



OHIO
UNIVERSITY

BIOSAFETY PROGRAM MANUAL



Institutional Biosafety Committee (IBC)
Department of Environmental Health & Safety (EHS)

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OHIO UNIVERSITY

BIOSAFETY PROGRAM MANUAL

The Biosafety Program at Ohio University (OU) was established to prevent disease, promote safety in research studies, to ensure safe handling of biological agents, safe disposal of infectious laboratory wastes, and compliance with applicable institutional policies and regulatory requirements. This manual, which describes the program and guidelines for safe operation of laboratories and performance of experiments involving biological agents, has been prepared and distributed to faculty members and research personnel. An important aspect of this program is the monitoring activities of the Institutional Biosafety Committee (IBC). It is the responsibility of this committee to review all research projects involving etiologic agents, recombinant DNA construction, and other materials specified in the OU Biohazards Policy #44.107 prior to initiation of experiments. The purpose of this process is to determine if all applicable regulations and guidelines are being complied with, that associated personnel are adequately trained, biosafety consultation is provided, and appropriate containment measures are taken for the protection of human health and the environment.

The Biosafety Officer (BSO), in the Department of Environmental Health & Safety (EHS), serves as a “coordinator” to ensure that the precautionary measures recommended or required by the committee are effectively applied. The coordinator function relies heavily on the input and work of others to achieve the desired goals under general coordination from EHS. Direct services (safety audits, biosafety cabinet certification, filter changing, staff training, etc.) are not routinely provided by EHS at this time, because staff and resources have not been allocated to the Biosafety Program for this purpose. Any necessary expenses must be paid by the Department needing the services. EHS and the Biosafety Officer will make every effort to see that these things are provided for as much as possible and in some manner on a limited basis, until adequate program support is secured to provide services directly.

1.0 INTRODUCTION

Ohio University has gained recognition as a center of excellence for teaching, medical services, and research programs. This is a highly commendable achievement and one that could not have been realized without the continued support and dedication of faculty, staff members, and employees. Similar cooperation and support is necessary for the institution to be equally successful in its development of a comprehensive occupational health and safety program for the protection of university personnel, students, and the community. An important part of this program is concerned with safety in research studies, laboratories, and safe disposal of laboratory wastes. The OU Biosafety Program has been established to assist with accomplishing these goals.

The purpose of this manual is to describe the operation of the biosafety program and to provide guidelines for the safe operation of laboratories and the performance of experiments involving potentially hazardous biological agents. While most of the requirements mentioned herein have long been recognized by prudent members of the scientific community as essential when

conducting research with potentially hazardous biological materials, additional requirements may be necessary because they constitute recommendations, grant requirements, or laws promulgated by government agencies.

Faculty and staff members are urged to carefully review this manual which focuses on institutional practices, requirements, researcher responsibilities, liabilities, and related issues. Lengthy written technical resources such as copies of regulations, guidelines, reference materials and such have not been included. Instead an extensive listing of internet web sites which offer continually updated information has been provided in Appendix I. This manual is also on the EHS web site and contains clickable links to resources ([Online Manual](#)). In addition, the Biosafety Officer can assist with your questions and has a library of resources, new and historic, available at the EHS offices in Hudson Health Center.

2.0 DEFINITION AND CATEGORIES OF BIOHAZARDOUS AGENTS

For purposes of this manual, a "biohazardous agent" is defined as one that is capable or potentially capable of producing an undesirable effect upon man or the environment. The agent may be a biological or their metabolic product. Recommended safety guidelines for handling and use of chemical agents are provided by the Ohio University Hazardous Materials Program and your departmental Chemical Hygiene Plan. Procedures for the proper handling of radioisotopes on campus are described in the Ohio University Radiation Safety Handbook. This program manual deals only with those biological and related materials regulated by the IBC under OU Policy #44.107 - Biohazards Policy.

2.1 Biological Agents

- 2.1.1 Microorganisms pathogenic to man (bacteria, viruses, rickettsia, fungi, parasites, etc.)
- 2.1.2 Harmful metabolic products of microorganisms, e.g., bacterial exotoxins and mycotoxins (aflatoxins, sterigmatocystin, luteoskyrin, rugulosin, cyclochlorotine, patulin, etc.)
- 2.1.3 Oncogenic viruses
- 2.1.4 Recombinant DNA molecules
- 2.1.5 Unicellular and multicellular parasitic agents
- 2.1.6 Infectious materials of human, animal, plant origin
- 2.1.7 Invertebrate vectors of human diseases
- 2.1.8 Any infectious agents or toxins regulated by the "Anti-Terrorism and Effective Death Penalty Act", commonly called the Agent Transfer Law. See Appendix H.

- 2.1.9 Any agent or toxin designated by CDC or USDA as a “Select Agent”.
- 2.2 Human Blood, Tissue, Body Fluids, and other potentially infectious molecules
 - 2.2.1 Human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne infections that could be transmitted through:
 - a. Blood, serum or body fluids containing visible blood;
 - b. All tissues;
 - c. Semen and vaginal secretions;
 - d. Cerebrospinal fluid, pericardial fluid and amniotic fluid.
 - e. Human or primate cell lines.
 - 2.2.2 Although the risk of transmission of HIV or HBV from feces, nasal secretions, sputum, tears, urine and vomitus is considered low, these body fluids or excretions may be mixed with blood or contain other transmissible pathogens.
- 2.3 Certain Specific Chemical Hazards
 - 2.3.1 Carcinogens
 - a. Direct primary research focus on a carcinogen or family of carcinogens
 - b. Not incidental use of carcinogens in normal laboratory research
 - 2.3.2 Antineoplastic or cytotoxic drugs
 - 2.3.3 Biological toxins

3.0 PHYSICAL CONTAINMENT

Experiments with infectious agents and other potentially hazardous substances are expected to be performed under containment conditions which minimize the possibility of dissemination both within and outside the laboratory area. For purposes of this manual and for research on Ohio University premises, the containment levels are listed as Biosafety Level 1 (BL1) (minimum-level), Biosafety Level 2 (BL2) (low-level), Biosafety Level 3 (BL3) (moderate-level), and Biosafety Level 4 (BL4) (high-level). Level designations denote level of increasing containment needs and relative hazard. Serious human diseases can, however, be caused even by agents in BL2 laboratories. A description of physical conditions and practices for BL1, BL2, and BL3 containment levels is given in the reference manual "Biosafety in Microbiological and Biomedical Laboratories" by CDC/NIH (herein called the "CDC/NIH Book"). This manual can be viewed on the internet. See address in Appendix I – Reference Websites. BL3 laboratory facilities are not available at Ohio University. BL4 agents are not

permitted at Ohio University or anywhere else in the United States, outside of a few specialized governmental institutes and special research facilities.

The containment requirements for various types of experiments are as follows:

3.1 Human Pathogens

3.1.1 The Center for Disease Control has classified etiologic agents on the basis of hazard and defined minimal safety conditions for their management in the laboratory. Human pathogens are divided into four Risk Groups (RG), those considered to be least hazardous to work with are in RG1, and those that are extremely hazardous to laboratory personnel or may cause serious epidemic disease are in RG4. A fifth class is composed of numerous animal pathogens which are forbidden from entry into the United States either by law or U.S. Department of Agriculture (USDA) regulations or administrative policy. The USDA maintains a list of restricted animal pathogens, which can be found on the USDA's Animal and Plant Health Inspection Service website (See Appendix I – Reference Websites).

3.1.2 Questions concerning the hazard classification of pathogenic agents not specifically listed in the CDC/NIH Book should be directed to the Biosafety Officer at EHS for evaluation through the Office of Biosafety, Center for Disease Control, Atlanta, Georgia 30333, telephone 1-800-311-3435.

3.1.3 Except for situations where the nature of the work with a particular agent may dictate a higher level of containment than that generally deemed acceptable, experiments involving human and animal pathogens must be performed under the following containment conditions:

RG1 agents require BL1 physical containment and practices. RG2 agents require BL2 physical containment and practices. RG3 agents require BL3 physical containment and practices (facilities not currently available or anticipated at OU). RG4 agents are forbidden at OU.

3.1.4 Detailed documentation of significant reduction in pathogenicity must accompany all written requests made to the IBC to lower the specified physical containment and practices for "attenuated" etiologic agents.

3.2 Oncogenic Viruses

3.2.1 All studies with viruses capable of inducing tumors in animals or transformation of cells in culture will be performed according to

current safety standards. Refer to the appropriate NIH and CDC sources to determine the risk group for each specific agent and the biosafety level recommended.

3.3 Plant and Animal Pathogens

The U.S. Department of Agriculture (Bulletin PA-967) has listed five (5) separate classes of plant and animal pathogens:

- 3.3.1 Class I - domestic invertebrate pests or animal pathogens widely distributed in the United States.
- 3.3.2 Class II - domestic invertebrate pests, plant or animal pathogens with limited distribution in the United States.
- 3.3.3 Class III - pests and pathogens subject to federal and state quarantines and foreign pests of minor importance. A permit is required for interstate movement or importation.
- 3.3.4 Class IV - foreign invertebrate pests and pathogens of plants or animals of major importance and introduced organisms confined to a limited geographical area. Few permits for importation are issued.
- 3.3.5 Class V - includes arthropods and pathogens of potential importance as biological control agents and pollinators.

Since federal regulations do not describe specific containment conditions for each of the above-mentioned classes of pests or pathogens, it is recommended that the Biosafety Officer be consulted on any proposed experiments.

3.4 Recombinant DNA Studies

3.4.1 Experiments involving the in-vitro construction or propagation of recombinant DNA molecules must be conducted in accordance with latest guidelines established by the National Institutes of Health (NIH) and any recommendations that may be issued on a case-by-case basis by the NIH Office of Recombinant DNA Activities. This shall be required of all studies regardless of the source of funds used to support the work. Copies of guidelines may be obtained from NIH website found in the back of this manual in Appendix I. Questions concerning recombinant experiments that require prior NIH approval should be directed to the Biosafety Officer at EHS for review with the NIH Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892, telephone: 301-496-9838. The guidelines describe permissible levels of physical containment and practice as well as biological containment (host-vector systems) for many, but not all, conceivable types of experiments. In instances where containment conditions for a proposed recombinant DNA experiment are not explicitly given in these

guidelines, it shall be the responsibility of the investigator concerned to obtain an official appraisal from the NIH Office of Recombinant DNA Activities.

The recombinant DNA guidelines exempt certain experiments from the procedures of the guidelines. It should be noted that these experiments need not be reported to or reviewed by the Institutional Biosafety Committee per NIH, however, they should be submitted to the OU IBC on a Biosafety Review Form so that the IBC can make sure the proposed research is exempt.

3.5 In-Vitro Cell Cultures

The following minimal containment conditions will be required for experimental cell culture work not involving purposeful infection with human or animal pathogens:

- 3.5.1 BL1 physical containment and practices may be used for primary cell cultures of nonmammalian origin. However, BL2 conditions must be used for primary cell cultures of malignant avian tissue.
- 3.5.2 BL1 containment conditions may be used for established cell cultures derived from normal or malignant mammalian tissue provided it has been clearly demonstrated that they do not carry or release endogenous microbial agents; otherwise, at least BL2 containment conditions are required.
- 3.5.3 BL2 containment conditions may be used for primary cell cultures of rodent origin if the animals are from breeding colonies known to be free of infection with lymphocytic choriomeningitis virus (Class 3 agent). BL3 conditions must be used whenever infection status of the donor animals with this virus is unknown.
- 3.5.4 A minimum of BL2 containment conditions are required for all cell lines of primate origin. All primate cell lines must be tested for human pathogens and other disease causing agents prior to purchase or use. The test results and researchers' risk assessment must be done prior to purchasing the cells and must be included with all IBC Health and Safety review forms.

3.6 Human Blood and Body Fluids

The Centers for Disease Control, OSHA, and the medical community recommend implementing the principle of "universal precautions." Under these precautions, blood and certain body fluids of all patients are considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus and other bloodborne pathogens. It is appropriate that similar precautions be used in all laboratories handling human blood, human tissue and body fluids; including laboratories that

are not hospital-based. With regard to physical containment, BL-2 procedures should be used for all human blood, tissues or body fluids. Compliance with the OSHA Bloodborne Pathogens Standard is required.

4.0 PROHIBITED RESEARCH ACTIVITIES

Until such time as Federal law, agency policies, guidelines permit, or appropriate physical containment facilities are available, the following types of studies are not to be undertaken on Ohio University premises:

- 4.1 Experiments with etiologic agents requiring BL3 (no facilities available at OU) and BL4 (forbidden) levels of containment.
- 4.2 Experiments with animal pathogens (Class V) that are forbidden from entry into the United States.
- 4.3 Experiments with plant pathogens or vectors for which the U.S. Department of Agriculture may refuse to issue a permit for importation or interstate movement.
- 4.4 Experiments with primates (no facilities at Ohio University).
- 4.5 The following recombinant DNA experiments:
 - 4.5.1 Formation of recombinant DNA's derived from pathogenic organisms classified as Class 3, 4 or 5 or from cells known to be infected with such agents, regardless of the host-vector system used.
 - 4.5.2 Large scale propagation (more than 10 liters of culture) of recombinant DNA containing organisms that require BL3 or higher containment conditions and practices.
 - 4.5.3 Creation by the use of recombinant DNA of a plant pathogen with increased virulence and host range beyond that which occurs by natural genetic exchange.
 - 4.5.4 Deliberate release into the environment of any organism containing recombinant DNA, unless specifically approved in writing by NIH or EPA. Since NIH has no legal regulatory function, it appears that eventually EPA will assume jurisdiction over release of recombinant DNA containing organisms into the environment.
 - 4.5.5 Transfer of a drug-resistant trait to microorganisms that are not known to acquire it naturally, if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture.

4.6 Agents or toxins listed in the Department of Health and Human Services “Possession, Use and Transfer of Select Agents and Toxins” rule (Select Agents Rule) for which Ohio University is not licensed or approved.

5.0 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

5.1 Organization Structure and Responsibilities

5.1.1 The Vice President for Research will appoint members to the Institutional Biosafety Committee (IBC) in accordance with IBC standard operating procedures (See Appendix E). In order to provide the quality of input needed for consideration of research activities presenting real or potential hazards, the membership shall include persons knowledgeable in microbiology, infectious disease, medicine, chemistry, toxicology, occupational health and safety, recombinant DNA technology, animal experimentation, public health and community attitudes, applicable law, biological safety, engineering, and commitments and policies of Ohio University. In compliance with existing NIH requirements, at least two of the members, shall not be affiliated with the University and represent the community with respect to health and protection of the environment, herein called “community members”. Currently, the OU IBC has ten (10) members; eight (8) OU faculty and staff, two (2) community members. Chair and other officers are elected annually at the fall quarter meeting. The EHS Biosafety Officer and a staff member representing the VP for Research are ex-officio members.

5.1.2 The Institutional Biosafety Committee has the responsibility of assessing dangers and potential environmental impacts associated with investigations involving biological agents and making recommendations for safe conduct of such studies. It also functions on behalf of the institution to ensure that the experimental work is performed in compliance with current laws, policies, and guidelines promulgated by granting and regulatory agencies. The Committee does not monitor activities which are appropriately the concern of other established institutional groups, e.g., Radiation Safety Committee, Institutional Research Board, and Institutional Animal Care and Use Committee; however, it will endeavor to interact closely with these groups in a concerted effort to coordinate programs and to minimize health risk to OU personnel, students, and the general public.

5.1.3 All requests for action by the IBC should be put in writing and submitted to the Biosafety Officer. It will be the responsibility of the Biosafety Officer (1) to determine when and how often the IBC is to meet, (2) to officially inform appropriate person(s) of the actions taken by the IBC, and (3) to see that a complete file is kept of minutes of

meetings and of all documents and reports received by the IBC. The Biosafety Officer at EHS will coordinate the activities of the IBC with the chairperson, maintain the records, and staff the IBC needs within the limits of resources provided to EHS for this purpose.

- 5.1.4 It is important for faculty and staff members to understand that certain information in IBC files may be subjected to public scrutiny under a disclosure provision of current NIH guidelines and public record laws. This disclosure provision requires Ohio University, upon request, to make available to the public all minutes of Institutional Biosafety Committee meetings pertaining to recombinant DNA activities and any documents or reports submitted or received from federal funding agencies which the latter are required to make public (e.g., Memoranda of Understanding and Agreement, reports of guidelines, violations and significant research related incidents, facilities inspection reports, and agency directives to modify projects). In addition, OU is required to forward to NIH any comments by members of the public concerning actions taken by the IBC together with the response of the committee to these comments.

5.2 Review and Approval of Biohazardous Studies

- 5.2.1 The IBC cannot be expected to effectively carry out its designated functions unless it has adequate knowledge beforehand of the biohazardous work to be undertaken on OU premises. Therefore, all research projects involving etiologic agents of RG1 or higher, oncogenic viruses, in-vitro construction or propagation of recombinant DNA molecules, human blood, or other potentially infectious materials, invertebrate vectors of human disease or other materials specified by the IBC must be reviewed and approved in writing by the IBC.
- 5.2.2 It is not the purpose of the IBC to pass judgment on scientific merits, or even to consider "risk" versus "expected benefits" of potentially hazardous research projects. Rather, it is the concern of this Committee to know whether or not the safety precautions proposed for the experimental work appear to be adequate for protection of personnel and the environment. In general, the review process will focus on (1) qualifications of the investigator, (2) agents to be employed, (3) risks presented by experimental procedures, (4) adequacy of containment equipment and facilities, (5) training level of persons directly associated with the work, (6) need for health surveillance of laboratory personnel, (7) regulatory compliance, and (8) other factors relevant to safe conduct of the study and compliance with regulations and appropriate guidelines.

- 5.2.3 The Principal Investigator (PI) and the IBC must concur on all matters relating to containment requirements, safe practices, and handling procedures for biohazardous agents. In event of non-concurrence, the recommendations of the Committee shall prevail until such time as they are modified or rescinded by appellate decision of appropriate University officials, starting with the VP for Research. Questions relating to recombinant DNA studies will be referred to the NIH Office of Recombinant DNA Activities for final opinion.

6.0 BIOLOGICAL SAFETY OFFICER

The Biological Safety Officer (BSO) is appointed from the Environmental Health and Safety staff by the Director of Environmental Health & Safety and is primarily responsible for implementation of the biosafety program in all Ohio University premises within the limits of their staffing and resources. Major duties or activities are as follows:

- 6.1 Assist in the preparation and periodic updating of a biosafety manual which is in accordance with OU policy, consistent with government regulatory guidelines, and best professional practices.
- 6.2 Provide consultation to investigators on matters relating to laboratory safety, appropriate handling and containment of biohazardous agents, decontamination, and disposal of infectious (excluding radioactive and chemical) wastes.
- 6.3 Aid investigators in the development of appropriate emergency measures for dealing with accidental spills and personnel contamination.
- 6.4 Surveillance of laboratories in which biohazardous agents are employed to ensure compliance with prescribed safety guidelines and rectification of any deficiencies.
- 6.5 Investigate incidents involving biohazardous agents (excluding radionuclides) to determine causes and necessary corrections. Upon completing the investigation, the Biosafety Officer will prepare a written report of findings for review and action, if any, by the IBC.
- 6.6 Monitor intra-campus transport and provide information for off-campus shipment of biohazardous (excluding radioactive and chemical) materials.
- 6.7 Review plans for new facilities and modifications of existing structures where etiologic agents, chemical carcinogens, or recombinant DNA materials will be used.
- 6.8 Develop, arrange, or conduct training programs for laboratory personnel using biohazardous agents.

- 6.9 Serve as liaison between OU and outside regulatory agencies concerned with the use of biohazardous agents.
- 6.10 Serve as an ex-officio member of the IBC and serve as coordinator of IBC activities.
- 6.11 The Biological Safety Officer, upon concurrence by the VP for Research or chairperson of the IBC (or in his/her absence, by at least three other technically qualified members of the Committee), may temporarily stop any work with etiologic agents or other regulated materials that creates a recognized hazard to personnel, the public or environment, or involves experiments prohibited by the institution. The entire IBC then will review the problem and forward written recommendation(s) to the Vice President of Research and Director of Environmental Health and Safety for final action.

7.0 RESPONSIBILITIES OF INVESTIGATORS

- 7.1 The investigator is expected to be familiar with relevant safety guidelines described in this manual, to personally monitor and be responsible for the day-to-day operation of the laboratory, and to take all necessary steps for protection of staff, students, and the general public against undesirable consequences of experimental work conducted on Ohio University premises. The investigator is also expected to be familiar with other regulations appropriate to their laboratory work, such as OSHA, EPA, NRC, and other applicable laws. It should be emphasized, that this responsibility is reduced in no way by activities of the IBC and Safety Officers. Additional duties of the investigator are as follows:
 - 7.1.1 Obtain written approval of the IBC before work involving the use of etiologic agents of RG2 or higher, oncogenic viruses, chemical carcinogens, recombinant DNA or other regulated materials is initiated. The document submitted for this is the IBC Biosafety Review Form (found in Appendix C) and should describe: (1) the agents and experiments to be performed; (2) the level of containment judged necessary for the work; (3) the containment facilities available; (4) the training level of relevant laboratory personnel; and (5) indicate whether health surveillance of persons directly involved is deemed necessary.
 - 7.1.2 Thoroughly inform all persons directly involved in hazardous experiments, e.g., infectious agents and harmful chemicals, of the potential health risk presented and the safety procedures necessary to minimize exposure. Failure to do so may be considered neglect on the part of the investigator.
 - 7.1.3 Establish emergency procedures to be followed in the event of an overt spill or contamination with potentially hazardous biological material.

These procedures should be posted in a prominent place in the laboratory. Moreover, it is recommended that a responsible member of the laboratory staff be designated to handle emergency situations whenever the principal investigator is absent from the premises.

- 7.1.4 Immediately report any unusual incident, such as spill, break in containment, or overt contamination, to the Biosafety Officer and to either the Department Chairperson, Research Institute or Center Director, whichever is appropriate. In case of injury or suspected injury, an OU Incident Report Form available from your department, the Worker Compensation Administration office, Environmental Health and Safety office, or the EHS website (see Appendix I) should be completed immediately. The principal investigator must conduct an investigation and send the form to the Worker Compensation Administration office (they send a copy to EHS) immediately afterwards.

If a needlestick or sharps injury is involved, a sharps injury form must be filled out and attached to the OU Incident Report form when sent to the WCA office and EHS (see Appendix J).

- 7.2 Post working areas and facilities with biohazard warning signs.
- 7.3 Arrange for health surveillance of laboratory personnel if deemed appropriate for the research project.
- 7.4 Cooperate with Biological, Chemical, Radiation Safety Officers, or regulatory personnel, during inspection visits and other projects.
- 7.5 Implement and keep appropriate records for all biosafety activities and required OSHA programs related to labs, such as Chemical Hygiene, Bloodborne Pathogens, Personal Protective Equipment, Training, etc.
- 7.6 Monitor the use and maintenance of all safety equipment and devices.

8.0 RESPONSIBILITIES OF DEPARTMENT CHAIRPERSONS, RESEARCH INSTITUTE OR CENTER DIRECTORS

- 8.1 The chief administrator of each Department, Research Institute or Center is responsible for the general safety of faculty, staff, and students working with biohazardous agents in his/her overall area of jurisdiction. It should be emphasized that this responsibility is in no way altered by the duties of the Institutional Biosafety Committee and Safety Officers.

- 8.2 The chief administrator shall ensure that each principal investigator in his/her area of jurisdiction is provided with a copy of the Ohio University Biosafety Manual and should stress the importance of compliance with the guidelines therein.
- 8.3 The chief administrator is jointly responsible, with the principal investigator, for informing the Institutional Biosafety Committee of work involving biohazardous agents and reporting incidents involving such agents to the Biosafety Officer.
- 8.4 The Department Chairperson is jointly responsible, with the faculty members supervising teaching laboratories, for informing students of proper precautions to be taken when working with pathogenic microorganisms.

9.0 CONSIDERATION OF THE LIABILITY ASPECTS OF WORKING WITH BIOHAZARDOUS AGENTS

- 9.1 All faculty members and investigators should be aware of their exposure to personal liability in performance of research and teaching involving biohazardous agents. No rules specifically relating to liability in working with biohazardous agents may be stated. However, the general rule of law that every individual is liable to others for negligent acts or omissions which cause injury to other persons is likely to be applicable to this situation. The rule applies whether a faculty member is working with a biohazardous agent or pursuing other routine duties of teaching, research, and administration. The increased potential for personal injury in a laboratory where persons are working with biohazardous agents is known or should have been known.
- 9.2 To avoid injury and liability for injury, an investigator should exercise due care in research activities. What "due care" is, of course, will vary with the facts of a research situation and legal interpretations. In everyday life activities, the question to be asked in determining liability is whether a person acted as a reasonable person would have done. In a laboratory then, the question is whether the person in charge of research has behaved in a way that others with appropriate training and experience would have behaved. (One notable exception to the "reasonable man" standard is the principle of strict liability. Some activities have been judged to be so inherently dangerous that liability for injury attaches even in absence of negligence. Research with some biohazardous agents may fall into such a category of activities.) Whenever there is a widely accepted procedure for handling materials or laboratory situations, well-known professional guidelines will usually be the standard against which "reasonableness" is measured. Departures from written policies of an institution or regulations are also indications of a failure to exercise requisite care. The Office of Legal Affairs shall be consulted in this regard.
- 9.3 As injuries are most likely to involve employees, the most important responsibilities of a principal investigator are adequate instruction to other personnel handling a biohazardous agent about how it should be handled and

adequate supervision of such persons. The actual degree of instruction and supervision necessary in each case will depend upon the project and the degree of education and sophistication of the persons involved.

10.0 GENERAL LABORATORY RULES FOR THE USE OF BIOHAZARDOUS MATERIAL

All laboratory personnel are expected to be familiar with the following rules and to conduct their work in accordance with them:

- 10.1 Storage of food in refrigerators or freezers used for infectious materials, radioactive materials, or chemical carcinogens is not permitted. In addition, there should be no eating, drinking, smoking, chewing of tobacco, application of cosmetics, shaving, brushing of teeth, or storage of food in areas where these biohazardous materials are stored or used.
- 10.2 Outer street clothing (coats, hats, etc.) should not be kept in an area where accidental contamination with infectious or other hazardous materials can occur. Contaminated lab coats cannot be taken home or laundered at home.
- 10.3 Mechanical pipetting aids should be used when pipetting any biohazardous material. Mouth pipetting is not permitted at any containment level.
- 10.4 Hands should be washed immediately after completion of any procedure in which biohazardous material is used. Persons working with infectious material should be especially careful not to inadvertently touch the face or eyes with unwashed hands.
- 10.5 The use of cleaning tissue rather than cloth handkerchiefs is recommended in laboratories handling infectious materials.
- 10.6 Rubber or plastic gloves should be worn when working with an etiologic agent which may cause infection by entry through skin abrasions. Gloves are the most widely used form of personal protective equipment. They act as a primary barrier between your hands and blood and etiologic agents. Latex or vinyl gloves are used for medical, dental, and laboratory procedures. Heavy duty utility gloves may be used for housekeeping duties. Gloves must be worn when one anticipates hand contact with blood, potentially infectious materials, mucous membranes, or non-intact skin. Vinyl and latex single-use, disposable gloves should be replaced as soon as possible if contaminated, torn, punctured or damaged in any way. Never wash or decontaminate for reuse. Be aware of the possibility that employees may have allergies to latex which can be life-threatening to some individuals. When chemical hazards are also present more extensive consideration of the many available types of glove materials is necessary. Consult EHS for assistance as needed with your Personal Protective Equipment program and required OSHA PPE assessment.

- 10.7 Long hair, beards, and loose-flapping clothing are potentially dangerous when working near an open flame, biohazard materials that could be inadvertently spilled, or moving laboratory equipment. Tying back hair or employment of hairnets should be encouraged in all laboratories. Keep jewelry to a minimum and do not wear dangling jewelry in the lab.
- 10.8 Protection of the eyes is a matter which should be given high priority in every laboratory. Signs indicating "Eye Protection Required" should be prominently displayed in all areas where a hazardous exposure may exist. Infection can occur through the eyes if a pathogenic microorganism is splattered into the eye, and many chemicals commonly employed in the laboratory can cause serious damage if similarly deposited. Safety spectacles or goggles should be worn when necessary. Every laboratory that uses materials that are irritating to the eyes must have an eyewash fountain. These eyewash fountains must be ANSI approved. Contact lenses provide little or no practical protection to the eyes. In fact, foreign material present on the surface of the eye often becomes trapped beneath the contact lens, and similarly entrapped caustic chemicals, irritating vapors, and infectious agents cannot be readily washed from the eye without removal of the lenses. Supervisors and/or instructors are responsible for the enforcement of all regulations regarding the wearing of safety glasses, use of contact lenses, and the use of additional eye protection.
- 10.9 Consideration should be given to whether a person should be permitted to work alone on a biohazardous laboratory operation. Emergency situations often necessitate actions by others if someone is contaminated in the incident, such as a spill, in order to prevent injury and avoid additional contamination away from the spill site. The PI shall evaluate and set lab policy in this regard.
- 10.10 Procedures or activities likely to produce aerosols of infectious material must be conducted in an approved biological safety cabinet. Centrifuges, sonicators, blenders, and shaking (aerating) equipment require special attention because they can disperse aerosols easily if not operated with proper precaution. Insure proper experimental set up in the biosafety cabinet and proper use of the cabinet by personnel.
- 10.11 Disposable and reusable laboratory clothing (coats, gowns, etc.) overtly contaminated with infectious materials, or worn in BL3 containment facilities or laboratories in which Class 3 etiologic agents are employed (not currently done at OU), must be decontaminated by steam sterilization (autoclaving) or other proven effective means before discarding or releasing to the laundry. In exceptional circumstances, the Institutional Biosafety Committee may recommend routine decontamination or sterilization of laboratory clothing worn in certain BL2 containment facilities or in laboratories where certain Class 2 etiologic agents are used prior to laundering.

- 10.12 All biohazardous materials must be placed in rigid, leak proof containers labeled with a biohazard symbol for intra-campus transport between buildings or from one laboratory to another located in the same building. Rigid containers are recommended but not mandatory when transport between laboratories is by a passageway restricted to authorized laboratory personnel. All infectious waste will be treated through the OU Infectious Waste Management program, by autoclaving at Irvine Hall, or picked up for incineration at one of the campus pick up sites.

11.0 PREVENTION OF LABORATORY TRANSMISSION OF HIV, HBV AND OTHER AGENTS THAT MAY BE PRESENT IN HUMAN BLOOD, TISSUE OR BODY FLUIDS

The risk of transmission of HIV, HBV and other bloodborne pathogens can be minimized if laboratory workers use the following guidelines:

- 11.1 Be careful when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Do not recap used needles by hand. Do not remove used needles from disposable syringes by hands. Do not bend, break, or otherwise manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in puncture resistant containers for disposal. Locate the puncture resistant containers as close to the work site as is practical. Dispose of contaminated pipettes or broken glass in appropriate biohazard containers. Employ safe needle devices, needless systems, and engineered sharps devices and systems.
- 11.2 Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated.
- 11.3 Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids. It is good practice to wash hands frequently throughout the day as well, as a routine measure.
- 11.4 Implement an effective OSHA Bloodborne Pathogens Program, conduct an exposure assessment, vaccinate for HBV, conduct training, establish effective policies and procedures, medical follow-up for injuries, recordkeeping, evaluation of sharps devices, etc.
- 11.5 All specimens of blood and body fluids should be put in a well-constructed container with a secure lid to prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and the laboratory form accompanying the specimen. All persons processing blood and body-fluid specimens (e.g., removing tops from vacuum

tubes) should wear gloves. Masks and protective eyewear should be worn if mucous-membrane contact with blood or body fluids is possible. Gloves should be changed and hands washed after completion of specimen processing.

- 11.6 For routine procedures, such as histologic and pathologic studies or microbiologic culturing, a biological safety cabinet may not be necessary. However, appropriate biological safety cabinets should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating, and vigorous mixing.
- 11.7 Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting is completely prohibited.
- 11.8 Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles should be followed. Alternative safety devices should be used where possible.
- 11.9 Laboratory work surfaces should be decontaminated with an effective chemical germicide after a spill of blood or other body fluids and when work activities are completed for the day. A routine daily decontamination at the end of the workday is a standard minimum decontamination schedule when work is ongoing, regardless of work activities.
- 11.10 Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with current policies for disposal of infectious waste.
- 11.11 Scientific equipment that has been contaminated with blood or other body fluids should be decontaminated and cleaned before being repaired in the laboratory or transported to the manufacturer.
- 11.12 All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.
- 11.13 Warning signs should be posted when there is a hazard to laboratory employees of infectious disease transmission.
- 11.14 Implementation of universal blood and body fluid precautions for ALL patients, samples, and lab procedures is required for Bloodborne Pathogens.
- 11.15 All workers whose jobs involve participation in tasks or activities with exposure to blood or body fluids to which universal precautions apply should be vaccinated with hepatitis B vaccine.
- 11.16 All exposures should be reported on the Ohio University Incident Report form.

- 11.17 For exposure to human blood or other body fluids that could contain HIV, HBV or other bloodborne agents, lab or clinic personnel will evaluate and manage the incident according to current CDC and Ohio Department of Health guidelines.

12.0 EXPERIMENTAL ANIMAL WORK

12.1 General Rules and Procedures

- 12.1.1 Persons performing experimental animal studies are expected to be thoroughly familiar with guidelines described by the Institutional Animal Care and Use Committee (IACUC) and Ohio University Policy 19.049, and to conduct their work in accordance with operating policies of the IACUC. These guidelines are available from the Department of Laboratory Animal Resources (LAR), or from the Compliance Manager in the office of the Vice President for Research.
- 12.1.2 It is essential that research requiring the use of hazardous agents in animals be carefully planned to minimize health risk to personnel and to prevent unwanted exposure of other experimental animals. All personnel participating in such work are expected to be given explicit instructions concerning the safety precautions and procedures to be followed. This responsibility shall rest with the principal investigator conducting the study. Any incident or emergency involving a break in containment conditions and practices must be immediately reported to Director of Laboratory Animal Resources (LAR).
- 12.1.3 The Director of LAR must be fully informed by the principal investigator before studies requiring administration of radionuclides to experimental animals are undertaken. Both animal rooms and cages containing radioactive animals are to be posted with "CAUTION RADIOACTIVE MATERIAL" signs, and the rooms are to be restricted to entrance by authorized personnel only. Animals given radioactive materials and animal wastes are to be disposed of according to instructions given by the Radiation Safety Officer at EHS.
- 12.1.4 The Director of LAR and the Biosafety Officer must be fully informed of studies involving use of infectious agents, chemical carcinogens, or other hazardous substances in animals. These persons and the principal investigator must concur on all aspects of containment conditions and practices essential for protection of personnel and other experimental animals. It is imperative that no hazardous work is begun until complete agreement is reached.

- 12.1.5 Animal rooms and cages containing infected animals are to be posted with "BIOHAZARD" signs. Experimentally or naturally infected animals likely to shed pathogens in body secretions or excretions must be isolated from non-infected animals. Animals infected with Class 3 agents, or agents not yet classified as to hazard, MUST be housed under conditions providing at least BL3 level of physical containment (not available at OU).
- 12.1.6 Depending upon the degree of risk and complexity of the containment procedures deemed necessary, the investigator may be required to assume responsibility for routine husbandry of animals used in the experiments. Persons performing such husbandry must be provided with and are expected to wear protective devices (wrap-around garments, gloves, masks, etc.) as dictated by the particular hazard involved. Protection devices should also be worn when handling necropsy material, excreta, etc.
- 12.1.7 After each set of experiments, the investigator should arrange for LAR to decontaminate containment areas. Cages (including litter), water bottles, feed hoppers, and other nondisposable items used for infected animals should be steam sterilized (autoclaved) before cleaning and washing for reuse. Dead animals should be placed in leak proof double-wall plastic bags which are closed prior to removal from the work area and disposed of by incineration or other acceptable methods. Litter from cages used for carcinogen treated animals should also be placed in double-wall plastic bags and sealed prior to removing from the containment area for disposal. Animal litter contaminated with hazardous chemicals must be disposed of according to OU Hazardous Waste policies and infected animals according to OU Infectious Waste policies.
- 12.1.8 Filter-top cages with solid bottoms and sides must be used for transfer of infected rodents between buildings. The Director of LAR should be consulted regarding appropriate transfer procedures for non-rodent species.
- 12.1.9 Studies with non-human primates (not allowed at Ohio University), captive wild animals, and certain domestic animals with unknown health history are potentially dangerous even though no experimental infectious agent or hazardous substance is used. This is because the animals may harbor inapparent infections with human pathogens. Unless the absence of human pathogens is indicated by appropriate screening procedures, it is best to regard tissues and other biological materials from questionable animals as potentially infectious. Transplantable rodent tumors are of particular concern since it has been shown that they frequently harbor a variety of indigenous

viruses, such as lymphocytic choriomeningitis virus, a Class 3 human pathogen. Before arranging to obtain tumor-bearing rodents of unknown health history from sources outside Ohio University, it is imperative that the LAR and EHS be informed to assure availability of a suitable isolation room. Screening procedures for detection of indigenous viruses in transplantable rodent tumors should be performed before use.

- 12.1.10 BSL-3 organisms or experiments are not permitted at Ohio University at this time, since there are no BSL-3 lab facilities available.

12.2 Use of Non-Human Primates

- 12.2.1 Experimental use of non-human primates is not authorized at Ohio University at this time. Experimental studies involving non-human primates present significant risk because these species may injure personnel and may be inapparent carriers of serious infectious diseases, such as shigellosis, tuberculosis, and herpes B virus infection, which can be transmitted to man. Ohio University has no primate facilities.

- 12.2.2 Any cells, tissues, or biological samples from non-human primates must be obtained and approved according to current IBC procedures.

12.3 Medical Surveillance

- 12.3.1 Persons having significant contact with any experimental animals should report to the OU Occupational Health Clinic (593-1660) for evaluation and consultation if needed. Those associated with hazardous experiments may require periodic health evaluation or protection from certain diseases by immunization. This may include hepatitis B, tetanus, rabies, or others.

- 12.3.2 Individuals who work with experimental animals or their tissues and who develop a fever or other symptoms associated with infection must promptly notify their supervisors. Maintenance of an illness record for persons exposed to hazardous experiments is recommended.

- 12.3.3 Review medical surveillance needs for experiments and use of certain animals as needed with the Director of LAR, EHS, and the Occupational Health Clinic Medical Director

- 12.3.4 Scratches or bites (even superficial ones) inflicted by animals should be scrubbed with Betadine and water, thoroughly rinsed with warm water, and dried with clean absorbent cotton or a surgical sponge. Injuries should be promptly reported to the supervisor who will

arrange for medical care at the OU Occupational and Health Clinic or other appropriate medical facility.

12.3.5 All employee injuries must be reported immediately on the OU Incident/Injury report form available from your supervisor.

12.3.6 Should problems with animal allergies arise, consult the Occupational Health Clinic.

13.0 USE OF RADIOACTIVE MATERIALS

13.1 Persons intending to use radioactive material in their work must obtain written approval from the Ohio University Radiation Safety Committee. The authorized investigator, as well as other laboratory personnel under his/her supervision, are expected to be familiar with the provisions described in the OU Radiation Safety Handbook and to conduct their work in accordance with them.

13.2 Radioactive wastes and animals given radioactive materials are to be disposed of according to instructions given by the Radiation Safety Officer.

13.3 Mixed infectious and/or hazardous and radioactive waste will be handled on a case-by-case basis, contact EHS.

14.0 LABELING OF FACILITIES OR WORK AREAS USED FOR BIOHAZARDOUS MATERIALS AND LABORATORY SIGNAGE

14.1 All biological safety cabinets, incubators, refrigerators, and freezers used for infectious materials shall be posted with "BIOHAZARD" signs. Signs showing the conventional radiation symbol and the words "CAUTION RADIOACTIVE MATERIAL" must also be posted on these facilities if they are used for storage of radioactive materials. This is the minimum signage requirement. Where regulations require higher levels of warning signage, this shall be done. The equipment must be kept locked at all times when located in an area accessible to persons other than laboratory personnel.

14.2 Liquid nitrogen storage containers used in association with infectious material shall be posted with "BIOHAZARD" signs and provisions should be made for locking these facilities when located in an area accessible to persons other than laboratory personnel.

14.3 The entrance to work areas used for Class 2 or above etiologic agents, and recombinant DNA activities shall be posted with "BIOHAZARD" signs.

14.4 A sign or label giving the name(s) and telephone number(s) of responsible person(s) who may be contacted in case an emergency occurs when the laboratory is not in operation, should be affixed to BIOHAZARD signs posted at the

entrance to work areas and on biohazard storage facilities located in unrestricted corridors and rooms. It is recommended that the name of the infectious agent be on the sign so that emergency personnel can assess the scene without entering the laboratory in an emergency. Due consideration should be given to lab security as well.

14.5 BIOHAZARD signs and labels may be procured from many safety supply companies. You can also contact EHS or the EHS web site for safety supply companies.

14.6 No BSL-3 facilities exist at OU at this time.

15.0 DECONTAMINATION AND DISPOSAL OF WASTE (INFECTIOUS WASTE)

15.1 Laboratory Spills

15.1.1 Despite any precautions that may be taken, spills may occur in the laboratory. When infectious materials are involved, it is important that the area be immediately isolated to prevent spread of the spillage. Remove any clothing known or suspected to be contaminated, place in a leak proof container, and decontaminate by steam sterilization (autoclaving) at the Irvine infectious waste autoclave. Call the Biology Department Technician, at 593-2301 before bringing the materials for autoclaving. Thoroughly wash all potentially contaminated areas of the body with soap and water and any significant cuts or lacerations should be given medical attention.

15.1.2 It is important to wear personal protective equipment, such as rubber or plastic gloves and disposable footwear, when cleaning the spill area. After transferring broken glass and other contaminated objects to a discard container, carefully pour a hypochlorite solution containing 1:10 dilution of household or laundry bleach, iodophor solution containing at least 3000 PPM iodine (1:2 dilution of Wescodyne), or other appropriate chemical disinfectant around and into the visible spill. (These recommended concentrations of disinfectants are higher than those usually used for surface decontamination because the volume of spill may reduce the concentration of active ingredient in the disinfectant). After an interval of 15-20 minutes, wipe up the disinfectant and spill with paper or cloth towels. Place the absorbent material in a biohazard bag and place it in the infectious waste containers for treatment. (Note: Bleach can discolor fabrics, carpets, etc.)

15.1.3 All major spills involving infectious or radioactive materials should be reported, respectively, to the Biological or Radiation Safety Officer immediately. Ohio University Police Department (OUPD) (740-593-

1911) has EHS home and emergency phone numbers for after-hours assistance.

15.2 Disposal of Laboratory Wastes

15.2.1 Infectious Wastes

15.2.1.1 No microbial preparation of any kind, infectious material or equipment (e.g., disposable pipettes and containers) contaminated with same, shall be disposed of in any manner or placed in waste receptacles intended for collection by non-laboratory personnel without first being rendered non-viable preferably by appropriate infectious waste treatment. Chemical disinfection may only be used for bacterial cultures. In such cases, it shall be the responsibility of the investigator to assure that the disinfecting method employed will provide the expected effective treatment.

15.2.1.2 Infectious waste shall be rendered non-infectious at the Irvine autoclave for biological or medical departments. Other areas have designated infectious waste pick up sites. These locations are picked up approximately every two weeks by our licensed infectious waste hauler for incineration off site.

15.2.1.3 See Appendix F for current campus infectious waste pick up sites and definitions of materials considered infectious in Ohio.

15.2.2 Radioactive and Mixed Wastes

15.2.2.1 It is the responsibility of laboratories approved for radionuclide studies to provide appropriately labeled receptacles for both dry and liquid radioactive wastes. These receptacles are to be used only for non-infectious materials. Any radioactive wastes known or suspected to contain infectious material must be handled in such a way that both potential hazards are addressed. Please contact the Radiation Safety and Biosafety Officer if you have mixed waste disposal needs.

16.0 EFFICIENCY OF FUMEHOODS, SPECIAL VENTILATION HOODS, AND CERTIFICATION OF BIOLOGICAL SAFETY CABINETS

16.1 Fumehoods

- 16.1.1 Experience has shown that there is considerable variation in the operational efficiency of fume hoods installed in laboratories at OU, and some may not always provide the recommended average inward air velocity of at least 100 feet per minute. In view of this circumstance, manometric pressure gauges or flow gauges have been installed on all campus fumehoods so that researchers can monitor proper operation on a continuing basis. Contact EHS if you need assistance or training in fumehood use.
- 16.1.2 EHS contracts with an outside testing company every year to test fumehoods for proper operation. Maintenance is done by Facilities Management and our contractor.
- 16.1.3 Any time that improper operation or problems are suspected, contact Facilities Management (593-2911)
 - 16.1.3.1 Primary researchers are responsible for the daily monitoring of their fumehood air flow meters, alarms, manometric gauges or other flow or static pressure devices.

16.2 Biological Safety Cabinets

- 16.2.1 The capability of a biological safety cabinet to protect laboratory personnel and the environment from exposure to potentially hazardous aerosols is primarily dependent on proper functioning of the cabinet. No biological safety cabinet should be used to contain hazardous materials unless it has been demonstrated by appropriate test procedures to meet the minimum safety specifications given in NSF Standard 49 and other appropriate guidelines.
- 16.2.2 The procedures to be used for the certification of safety specifications of cabinets shall be those recommended by the National Sanitation Foundation in their Standard 49. Certification is required (1) before a newly installed cabinet is used, (2) after a cabinet is moved, relocated or partially dismantled for cleaning or repair, and (3) at least annually. EHS has established a program for periodic inspection and recertification of biological safety cabinets installed in buildings on the O.U campus using an outside certification company. Departments are responsible for payment of the cost of certification directly to the company.
- 16.2.3 EHS maintains a file of current cabinet users and locations. Primary researchers or their departments are responsible for scheduling their annual certification prior to the one-year date on the cabinet sticker. In order to minimize interference with laboratory work schedules,

investigators responsible for safety cabinets will contact the Department Chair, Institute Director, or assigned person prior to the one-year date and arrange a suitable time for certification. If all department cabinets are certified at one time as a group the department must coordinate and implement this effort. Since an outside contractor is used to certify cabinets this is usually the most efficient and cost effective method. The personnel are expected to ensure that working surfaces of cabinets are effectively decontaminated and all hazardous work safely contained prior to any scheduled inspection or certification. In certain instances the Biosafety Officer, after consultation with the investigator, may recommend that a safety cabinet be decontaminated with formaldehyde vapor or other effective method immediately prior to making repairs, replacement of HEPA filters and/or certification. Additional time is required for this precautionary measure and additional costs will be incurred.

16.2.4 A certification company label indicating the date of service and other pertinent information will be affixed to each safety cabinet that conforms to minimum performance standards. If a cabinet fails to meet performance standards, person(s) using the cabinet will be promptly informed as to the nature of the problem and how it can be corrected. Please notify the EHS officer as well. The cabinet must not be used until repaired.

16.2.5 The certification company will make arrangements for and supervise the installation of replacement HEPA filters, but responsibility for payment of replacement filters rests with the investigator or their department. If major repairs, e.g., electrical components, airflow detectors, motors or blowers, are necessary for certification, it is recommended that the service of a qualified factory representative be obtained. Contact EHS if assistance is needed or when these types of problems occur.

17.0 SHIPMENT OF BIOHAZARDOUS MATERIALS TO OR FROM OHIO UNIVERSITY PREMISES

17.1 The transport of any biohazardous material from the OU, or from other facilities owned or leased by OU, shall be in accordance with current federal and state regulations governing the packaging, labeling, and shipment of such materials. Included are human and animal pathogens or their harmful products, diagnostic specimens reasonably believed to contain viable infectious agents, recombinant DNA molecules contained in an organism or virus, plant pathogens, radioactive materials, chemical carcinogens, and other dangerous chemicals. Contact EHS or appropriate web sites for regulatory requirements or availability of commercial packaging and labeling kits found in Appendix I.

- 17.2 Any current standard operating procedures (SOPs) of the Ohio University IBC for transfer of materials must be met.
- 17.3 The transfer of some highly infectious agents and deadly toxins is regulated by the Possession, Use, and Transfer of Select Agents and Toxins Rule (“Select Agents Rule”). See Appendix H for the list of these agents. OU is not currently licensed or authorized to receive these agents and the cost of becoming licensed is very high. Please contact EHS for assistance.
- 17.4 References for packaging and shipping requirements can be found on the Department of Transportation (DOT) website in Appendix I under Federal Agencies and Regulations. Airline requirements can be found on the International Air Transport Association (IATA) website in Appendix I under Standards and Organizations. The U.S. Postal Service also has regulations for shipment of hazardous materials. In addition, most airlines have their own requirements. Contact EHS for assistance.

18.0 IMPORTATION AND INTERSTATE TRANSPORTING PERMITS

- 18.1 A limited permit, issued by the U.S. Public Health Service or Department of Agriculture, is required for each importation and interstate movement of certain human, animal and plant pathogens. Importation of wildlife disease agents, wildlife and eggs thereof, requires a permit issued by the Department of Interior. Information concerning the procurement of permits can be obtained from EHS. Investigators are urged to obtain permits to avoid unpleasant situations and possible embarrassment to themselves and to Ohio University.
- 18.2 The USDA requires a permit for the importation of all cultured cells, etc., such as hybridomas and others, because they might contain or harbor potentially dangerous etiologic agents such as foot-and-mouth disease virus. Cultures brought illegally into the country will be confiscated and destroyed at place of importation. Request for a permit to import a questionable cell culture (i.e., not previously tested for indigenous agents dangerous to domestic animals) will be denied if specific arrangements have not been made for the culture to go through quarantine and testing at the Plum Island Animal Disease Center. Assistance with permit applications is available through the Biosafety Officer at EHS. The USDA office responsible for permits is listed below:

USDA, APHIS, VS NCIE
4700 River Road
Unit 40
Riverdale, Maryland 20737
Telephone: (301) 734-3277 Fax: (301) 734-4704
http://www.aphis.usda.gov/animal_health/permits/

19.0 U.S. DEPARTMENT OF COMMERCE EXPORT LICENSE

- 19.1 Faculty and staff members planning to ship viable or inactivated microbial agents or in-vitro cell cultures (or frozen cells) to colleagues in foreign countries should bear in mind that the export of these materials is controlled by the Export Administration, Bureau of Industry and Security, U.S. Department of Commerce. A license may be required even though such shipments generally are made on a courtesy basis by research personnel of educational institutions. The type of license needed depends upon the material and the country to which it is sent. Information concerning export regulations is available through the Biological Safety Officer at EHS. Persons desiring to export research materials are advised to contact:

The Bureau of Industry and Security
<http://www.bis.doc.gov/>

An export license may not be required for shipment of microbial agents to Canada. However, the Canadian investigator must obtain and furnish to the U.S. exporter an import permit to be attached to the package in a readily accessible manner to facilitate clearance through Canadian Customs. Requests for Canadian import permits are sent to:

Veterinary Biologics Section
2 Constellation
Ottawa, Ontario K1A 0Y9
<http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml>

20.0 REGULATORY COMPLIANCE

- 20.1 Ohio University strives to be in compliance with all federal, state, and local regulations, as well as applicable agency guidelines. This is possible to the extent that adequate staff and resources are provided to EHS and other departments on campus and cooperation is received from researchers and their departments.
- 20.2 Ohio University is regulated in whole or in part by numerous regulations and guidelines. It is the primary investigator (P.I.) and departments' direct responsibility to comply with and find all regulatory requirements required for their research initiatives. No experimental program should be initiated until adequate, safe, and compliant facilities, equipment, and training are arranged for.
- 20.2.1 EHS staff and the Biosafety Officer are available for consultation and assistance with compliance, health, safety, and environmental issues.
- 20.2.2 Some services may be provided centrally through university-wide programs if funds are available (fumehood testing, normal maintenance).

20.2.3 Some programs may be coordinated by Environmental Health and Safety, but paid for by individual departments (infectious waste disposal, biosafety cabinet certification).

20.3 Some of the regulations and guidelines that researchers may be regulated by are:

20.3.1 Environmental Protection Agency

20.3.1.1 Resource Conservation and Recovery Act (RCRA) – Hazardous Waste Disposal

20.3.1.2 Toxic Substances Control Act (TSCA) – new products

20.3.1.3 Biotechnology TSCA Requirements – (rDNA)

20.3.1.4 Emergency Planning, Continuity Right-To-Know Act (EPCRA) – reportable quantities

20.3.1.5 State of Ohio EPA (parallel regulations)

20.3.2 Occupational Safety and Health

20.3.2.1 Public Employees Risk Reduction Act (PERRP) -State Employees OSHA

20.3.2.2 Chemical Hygiene

20.3.2.3 Bloodborne Pathogens

20.3.2.4 Personal Protection Equipment

20.3.2.5 Formaldehyde

20.3.2.6 Tuberculosis (proposed at this time)

20.3.3 Public Health

20.3.3.1 Ohio Department of Health Regulations

20.3.3.2 Etiologic Agent Regulations of USPHS

20.3.4 Health and Hygiene in Research Laboratories

20.3.4.1 CDC/NIH Biosafety Guidelines

20.3.4.2 NIH rDNA Guidelines

- 20.3.4.3 Laboratory Animal Handling Guidelines
- 20.3.4.4 Good Laboratory Practices Act
- 20.3.4.5 Possession, Use, and Transfer of Select Agents and Toxins
- 20.3.4.6 National Cancer Institute (NCI) – Carcinogens Guidelines

20.3.5 Other

- 20.3.5.1 NRC Radiation Regulations
- 20.3.5.2 Non-Ionizing Radiation Guidelines (lasers, IR, UV, etc.)
- 20.3.5.3 DOT Packaging and Transportation Regulations
- 20.3.5.4 U.S. Department of Agriculture Regulations (animals, plants, field trials, rDNA, export/import)
- 20.3.5.5 U.S. Department of Commerce – Export
- 20.3.5.6 Food and Drug Administration (FDA) – drug development, medical devices
- 20.3.5.7 Ohio State Fire Marshall

20.4 Copies of the regulations and numerous other helpful web sites can be found on the EHS website, www.ohio.edu/ehs.

20.5 Assistance is available from the Biosafety Officer and other EHS Staff.

21.0 PREPAREDNESS FOR BIOLOGICAL EMERGENCIES AND SPILLS

21.1 General Comments on Emergencies

Safety is an intrinsic part of each laboratory and/or biohazardous operation. Work is planned so that exposures to potentially hazardous agents will not occur. In spite of this, incidents that create hazards do occur. These may involve spills or releases of potentially hazardous, infectious or chemical agents. Also, failure of important equipment and facility safeguards may place workers at a high risk of exposure. Likelihood of severe injury or infection can be reduced if plans for emergencies are established and well known to all who need to know. For this reason, various regulations, standards and the National Institutes of Health (NIH) "Guidelines" require the preparation of emergency plans for laboratories and facilities involved in certain activities where there are potential biohazards.

It is not possible to recommend a single plan of action that would be applicable in all situations because individual laboratories and the properties of different etiologic agents are so varied. Laboratory personnel must be trained with regards to the emergency procedures to be followed in their area. The following basic principles, however, may be useful in developing specific procedures for dealing with accidental spills or releases of potentially hazardous materials in this type work.

1. Take care of the injured first, render assistance to persons involved and remove them if necessary and safe to do so.
2. Warn personnel of the potential hazards to their safety and evacuate the area if necessary.

21.1.1 Reporting of Emergency Incidents

All emergency incidents must be reported immediately to the laboratory PI or supervisor. Such incidents include but are not limited to inadvertent fires, explosions, personnel exposures, injuries, releases of biohazard materials, and failure of biohazard containment. The PI or supervisor will in turn make (using such help as necessary by the fire authority, medical personnel, Biosafety Officer, etc.) such investigations and reports as required. An OU incident report should be filed with OU Environmental Health and Safety (EHS). If a needlestick or sharps injury is involved, attach a sharps injury form before sending to the WCA office and EHS (see Appendix J). All external reports, other than those of an immediate nature such as summoning the fire department in case of a fire, are to be made by or through the Director of EHS.

21.1.2 All incidents shall be reported as follows:

- 21.1.2.1 Each person involved in or supporting biohazard work shall report to his/her PI or supervisor:
 - a. Each incident (both injury causing and those without injury).
 - b. Each incident resulting in significant damage to University or other property.
 - c. Each situation or condition observed on the job, which has the potential for injuring or endangering the health of people and/or causing damage to property. In case of injury, illness, disease, or

exposure to infectious material or disease, the person involved or someone on their behalf, must try to report it to their department immediately, but always within 48 hours.

- 21.1.2.2 Report incident to your department as soon as possible.
- 21.1.2.3 When a person is injured on the job, the PI or supervisor will arrange for prompt medical treatment as required. (Employees must receive care in accordance with good medical practice, University procedures, and regulatory requirements.) The correct telephone number for emergency medical services shall be posted for ready reference. For Athens this number is 911.
- 21.1.2.4 Each department is responsible for reporting all incidents to EHS immediately, but always within three (3) working days, to properly document and investigate the incident for prevention purposes. The BSO and/or EHS may be contacted for clarification and assistance in this requirement. Incident reports should be sent to the Worker Compensation Administration Office, who automatically sends a copy to EHS.
- 21.1.2.5 Serious incidents shall be reported immediately by telephone to OUPD (593-1911) and to EHS (593-1666). Call 911 if injury, fire, or the emergency warrants it. Serious incidents for this purpose are those which result in:
 - a. Fatality.
 - b. Hospitalization or medical treatment (beyond first aid) of three or more persons. NOTE: This includes non-OU personnel.
 - c. First aid treatment of five (5) or more persons.
 - d. Property damage of significant magnitude.
 - e. Biohazard exposure resulting in lost time or release of biohazards with a potential for involving the public or exposure of non-involved persons.

21.2 Infectious Material Incidents (Including rDNA and Infected Animals)

21.2.1 All incidents involving infectious materials are to be immediately reported to the BSO (or EHS Standby). Such incidents may include spills or releases of materials or agents, escape of infected animals, rupture of plastic bags of infectious/medical waste, other loss of containment, or equipment failure. The BSO will consult and assist with capture of animals, protection of personnel, packaging and disposal (after sterilization if possible) of residues and/or make arrangements for temporary storage and treatment of equipment, wastes and/or the area.

Any emergency incident requiring immediate assistance from OUPD or EHS, or from non-campus agencies such as the fire department, is to be reported immediately through 911 and OUPD Dispatcher. Such report should tell dispatcher:

1. Where and what type incident has occurred.
2. Assistance needed, if not obvious as firefighters for a fire.
3. Nature and type of any injured or trapped persons.
4. What has happened since the incident: i.e., building evacuation has been started, etc.
5. Identity of caller and location from which he/she is calling and who and where someone will be to meet and/or assist response personnel upon their arrival.
6. Beeper or cell phone numbers (if available) of personnel at scene.

21.2.2 Any injury or illness to an employee is to be reported to EHS in accordance with OU's policies. Employees are to be treated by designated medical provider; this may be in consultation with the BSO, EHS, PI or supervisor if necessary.

Students and others not on OU payroll who are injured or made ill as a result of a biohazard activity are to be reported and their exposures investigated. Their medical care is to be handled through Hudson Health Center, hospitals, or private physicians, as necessary. Medical care providers may be assisted by the BSO, EHS, or other University personnel with biosafety expertise as needed to treat the patient.

If an infectious organism or one containing recombinant DNA molecules were to acquire the capacity to infect and cause disease in man, the first evidence of this potential may be demonstrated as a laboratory-acquired infection. For this reason, it is important to investigate any serious, unusual, or extended illness of a biohazard worker or any incident that involves inoculation of infectious organisms or those containing rDNA molecules through the skin, by ingestion, or probable inhalation. A finding that an infection is associated with such work or research will provide sufficient warning for evaluation of hazards and initiation of additional precautions to protect the general public, if necessary, in addition to other workers.

Prompt reporting of all incidents involving overt releases of or exposures to microorganisms is essential. The laboratory worker involved with such an occurrence should notify the PI or supervisor (or another person in authority in their absence) immediately. The PI or supervisor should determine the immediate response to be taken. This response may include requesting the support of the medical service to help identify the possibility of infection and disease. A thorough investigation by the medical service would include the collection and analysis of appropriate clinical specimens, such as blood samples, stool samples, and the like.

The investigation of all incidents associated with infectious agents or rDNA research should also include a review of techniques, procedures and types and uses of equipment that may have been involved in the incident. The investigation should also establish the circumstances leading to the incident. In addition, the investigation report, by the BSO to the Institutional Biosafety Committee (IBC), should provide recommendations for preventing similar occurrences.

- 21.2.3 With assistance from fire department, State Health, police and/or other departments; EHS and the PI will make determination that the facility/room is safe for reentry after a biohazard incident. Others are not to enter or reenter the area without the consent of the Emergency Coordinator (or Incident Commander in coordination with the Emergency Coordinator) in case of fire or explosion until area is released. Emergency Coordinator may however, if appropriate, allow only limited reentry of specialists who in turn may investigate, remove, rebuild, reinforce, perform temporary fixes or raze the facility as necessary before others are permitted to enter.

21.3 Decontamination

The major emphasis of this section is placed on preplanning for the immediate actions and decontamination procedures to cope with overt biohazard spills that may occur in the open laboratory and in safety cabinets. In addition, measures should be devised for the proper decontamination of any potential contaminated equipment.

No equipment, facility, residue, or other biohazardous material is to be transferred until it is decontaminated or assured that such persons are qualified to receive and handle biohazardous material in a safe, legal manner.

21.4 Transportation of Materials

The need for frequent movement of infectious materials is a primary factor in the occurrence of biohazard spills. The dropping and breaking of primary agent containers is of particular concern. Protective secondary containers for transporting potentially infectious materials are effective in preventing such spills. These secondary containers are easily devised from stock items. The use of secondary protective containers is strongly recommended and should be mandatory for transport of infectious materials within the corridors serving the laboratories. Mistakenly, individual laboratory workers may be inclined to ignore the need for secondary containers, particularly if: (a) distances are short; (b) the agent is thought to have little or no pathogenicity for humans; and (c) use of secondary containers tends to interfere with the desired pace for completing a phase of the experiment.

It should be recognized that air-handling systems in the majority of modern laboratories maintain the air pressure positive in the corridors with respect to that of connected individual laboratories. Airborne microorganisms generated during a spill in a hallway are quickly dispersed into adjoining laboratories. Some buildings have return air grills in the corridors that return air to the air handling unit, for distribution to other parts of the building; sometimes far removed from the spill site. Spilled research materials may be inadvertently tracked over a wide area during ensuing confusion. Decontamination can then become a formidable task and invariably causes a major disruption of laboratory effort. Consequently, non-breakable secondary containers for transport of infectious materials are essential, especially when leaving a laboratory and using hallways and corridors.

Biological spills may take many forms, as follows:

- a. Breakage or overturning of a primary container of infectious material in the open laboratory.
- b. Breakage or overturning of a primary container of infectious material in a biological safety cabinet.
- c. Assumed release of infectious material in airborne particulates within a biological safety cabinet by procedures known to produce aerosols.
- d. Assumed release of infectious material following disastrous events, such as fire, explosion, etc.
- e. Suspected release of infectious material, airborne or otherwise, by a recognized malfunction of equipment or failure to adhere to experiment protocols.

- f. Unsuspected release of infectious material primarily in airborne particulates as a result of procedures inadequately evaluated for potential aerosol production.

21.5 Basic Concepts For Dealing With Spills Of Biological Agents

21.5.1 The possibility of an overt spill of potentially infectious material is always present in biological laboratories; but the time, circumstances, and exact location of such an event cannot be predicted with any degree of certainty. Standard safety practice requires that known aerosol-producing procedures be performed within biological safety cabinets where containment and decontamination of airborne microorganisms are possible. To avoid unrecognized aerosol release requires thoughtful planning, thorough evaluation of procedures and equipment, and constant adherence to aseptic techniques. Routine laboratory housekeeping and disinfection procedures may provide some decontamination of unsuspected agent releases.

21.5.2 Laboratory Area and Program Survey: It is critical in planning action protocols to be used in the event of biohazard spills that supervisors survey the laboratory and adjacent areas in relation to the research program. This assessment should provide information that can be used to prevent exposure of personnel and the environment and to make preparations to contain and decontaminate the spill. Kinds and levels of potential risks that may accompany the program must be known and assessed. Decontamination practices must be established for the biohazards involved before it happens. Facts should be determined about air handling systems, namely which unit serves which laboratories; arrangement of air particulate filters, of safety cabinet ventilation, and interconnected ducting; layouts of furniture and equipment; storage locations of biological materials; and routes for evacuation. Once these facts are known, appropriate emergency actions can be planned and taken in the event of a laboratory incident or spill to evacuate personnel appropriately from areas affected, to decontaminate without affecting adjacent areas or destroying valuable stock biological material, and to render assistance in the event of fire, flooding or other emergency.

21.5.3 Devising Immediate Action Protocols: Immediate action protocols are the step-by-step procedures to be followed by laboratory workers immediately after the occurrence of a biohazard spill. The primary objectives are to protect personnel and prevent spread of the microorganism to the environment. The protocols should be brief, forceful and informative, leaving little room for misinterpreting the required action under the stress of the unanticipated event.

Additional directives may be required with respect to: (a) location of spill alarm, if available; (b) how room ventilation is handled; (c) activation of U.V. lamps, if available; and (d) manner of precluding inadvertent entry into the contaminated area. The supervisor should coordinate before hand with medical personnel those actions that might require departure from protocol in the event that personal injury accompanies the mishap. Prominent display of the immediate action protocol at strategic locations within the laboratory may be particularly advantageous if the laboratory is frequently used by transient personnel.

21.5.4 Biohazard Spills Outside Biological Safety Cabinets: Spills outside biological safety cabinets are complex events. They may involve amounts of material ranging from less than a milliliter up to several hundred milliliters or more. The amount spilled, the physical characteristics of the material, and how the spill occurs are important factors in determining the area of involvement. Each spill is composed of three somewhat overlapping fractions of the spilled material. The first of these is the bulk of the material that remains in a more or less confluent puddle. The second is that portion separating from the main body of material in large drops and rivulets (splatter). The third is that portion that separates from the main body in airborne particulates of various sizes (aerosols). The ratios of the various fractions to the whole will be directly affected by interrelations among such factors as energy input into the system, viscosity, and surface tension of the biological preparation. The first two portions comprise the greatest bulk of material that must be decontaminated. The third represents only a small portion of the overall bulk, but the very small particles have very low settling rates and once airborne can remain so for relatively long periods of time. The hazard represented by airborne particulates containing microorganisms remains largely unknown; however, these small particles have been shown to represent a significant hazard when they contain certain of the known human pathogens. For some of these, ten or fewer viable particles can cause human infection. Infective doses, routes of exposure, and other important factors vary greatly from agent to agent. The airborne particles emanating from a biological spill are responsible for the preliminary phase of the decontamination procedure. This is a passive phase in that the only required action is to isolate the area to allow the occurrence of physical settling and air dilution of the particles. A minimum of 30 minutes should be sufficient to achieve a reduction of airborne particles per unit volume permitting the actual decontamination effort to proceed.

Laboratory personnel responsible for the decontamination of a spill should be provided minimally with a long-sleeve gown, and medium- or heavy-duty rubber gloves. Laboratories dealing with agents where infection through the respiratory route could be a significant problem should contact EHS about the need to be in the Respiratory Protection Program for respirator use. For laboratories included in the respiratory protection program, respirators may be supplied for decontamination of a spill. The gown should be worn over conventional two-piece or jumpsuit type laboratory clothing. Rubber boots are also useful because they are more easily decontaminated than conventional foot-wear and provide greater protection to the wearer against the chemical action of strong decontaminating solutions. Non-laboratory type outer garments should not be worn under the gown. This is not only to preclude potential removal of infectious materials from the laboratory on personal clothing, but also in recognition of the strong bleaching action of the hypochlorites often used in decontaminating spills.

When properly clad and in possession of the equipment and an effective decontaminating fluid required for the cleanup, decontamination personnel should enter the spill area and quickly survey the extent of the spilled materials. Particular attention should be given to splashed materials to avoid tracking the agent about the laboratory. If the spill resulted from a container dropped from some height to the floor or the material dropped to the floor by overrunning the top of a laboratory bench or front of a safety cabinet, the area contaminated may be quite large. Starting from the outer perimeter of the area encompassed by the splashed as well as the major bulk of the spilled material, liquid decontaminant should be gently poured around the spill area and allowed to flow into the spilled material. Paper towels soaked with the liquid decontaminant may be used to cover the area. Avoid spraying or pouring decontaminating solutions directly onto the spilled materials or other abrupt actions that may create airborne particles containing the spilled agent. Allow the decontaminant to remain in contact with the spilled agent for at least 20 minutes. Make sure that the amount and concentration of decontaminant used is sufficient to overcome the inactivating action of proteinaceous media or tissues that may be intimately associated with the material.

During the decontaminant contact time, the surrounding area should be observed to locate potential areas that may harbor the spilled agent. If these are extensive and/or cannot be readily reached by liquid decontaminant consideration should be given to a follow-up decontamination with paraformaldehyde gas. Except in the case of the higher risk agents, materials in areas difficult to obtain decontaminant

contact may not pose a particular hazard for personnel; however, media and other suspending components may provide a haven for proliferation of spore-forming fungi and bacteria that may subsequently prove troublesome in preserving the integrity of experiments.

Decontamination of laboratory spills should also involve the application of common sense. Obviously, all spills do not present the same degree of risk. The foregoing discussion is most applicable to relatively large spills of biological materials or for those where a few viable particles may cause infection. Minor spills do occur, however, and may involve very small quantities of agent materials without involving container breakage or significant splashing. Moreover, it is most likely that aseptic techniques were being used and the spill will occur on a surface protected with an absorbent covering dampened with an effective decontaminant. When a minor spill occurs, in a laboratory that participates in the respiratory protection program, immediate donning of respiratory protection, if not already in use, is advisable. For minor spills, isolation of the area may be less important, unless the agent is suspected to have a high degree of infectious potential. Additional liquid decontaminant should be added immediately but gently to the absorbent surface covering; rubber gloves should be worn. Potentially contaminated objects should be wiped down with decontaminant and set aside. All nearby surfaces should be similarly wiped down. The absorbent surface covering should be gently rolled into a compact package and, along with the rubber gloves, placed in a container of decontaminating solution or in an appropriate covered container for autoclaving or incineration. The investigator should then wash hands and face with germicidal soap, change to fresh laboratory clothing, and bag the used clothing for autoclaving.

Laboratories involved in an overt spill should subsequently receive detailed treatment during application of routine housekeeping procedures afterwards.

- 21.5.5 Biohazard Spills in Biological Safety Cabinets: It should be borne in mind that the function of safety cabinets is not only to provide a work area free from background contaminants, but also to contain any microorganisms released by various manipulations of biological materials. Many routine laboratory procedures produce airborne microorganisms. For example, operations such as centrifuging, blending, and homogenizing tissues, in particular, should be regarded as producers of "controlled spills." To these must be added the potential for an overturned or broken primary container of concentrated virus or an overturned stack of infected tissue culture

plates. Potential contamination resulting from routine procedures is normally dealt with following completion of an experimental procedure or at the conclusion of a work session. An overt biological spill occurring in the biological safety cabinet should be decontaminated immediately and the cabinet airflow maintained. The operator should have available at all times within the cabinet a supply of an effective decontaminant so that it is not necessary (barring operator injury) to withdraw the arms before proceeding with decontamination. If the operator's hands and arms have come into direct contact with the biological material, decontaminant should be liberally applied to them. (NOTE: A plastic over-sleeve that prevents spilled materials being absorbed by garments is available from supply companies.) Then the area of the spill should be gently flooded with decontaminant sufficient to cover the top tray, drain pans and catch basin below the work surface. While waiting for the elapse of 15 minutes' contact time, the walls, any work surface, equipment, and recoverable supplies not previously treated should be wiped down with a cloth or sponge saturated with decontaminant. Excess decontaminant from the tray and drain pans should be dumped into the cabinet base. Lift out removable tray and exhaust grille work. Wipe down all surfaces of these with decontaminant and replace in position. Place all used cleaning materials in a suitable container and autoclave or treat with a strong hypochlorite solution. Drain liquid decontaminant from cabinet base into appropriate container and autoclave according to standard procedures. If sodium hypochlorite or an iodophor decontaminant was used, add sufficient thiosulfate to inactivate the halogen immediately before autoclaving.

If the cabinet contained instruments or other equipment not compatible with liquid decontaminants or that present problems in assuring penetration by the liquid decontaminant, modification of procedures will be required. The bulk of the spilled material should be gently flooded with decontaminant as before. Salvageable biological materials in intact containers should be surface decontaminated and placed in a covered container. The secondary container is surface decontaminated and removed to another safety cabinet to continue the experiment or to ready the materials for appropriate storage, pending continuation of the experiment. The contaminated safety cabinet is then decontaminated by the paraformaldehyde or other gas procedure by our contractor. Alternatively, small instruments may be placed in plastic bags, the bags sealed, surface decontaminated, and removed to an autoclave equipped for ethylene oxide sterilization (not available at Ohio University). The wet chemical decontamination can then proceed as before. Spills occurring in total containment cabinets need not be as disruptive for work schedules. Spills in these can usually be flooded with a liquid decontaminant, wiped up (taking care not to cut

or otherwise damage gloves with broken glass or other sharp materials present), and cleaning materials placed in a covered container of liquid decontaminant. Remaining materials can then be surface decontaminated and, with adherence to aseptic techniques, the experiment continued. Total decontamination of the cabinet may thus be delayed until the end of the work session.

21.5.6 Establishing Criteria for Re-occupancy

The supervisor, upon completion of appropriate decontamination procedures, should have some assurance that the decontamination has been effective to the degree required by the risk category of the biological material released. As the supervisor defines a level of assurance required, the conditions will be established under which the spill area can be reoccupied for continuation of the research effort. Obviously, the greater the infectious potential of the spilled agent, the more stringent the re-occupancy criteria.

Personal supervision of the application to the spill area of a known effective chemical decontaminant in sufficient concentration with adequate contact time may be the criterion selected by some supervisors for allowing the research to be resumed following the spill of an agent having little potential as a human pathogen. Other supervisors may delegate this responsibility to an appointed safety officer. This approach, in preparation for re-occupancy, may be entirely adequate for overt spills of low risk agents, particularly if the area has been isolated for a sufficient time to allow air dilution and settling of airborne particulates prior to the decontamination. A critical criterion affecting decisions to reoccupy facilities following a spill, therefore, is personal knowledge by the responsible supervisor or safety officer that a prescribed decontamination procedure has been accomplished. This criterion is usually adequate for spills confined to properly operating Class II and Class III safety cabinets (Class III cabinets are not available at Ohio University).

As the degree of potential hazard for humans increases, the supervisor may want to add a refinement, such as swab sampling of surface areas for residual viable organisms following decontamination.

Alternatively, strategically located cloth or paper patches seeded with resistant microorganisms, such as spore of B. subtilis var. niger are effective indicators of decontamination efficacy. Such refinements are not achieved without some sacrifice of time because of incubation requirements to confirm the absence of viable indicator microorganisms. Swab sampling for the organisms can only be relied upon to accurately reflect the extent of residual organism, if actual laboratory tests have established the reliability of sampling and assay

methodologies and quantitative relationships between sample recoveries and actual level of contamination. Such methodologies are established and available for spores of indicator microorganism, but their use during wet chemical decontamination restricts selection of a chemical decontaminant to those effective for the more resistant spores. This may not be consistent with other laboratory restrictions on the use of decontaminants having the undesirable properties often associated with sporicidal decontaminants. The spore indicators are, however, particularly effective for determining the efficacy of gaseous decontamination procedures. Use of spore indicators with the criterion that no viable cells are recovered is recommended for determining when laboratory operations may resume following a major spill of more hazardous agents in the open laboratory.

21.6 Availability of Effective Decontaminants and Supplies

After selection of a chemical decontaminant effective against the microorganisms being investigated, the laboratory supervisor will need to devise schedules for regular procurement of bulk concentrate and for maintenance of an adequate supply of use concentrations in the laboratory. The effective decontaminant will often be the same as that used in routine laboratory housekeeping and as adjuncts to routine sterile technique and have a way of being depleted when most needed. One way to assure a continuous supply is to maintain two sources of decontaminating fluid, i.e., one for immediate use in any way needed and the other reserved for emergency use. As the immediate-use supply is depleted, the emergency-use lot replaces it and a freshly prepared solution becomes the emergency-use supply. This assures the availability of freshly prepared decontaminant for the emergency situations. In small laboratories, effective shelf life of use-concentrations of a decontaminant may be exceeded before the working supply is exhausted through normal activities. Supervisors must devise schedules for disposal of ineffective residual decontaminants and replenishment with fresh solutions. Economics must not take precedence over provision of adequate quantities to cope with concentrated virus spilled in the laboratory.

Adequate decontamination supplies and equipment should be kept on hand in a “spill kit.” These kits may include such things as: personal protective equipment (masks, suits, gloves, shoe covers, etc.), cloths and pillows, disinfectant, small squeeze bottle, emergency phone numbers, emergency procedures, barrier tape, warning signs, tongs, infectious waste bags, labels, and any other necessary supplies and equipment. Kits can be assembled yourself or commercially prepared kits are available from safety supply companies.

22.0 TRAINING AND INFORMATION

22.1 Information and assistance for researchers is generally available in at least three (3) ways:

- 22.1.1 Consultation assistance from the Biosafety Officer, IBC members, EHS Staff and Laboratory Animal Resources Staff. Contact them directly.
- 22.1.2 Computerized and written information from this manual, EHS web site, EHS library, governmental agencies, and many other sources. See Appendix I. The EHS library stocks many major safety catalogs for equipment, supplies, and PPE.
- 22.1.3 Training programs:
 - 22.1.3.1 Video, slide, PowerPoint, and other formats (audio visuals)
 - 22.1.3.2 Formal training programs.
- 22.1.4 The EHS website, www.ohio.edu/ehs
- 22.2 Audio Visual Resources
 - 22.2.1 EHS maintains a library of slides, slide series, videotapes, PowerPoint presentations and other resources.
 - 22.2.1.1 Contact the Biosafety Officer or stop in at EHS in Hudson Health Center.
 - 22.2.2 The Alden Library, Instructional Media and Technology Services (IMTS), Film/Video Library has many videos on safety, health, environment, and laboratory topics.
 - 22.2.3 There are some sources of free videos and other resources. Contact the Biosafety Officer.
- 22.3 Training
 - 22.3.1 Training offered by Ohio University Environmental Health and Safety takes in a whole range of environmental and occupational health and safety topics. EHS training is currently being coordinated with the Ohio University Professional Development program as well.
 - 22.3.1.1 The EHS course catalog and training schedule for the quarter is on the EHS website, under the Training button.
 - 22.3.2 Biosafety Training at Ohio University

- 22.3.2.1 Biosafety training is available by contacting the Biosafety Officer at 593-1662. Bloodborne Pathogens training is also available.
- 22.3.2.2 Institutional Biosafety Committee (IBC) Orientation – One hour orientation for new faculty and staff to the Ohio University Biosafety Program, the IBC, Biosafety Review Forms, the project approval and approval number systems, and the review procedures needed to get their research proposal IBC approval number. Contact the Biosafety Officer.
- 22.3.2.3 Basic Biosafety Series – EHS is currently developing a multi-part biosafety training series to include areas of lab-acquired illness, basic biosafety levels and containment, biosafety cabinets, infectious waste disposal, and bloodborne pathogens.
- 22.3.2.4 Bloodborne Pathogens Training – Initial course (one hour) covers the information required by the Standard and completely reviews the Standard. An Annual Refresher Course (one hour) is offered for those who have previously taken the initial course.
- 22.3.3 Individual Needs – As needed, the Biosafety Officer is available for assistance when designing and presenting training programs for individual needs or audience.

APPENDIX A

[Ohio University](#)
[Biohazards Policy](#)
[#44.107](#)



OHIO
UNIVERSITY

administration
policy & procedure

44.107: Biohazards

Status:	Approved on January 6, 2004	Signatures and dates on archival copy
Effective:	when approved	
Initiated by:	Charles Hart Director of Environmental Health and Safety	
Reviewed by:	Herman ("Butch") Hill, Chair Policy and Procedure Review Committee	
Endorsed by:	Gary North Vice President for Administration	
Approved by:	Stephen Kopp Provost	

Purpose

To standardize procedures for the safe handling, containment, and disposal of etiologic agents, "select agents" as defined by CDC and USDA, potentially infectious clinical materials, oncogenic viruses, invertebrate vectors of human disease, human blood products and other potentially infectious materials, recombinant DNA products, carcinogens and related materials that are known to cause or may be capable of causing infection or disease in humans. To comply with all applicable governmental regulations and required guidelines. To insure as much as possible, a safe and healthful workplace and campus environment.

Policy

All persons intending to conduct research or otherwise use the listed materials on campus or in University-sponsored, -funded, or -sanctioned activities on or off campus will comply with all applicable regulations, **NIH Guidelines for Recombinant DNA Research**, guidelines of Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and the National Cancer Institute (NCI), U. S. Department of Agriculture (USDA), policies of Ohio University, and policies and standard operating procedures (SOP's) of the Ohio University Biosafety Program. The Biosafety Program is administered by the Ohio University Department of Environmental Health and Safety (EHS), in conjunction with the Institutional Biosafety Committee (IBC). The IBC reports

to the Vice President for Research. The Biosafety Officer (BSO) in the Department of Environmental Health and Safety coordinates the Biosafety Program and the activities of the IBC for Ohio University. The Biosafety Program is documented in the Biosafety Manual, which is available on-line from http://www.ohiou.edu/ehs/eh_biosafety_documents.htm. This policy covers all university units and grant-funded or commercial operations conducted on university property or using university services.

Procedures

All persons intending to use the listed materials for research, teaching or related purposes on or off campus, must receive the approval of the IBC prior to beginning the work, if the proposed work involves materials at or above Biosafety Level 2 (BSL2). A risk assessment will be conducted by the principal investigator, and information submitted to the Institutional Biosafety Committee (IBC), in the form prescribed by the committee; dealing with the laboratory facilities, clinical or field protocols and procedures, containment methods, emergency procedures, waste disposal, occupational health and safety, regulatory compliance and other information as required. Approval of the IBC will be in writing for experiments or uses at or above BSL2.

The IBC meets several times a year, and as needed. All employees will comply with regulations, such as those required by the Occupational Safety and Health Administration (OSHA), U. S. Environmental Protection Agency (USEPA), Department of Transportation (DOT), U. S. Department of Agriculture, Ohio EPA, Ohio Department of Health (ODH), Ohio Division of Industrial Relations/Public Employees Risk Reduction Program, U. S. Postal Service, and other agencies and with all applicable guidelines or other requirements such as those issued by Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH). All persons will comply with applicable requirements of the IBC and Ohio University. For information, contact the Ohio University Biosafety Officer or the Chair of the IBC.

Reviewers

Proposed revisions of this policy should be reviewed by:

1. Policy and Procedure Review Committee
2. Vice President for Research
3. Associate Provost for Graduate Studies
4. Chair of the Institutional Biosafety Committee (IBC)
5. Director of Research Compliance
6. Dean of the College of Arts and Sciences

Forms

The following form is specific to this policy:

1. The IBC Proposal Review form is available on-line from http://www.ohiou.edu/ehs/eh_biosafety_documents.htm.

APPENDIX B

Institutional Biosafety Committee (IBC) Current Members

<p>Kenneth Goodrum, Ph.D. (Chair) Associate Professor, Immunology Ohio University COM/Department of Biomedical Sciences Irvine Hall 404 740-593-2390 - Phone 740-597-2778 – FAX goodrum@ohio.edu</p>	<p>Joan Cunningham, Ph.D. (Vice Chair) Assistant Professor, Microbiology Ohio University Department of Biological Sciences Irvine Hall 060 740-593-9482 - Phone 740-593-0300 – Fax cunninj1@ohio.edu</p>
<p>Mark Berryman, Ph.D. Associate Professor Medical Histology-COM Biomedical Sciences Life Sciences 237 740-593-2364-Phone 740-597-2778-FAX berryma@ohio.edu</p>	<p>James Schulz, R.N. (Community Member) Nursing Supervisor/Emergency Preparedness O'Bleness Hospital 55 Hospital Drive Athens, OH 45701 740-592-5250-Phone jschulz@obleness.org</p>
<p>Ahmed Faik, Ph.D. Assistant Professor Environmental & Plant Biology Ohio University Porter Hall 512 740-593-1121 – Phone 740-593-1130 – Fax faik@ohio.edu</p>	<p>Charles Hammer, MS, RS (Community Member), Administrator Athens City-County Health Department 278 W. Union Street Athens, Ohio 45701 740-592-4431 - Phone (ext: 233) 740-594-2370 – FAX health@frognet.com</p>
<p>Jo Ellen Sherow, BS Director, Office of Research Compliance RTEC 117B 740-597-1267-Phone 740-593-9839-Fax sherow@ohio.edu</p>	<p>Interim Director Dept. of Environmental Health & Safety Hudson Health Center 202 740-593-1667 - Phone 740-593-0808 – FAX</p>
<p>Susan Evans, Ph.D. Assistant Professor Chemistry & Biochemistry Clippinger Lab 740-597-1319-Phone 740-593-4795-FAX evanss1@ohio.edu</p>	<p>Adriane Mohlenkamp, MS Laboratory Safety Coordinator Biosafety Officer Dept. of Environmental Health & Safety Hudson Health Center 215 740-593-1662 - Phone 740-593-0808 – FAX Mohlana1@ohio.edu</p>

APPENDIX C

Institutional Biosafety Committee

Proposal Application and Forms

IBC Approval #'s

Numbering System

1. Letter designates the type of materials.

- A = Antineoplastics, cytotoxics
(direct research on these materials only)
- B = Blood, OPIM, needles, human tissues
- C = Carcinogens (direct research on chemical carcinogen only)
- D = DNA, RNA
- I = Infected vectors of human disease
- M = Microorganisms, pathogenic fungi, parasites
- N = None or non-issue for IBC
- V = Viruses, oncogenic viruses
- U = Unknown infection status, animals from the wild

2. Middle number designates biosafety level.

- 0 - Not applicable
- 1 - BL1
- 2 - BL2
- 3 - BL3

3. Their individual approval number (3 digit).

- Examples:
- a) Person doing rDNA experiments, using BL1 viruses and blood products.
#DVB-1-001
 - b) Person doing BL2 infectious bacteriology work.
#M-2-009
 - c) Person doing work not regulated by IBC.
#N-0-002

4. Approval number is good for 5 years from issue date for projects with the same agents, biosafety levels, etc. as the original approval. Any deviation requires a new "Biosafety Review Form" to be filed and another approval number!



Environmental Health & Safety

Hudson Health Center
Athens, OH 45701
Phone: 740-593-1666
Fax: 740-593-0808

November 27, 2007

To:
From: IBC
Subject: PROPOSAL REVIEW

- Your IBC proposal has been approved and your IBC Approval Number is .
- New 3 Year Renewal Additional information required below.

Your "Biosafety Review Form" has been reviewed by the IBC. Please note the items checked off below. If you have any questions, please call Adriane Mohlenkamp at 593-1662. Thank You!

Your IBC Approval Number is required on grants and proposals submitted to the Research Office for processing!

Remember, this approval only applies to the information submitted on your form. Changes in the agents or Biosafety Level's (BSL) will require a new form to be submitted and approval obtained in the future.

The following are also required:

1. A Bloodborne Pathogens Program is required.
2. A Chemical Hygiene Program is required.
3. Proposals \geq BSL2 require a signature. Please make a copy of your approval proposal, sign at the bottom of the last page where indicated and return to: Biosafety Officer/EHS/Hudson Health Center.
4. Other (Specify:)

APPENDIX D

My IBC Proposals/Approvals

(Researchers can put a copy of their own IBC form & Approval Letters)

APPENDIX E

Ohio University IBC Standard Operating Procedures (SOPs)

SOP INDEX

98-01	Terms and Rotation of IBC Committee Members
98-02	Election of Officers
98-03	Review of Research Proposals
2000-01	Compliance with OSHA Bloodborne Pathogens Standard for the Use of Human & Primate Cell Lines
2000-02	Who May Submit IBC Proposals for Approval Numbers
2002-01`	Procedures for Three (3) Year Reviews of IBC Proposals and Approval

Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP #98-01

Terms and Rotation of IBC Committee Members

1. IBC members shall be appointed by the Vice President for Research.
2. The IBC will be made up of seven (7) voting members. Five (5) shall be university employees with expertise appropriate for the committee and meeting current NIH, rDNA guidelines. Two (2) members shall be non-university employees, herein called “community representatives”, which have no direct affiliation with the university per NIH, rDNA guidelines. The Biosafety Officer and Research Office, Compliance Manager will be ex-officio members.
3. In general, the committee will try to maintain expertise in various disciplines dealing with infectious agents, rDNA, and disciplines pertaining to the mission of the committee. At least one member should also be a clinician/physician.
4. Terms of office will be for two (2) years, renewable for two (2) more years. A minimum of two (2) years off the committee is required before additional service in the future.
5. Each year, at least one (1) member and no more than two (2) members will rotate off the committee. The Biosafety Officer, with recommendations from the committee, will present a list of possible replacements to the VP for Research during the summer. The VP will make committee appointments by September of each year.

Approval Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer

Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP #98-02

Election of Officers

- 1.0 At the fall quarter IBC meeting, election of officers will take place.
- 2.0 A Chair and Vice-Chair shall be elected from the membership for the year. Officers serve for a one (1) year period, with re-election to a second one (1) year period allowed. The Vice-Chair shall act in the capacity of Chair when the Chair is unavailable.
- 3.0 The Chair will moderate IBC meetings and set agenda with the Biosafety Officer.

Approval Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer

Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP #98-03

Review of Research Proposals

1. All researchers or faculty members using materials regulated by the IBC and OU Policy #44.107 - Biohazards shall have their research projects reviewed by the IBC.
2. Any new faculty or existing faculty proposing new projects not already approved or where new or additional hazards or materials may be used, shall submit a new “Biosafety Review Form” completed in full, to the Biosafety Officer at the Department of Environmental Health and Safety for review. Proposals will be reviewed by the Biosafety Officer and the IBC Chair (and subcommittee of the IBC if determined necessary by the Chair).
3. Approved research proposals will be signed and assigned an IBC Approval Number on a committee approval form. The researcher will be assigned an approval number based on the IBC numbering scheme and the approval logged into the Biosafety Program database at Environmental Health and Safety. An approval letter with the approved IBC Number will be sent to the researcher by the Biosafety Officer. The Biosafety Officer will follow up on any deficiencies or required information checked off on the approval letter.
4. For proposals not initially approved, the Biosafety Officer and IBC Chair will work with the researcher to correct deficiencies and prepare the proposal for approval if appropriate.
5. Researchers in the Departments of Biological Sciences, Biomedical Science and COM must submit a Biosafety Review Form and receive an IBC Number even if they do not use materials regulated by the IBC committee. An “N” number will be assigned as their IBC Number, indicating that they are not regulated. This will expedite proposals through the Office of Research and Sponsored Programs when proposals come through the office from department faculty in these departments who do not need to be reviewed.
6. IBC Numbers should be put on all health and safety checklists and review sheets submitted through Research and Sponsored Programs.
7. Researchers may have more than one approved IBC Number if they have different research work in progress with different types of hazards or materials used.

Approval Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer

Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP #2000-01

Compliance with OSHA Bloodborne Pathogens
Standard for Use of Human and Primate Cell Lines

1. All human cells and some primate cells may transmit disease to humans. The OSHA Bloodborne Pathogens Standard regulates the occupational exposure of humans to bloodborne pathogens from blood, other potentially infectious materials, including cells from humans living and dead and infected animals.
2. The IBC requires documentation in the form of laboratory testing for common and/or likely pathogens by a reputable laboratory or cell repository with negative test results, in order for research with these materials to be considered exempt from compliance with the OSHA Bloodborne Pathogens Standard.
3. The IBC reserves the right to also require testing of any cells from animals other than primates, when the possibility with infection by organism transmissible to man are considered significant.

Approved Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer, EHS

Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP #2000-02 (rev 5/2/01)

Who May Submit IBC Proposals for Approval Numbers

4. All full or part-time faculty or research scientist may submit research proposals to the IBC for consideration and approval. All proposals shall be submitted on the “Ohio University Biosafety Review Form” to the Biosafety Officer at the Department of Environmental Health and Safety.
5. Graduate students conducting research with materials regulated by the IBC cannot submit proposals directly. Proposals must be submitted by and responsibility accepted by the student’s faculty research advisor.

Approved Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer, EHS

This SOP needs to be approved.
Institutional Biosafety Committee (IBC)
Standard Operating Procedures
SOP# 2002-01

Procedures for Three (3) Year Reviews of IBC Proposals and Approval Numbers¹.

1. All IBC proposals and approval numbers will be reviewed and updated by the IBC every three (3) years.
2. The forms and format for the 3-year reviews shall be established by the IBC.

Approved Date: _____

Vice President for Research

Chair, IBC

Biosafety Officer, EHS

APPENDIX F

INFECTIOUS WASTE TREATMENT, COLLECTION, AND DISPOSAL

Infectious Waste Disposal Sites

- 1.0 Ohio University has only one autoclave approved for the treatment of infectious waste. It is operated by the Department of Biological Sciences and is located in the Irvine Hall, ground floor service corridor. This service is available to the departments of Biological Sciences, Biomedical Sciences, and College of Medicine.
- 2.0 Ohio University retains a licensed infectious waste hauler to provide boxes and bags, pick up infectious waste and insure proper incineration at a licensed facility off campus. Departments must pay for disposal by the box. Pick-ups occur about every 2 weeks or on a schedule coordinated with the infectious waste hauler. Contact the Biosafety Office at EHS if you require service.
 - 2.1 On Campus Sites as of October 9, 2007
 - 2.1.1 Hudson Health Center
 - 2.1.2 Irvine Animal Facilities
 - 2.1.3 Edison Biotechnology Institute, Ridges (on call)
 - 2.1.4 Charles J. Ping Student Recreation Center
 - 2.1.5 Clippinger Laboratories (on call)
 - 2.1.6 Biochemistry Building – Chemistry & Biochemistry Department
 - 2.1.7 Stocker Center 172 - Chemical Engineering Department (on call)
 - 2.1.8 Diagnostic Hybrids - Biochemistry Building (W. Union Street)
 - 2.1.9 Grover Center
 - 2.1.10 Clippinger Laboratories - Physics Department
 - 2.2.11 Biological Sciences
 - 2.2 Remote Sites (off-campus) as of October 9, 2007
 - 2.2.1 Lancaster Campus (on call)
 - 2.2.2 Chillicothe Campus (on call)
 - 2.2.3 Ohio University Physical Therapy Association

- 3.0 The State of Ohio has infectious waste regulations that must be met.
- 3.1 “Infectious waste” includes all of the following substances or categories of substances:
- 3.1.1 Cultures and stocks of infectious agents and associated biological, including, without limitation, specimen cultures, cultures and stocks of infectious agents, wastes from production of biologicals, and discarded live and attenuated vaccines;
 - 3.1.2 Laboratory wastes that were, or are likely to have been, in contact with infectious agents that may present a substantial threat to public health if improperly managed;
 - 3.1.3 Pathological wastes, including, without limitation, human and animal tissues, organs, and body parts, and body fluids and excreta that are contaminated with or are likely to be contaminated with infectious agents, removed or obtained during surgery or autopsy or for diagnostic evaluation, provided that, with regard to pathological wastes from animals, the animals have or are likely to have been exposed to a zoonotic or infectious agent;
 - 3.1.4 Waste materials from the rooms of humans or the enclosures of animals, that have been isolated because of diagnosed communicable disease that are likely to transmit infectious agents. Also included are waste materials from the rooms of patients who have been placed on blood and body fluid precautions under the universal precaution system established by the “Centers for Disease Control” in the public health service of the United States Department of Health and Human Services, if specific wastes generated under the universal precaution system have been identified as infectious wastes by rules referred to in paragraph (B) (15) (h) of this rule;
 - 3.1.5 Human and animal blood specimens and blood products that are being disposed of, provided that, with regard to blood specimens and blood products from animals, the animals were or are likely to have been exposed to a zoonotic or infectious agent. “Blood products” does not include patient care waste such as bandages or disposable gowns that are lightly soiled with blood or other body fluids, unless such wastes are soiled to the extent that the generator of the wastes determines that they should be managed as infectious waste;
 - 3.1.6 Contaminated carcasses, body parts, and bedding of animals that were intentionally exposed to infectious agents from zoonotic or

human diseases during research, production of biologicals, or testing of pharmaceutical, and carcasses and bedding of animals otherwise infected by zoonotic or infectious agents that may present a substantial threat to public health if improperly managed;

- 3.1.7 Sharp wastes used in the treatment, diagnosis, or inoculation of human beings or animals that have, or are likely to have, come in contact with infectious agents in medical research or industrial laboratories, including, without limitation, hypodermic needles and syringes, scalpel blades, and glass articles that have been broken. Such wastes are hereinafter in this chapter referred to as “sharp infectious waste” or “sharps;”
- 3.1.8 Any other waste materials generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, that the public health council created in section 3701.33 of the Revised Code, by rules adopted in accordance with Chapter 119 of the Revised Code, identifies as infectious wastes after determining that the wastes present a substantial threat to human health when improperly managed because they are contaminated with or are likely to be contaminated with infectious agents; and
- 3.1.9 Any other waste materials the generator designates as infectious waste.

APPENDIX G

Emergency Phone Numbers



Emergency Phone Numbers

(Please post!)

Athens County Emergency Number (fire, police, medical or other major emergencies)	911
Athens Ambulance (SEOEMS)	446-9840
Athens County Sheriff	593-6633
Athens City Police	592-3313
Athens City Fire Department	
Station 1 (Columbus Road)	592-3301
Station 2 (Richland Avenue)	592-3304
Athens County Emergency Coordinator	594-2261
National Poison Control Centers Hotline (automatically links you to the closest Poison Control Center)	1-800-222-1222
Ohio University Environmental Health & Safety (for home or cell phone numbers of EHS staff contact OUPD)	593-1666
Ohio University Radiation Safety Program	
Alan Watts	593-4176
Larry Gingerich	593-1663
Ohio University Biosafety/Infectious Waste/ Lab Safety Program	593-1662
Adriane Mohlenkamp	
Ohio University Emergency/Chemical Spills (large spills, explosions, etc)	911
Larry Gingerich	593-1663
Ohio University Fire Staff Sara Fares (Home-Contact OUPD)	597-1748
Ohio University Police Department (they have all EHS emergency and home numbers)	593-1911
Ohio University Facilities Management (Utilities/Emergency Crew)	593-2911
Ohio University Laboratory Animal Resources Scott Carpenter – (Home – Contact OUPD)	593-2997
My Department Chair/Director _____	_____
My Supervisor _____	_____
My Lab/Area/Office _____	_____
Other _____	_____

Appendix H

List Of Agents Regulated By The “Anti-Terrorism And Effective Death Penalty Act” (Agent Transfer Law)

HHS AND USDA SELECT AGENTS AND TOXINS: 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS Select Agents and Toxins

Abrin
Cercopithecine herpesvirus 1 (Herpes B virus)
Coccidioides posadasii
Conotoxins
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Ebola viruses
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
South American Haemorrhagic Fever viruses
(Junin,
Machupo,
Sabia,
Flexal,
Guanarito)
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
(Central European Tick-borne encephalitis,
Far Eastern Tick-borne encephalitis,
Russian Spring and Summer encephalitis,
Kyasanur Forest disease,
Omsk Hemorrhagic Fever)
Variola major virus (Smallpox virus) and
Variola minor virus (Alastrim)
Yersinia pestis

Overlap Select Agents and Toxins

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern Equine Encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan Equine Encephalitis virus

USDA Select Agents & Toxins

African horse sickness virus;
African swine fever virus;
Akabane virus;
Avian influenza virus (highly pathogenic);
Bluetongue virus (exotic);
Bovine spongiform encephalopathy agent;
Camel pox virus;
Classical swine fever virus;
Cowdria ruminantium (Heartwater);
Foot-and-mouth disease virus;
Goat pox virus;
Japanese encephalitis virus;
Lumpy skin disease virus;
Malignant catarrhal fever virus
(Alcelaphine herpesvirus type 1);
Menangle virus;
Mycoplasma capricolum/*M. F38*/*M. mycoides capri*
(contagious caprine pleuropneumonia);
Mycoplasma mycoides mycoides
(contagious bovine pleuropneumonia);
Newcastle disease virus (velogenic);
Peste des petits ruminants virus;
Rinderpest virus;
Sheep pox virus;
Swine vesicular disease virus;
Vesicular stomatitis virus (exotic).

**USDA Plant Protection and Quarantine (PPQ)
Select Agents and Toxins**

Candidatus Liberobacter africanus;
Candidatus Liberobacter asiaticus;
Peronosclerospora philippinensis;
Ralstonia solanacearum, race 3, biovar 2;
Sclerophthora rayssiae var. *zeae*;
Synchytrium endobioticum;
Xanthomonas oryzae pv. *oryzicola*;
Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix I

Reference Websites

References -- Web Sites

Ohio University

Environmental Health & Safety

<http://www.ohio.edu/ehs/>

Ohio University Biosafety Manual (this manual)

http://www.ohiou.edu/ehs/docs/biosafety_manual.pdf

Department of Biological Sciences

<http://www.biosci.ohiou.edu/index.html>

Department of Biomedical Sciences

<http://www.oucom.ohiou.edu/dbms/index.htm>

College of Osteopathic Medicine

<http://www.oucom.ohiou.edu/>

Edison Biotechnology Institute

<http://www.ohiou.edu/biotech/>

Office of Research and Sponsored Programs Vice President for Research

<http://www.research.ohiou.edu/orsp/index.php>

College of Medicine Office of Research

<http://www.oucom.ohiou.edu/SOM/research.htm>

Department of Laboratory Animal Resources (LAR)

<http://www.research.ohiou.edu/compliance/index.php?section=236>

Federal Agencies and Regulations

OSHA: Occupational Safety and Health Administration/DOL

<http://www.osha.gov>

Chemical Hygiene (Lab)

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106

Bloodborne Pathogens

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

Personal Protective Equipment

<http://www.osha.gov/SLTC/personalprotectiveequipment/standards.html>

Formaldehyde

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10075

Tuberculosis (Proposed)

<http://www.osha.gov/SLTC/tuberculosis/standards.html>

NIOSH: National Institute for Occupational Safety and Health/HHS

<http://www.cdc.gov/niosh/homepage.html>

CDC: Centers for Disease Control and Prevention/HHS

<http://www.cdc.gov/>

Office of Safety and Health

<http://www.cdc.gov/od/ohs/>

“Biosafety in Microbiological and Biomedical Laboratories” (CDC/NIH Manual)

<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>

Etiologic Agent Import Permit Program

<http://www.cdc.gov/od/eaipp/>

*Explanation of Different Types of Biosafety Cabinets (BSC)

http://www.cdc.gov/od/ohs/biosfty/bmb15/Appendix%20A_Greenbook%20for%20BMBL_Final.pdf

Packaging of Infectious Materials

<http://www.cdc.gov/od/ohs/biosfty/shipdir.htm>

Public Health Training Network

<http://www.phppo.cdc.gov/phtn/default.asp>

Workplace Health & Safety

<http://www.cdc.gov/workplace/>

USEPA: U.S. Environmental Protection Agency

<http://www.epa.gov>

TSCA Biotechnology Program

http://www.epa.gov/biotech_rule/index.htm

USDOC: U.S. Department of Commerce

<http://www.commerce.gov>

National Institute of Standards and Technology (NIST)

<http://www.nist.gov>

Bureau of Industry and Security

<http://www.bis.doc.gov/>

CPSC: Consumer Products Safety Commission

<http://www.cpsc.gov>

USDOT: U.S. Department of Transportation/DOT

<http://www.dot.gov>

NIH : National Institute of Health

<http://www.nih.gov>

NIH, Office of Recombinant DNA Activities

<http://www4.od.nih.gov/oba/>

rDNA Guidelines

<http://www4.od.nih.gov/oba/rdna.htm>

National Cancer Institute (NCI)

<http://cancernet.nci.nih.gov/>

FDA: Health & Human Services, Food and Drug Administration

<http://www.fda.gov>

HHS: U.S. Department of Health and Human Services

<http://www.os.dhhs.gov>

USPHS : Health & Human Services, U.S. Public Health Service (Surgeon General)

<http://www.surgeongeneral.gov>

Interstate Shipment of Etiologic Agents

<http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>

USDA: U.S. Department of Agriculture Animal

<http://www.usda.gov>

USDA Plant Health Inspection Service (APHIS)

<http://www.aphis.usda.gov>

USDA, APHIS, Permits

<http://www.aphis.usda.gov/permits/>

USDA, APHIS, Forms

<http://www.aphis.usda.gov/forms/>

Federal Register: National Archives & Records Administration Federal Register on-line

<http://www.gpoaccess.gov/fr/index.html>

DOE: U.S. Department of Energy

<http://www.doe.gov/>

State of Ohio Agencies and Regulations

OBWC: Ohio Bureau of Workers Compensation

<http://www.ohiobwc.com/>

BWC Safety Service

<http://www.ohiobwc.com/employer/services/safetyhygiene.asp>

ODA: Ohio Department of Agriculture

<http://www.ohio.gov/agr>

ODOT: Ohio Department of Transportation

<http://www.dot.state.oh.us/>

OEPA: Ohio Environmental Protection Agency

<http://www.epa.ohio.gov>

Division of Solid & Infectious Waste Management (Infectious Waste Regulations)

<http://www.epa.state.oh.us/dsiwm/>

ODH: Ohio Department of Health

<http://www.odh.state.oh.us/>

PERRP: Ohio Department of Employment Services

Public Employees Risk Reduction Program (“State Employees” OSHA)

<http://codes.ohio.gov/orc/4167>

SFM: State Fire Marshall

<http://www.com.state.oh.us/ODOC/sfm/>

Standards and Organizations

American Biological Safety Association (ABSA)

<http://www.absa.org>

Risk Group and Biosafety Level Definitions and Lists

<http://www.absa.org/resriskgroup.html>

National Sanitation Foundation (NSF) Standard 49 -- Biosafety Cabinet Certification

<http://www.nsf.org>

International Air Transport (IATA) (packaging an air transport for biologicals)

<http://www.iata.org>

Campus Safety, Health & Environmental Management Association (CSHEMA)

<http://www.cshema.org/>

American Cancer Society

<http://www.cancer.org>

Miscellaneous and Commercial

Health Canada

http://www.hc-sc.gc.ca/index_e.html

MSDS for Infectious Substances

<http://www.phac-aspc.gc.ca/msds-ftss/index.html>

Saf-T-Pak -- Packaging for Infectious Materials

<http://www.saftpak.com>

Howard Hughes Medical Institutes

Laboratory Safety

<http://www.hhmi.org/about/research/labsafe.html>

Canadian Centre for Occupational Safety and Health

<http://www.ccohs.ca/resources>

American Type Culture Collection (ATCC)

<http://www.atcc.org>

Coriell Cell Repositories (Cell Repository)

<http://locus.umdj.edu/nigms/>

Cedra Corporation (Cell Repository)

<http://www.cedracorp.com/>

World Federation for Culture Collections (WFCC)

<http://wdec.nig.ac.jp/wfcc/wfcc.html>

Worldwide Web – Epidemiology (Valuable epidemiology & agency sites)

<http://www.epibiostat.ucsf.edu/epidem/epidem.html>

Safety Information

<http://www.safetyinfo.com>

Lab Safety Supply (Safety Equipment and Supplies)

<http://www.labsafety.com>

Fisher Safety Products (Safety Equipment and Supplies)

<http://www.fishersci.com>

Baker Company (Biosafety Cabinets)

<http://www.bakerco.com>

NuAire (Biosafety Cabinets)

<http://www.nuaire.com>

Thermo Scientific (Biosafety Cabinets)

<http://www.thermo.com/com/cda/landingpage/1,10255,640,00.html>

Laboratory Animal Resources

Animal Welfare Institute (AWI)

<http://www.animalwelfare.com>

Animal Care and Use Committee American Society of Mammalogist

<http://www.mammalsociety.org/committees/index.asp>

Canadian Council on Animal Care

<http://www.ccac.ca>

APHIS Animal Welfare

http://www.aphis.usda.gov/animal_welfare/index.shtml

Animal Welfare Information Center (AWIC)

<http://www.nal.usda.gov/awic>

Office for Human Resource Protections

<http://www.hhs.gov/ohrp/>

Guide for the Care and Use of Laboratory Animals

<http://www.nap.edu/readingroom/books/labrats/>

The Whole Mouse Catalog

<http://www.MURIDAE.COM/wmc/>

NetVet

<http://netvet.wustl.edu/>

Recommendations for the Care of Amphibians and Reptiles in Academic Institutions

<http://netvet.wustl.edu/species/reptiles/pough.txt>

American Association for Laboratory Animal Science

<http://www.aalas.org>

American Society of Mammologists

<http://www.mammalsociety.org/>

OU – IACUC Links

<http://www.research.ohiou.edu/compliance/index.php?section=11&page=45>

(Source: Thank you to Ohio University, Department of Laboratory Animal Resources)

Appendix J

Ohio University Incident Report Form

An electronic copy of the incident report form and reporting instructions can be found at:
<http://www.ohiou.edu/ehs/general/forms.htm>

OHIO UNIVERSITY

EMPLOYEE INJURY/ILLNESS/INCIDENT REPORT FORM

Supervisors must investigate the incident thoroughly, fill out their section, and submit the completed form to the Workers Compensation Department immediately following their investigation. Employees must fill out this report completely and accurately and submit it to their supervisor immediately after a work-related injury, illness or incident. Report severe hazards by phone (593-1666) immediately. **Print and complete this form, make a copy for your internal records and your department and mail original to Marilyn McVey, Workers Compensation, University Human Resources Building.**

EMPLOYEE SECTION:

1. Name _____ 2. Soc. Sec. # _____ 3. Age _____ 4. Sex _____
5. Mailing Address _____ 6. City _____ 7. Zip _____
8. Home Phone _____ 9. Campus Phone _____ 10. Dept _____
11. Div./Area/Shop _____
12. Normal Occupation _____
13. Date of Incident _____ 14. Day of Week _____ 15. Time of Day ____:____AM/PM
16. Exact duties when injured _____
17. Location where injury occurred _____
18. Witnesses to incident/Did anyone see the incident occur? _____
19. Complete names and phone # of all witnesses _____
20. Describe the incident in detail (include weights, lengths, distances, events leading up to, what were you doing, what caused the injury, etc.). **List all medical treatment(s). Please be specific. For example: What did the doctor tell you? Did you receive stitches, prescriptions, ice pack, bandages etc.?** If the injury/illness developed over time, please document. Attach additional sheet(s) as necessary.

21. Medical Treatment: No Yes: at _____ Dr. _____ Date: _____
22. Signature of Injured/Ill Person _____ 23. Date Report Completed _____

SUPERVISOR & EMPLOYEE SECTION: Must be completed by supervisor, along with the injured employee.

24. Planning Unit _____ 25. Employees regular job? Yes No
26. Results of your investigation - attach additional sheet(s) as necessary: Draw picture if helpful.

Did the employee demonstrate how the incident occurred? Yes No If No, Why Not? _____

- *See Code List *27. Class: F A CS S O *28. Shift: 1 2 3 *29. Status: F P T I**
- *30. Where did the incident happen: _____ *31. Type: _____ *32. Nature: _____ *33. Agent: _____ *34. Source of Injury: _____ *35. Body Part(s): _____ *36. Unsafe Acts: _____**

***37. Hazardous Conditions: _____ *38. Other Factors: _____**

39. Check One: No Medical First Aid Incident Only Death

OHC: Seen by _____ Date _____ Rx? XRay?

40. Will employee be out of work? No Yes: Expected date back? _____ # lost time days _____
41. **What has been/will be done to prevent this type of incident (corrections, actions, repairs, training, etc.)**

42. Any pre-existing injury/condition of which you're aware that could have contributed to this No Yes

43. Date injury reported to supervisor by employee _____ 44. Date Investigated _____

45. Employee reported promptly (same day)? Yes No: (If no, why not?) _____

46. Supervisor's Name (please print) _____ 47. Phone # _____

48. E-mail Address: _____

APPENDIX K

RISK GROUPS AND BIOSAFETY GUIDELINES

Risk Group and Biosafety Level Definitions:

European Economic Community (DIRECTIVE 93188/EEC, Oct, 1993)

- (1) **Group 1** biological agent means one that is unlikely to cause human disease;
- (2) **Group 2** biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;
- (3) **Group 3** biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;
- (4) **Group 4** biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

NIH Guidelines on Recombinant DNA (April 2002)

- (1) **Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.**
- (2) **Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.**
- (3) **Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.**
- (4) **Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.**

Canadian Laboratory Biosafety Guidelines (2nd ed. 1996)

- (1) **Risk Group 1** (low individual and community risk) This group includes those microorganisms, bacteria, fungi, viruses and parasites, which are unlikely to cause disease in healthy workers or animals
- (2) **Risk Group 2** (moderate individual risk, limited community risk) A pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy 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.
- (3) **Risk Group 3** (high individual risk, low community risk) A 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.
- (4) **Risk Group 4** (high individual risk, high community risk) A pathogen that usually produces very serious human animal disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa directly or indirectly or casual contact.

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (4th Edition 1999)

- (1) **BIOSAFETY 1 is suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.**
- (2) **BIOSAFETY LEVEL 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.**
- (3) **BIOSAFETY LEVEL 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.**
- (4) **BIOSAFETY LEVEL 4 is required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.**

Appendix L

Chemical Hygiene Plan

Department _____

All laboratory researchers (departments) must have a written and implemented Chemical Hygiene Plan (CHP). You can put a copy of your department's CHP plan here if you like.

Appendix M

Bloodborne Pathogens Plan

Department _____

All researchers using human blood, tissues, or other potentially infectious materials, must have a written and implemented Bloodborne Pathogens Program (BBP). You can place a copy of your program here if you have one

Appendix N

Personal Protective Equipment Plan

Department _____

All departments using personal protective equipment (PPE) are required to have a written PPE assessment and plan addressing issues in the OSHA PPE Standard. This would affect nearly all labs. You can insert your department's PPE plan here.

PPE includes:

- Gloves (lab, surgical, rubber, cloth, etc.)
- Eye Protection (safety glasses, goggles, face shields)
- Body Protection (lab coats, disposable clothing)
- Foot Protection (steel-toed shoes, metatarsal guards, disposable booties)
- Head Protection (hard hats)
- Hearing Protection (muffs, plugs)

APPENDIX O

MY PERSONAL NOTES AND INFORMATION

NAME _____

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