7.1 USE OF BIOHAZARDS

Anyone working with microbiological techniques, or involved in the treatment or disposal of biohazardous waste, must receive proper training prior to work with these materials. The supervising faculty member is responsible for providing this training.

Areas in which biohazards are used (BioSafety Level 2 laboratories and work areas) must clearly display a biological hazard sign with the international biological warning symbol in the entrance area or on the door. In addition, equipment used to store biohazardous materials (e.g., incubators, refrigerators, freezers) and receptacles for storage of biohazardous waste will be labeled and display a biological hazard sign.

Biological safety cabinets should be used for hazardous microbiological work, particularly work with pathogens. Laminar flow hoods should not be used for pathogens or hazardous microbiological work. See Section 4.6 for a description of hood types.

7.1.1 Pathogenic Microorganisms

Any work involving possible pathogens requires a written protocol approved by the Safety Committee prior to the initiation of the work, and must be supervised by the involved faculty/staff. Possible pathogens include any organism known or suspected of causing infection in humans, animals, insects or plants. Protocols must be submitted at least 3 weeks prior to the proposed order or start date.

All faculty, staff or students working with microorganisms or materials potentially infected with such organisms are expected to follow the guidelines specified in *BioSafety in Microbiological and Biomedical Laboratories* (US Dept. of Health and Human Services). These guidelines describe four BioSafety levels that specify microbiological practices, laboratory facilities, and safety equipment. Work with infectious agents is assigned to a specific BioSafety level based on the potential hazard of the agent to people. Four BioSafety levels are also described for infectious disease activities in which small laboratory animals are used. All questions about biological safety should be directed to the Safety Committee.

Possible pathogens and diagnostic specimens must be transported (packaged, labeled, and shipped) in accordance with regulations from the Department of Transportation and other applicable agencies (e.g. CDC). Secondary packaging of all biological material for transport is required. Primary containers must be sealed tightly, surrounded by adsorbent packing material to retain any leakage, and placed in secondary containers. Secondary containers must be sealed and break resistant. A shipping container with the address label should surround the secondary containment. Both primary and secondary containers must be labeled with the amount and type of material being shipped, and the names and addresses and telephone numbers of both the shippers and receivers. The specified carrier may require additional labeling.

In addition, importation of vectors of human disease is subject to Public Health Service foreign quarantine regulations, and permits are required by the Center for Disease Control (C.D.C.). The US Department of Agriculture regulates the importation and interstate shipment of animal and plant pathogens; permits may be required for interstate movement of certain animal or plant pathogens.

7.1.2 Laboratory Animals

The Lab Manager must be notified prior to bringing any animals into Cole Science Center. The Cole Science Center Animal Care and Use Committee must approve a written protocol detailing the handling of teaching/research animals prior to the acquisition of materials or commencement of work. The Safety Committee is required to review and approve protocols for animal research involving the use of any chemical (including chemicals used for anesthesia) or biological materials or related waste products. The Animal Care and Use Committee has been established in accordance with all applicable federal, state, and local laws and regulations. The Safety Committee and Dean of Natural Science have the final responsibility for assessing the proper use and handling of laboratory animals and associated chemical and biological materials.

The "Guide for the Care and Use of Laboratory Animals" by the Institute of Laboratory Animal Resources Commission on Life Science, National Research council (current edition at this time is the 1996 edition), will be used as a guideline for the use and care of laboratory animals in Cole Science Center.

All users of laboratory animals should have an active tetanus immunization, and other immunizations as appropriate. Concern for the health of others who do not work directly with the animals should be paramount when laboratory animals are transported or used in general laboratory areas outside of the designated animal research areas. Users of laboratory animals must recognize that virtually all laboratory animal species can carry pathogens that are infectious to humans. Caution should be taken when working with any animal. Bites and scratches that break the skin should be washed thoroughly with soap and water, and reported to Employee Health and the Lab Manager. Lab coats should be changed and hands thoroughly washed if an animal, its fluids or feces is touched.

Allergic responses to laboratory animals are the most common cause of human disease related to use of animals in research. Continued exposure can be life threatening. The wearing of a facemask, gloves and lab coat is strongly encouraged for users of animals. Pregnant employees should not expose themselves to cat feces, dander or biohazard areas.

7.1.3 Human and Other Primate Blood and Body Fluids

All faculty, staff, and research students who are potentially exposed to bloodborne pathogens in the laboratory, with the exception of the use of their own blood or tissue, are covered by the Hampshire College Bloodborne Pathogen Exposure Control Program and

must comply with all requirements including work practice controls, use of personal protective equipment, housekeeping, labeling, waste disposal and training. As participants in that Program they are eligible for hepatitis B vaccinations and post-exposure medical evaluation and follow-up. Prior to the use of human, or other primate, blood, blood products, body fluids, and tissue in any laboratory, the responsible faculty member must contact Human Resources to register her/himself and the staff and/or research students she/he supervises as participants in the Hampshire College Program. Training must be completed prior to potential exposure. The Human Resources department coordinates this training.

Written protocols involving any human blood, body fluids or tissues must be reviewed and approved by the Safety Committee, and the Animal Care and Use Committee or Human Subject Committee, as appropriate, prior to the initiation of work. Protocols must be submitted at least three weeks prior to projected use. Laboratory practices should be developed assuming that all human blood, body fluid, and tissues are infectious (universal precautions). The Center for Disease Control and National Institutes for Health recommend that BioSafety Level 2 (BSL 2) standards, containment and facilities be used for activities involving clinical specimens, body fluids and tissues from humans or from laboratory animals infected or inoculated with human material. These standards should also be applied to work with human cells in culture, or human serum-derived reagents that may be used as controls.

Students may only use their own blood or tissue in the laboratory. Samples must be collected by the student (e.g., finger prick, cheek scraping), or, for blood samples, by a person licensed to draw blood; and can only be handled by that student or a trained faculty or staff member. Students must consent to the use of their blood or tissue, and cannot be required to participate in the laboratory. All students in the laboratory must be informed of the potential hazards of bloodborne pathogen exposure.

Each student must be assigned a discrete laboratory space and all student work is restricted to that location. Each student must also be provided with all equipment and supplies necessary for the experiment. Equipment and supplies cannot be shared between students. Procedures that could result in splashing or generation of aerosols (e.g., open tube centrifugation) are not allowed.

A written protocol must be developed by the faculty member detailing the experimental procedures and describing procedures to prevent contamination of adjacent spaces or other areas of the laboratory, and to properly decontaminate or dispose of all work areas, supplies and equipment.

7.1.4 Recombinant DNA

All recombinant DNA research must be conducted in accordance with the National Institute of Health's, *NIH Guidelines for Research Involving Recombinant DNA Molecules* (March 2013), (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines_new.pdf), available from the

Lab Manager. Projects proposing recombinant DNA methodologies require a written protocol approved by the Safety Committee.

7.2 STORAGE, TREATMENT AND DISPOSAL OF BIOHAZARDOUS WASTE

Biohazardous wastes generated during experiments should be placed in covered and labeled (biohazard label) containers or in a bag within a secondary container. All needles, syringes and sharps should be placed in puncture proof "sharps" containers. Biohazard sharps should be kept in separate containers from general biohazardous waste, for decontamination and disposal purposes. All biohazardous waste must be sent off-site for licensed incineration.

All efforts should be made to avoid generating mixed wastes (e.g., chemical and biological). If hazardous chemicals are present with biohazards, please contact the Lab Manager for appropriate decontamination and disposal protocol.

Disposal of dead animals or animal tissue generated in research or teaching activities must be double bagged prior to disposal. Any animals that are known to carry infectious agents must be disposed of as biomedical waste. If the animals or animal tissues have been placed in formaldehyde solution, they must first be separated from the solution. The solution is handled as a hazardous waste.

Non-contaminated animal bedding, bagged properly, can go directly to refuse. All bedding should be placed in heavy-duty leak proof bags, tied securely and placed in dumpsters. Loose bedding shall not be placed in trash containers or dumpsters. Bedding contaminated with biohazardous waste (e.g., from animals shedding pathogens) must disposed of as biomedical waste. Bedding contaminated with chemical toxins as a result of the experiment must be evaluated to determine if it is a hazardous waste.

7.3 AUTOCLAVE MAINTENANCE AND TESTING

Users of the autoclaves must be trained in their use and maintenance. To insure sterility of materials and adequate decontamination of wastes, the manufacturers' representative will check autoclaves annually.

7.4 CONTROLLED SUBSTANCES

The federal Food and Drug Administration (FDA) and the Massachusetts Department of Public Health (DPH) define Controlled Substances. The citations are listed below. Copies of the current lists referenced are available from the Lab Manager.

- 21 CFR 1308.00 Schedules I through V.
- 105 CMR 700.001 "Controlled Substance" means a drug, substance, or immediate precursor in a schedule or class referred to in M.G.L. c94C or 105 CMR 700.000:

FDA Schedules I - V, Massachusetts Schedule VI which includes all other prescription drugs.

Both FDA and DPH regulations also lists "excluded" non-narcotic substances, which are exempt from regulation. The federal list is much more extensive than the state, with the result that certain substances are exempt from federal requirements but not from state.

FDA regulation also list "exempt chemical preparations" which are exempt when intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal. DPH regulations also list "excepted compounds" which are exempt from requirements of Schedule I through V but still subject to Schedule VI requirements.

7.4.1 Registration and Protocol Requirements

Each faculty member wishing to purchase or use any Controlled Substance must obtain registrations in their name from both FDA and DPH. Certain substances that are exempt from FDA requirements but not DPH will only require a DPH registration. You cannot purchase any Controlled Substance until you are issued registration numbers. You must also have a written protocols approved by the Safety Committee prior to purchase of Controlled Substances. Protocols must be submitted at least three weeks prior to proposed use or purchase, and should include copies of registration application and approval.

7.4.2 Guidelines for Controlled Substance Protocols

One of the requirements of application for FDA and DPH registration is submission of a protocol detailing the proposed use of the Controlled Substance(s). Copies of the applications and approvals must be provided with the protocol. The following requirements are taken directly from 105 CMR 700.005, .006 and 21 CFR 1304.00. The regulations should be referred to for additional details.

Drug Enforcement Administration, 21 CRF 1308.00 at
http://www.deadiversion.usdoj.gov/21cfr/cfr/2108frt.htm

Mass. Department of Public Health, 105 CMR 700.000 at
http://www.mass.gov/eohhs/docs/dph/regs/105cmr700.pdf

Each protocol should describe how these requirements will be met and include the following elements.

1. Description of Research

2. Security
   - physical security from theft

- all student use must be directly supervised
- personnel security to ensure employees are responsible persons (e.g., CVs on-file)
- security upon receipt (e.g., direct delivery by stockroom personnel to the licensed individual
- procedures for report of loss or theft by telephone upon discovery, and by mail on form BND 106 within 7 days

3. Records, Inventories, and Reports
   - records must be maintained for 2 years
   - records must be kept separately from all other records, (e.g., in a separate log or file)
   - each registrant must take an initial inventory of all Controlled Substances on-hand and biennial inventories
   - thereafter (date to be used must be specified, e.g., anniversary date or initial inventory)
   - records must be kept of receipt, date and amount dispensed, consumptive use, and disposal

7.4.3 Disposal of Controlled Substances

Controlled substances that need to be disposed of should be handled in accordance with the requirements of the FDA and DPH that specify procedures for shipment of the substances to those agencies and require special approval for destruction of controlled substances.

7.5 FOREIGN SOILS

All researchers who handle Foreign Soils must comply with the conditions of the USDA Soil Permit and its associated Compliance Agreement. Requirements include:

- storing Foreign Soils under lock and key
- a labeling system for Foreign Soils that visually separates them from other samples sharing storage
- procedures for accidental spill clean-up that prevents entry of Foreign Soils into normal waste streams prior to treatment
- procedures for on-site treatment of waste shipping materials
- log showing receipt and disposition of Foreign Soils and associated shipping materials

7.6 SELECT AGENTS

Hampshire College does not have the facilities required to work with Select Agents as defined by the Public Health Security and Bioterrorism Preparedness Act of 2002, the

USA Patriot Act of 2001, Department of Health and Human Services (DHHS) Select Agent Regulations (42 CFR 73) and the USDA Agricultural Bioterrorism Protection Act of 2002 regulations (7CFR 331 and 9CFR 121). Select Agents may not be purchased or brought to campus from any other source. A list of Select Biological Agents and Toxins, High Consequence Pathogens and Toxins, and Plant Pathogens is available at http://www.cdc.gov/od/sap/docs/salist.pdf.