilings sealed with non-shrinking sealant.