

Simon Fraser University
Memorandum

To: Senate

From: Alison Watt, Secretary
Senate Committee on Agenda and Rules

Date: May 3, 2006

Subject: Policy Revision: R20.02 – Biosafety Policy

At its meeting on May 2, 2006, SCAR recommended that the revisions to Policy R20.02 – Biosafety Policy be placed on the Senate agenda for information.

Alison Watt

Biosafety Policy R20.02

1. Purpose

To ensure the safety of students, faculty, staff, the community and the environment when using biohazardous materials under the auspices of Simon Fraser University, and to facilitate research, teaching and testing in compliance with the applicable regulations and standards outlined below.

2. Definitions

Biological Materials

- a. "Biohazardous Materials" are defined as biological agents and materials that are potentially hazardous to humans, animals and other forms of life. They include known pathogens and infectious agents including bacteria and their plasmids and phages, viruses, fungi, mycoplasmas, and parasites; cell lines, animal remains, and laboratory animals (including insects) which might harbor such infectious agents, primate body fluids and plant materials. Also included are nucleic acids used in procedures such as recombinant DNA and genetic manipulations;
- b. "Human materials" are defined as human blood, blood products, blood components, body fluids, tissues or organs;
- c. "Animal materials" are defined as animal blood, blood products, blood components, body fluids, tissue or organs;
- d. "Plant materials" are defined as plant pathogens, transgenic plants, plant toxins and exotic plants;
- e. "Recombinant DNA" are defined as molecules constructed by joining natural or synthetic DNA or RNA segments to DNA or RNA molecules, able to replicate in a living cell.

Biosafety Containment Levels

Biosafety containment levels are described in general terms. Health Canada Laboratory Biosafety Guidelines apply except in cases where the research is funded by institutions which require containment practices that conform to those specified by the US CDC.

- f. "CL1" applies to a basic microbiology laboratory, where work may be done on an open bench top;
- g. "CL2" applies to a laboratory that handles agents requiring containment level 2. The primary exposure routes associated with organisms requiring level 2 containment are ingestion, inoculation, and mucous membranes. Although these agents are less commonly transmitted by airborne routes, the generation of aerosols must be avoided through use

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of biosafety cabinets, sealed rotor centrifuges as well as appropriate personal protective equipment;

- h. "CL3" applies to a laboratory that handles agents requiring containment level 3. These agents may be transmitted by the airborne route, often have a low infectious dose to produce effects and can cause life threatening disease. Containment level 3 emphasizes additional primary and secondary barriers to minimize the release of infectious organisms into the immediate laboratory and the environment, such as HEPA filtration of exhausted laboratory air and controlled laboratory access.

Regulators

- i. "PHAC" Public Health Agency of Canada;
- j. "CFIA" Canadian Food Inspection Agency;
- k. "NIH" National Institutes of Health;
- l. "TDG" Transportation of Dangerous Goods
- m. "WCB" Workers Compensation Board, Occupational Health and Safety Regulation;
- n. "GVRD" Greater Vancouver Regional District.

Administrative Requirement

- o. "Biosafety Permit" is defined as the document certifying approval by the Biosafety Committee for use of biohazardous materials under specified conditions. Biosafety Permits are granted to SFU faculty or adjunct faculty members proposing to carry out research or teaching involving biohazardous material.

Personnel

- p. "Principal Investigator (PI)" is defined as the SFU faculty member (or acceptable equivalent as defined in other SFU policies) in charge of a research or teaching project;
- q. "Biosafety Officer" shall be appointed by the Vice President, Research, shall be qualified to assume responsibility for the SFU Biosafety Program, and give technical advice on projects and laboratory facilities involving biohazards;
- r. "Certified User" is defined as the individual whose name appears on the approved Biosafety Permit;
- s. "Laboratory Workers" are defined as all employees, students and visitors conducting research or educational activities under the auspices of SFU in SFU laboratories involving "biohazardous materials" as defined above.

3. Scope

This policy applies to all research, teaching and testing involving biohazardous material that is undertaken under the auspices of SFU and/or using the resources of SFU. All projects must have an SFU faculty member

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(or equivalent as defined in 2p above) as PI. Where the SFU Biosafety Committee grants "in principle" approval for research involving biohazards at another institution, a copy of that institution's permit, for the research, must be filed at SFU.

4. Standards

The University adopts standards compliant with:

- a. the Memorandum of Understanding between the three Canadian federal granting agencies and Institutions that receive their awards;
- b. the policies and procedures of SFU and the SFU Biosafety Committee;
- c. all relevant federal and provincial regulations (Public Health Agency of Canada, Canadian Food Inspection Agency);
- d. the National Institutes of Health;
- e. the Workers' Compensation Board; and
- f. Transportation of Dangerous Goods.

5. Policy

a. Authority

The SFU Biosafety Committee has the authority, on behalf of the Vice-President, Research, to:

- i. stop immediately any use of biohazardous material which deviates from the approval outlined in the Biosafety Permit or is deemed to be in non-compliance with the applicable standards as in part 4.
- b. Responsibility
 - i. The day-to-day requirement to comply with safe use of biohazardous materials in research and teaching under the auspices of SFU is the responsibility of the PI.
 - ii. All lab workers using biohazardous materials in research or teaching must have the necessary expertise and appropriate training in accordance with the policies of SFU and Standards outlined in part 4. The Biosafety Officer in consultation with the SFU Biosafety Committee will decide upon the appropriate methods of achieving the appropriate expertise and training levels.
 - iii. The acquisition of all biohazardous materials (by purchase, culture or transfer from another source) must be arranged in accordance with protocols approved by the SFU Biosafety Committee.
 - iv. The disposal of all biohazardous materials must be in accordance with protocols approved by the SFU Biosafety Committee and in compliance with all relevant federal, provincial and GVRD regulations and guidelines.

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- v. The Biosafety Officer, in close collaboration with and support of the SFU Biosafety Committee, is responsible for monitoring the compliance of researchers and instructors with SFU policy and the terms of the approval of their projects. If the Biosafety Officer observes or becomes aware that relevant regulations or guidelines are not being followed in any teaching program or research study, she/he advises the Principal Investigator so that prompt remedial action can be taken. In the event that this is not done to her/his satisfaction, the Biosafety Officer will alert and consult with the SFU Biosafety Committee. In circumstances where the Biosafety Officer is of the opinion that the situation presents an immediate significant risk, the Biosafety Officer may take whatever action she/he considers necessary to remedy the situation. The Biosafety Officer keeps the SFU Biosafety Chair and the Vice President, Research fully informed of such incidents and the reason for the action taken. She/he may also, at her/his discretion, seek the advice of PHAC, CFIA, or other experts as may be appropriate.
- vi. The Biosafety Officer maintains up-to-date records of all Biosafety Permits, approved locations, certified users, containment equipment, equipment certifications and personnel training. The Biosafety Officer reports, at least yearly to the Chair of the SFU Biosafety Committee with a summary of such records, and granting agencies as required.
- vii. The SFU Biosafety Committee ensures that researchers use appropriate containment facilities for the proposed research involving biohazardous materials.
- viii. All proposals involving the use of biohazardous materials in research and teaching require the prior approval of the SFU Biosafety Committee. The detailed responsibilities and powers of the SFU Biosafety Committee are those set out in its Terms of Reference and its Procedures. These are published and may be modified from time to time under the authority of the Vice-President, Research. The current procedures for consideration of Biosafety Permit application for the use of biohazardous materials are attached to this policy.
- ix. The Biosafety Officer shall undertake continuing education and training opportunities in biocontainment and security of biohazardous materials.

c. SFU Biosafety Committee membership

The SFU Biosafety Committee members will be appointed by the Vice-President, Research for renewable terms of three to four years. The committee membership should include:

- i. five faculty members drawn from key units where faculty members hold biosafety permits. Expertise of the faculty must encompass microbiology, plant or animal pathogens, recombinant DNA, and containment principles;

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- ii. the Director of the Animal Care Facility;
 - iii. one member representing laboratory technical staff;
 - iv. two members representing community interests and concerns, with appropriate expertise in biosafety, and who have no affiliation with the University.
 - v. the Biosafety Officer;
 - vi. a graduate student representative;
 - vii. the Manager of Occupational Health and Safety as non-voting resource member;
 - viii. the SFU Biosafety committee must have a Vice Chair who can become designated Chair as required; and
 - ix. a quorum of two thirds of the members should be established for the SFU Biosafety Committee meetings.
- d. Standard Operating Procedures (SOPs)
- SOPs and other guidelines for compliance inspections, acquisition, use, storage, and disposal of biohazardous materials are developed and published by the Biosafety Officer after having been approved by the SFU Biosafety Committee.

6. Interpretation

Questions of interpretation or application of this policy or its procedures shall be referred to the VP Research, whose decision shall be final.

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Simon Fraser University Biosafety Committee

Procedures

Consideration of Application to Use Biohazardous Materials

The Principal Investigator (PI) submits a completed form entitled "Application for a Biosafety Permit for Research or Teaching" to the Biosafety Officer at least eight weeks before the planned commencement of the project. In certain cases, such as teaching protocols, the Biosafety Officer may agree to a different time scale. In all cases sufficient time must be allowed for the review of the procedures to be employed in the project. It is recommended that the application be reviewed by the Biosafety Officer prior to submission to the SFU Biosafety Committee. The application form is available from the Biosafety Officer (604-291-5728) or from the OH&S, and SFU Research Policies web site. The PI must renew their research applications annually and in the case of teaching protocols, they must be renewed every semester. Any changes to the application must be submitted as an amendment and approved before implementation. Major changes may warrant submission of a new application.

- a. As part of the application, the PIs assign the risk group for each organism they propose to work with. Information on risk groups can be obtained by contacting the Biosafety Officer or Safety Advisors in Occupational Health and Safety.
- b. Upon receipt by the Biosafety Officer, she/he reviews the application for consistency with the SFU Biosafety Committee Terms of Reference, assigns a permit number and considers the following:
 - i. the determination of whether the proposed handling of biohazardous materials conforms to the standards specified in this Policy; and
 - ii. the availability of required containment facilities and containment equipment.
- c. For CL 1 and 2 projects:
 - i. After review by the Biosafety Officer, the application is forwarded to the Chair of the SFU Biosafety Committee for review and decision. If a decision cannot be made, the permit application is forwarded to the SFU Biosafety Committee for the final decision.

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- ii. The SFU Biosafety Committee is informed of all decisions made by the Chair at the next SFU Biosafety Committee meeting.
- d. For CL 3 projects and for projects described under section c(i) above that were not approved by the Chair:
 - i. After a review is made by the Biosafety Officer, the application is sent to all SFU Biosafety Committee members for review. A decision by majority vote is made by the SFU Biosafety Committee at their next committee meeting. The Chair does not normally vote except to create or break a tie.
 - ii. For all CL 3 projects, or any protocols of concern to the SFU Biosafety Committee, a presentation by the PI is required at the SFU Biosafety Committee meeting at which the application is considered.
- e. For Biosafety Permit renewals:
 - i. The application is forwarded to the Biosafety Officer and if necessary to the Biosafety Committee Chair.
 - ii. The SFU Biosafety Committee is informed of all renewals made by the Biosafety Officer or Chair at the next SFU Biosafety Committee meeting.
- f. The Chair of the SFU Biosafety Committee informs the PI of the SFU Biosafety Committee decision in writing.
- g. If the project is approved, the Biosafety Permit information will be made available to the Office of Research Services. The Occupational Health and Safety Office retain signed copies of all approved applications and permits.
- h. If the project is not approved, the PI is asked for more information, and may be required to submit a revised project proposal for review by members of the SFU Biosafety Committee.

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- i. If these actions fail to lead to approval of the project, the Chair of the SFU Biosafety Committee provides the PI with a written statement of reason for non-approval of the project.

- j. The PI may ask for a hearing before the SFU Biosafety Committee to appeal the decision. In the event the appeal is not successful, the PI may appeal to the Vice President, Research who may appoint an appeal committee. The decision of that committee, if ratified by the Vice President, Research, would be final. Health Canada may be called upon for information purposes; however, appeals cannot be directed to Health Canada.

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Biosafety Committee (R20.02)



SIMON FRASER UNIVERSITY

Policies and Procedures

Date

September 23, 1999

Revision Date

Number

R 20.02

Revision No.

Biosafety Committee

1. Purpose

Simon Fraser University is committed to providing a safe work environment. The Biosafety Committee will review and approve all potentially biohazardous research or teaching prior to the work being undertaken. All work shall comply with all relevant standards including Health Canada's Laboratory Biosafety Guidelines, Agriculture Canada's Containment Standards for Veterinary Facilities, and University procedures.

The Biosafety Committee will monitor research grant applications, facility design, and containment procedures and equipment. Teaching labs using biohazardous materials will be assessed by the same criteria as research labs.

2. Definition of Biohazards

Biohazards are defined as biological agents and materials which are potentially hazardous to humans, animals and other forms of life. They include known pathogens and infectious agents including bacteria and their plasmids and phages, viruses, fungi, mycoplasmas, and parasites; cell lines, animal remains, and laboratory animals including insects which might harbor such infectious agents; and primate body fluids. Also included are potentially biohazardous organisms used in procedures such as recombinant DNA and genetic manipulations. Biohazards will be classified according to risk levels requiring appropriate containment.

3. Applicability

This policy applies to all personnel at Simon Fraser University associated with biohazardous research and teaching, and students working in research and teaching laboratories involving biohazards.

4. Scope

The University acknowledges its responsibility to provide a program for the handling, storage and disposal of biohazardous waste material as well as a capacity to provide emergency response to biohazardous incidents, through the Biosafety Program. It also affirms the responsibility of the researcher to comply with the applicable guidelines. These guidelines have been adopted by many research granting agencies as a condition of issuing a research grant. A Biosafety Certificate is required to certify that the grant requester is aware of the hazards involved, is familiar with the applicable guidelines, develops safe work procedures and ensures anyone who may come in contact with the biohazard is appropriately trained.

5. Responsibility of the Occupational Health and Safety Office (O.H.&S.)

1. Publicizes guidelines, monitors adherence to guidelines and reports problems or infractions to the Chair of the Biosafety Committee.
2. Investigates reported accidents or spills of biohazardous material and reports to the chair of the Biosafety Committee if a perceived hazard persists. Ensures appropriate corrective measures are implemented.
3. Arranges for appropriate testing of Biosafety equipment.
4. Coordinates general biosafety training.
5. Processes applications for Biohazardous/Recombinant DNA Research for the approval of the Biosafety Committee.
6. Maintains records of certification for all certified users of biohazardous material.

6. Responsibilities of Principal Investigator

1. Ensures compliance with all relevant standards and guidelines including the Simon Fraser University Biosafety Policies and Procedures.
2. Initiates a review and seeks approval of research/teaching program by the Biosafety Committee. The process involves filling in the form "**Application for Approval of Biohazardous/Recombinant DNA/RNA Research or Teaching Facilities.**" This form must be completed to reflect the full range of projects contained in the research/teaching program . If necessary make duplicates of applicable pages where more than one project must be described.
3. Develops a detailed protocol of specific work procedures for handling biohazardous materials.
4. Ensures that researchers, students and employees for which he/she is responsible have been given adequate direction, training, and instruction in the safe performance of their work.
5. Limits the use of biohazardous material to the certified facilities.
6. Develops appropriate emergency and decontamination procedures for his/her area of work.
7. Ensures reports of potentially hazardous incidents and accidents are prepared and forwarded to the Biosafety Committee Chair with copy to the O.H.&S. Office.

7. Responsibilities of Certified User

1. Familiarity with SFU Biosafety Policy and Procedures.
2. Follows specified work procedures

3. Uses the appropriate protective equipment.
4. Reports to the Principal Investigator any incidents or accidents involving the use of biohazardous materials.

8. Biosafety Committee Terms of Reference

1. Advise the Vice-President, Research on matters related to biohazards and biosafety.
2. Develop, recommend and implement policies and procedures for the safe use of biohazardous materials in accordance with the current Medical Research Council guidelines and other pertinent regulatory agencies.
3. Review all research and teaching proposals involving biohazardous materials. When deemed necessary, approve containment requirements, inspect facilities and review work procedures to ensure compliance with regulatory agencies.
4. Issue certification for use of biohazardous material and stipulate the conditions of use to ensure compliance with current guidelines and other pertinent guidelines or regulations. Review certification periodically.
5. Ensure proper procedures are in place for acquisition, storage, use, disposal, and transport of biohazardous materials.
6. Advise the University Occupational Health and Safety Office on matters regarding biosafety, and arrange for dissemination of information pertinent to the use of biohazardous material.
7. Maintain in the Occupational Health and Safety Office records associated with use of potentially biohazardous material.
8. Investigate reports of user infractions of procedures and relevant guidelines and recommend corrective action.

9. Biosafety Committee Membership

The committee membership is to be drawn from those departments engaged in research considered biohazardous and be chaired by a senior committee member. The Manager of Occupational Health and Safety shall also be a member. The committee is to meet as needed, and report to the Vice-President, Research.

The Committee will also include the following *ex officio* members:

Consultants as required
Director, Research Services
Occupational Health and Safety Officer
Medical Team Leader, Health Services

Procedures for Approval to Work with Biohazardous materials

1. Application To Use Biohazardous Materials

Click here for the Biosafety Permit Application for use of biohazardous materials. The form is also available from the Occupational Health and Safety (OH&S) Office, and from the Chair of the Biosafety Committee. Once the form is completed, it is signed by the principal investigator and forwarded to the Chair of the Biosafety Committee for assessment and signature. The Chair forwards the signed application to OH&S where an Approval number is assigned. OH&S retains the original application and forwards to the principal investigator a copy of the cover page with both signatures and a cover letter explaining responsibilities of the permit. Research Services also receives a copy of the cover page as required to release funds from granting agencies.

Approval will be granted for a program and the associated facility. Approval for use of biohazardous material will only be issued to faculty members. Biohazardous material may not be used for any purpose or in any other location, other than that originally approved by the Biosafety Committee. Project changes will require an amendment to the application.

2. Amendments to Approved Applications

Should a new project be initiated, enquiries should be directed to OH&S to determine if an amendment to the application is necessary. If necessary, amendment requests must be received in writing at OH&S who will arrange for Biosafety Committee review. Personnel changes are to be reported to OH&S as they occur. Once a year OH&S will generate a list of certified personnel and request that the principal investigator verify it is current.

3. Renewal of Previously Approved Applications

Approval to work with biohazardous material is for a maximum period of four years. Two months prior to expiry, OH&S will issue a reminder of the expiry date. At that time, the principal investigator must specify whether the program is to continue and whether any changes are planned. Major changes to an application will require referral to the Biosafety Committee.

4. Certification of Granting Agency Forms

All granting agency biosafety forms are to be completed by the applicant and forwarded to Research Services. Research Services will ensure that biosafety forms for granting agencies are signed by a member of the Biosafety Committee (or a Biosafety Committee member other than the applicant).

5. Facilities and Equipment Assessment

The facilities and equipment will be assessed as part of the research/course approval. The assessment will be done by the O.H.&S. Office. Biosafety cabinets and all HEPA filtered equipment must have a valid performance certificate attached on a conspicuous location to verify current testing. Testing is required:

- a. Prior to use
- b. Annually thereafter
- c. After relocation
- d. After HEPA filter replacement
- e. After servicing such as a fan motor replacement.

The Biosafety Committee will reserve the right to periodically repeat the assessment to verify current status or implementation of guideline and regulation amendments.

6. Biohazard Signs

The sign shown in Appendix 1 should be posted for facilities approved for biohazardous work or storage of Risk Groups 2, 3 or 4. The sign signifies the presence of a biohazard, identifies the principal investigator, and displays emergency telephone numbers which are also registered with Security for emergency purposes.

7. Orientation and Training

Principal investigators are responsible for being cognizant of all hazards associated with their

research projects and for ensuring that personnel reporting to them are trained in safe laboratory practices and understand the hazards. Training and understanding cannot be assumed for employees or students transferring from another laboratory or institution.

8. Emergency Response

Emergency response procedures must be developed and posted for all facilities approved for biohazardous work or storage of Risk Groups 2, 3, or 4. Every person using the containment facility must be made aware of its contents. For practical purposes, procedures should be simple, and a copy filed with OH&S.

Interpretation

Questions of interpretation or application of this policy or its procedures shall be referred to the President, whose decision shall be final.

Appendix #1 Biohazard Sign

(for a copy of this sign, please contact the SFU Safety Office at 604.291.4978)

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