15 April 1997

To: Administrators, Principal Investigators, Researchers, Students

From: John H. Hall, Chair, Institutional Biosafety Coordinating Committee
Leona W. Ayers, Chair, Institutional Infection Prevention Committee
Cecil R. Smith, Jr., Institutional Biosafety Officer

Subject: *Institutional Laboratory Biosafety Manual*

Recent changes in federal and state laws have mandated that The Ohio State University take a closer look at safety issues within the University. Because of Federal and State mandates, the Institutional Biosafety Coordinating Committee, the Institutional Infection Prevention Committee and the Institutional Biosafety Officer have produced this *Institutional Laboratory Biosafety Manual* to inform the users of biohazardous materials of their duties and responsibilities. The *Biosafety Manual* describes present University policy and is an aid to help reduce accidents and potentially harmful exposures. The documentation and training required is mandated either by federal or state law. The *Biosafety Manual* clearly lays out the responsibilities for the use of biohazardous material at the University, from the President of the University to Deans, to Principal Investigators and to the individual graduate student or staff member. An educated and understanding employee is better able to respond appropriately to emergencies in the laboratory. Every attempt has been made to ensure that the document is as user-friendly as possible.

The committees have included with the *Biosafety Manual* a series of boilerplate documents which will be of use in bringing laboratories into compliance with biological regulations and OSHA standards which now apply to the University. Your college's OSHA Coordinator is another resource for help in these matters.

There are boilerplate documents for the Hazard Communication plan, the Bloodborne Pathogens plan, and a sample Chemical Hygiene Plan enclosed in this packet. We have also included documents from The OSU Medical Center Infection Control Plan concerning Bloodborne Pathogens and Personnel Practices. While the use of these documents is a first step, the individual Principal Investigator is advised to contact the Office of Environmental Health and Safety concerning training requirements and to especially make use of the OSHA Coordinator for their college to help in designing and keeping a laboratory which complies with safety, health and environmental standards.

Also included are a Risk Assessment Checklist and a Laboratory Safety Audit which are valuable tools for those planning new experiments or reviewing current research efforts which utilize biohazardous materials. The checklist and audit forms provide a list of questions and places to go for answers to those questions. The questions cover that information one needs to properly design experiments which involve the use of biohazards while the audit provides information on the compliance status of the laboratory.

The intent of the *Biosafety Manual* is to facilitate the compliance efforts of individual researchers and to ensure a safe and healthy place for employees of the University. Compliance with the safety standards should result in a laboratory in which science can be accomplished with an informed, enlightened and safe workforce.

Institutional Laboratory Biosafety Manual

The Ohio State University
March 2000

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Institutional Laboratory Biosafety Manual

February 2000
The Ohio State University

I. Introduction

The Ohio State University is committed to providing a safe and healthy working environment for its employees. To meet this commitment, the University has developed and implemented Safety, Health and Environmental (SHE) Practices that address safety and environmental concerns for all University employees. Additionally, the University is subject to strict local, state and federal regulations promulgated by such agencies as the Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA), and the Occupation Safety and Health Administration (OSHA). The University is also committed to current safety guidelines as issued by the National Institutes of Health (NIH) and the Centers for Disease Control (CDC).

Federal granting agencies specifically state that they are not liable for accidents, illnesses, or claims arising from research under an award granted by an agency. Organizations that accept awards are expected to take the necessary steps to protect their personnel from hazardous conditions. The NIH have provided *Health and Safety Guidelines for Grantees and Contractors* (NIH Guide, Volume 23, Number 23, June 17, 1994, *et seq.*) that recognizes the following classes of hazards:

- **Biohazards** (*e.g.*, human immunodeficiency virus (HIV); other infectious agents; oncogenic viruses);
- **Chemical hazards** (*e.g.*, carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials);
- **Radioactive materials**.

Both the NIH and Public Health Service (PHS) provide lists of standards to be consulted when hazards are present.

Biohazards at The Ohio State University are defined as **infectious agents (i.e., pathogens) or materials produced by living organisms that may cause disease in other living organisms.** This definition encompasses not only the human pathogens, but also materials that may contain such pathogens (human-, nonhuman-primate- and other animal- and plant-sourced materials) and other agents (toxins, allergens, venoms, arthropods, etc.) that can cause disease in humans, animals or plants. Work with experimental animals also constitutes potential exposure to biohazardous materials since these animals may harbor infectious agents and/or proteins in their dander, urine, saliva, serum, etc., to which personnel may be or may become allergic.

The University's Office of Environmental Health and Safety (OEHS) has developed a program for the safe procurement, receipt, handling, storage and disposal of biohazardous substances.

The University's biosafety program is designed to ensure compliance with federal OSHA

standards, other federal regulations (EPA, Department of Health and Human Services (HHS), Department of Transportation (DOT), US Postal Service, etc.), state and local regulations, and with applicable federal guidelines (NIH, CDC). Its purpose is to ensure the safe handling of biohazardous materials in any work performed under University aegis and thereby protect personnel, research outcomes and the environment .

I.1. Office of Environmental Health and Safety (OEHS)

OEHS has an institutional responsibility to help promote the safety of University employees. OEHS personnel are involved in the development of safety policies and practices for the University and provide guidance to personnel in safety matters through consultation. They also have the responsibility of ensuring, through the auditing of facilities and work practices, that the work of the University is completed in a safe and environmentally sound manner.

I.2. Office of Research Risks Protection (ORRP)

ORRP is a unit of The Ohio State University Office of Research. It shares with OEHS an institutional responsibility to promote safety in research and compliance with OSHA, HHS, Food and Drug Administration (FDA), EPA and other federal regulations as well as NIH and CDC guidelines as they apply to research. ORRP personnel are also involved in the development of safety policies and practices and serve as a resource for researchers using biohazardous agents to answer questions or find answers for individuals concerning the use of biohazardous agents in research. ORRP has been given investigative powers and investigates potential violations of University policies, providing information to the various standing committees, the Institutional Biosafety Officer and the Vice President for Research. ORRP specialists confer with University Laboratory Animal Resources (ULAR) and OEHS to ensure that adequate precautions are taken by ULAR personnel in the care and handling of laboratory animals exposed to biohazardous agents. Observations of unsafe handling of biohazardous materials should be reported to the Principal Investigator/Supervisor. If the result is unsatisfactory, then a report should be made to one's department chair, departmental biosafety officer, the chair of the IIPC, the Institutional Biosafety Officer, ORRP, or OEHS; such unsafe handling of biohazardous agents can be investigated by ORRP personnel.

I.3. Committees

I.3.1. Institutional Biosafety Committee (IBC)

All research involving recombinant DNA (rDNA) molecules is reviewed by the IBC. Recombinant DNA research is carried out under the often-updated *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*. The committee assures that research

involving rDNA is carried out under the appropriate biosafety levels established by the *Guidelines*. All rDNA research conducted at the University must be registered with the IBC, including research that is exempt from full committee review under the *Guidelines.* An approved Memorandum of Understanding and Agreement (MUA) is required for all research that is not exempt from full committee review under the *Guidelines*. Research that involves release of genetically-engineered organisms into the environment, testing of recombinant drugs or food products, or human-gene therapy protocols may also require a permit from the appropriate federal regulatory agency.

I.3.2. Institutional Infection Prevention Committee (IIPC)

The IIPC has responsibility for reviewing the use of biohazardous agents at the University. The IIPC is composed of principal investigators (PIs) with expertise in the use of biohazardous agents in research and trained staff who review the utilization of biohazardous agents and training of personnel at the University. The committee recommends policies and procedures for a biological safety program, including, but not limited to, education, laboratory inspections, containment requirements, waste disposal, and medical surveillance. The committee also reviews and approves Safety Plans submitted by investigators. Research reviewed by the IIPC may also be reviewed by other committees; for the project to proceed, it must be approved by all the committees having purview; rejection or deferral of research by one or more committees means that the research shall not proceed as submitted.

I.3.3. Institutional Biosafety Coordinating Committee (IBCC)

Various University committees (*i.e.*, ILACUC (Institutional Laboratory Animal Care and Use Committee), IIPC, IBC, and the Biomedical Sciences Institutional Review Board) and administrative units (*i.e.*, OEHS, OSURF, Institutional Biosafety Officer, and ULAR) have overlapping responsibilities for biosafety issues in research and teaching. The IBCC coordinates the biosafety-related activities of these committees and administrative units. The IBCC works with and is advisory to the Institutional Biosafety Officer, ORRP and OEHS, all of which have institutional responsibility and enforcement authority in matters of workplace safety. The IBCC also works with and is staffed by ORRP.

II. Responsibilities

The basic safety principle is that **all injuries are preventable**. **Management**, from the President to Principal Investigators/managers, has a responsibility to encourage the safety effort in a sustained and consistent manner by establishing safety goals, demanding accountability for safety performance, and providing the resources to the safety program.

II.1. Office of Environmental Health and Safety (OEHS)

OEHS has an institutional responsibility to help promote the safety and health of University employees. OEHS personnel serve as safety consultants to the departments and other units of the University and provide information on applicable safety-related regulations or guidelines. They assist in the development of standards and practices in the field of safety and provide routine auditing services to ensure compliance with University policies and governmental regulations. OEHS also has institutional responsibility for the disposal of radioactive materials, toxic chemicals and infectious wastes. Training in specific areas of safety concerns is provided by OEHS personnel, including that associated with the collection and disposal of biological wastes is provided by OEHS personnel.

II.2. Office of Research Risks Protection (ORRP)

ORRP shares an institutional responsibility to help promote the health and safety of University employees working in research with OEHS. ORRP personnel provide information concerning the use of biohazards and serve as liaisons between researchers and the OEHS staff. ORRP staff supports the various safety committees formed to ensure the safe use of biohazardous material at the University and assists in the development of standards and practices for safety. ULAR animal husbandry practices for research involved in the use of biohazardous agents and hazardous chemicals are set with consultation among PIs, ULAR, ORRP and OEHS staff.

II.3. President and Vice Presidents

The President of the University and the Vice Presidents encourage a climate of compliance with federal, state and local regulations and support an ongoing commitment to this compliance. The President and Vice Presidents shall be provided with an annual report of health and safety program accomplishments.

II.4. Deans

Deans encourage compliance with safety, health and environmental practices by departments within their jurisdiction. All academic and non-academic departments, schools and divisions shall participate in all applicable required programs.

II.5. Department Chairs, Center Directors and Other Facility Directors

Department Chairs/Directors shall:

- **Develop emergency and evacuation plans** for buildings, appoint building safety committees, departmental biosafety officers, and appoint building safety managers and alternates in cooperation with the University (in some cases with the associate dean for research and research officers);

- **Maintain discipline**, enforce rules and regulations, and take prompt, effective corrective action when necessary. The departmental chair shall also provide assistance to OEHS and ORRP staff when investigations arise involving PIs and other personnel in the department;

- **Implement medical surveillance programs** (MSPs) for all departmental personnel with occupational exposure to toxic chemicals, human blood or blood products, or any other potentially infectious materials (OPIMs) or biohazards;

- **Ensure compliance of principal investigators** and other supervisory personnel with federal, state, and local regulations and University policies applicable to the department's work. Regulatory and policy documents are available from OEHS and ORRP. The department chair may delegate safety- and health-related responsibilities to principal investigators or other supervisors, but it is the department chair's responsibility to understand the regulations and to see that the requirements are met;

- **Take corrective actions** to halt any violations should violations of University biohazard policies occur, in concert with the Institutional Biosafety Officer, ORRP, the departmental biosafety officer and the appropriate University standing committee (the Institutional Infection Prevention Committee in this case).

II.6. Principal Investigators (PIs) and Supervisors

Direct responsibility for compliance with the University's safety and health programs is assigned to the principal investigator. This means that the PI shall provide a safe workplace and shall implement University health and safety programs. This includes ensuring that personnel are adequately trained, Safety Desk Books are developed, Safety Plans are prepared and submitted, and laboratories are submitted to biennial inspections. PIs are responsible for the good working order of equipment in their laboratories (including the appropriate certification of biological safety cabinets (BSCs) that is recommended annually or when the BSC is moved).

Principal Investigators shall:

- **Communicate** to those in the laboratory the University's high priority regarding health and safety and concern for the environment and shall ensure that environmental, health and safety obligations are fulfilled by all personnel in the laboratory;

- **Analyze work procedures for hazard** identification and correction and implement measures to eliminate or control workplace hazards;

- **Submit a protocol (Safety Plan)** covering the use of biohazardous agents that has been reviewed and approved by the Institutional Infection Prevention Committee before laboratory work commences and submit the laboratory to biennial inspections by the Institutional Infection Prevention Committee;

- **Encourage regular self-assessment inspections** by employees to review work habits and correct deficiencies. Prompt reporting of health and safety problems by project personnel is to be encouraged. Persons who file reports in good faith will be protected from retaliatory actions based on such filing;

- **Distribute the Institutional Laboratory Biosafety Manual** to all individuals in the laboratory and maintain a written acknowledgment of understanding by these individuals;

- **Ensure training** of all individuals involved in the handling of biohazardous agents and disposal of the biohazardous agents and ensure that all training records are maintained as directed by the standards;

- **Ensure that Personal Protective Equipment (PPE)**appropriate to the biohazardous agent(s) is in good condition and is utilized appropriately;

- **Ensure the participation** of all personnel in a Medical Surveillance Program. OEHS should be informed of all biohazardous agents used in the laboratory (see Appendix C);

- **Stop work posing imminent danger**. Prudent practices are to be employed by those working in the laboratory;

- **Ensure** that **appropriate signage** is used at the entrance(s) to and within the laboratory. Signage must be in place in the vivarium before beginning animal experiments (contact ULAR staff if it is not);

- **Ensure that the ULAR veterinarian is notified** in writing at least three working days before animals under the care of ULAR staff are treated with biohazardous agents and that consultation with ULAR, OEHS and ORRP personnel has been completed.

II.7. The Individual

YOU ARE RESPONSIBLE FOR YOUR OWN SAFETY!!!

The health and safety of each employee is extremely important. Employees should bring their concerns to their supervisor, the departmental biosafety officer, department chair, the Institutional Biosafety Officer, ORRP or OEHS.

Each employee is expected to be conscientious in assuming personal safety responsibility from that first day on the job at the University. Each employee must understand that he or

she is responsible for working safely.

The individual shall:

- **Comply with the University's safety policies and rules** and follow both oral and written instructions from the principal investigator or supervisor. The individual shall report to the principal investigator any unsafe conditions and/or any accident or exposure to chemicals or biological agents. If the individual receives no response or an unsatisfactory response, he/she should contact the department chair, OEHS or ORRP;

- **Must know the hazards of the chemicals and biological agents** in the workplace as well as proper handling and disposal procedures. Training shall be provided by the principal investigator or designee prior to the commencement of work. The individual must minimize all potential exposures to infectious materials or contaminated items. He/she will learn what precautions and protective equipment are needed for specific jobs and practice good hygiene.

II.8. Students, Visitors and Guests

The Ohio State University is committed to providing a safe and healthy work environment to its employees that, in turn, fosters a safe learning environment for students. The University encourages students, visitors and guests to abide by applicable safety guidelines when using campus facilities. It is the policy of OSU to ensure that all students who might be exposed to hazardous materials in the course of their activities at the University are adequately protected. Therefore, Safety Plans shall be prepared for teaching laboratories. Students shall receive instruction in the appropriate safety precautions and will be expected to follow the safety rules.

III. Risk Assessment and Safety Plan

III.1. Risk Assessment

New research or development initiatives are evaluated by the Principal Investigator in the early planning stages for the hazards that can be posed by the biologic, toxic, flammable, reactive, and/or explosive materials required by the proposed work. New or inexperienced investigators are encouraged to read the *Institutional Laboratory Biosafety Manual* and attachments, to seek consultation with the departmental biosafety officers, the chair of the Institutional Infection Prevention Committee, the Institutional Biosafety Officer, and/or the University environmental health and safety or industrial hygiene personnel, as well as to review published expert opinion regarding regulatory requirements.

The assessment of infection risks associated with the laboratory use of biohazardous materials requires the proper **risk classification of the material**, the **risk modification of the manipulations of the biohazardous material**, the **environmental risks associated with the material**, and the **laboratory requirements for containment of those risks** Agents of = Risk Group 2 can usually be assessed in consultation with the departmental biosafety officer. Prior approval by the Institutional Infection Prevention Committee for the use of Risk Group 3 and Risk Group 4 agents is required. Agents of Risk Groups 3 and 4 require submissions for approval of research protocols and are best managed by early consultation with University health and safety personnel.

Established, ongoing research or development initiatives are evaluated yearly by the Principal Investigator to assure that risks have not changed and that the established safety program is in compliance with the current regulatory requirements (*Institutional Laboratory Biosafety Manual,* latest edition). The PI has the responsibility for auditing facilities and work practices to help insure that the work of the University is completed in a safe and environmentally sound manner. New investigation initiatives in the same laboratory that do not change the risk profile of that laboratory or its personnel only require the addition of the names of the new agents to the safety plan. New initiatives that increase the risk profile of the laboratory must be accompanied by appropriate changes in the laboratory safety plan (such as engineering controls, PPE, training requirements, spill containment, etc.) to reflect the increase in risk. Work at the new risk level must not begin until the appropriate safety plan is in place.

The training of personnel must be documented in writing and the records kept by the Principal Investigator. All personnel must be made aware of the potential hazards associated with their work and must be trained in the designated safety procedures as well as the appropriate use of the safety equipment (including personal protective equipment) required and the appropriate handling of

spills.

III.2. Risk Group Assessment

There are considerable variances in the assignment of risk to infectious agents. In order to standardize the University's approach to this important consideration, Risk Groups will be selected according to the information in Table III.1.

Table III.1 Basis for the Classification of Biohazardous Agents by Risk Groups (RG).

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease that is rarely serious and for which preventative of therapeutic interventions are *often* available.
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available (high individual risk but low community risk).
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk).

A list of the assignments of agents to risk groups may be found in Appendix B of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*and Appendix C of this manual.

This method of Risk Group assignment is the most consistent with that of the World Health Organization (WHO). While there are some variations with the assessment applied by the NIH/CDC approach in *Biosafety in Microbiological and Biomedical Laboratories (3rd Edition)*, the RGs in the *NIH Guide* will be updated at least annually by the American Society of Microbiologists and be listed in Appendix B of the *NIH Guidelines* as published in the Federal Register. This allows a continuous update of the list of agents based on the most recent information.

III.3. Safety Plan

The **Safety Plan** is a laboratory-specific biological hygiene plan for research and teaching laboratories or common facilities shared by more than one of these activities. Safety Plans are mandated by current federal and state regulations. In each laboratory/facility, the PI/supervisor must specify the safety practices/procedures to be used in the laboratory and must be responsible for the implementation of the plan. Approved practices must be based on the risk assessment for that laboratory and must comply with accepted national standards. A Safety Plan for the containment of Risk Group 3 and 4 infectious agents must be submitted to the Institutional Infection Prevention Committee (IIPC) prior to implementation. The Safety Plan must address the following issues as appropriate to the individual laboratory risks:

- **Risk Group of infectious hazard:** the characteristics of infectious agents, the laboratory requirements and primary laboratory hazards of working with the agents can be found in Appendix C of this manual, in *Biosafety in Microbiological and Biomedical Laboratories* (3rd Edition), in *Physical and Biological Hazards of the Workplace*, in similar references, or by contacting the Institutional Biosafety Officer, the Chair of the Institutional Infection Prevention Committee, ORRP or OEHS personnel.

- **Bloodborne Pathogens Standard (OSHA):** laboratory use of human or animal blood, blood components, or tissues;

- **Containment requirements/engineering controls:** for biosafety level (BSL) =2, biosafety cabinets, storage requirements, transport containers, personal protective equipment (PPE) (*i.e.*, hoods, eye covers, gloves, gowns, respirators, etc.), spills management and waste disposal;

- **University Laboratory Animal Resources:** animal husbandry matters and safety of researchers and animal facility (ULAR) personnel;

- **Exposure and Exposure Follow-up:** exposure definition, prophylaxis if available (*e.g.*, Hepatitis B vaccine), and exposure follow-up coordinated through University Employee Health;

- **Specific safety training requirements:** all laboratory personnel must be informed according to OSHA regulations of potential hazards associated with their work and must be trained in the designated safety procedures, use of

safety equipment and Personal Protective Equipment, appropriate waste disposal, and availability of preventive measures such as vaccines. Examples of OSHA required education: yearly bloodborne pathogens training for blood or body fluid exposure prevention, respirator training, safe animal handling, hazard communication (worker's Right-to-Know), laboratory chemical hazards, etc.;

- **Training records:** protocols for recording and maintaining records of initial personnel training and the OSHA required yearly exposure-prevention education programs.

III.4. Safety Plan Education

The OEHS will offer periodic courses for the preparation and implementation of Safety Plans. This is an educational program for students or a continuing education program for researchers and laboratory supervisors. Safety Plan specifics may be discussed at the time of the course or by requested consultation with OEHS.

The OEHS will conduct a yearly meeting with Department Safety Officers/Biosafety Officers to provide a forum for discussion of implementation issues and current regulations.

III.5. Safety Desk Book

Chemical and Biological Safety Program documents are designed to be compiled into a **Safety Desk Book**. The Safety Desk Book is intended to be the easily recognized and accessible central-safety resource for laboratory/facility safety personnel and safety officers. The chemical and biological safety program documents of the Safety Plans are compiled and regularly updated as needed to provide clear compliance with mandated safety activities. The laboratory Safety Desk Book may be comprehensive or may be developed for individual research or development projects. The complete Safety Desk Book includes the following:

- Hazard Communication Program (see tab for boilerplate);
- Chemical Hygiene Plan (see tab for boilerplate);
- Departmental Emergency Plans;
- Radiation Safety Information;
- Annual Chemical Inventory;

- Annual Biohazardous Agent Inventory;
- Material Safety Data Sheets or access thereto;
- Bloodborne Pathogens Exposure Control Plan (see tab for boilerplate);
- Safety Plans and Annual Reviews;
- Respirator Records (Respirator Plan (see tab for boilerplate) plus records of examinations and Fit Test Reports);
- Training Documentation.

Boilerplates of many of the elements of the Safety Desk Book are included in this publication (see tabs).

IV. Recombinant DNA Technology

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* are applicable to all research conducted at or sponsored by an institution that receives funds from the National Institutes of Health for recombinant DNA (rDNA) research. The University is required to monitor all and approve most rDNA research. Compliance is to protect employees, the community, and the environment from the creation and release of any novel organisms that might be pathogenic to man, animals, and plants or harmful to the environment. The *NIH Guidelines* deal primarily with laboratory research and human gene-therapy protocols. A few types of experiments are prohibited by the *Guidelines* and several others require approval by NIH. The rest come under the jurisdiction of the OSU Institutional Biosafety Committee (IBC), which reviews the research and sets the level of biosafety and containment necessary to safely conduct the experiments. In recent years, the *Guidelines* have been relaxed considerably and much of the rDNA research at the University is exempt from full committee review. But even the research that is exempted from full committee review must be carried out using prudent laboratory practices. Most regulated experiments involve hosts and/or genes that are derived from etiologic agents or have a known biohazard associated with them. The release ofgenetically-engineered organisms into the environment, their use as drugs or food products, and human gene-therapy protocols are regulated by the USDA, EPA and FDA. The IBC does not have the sole authority to approve research in these areas and researchers must also obtain permission from these agencies.

IV.1 Institutional Biosafety Committee (IBC)

The University has established the IBC to ensure compliance with the *NIH Guidelines*. The IBC is composed of researchers, administrators, OEHS and ORRP personnel, and community members. The committee meets as needed to review research protocols and advise the University on matters of rDNA safety.

IV.2 Registration of rDNA Research and Development

All work with recombinant DNA molecules must be registered with the ORRP and approved by the IBC if the research is not exempt from full committee review under the *NIH Guidelines*.

Recombinant DNA is defined as (1) molecules that are constructed outside of living cells by joining natural or synthetic DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of molecules described in (1).

Registration of rDNA research begins with the Preliminary Review Form (PRF) [see Appendix D]. This form is sent to investigators who submit grant proposals through OSURF. Intramurally-funded projects should also be registered using this form, which can be obtained from the ORRP. The purpose of the PRF is to determine where proposed experiments fall with the *NIH Guidelines*. Generally, the investigator should simply list the genes or type of genes to be cloned, their possible products, the species that are the source of the rDNA, the type of cloning vector(s), and the host (usually *E. coli* K-12) that will be used to propagate the rDNA molecules. It is also helpful to indicate if any of the organisms are pathogenic and, in the case of mammalian pathogens, their NIH Risk Group classification. Finally, the investigator is asked to determine the relevant sections of the *NIH Guidelines*

that pertain to his experiments if the research is exempt from full committee review. The ORRP has prepared a concise outline of classification of experiments used in the Guidelines (Appendix E). When in doubt, the investigator is encouraged to call OEHS or phone the Chair of the IBC for assistance. Many projects are exempt from full committee review under the*Guidelines* and, on the basis of the PRF, the investigator will receive notification from the Chair of the IBC that no further action is needed. Otherwise, the investigator will be asked to prepare a Memorandum of Understanding and Agreement (MUA) that describes the research in more detail.

The MUA form is available by calling ORRP. The IBC does not evaluate the project in terms of risks versus benefits. It seeks only to determine if the research is permitted under the*Guidelines*, establish the appropriate biosafety levels, and advise the investigator if additional regulatory permits are needed. As such, the MUA should contain a summary of the research that can be understood by scientists outside of the field, and the proposed experiments should be described in the context of a safety evaluation (as opposed to a grant proposal). The source of DNA should be clear, and, if known, what its products might be. Any potential biohazard associated with the gene products, the recipient host, or the modified organism should be discussed.

Either notification of exempt status or approval of an MUA is needed before OSURF can release new grant funds. Researchers are therefore encouraged to complete the approval process as soon as possible to prevent funding delays. Most importantly, some rDNA research requires IBC approval before it is initiated. Frequently, this is research involving human and animal pathogens as sources of DNA or as host-vector systems, alteration of animal or plant genomes, orexperiments involving more than ten liters of culture.

IV.3 Principal Investigator's Responsibilities

Under the *NIH Guidelines* a PI has the responsibility to:

1. Evaluate the proposed research and establish appropriate containment conditions for that research;
2. Inform all laboratory personnel of the potential hazards associated with the work;
3. Develop an appropriate safety plan and procedures to minimize potential personnel exposure to hazardous materials;
4. Insure that the host/vector systems used in all research projects are safe.**Note: Large-scale production of recombinant organisms is more stringently regulated than normal laboratory work. Appropriate biological containment should be considered in choosing hosts and vectors in early stages of the research if it is to be scaled up later.**

V. Registration of Biohazardous Materials

The location and working volumes of all hazardous materials must be reported to OEHS or ORRP personnel to ensure that appropriate precautions are being taken to protect personnel, research and the environment. The cataloging of biohazardous materials allows for rapid and appropriate response by trained personnel in case of spills or other accidental exposures.

- **The PI or supervisor of the laboratory must register any and all biohazardous materials (as defined in Section I of this document). Only human and animal pathogens need to be registered except as stated below. If the PI has any doubts, questions can be directed to either OEHS or ORRP staff.**

- Only plant pathogens registered with the United States Department of Agriculture need to be registered with OEHS/ORRP.

- A registration form for biohazardous material may be found in Appendix B.

- Registration must be repeated annually.

VI. Biohazard Signs and Tags

The United States Occupational Safety and Health Administration (OSHA) regulations (**29 CFR 1910.145**, *Specifications for accident prevention signs and tags*) require that warning signs and/or symbols be used to warn personnel and visitors of the potential for hazards in the workplace. Specifically, with regard to biohazards the universal biohazard sign must be used to **"... signify the actual or potential presence of a biohazard and to identify equipment, containers, rooms, materials, experimental animals or combinations thereof, which contain or are contaminated with, viable hazardous agents."** OSHA recommends that biohazard signs be fluorescent orange or orange-red with the lettering and symbols a contrasting color. An example of a sign (not the correct color) is given on the following page.

- The University requires that the universal biohazard symbol be used to designate the presence of materials defined as biohazardous (see Chapter I of this document);
- All laboratories will be provided with signs signifying the biohazards present, a person to call in case of emergency, and the necessary precautions to be taken when entering or working in the area;
- **PIs and/or supervisors are responsible for ensuring that all hazard signs are current and accurate;**
- When using experimental animals cared for by ULAR staff, the PI must give a minimum of three working days written notice to the attending veterinarian before exposing or treating the animals with biohazardous agents or hazardous chemicals so that ULAR staff can place the appropriate signage outside the vivarium room. A working day is defined as a "day" during which University offices are open and excludes weekends and holidays. If the appropriate signage is not in place, the PI must notify ULAR staff. A Safety Plan for the use of the particular agent/chemical as prepared by the PI with the consultation of the IIPC, ULAR, OEHS and ORRP must be in place before the research can begin.
- All biohazardous waste must be placed in a clearly labeled biohazard box for disposal. See Appendix F.

BIOHAZARD

ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

BIOSAFETY LEVEL

Agent(s):

Building/Room:

Special Procedures or Precautions for Entry:

NOTICE	CALL OR SEE	BLDG/ROOM	WORK PHONE	HOME	PAGER
Entry/Advice: Vivarium Personnel					
Emergency Phone					

VII. Containment

The term **containment** is used to describe safe methods for managing biohazardous agents in the laboratory environment. Three essential elements of containment are (1) laboratory practice and technique, (2) safety equipment, and (3) facility design. The purpose of containment is to reduce exposure of laboratory workers and others to potentially hazardous agents, to prevent their escape into the outside environment and to facilitate the project.

The NIH/CDC manual *Biosafety in Microbiological and Biomedical Laboratories* (3rd Edition) provides guidance for the appropriate containment of biohazardous work. The biosafety levels are based on the probability of occupationally-acquired infections resulting from the handling of specific agents in the laboratory. Biosafety Levels 1-4 have been designated. However, research at the University is limited to Biosafety Levels 1, 2 or 3. Containment facilities and laboratory practices have been developed to minimize the potential for personnel exposure to and release into the environment of biohazardous agents. Various combinations of physical containment and laboratory practice may be necessary for the safe handling of certain agents.

The NIH/CDC manual provides minimum guidelines for containment of biohazards. The University containment requirements and laboratory practices may be more stringent. When in doubt, contact the Institutional Biosafety Officer or the chair of the IIPC for confirmation of University requirements.

VII.1. Laboratory Practice

The most important element of containment is strict adherence to standard microbiological practice and techniques. Persons working with biohazardous agents or infected materials shall be aware of potential hazards and shall be trained and proficient in the practices and techniques required for safely handling. When standard laboratory practices are not sufficient to control the hazard associated with a particular agent or laboratory procedure, additional measures such as safety equipment and facility design must be used.

VII.2. Safety Equipment (Primary Barriers)

Safety equipment includes personal protective equipment, biological safety cabinets, enclosed containers, and other engineering controls designed to prevent or minimize exposures to hazardous biological materials. The use of vaccines, if available, is encouraged or in some instances specified to provide an increased level of personal protection.

VII.2.1. Biological Safety Cabinets (BSC)

The biological safety cabinet is the principal device used to provide containment of infectious

splashes or aerosols. Biological Safety Cabinets are designed to protect the worker, the integrity of the experiment, and the environment. There are three types of biological safety cabinets: Class I, Class II and Class III.

HHS, PHS, CDC and NIH have published a booklet entitled *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets* that is available for reference concerning the specifics of BSC use, including a section on appropriate risk assessment.

VII.2.1.1. The **Class I BSC** provides personnel and environmental protection but no product protection. It is similar in airflow to a chemical fume hood, but has a High Efficiency Particulate Air (HEPA) filter in the exhaust system to protect the environment. In the Class I BSC, unfiltered room air is drawn across the work surface. Personnel protection is provided by this inward airflow as long as the minimum velocity of 75 linear feet per minute (lfpm) is maintained through the front opening. With the product protection provided by the Class II BSCs, general usage of Class I BSCs has declined. However, Class I BSCs are favored to enclose equipment (*e.g.*, centrifuges, harvesting equipment or small fermenters), or procedures (*e.g.*, cage dumping, aerating cultures or homogenizing tissues) with a potential to generate aerosols.

The Class I BSC is hard-ducted to the building exhaust system, and the building exhaust fan provides the negative pressure to draw room air into the cabinet. Cabinet air is drawn through a HEPA filter as it enters the exhaust plenum. A second HEPA filter may be installed at the terminal end of the exhaust.

VII.2.1.2. Class II (Types A, B1, B2 and B3) BSCs provide personnel, environmental and product protection. Airflow is drawn around the operator into the front grille of the cabinet that provides personnel protection. In addition, the downward laminar flow of the HEPA-filtered air provides product protection by minimizing the chance of cross-contamination along the work surface of the cabinet. Because cabinet air has passed through the exhaust HEPA filter, it is contaminant-free (environment protection), and may be recirculated back into the laboratory (Class II Type A BSC) or ducted out of the building (Class II Type B BSC).

HEPA filters are effective at trapping particulates and infectious agents, but not at capturing volatile chemicals or gases. Only BSCs that have 100% of air ducted to the outside should be used when working with volatile chemicals. Class II Type B1 BSCs recirculate 30% of exhaust air to the work area and should NOT be used with volatile chemicals. See the booklet *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets* for details.

All Class II cabinets are designed for work with microorganisms assigned to Risk Groups 1, 2 and 3. Class II cabinets provide the microbe-free work environment necessary for cell culture propagation, and also may be used for the formulation of nonvolatile antineoplastics or chemotherapeutic drugs.

VII.2.1.3. Class III cabinets provide the highest level of protection. A Class III BSC is a totally enclosed glove-box cabinet of gas-tight construction. The cabinet is maintained under negative air pressure of at least 0.5 inches of water gauge. Supply air is drawn into the cabinet through HEPA filters, and the exhaust air is filtered by two HEPA filters in series before discharge to the outside. Generally, the ventilation system is separate from the facility's ventilation system. Class III cabinets are available for high-risk biological agents.

VII.2.1.4. Horizontal Laminar Flow "Clean Benches" are ***not*** BSCs. HEPA-filtered air flows across the work surface and toward the user. These devices provide product protection. They can be used for certain clean activities, such as dust-free assembly of sterile equipment or electronic devices. These benches should never be used when handling cell culture materials or drug formulations, or when manipulating potentially infectious materials. The worker is exposed to materials (including proteinaceous antigens) being manipulated on the clean bench and can experience hypersensitivity reactions. Horizontal clean air benches should never be used as a substitute for a biological safety cabinet in research, biomedical or veterinary laboratories and/or applications or as a substitute for a chemical hood.

VII.2.1.5. Vertical Laminar Flow "Clean Benches" are also ***not*** BSCs. They may be useful in hospital pharmacies when a clean area is needed for preparation of intravenous drugs. While these units usually have a sash, the air is discharged into the room under the sash, resulting in the same potential problems as the horizontal laminar flow clean benches.

VII.2.2. Use of Biological Safety Cabinets

Biological safety cabinets used to protect workers from hazardous biological agents shall be tested and certified after installation and before use, any time they are moved, and at least annually. The department chair shall provide annual certification records for the department. Testing shall meet the criteria in **National Sanitation Foundation Standard Number 49.** Call OEHS for information on the standard and a list of companies qualified to certify biological safety cabinets.

- A BSC is required in Biosafety Level 2 laboratories whenever a laboratory procedure results in the formation of an aerosol;
- A BSC is required for all pathogen manipulations performed in a Biosafety Level 3 laboratory;
- **Biological safety cabinets are only effective when personnel operate them properly.**
  - Understand the function and use of the biosafety cabinet before working with them;
  - Demonstrate proficiency in working in the BSC;
  - **No modifications may be made to any BSC without first contacting the Institutional Biosafety Officer.**

A thorough evaluation of the proposed work (including the biological and chemical agents to be used and the procedures to be performed) must be executed before selecting the appropriate biosafety cabinet.

VII.2.3. Other Safety Equipment

Enclosed containers for the processing, transporting or storage of etiologic agents are also safety equipment. An example of an enclosed container is the safety centrifuge cap that is designed to prevent release of aerosols during centrifugation.

Personal protective equipment (PPE) (*e.g.*, gloves, coats, gowns, shoe covers, boots, respirators, face shields, and safety glasses or goggles) is clothing and equipment generally used in combination with BSCs and other devices that contain the agents, animals, or materials with which one works. PPE is covered in Chapter VIII of this manual.

In situations where it is impractical to work in BSCs, personal protective devices may form the primary barrier between personnel and the infectious materials. Examples of such situations include certain animal studies, animal necropsy, and activities relating to maintenance, service, or support of the laboratory facility.

The need for this other safety equipment must be considered when performing the risk assessment for a particular project. The Institutional Biosafety Officer, OEHS, ORRP, or the IIPC must be consulted when other containment devices are determined to be necessary.

! WARNING: **Chemical fume hoods and horizontal laminar-flow clean-air benches are *not* to be used for work with biohazardous materials.**

VII.3. Facility Design (Secondary Barriers)

Secondary barriers protect the environment within the facility but outside the laboratory (and the community outside the facility) from exposure to infectious materials. The design of the facility provides the secondary barrier. The three facility designs are the basic laboratory, the containment laboratory, and the maximum containment laboratory.

Laboratories at the University must be biennially inspected by the Institutional Infection Prevention Committee and found to be compatible with the appropriate biosafety-level containment for the biohazards in use as defined by the NIH/CDC and University guidelines.

Work with agents classified as Biosafety Level 3 must be approved by the IIPC before being initiated.

VII.3.1. **The Basic Laboratory** provides general space where work is done with viable agents that are not associated with disease in healthy adults; it may include Biosafety Levels 1 and 2 facilities. This laboratory is also appropriate for work with infectious agents or potentially infectious materials when the hazard levels are low and laboratory personnel can be adequately protected by standard laboratory practice. While work is commonly conducted on the open bench, certain operations are confined to BSCs. Conventional laboratory designs are adequate.

VII.3.2. **The Containment Laboratory** has special engineering features that enable laboratory workers to handle hazardous materials without endangering themselves, the community, or the environment. The containment laboratory is described as a Biohazard Level 3 facility. The features that distinguish this laboratory from the basic laboratory are the provisions for access control and a specialized ventilation system. In all cases, a controlled access zone separates the laboratory from areas open to the public.

VII.3.3. **The Maximum Containment Laboratory** has special engineering and containment features that allow laboratory workers to safely conduct activities involving infectious agents that are extremely hazardous to humans or capable of causing serious epidemic disease. The maximum containment laboratory is described as a Biosafety Level 4 facility. Containment requirements at this level will not be approved at the University.

VII.4. rDNA Biosafety Levels

Laboratory-scale rDNA research and development (*i.e.*, <10 liters) must be carried out at the biosafety level determined to be appropriate by review of the *NIH Guidelines for Research Involving Recombinant DNA Molecules.* **Although some experiments are found to be exempt from IBC review under the *NIH Guidelines* for purposes of genetic engineering, the containment necessary for performing these experiments is dependent upon the biosafety level assigned to the host/vector system.**

Large-scale rDNA production (= 10 liters) must be approved by the IBC. The appropriate level of containment will be determined by the IBC upon review of the protocol.

VIII. Personal Protective Equipment

The appropriate use of personal protective equipment (PPE) (gloves, protective eyewear, respirators, etc.) minimizes the potential for worker exposure to biohazardous, toxic, and corrosive agents. The use of PPE also reduces the potential for release of hazardous substances to the facility environment.

The principal investigator must provide or ensure provision of appropriate PPE to each employee who is subject to occupational exposure to human blood or other potentially biohazardous material. The PPE is provided at no cost to the employee. Appropriate equipment does not permit blood or other potentially biohazardous materials to pass through (**strikethrough**) or to reach street clothes. Examples of such equipment include gloves, gowns, laboratory coats, head and foot coverings, face shields, eye protection, respirators, resuscitation bags, and other ventilation devices.

The PI must either directly or through delegation ensure that each employee uses PPE when warranted.

Protective equipment in appropriate sizes must be available in the work area or issued to employees. Hypoallergenic gloves or similar alternatives must be readily available to those allergic to the latex or vinyl gloves normally provided. Additionally, the type of glove used must be compatible with the usage: some gloves are permeable to certain compounds. Check the Material Safety Data Sheet for incompatibility.

The PI must ensure that PPE is cleaned, laundered, or disposed of at no cost to the employee. PPE must be repaired or replaced as needed to maintain effectiveness.

Gloves must be worn when it is reasonably anticipated that hand contact with blood or other potentially infectious materials, mucous membranes, or nonintact skin might occur as well as when employees perform vascular-access procedures and handle or touch contaminated items or surfaces.

Disposable gloves must be replaced as soon as practical when contaminated or when torn, punctured, or otherwise compromised in their ability to function as a barrier. They must not be decontaminated for reuse.

Utility gloves (nondisposable gloves) may be decontaminated for reuse provided the integrity of the glove is not compromised. They must be discarded if cracked, peeling, torn or punctured or exhibit other signs of deterioration.

Gloves must be removed and hands washed when exposure is no longer anticipated and prior to leaving the work area.

IX. Biosafety Laboratory Practices and Equipment

Good microbiological laboratory practice is required by all laboratory personnel at all times. The following practices incorporate minimal practices and provide guidance for ensuring the protection of personnel, research, and the environment for the level of containment used in University academic and research laboratories.

Hands should be washed frequently during the day. Wash hands after removing gloves, before leaving the laboratory, before and after contact with patients or animals, and before eating or smoking.

Hands must also be washed immediately after accidental contact with blood, body fluids, and contaminated materials.

Refrigerators, freezers, water baths, and centrifuges should be cleaned and disinfected periodically (the frequency to be established by the PI/laboratory director) and when gross contamination occurs. Wear gloves, gown, and appropriate PPE during cleaning.

Exits and aisles must not be obstructed in any way. No trash, supplies, equipment, or furniture should be permitted in exit routes or aisles.

Exit doors must not be obstructed, bolted, or blocked in any way. Smoke doors must not be obstructed in any way that prevents automatic closing in case of fire.

Do not cover or block access to fire extinguishers, fire alarm boxes, emergency blankets, safety showers, or exits at any time, for any reason.

IX.1. Biosafety Level 1 (BSL-1)

Biosafety Level 1 practices, safety equipment, and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans. *Bacillus subtilis, Nægleria gruberi,* infectious canine hepatitis virus, and exempt organisms under the *NIH Recombinant DNA Guidelines* are representative of microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, and immunodeficient or immunosuppressed individuals. Vaccine strains that have undergone

multiple *in vivo* passages should not be considered avirulent simply because they are vaccine strains.

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.
The following standard and special practices, safety equipment and facilities apply to agents assigned to Biosafety Level 1:

IX.1.1 BSL-1 Practices Standard Microbiological

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures and specimens are in progress.
2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in the work areas. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.
4. **Mouth pipetting is prohibited**; mechanical pipetting devices are used.
5. Policies for the safe handling of sharps are instituted.
6. All procedures are performed carefully to minimize the creation of splashes or aerosols.
7. Work surfaces are decontaminated at least once a day and after any spill of viable material.
8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated outside of the immediate laboratory are packaged in accordance with applicable local, state, and federal regulations before removal from the facility.
9. A biohazard sign can be posted at the entrance to the laboratory whenever

infectious agents are present. The sign may include the name of the agent(s) in use and the name and phone number of the investigator.

10. An insect and rodent control program is in effect.

IX.1.2 BSL-1 Special Practices None

IX.1.3 BSL-1 Safety Equipment (Primary Barriers)

1. Special containment devices or equipment such as a biological safety cabinet are generally not required for manipulations of agents assigned to Biosafety Level 1.
2. It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.
3. Gloves should be worn if the skin on the hands is broken or if a rash is present. Alternatives to powdered latex gloves should be available.
4. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.

IX.1.4 BSL-1 Laboratory Facilities (Secondary Barriers)

1. Laboratories should have doors for access control.
2. Each laboratory contains a sink for handwashing.
3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.
5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
6. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

IX.2 Biosafety Level 2 (BSL-2)

Biosafety Level 2 practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low. Hepatitis B virus, HIV, the salmonellae,

and *Toxoplasma* spp. are representative of microorganisms assigned to this containment level.

Biosafety Level 2 is appropriate when work is done with any human-derived blood and body fluids, tissues, or primary human cell lines where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the OSHA *Bloodborne Pathogen Standard* for specific required precautions.

Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures, or ingestion of infected materials. Extreme caution should be taken with contaminated needles or sharp instruments. Even though organisms routinely manipulated at Biosafety Level 2 are not know to be transmissible by the aerosol route, procedures with aerosol or high splash potential that may increase the risk of such personnel exposure must be conducted in primary containment equipment, or in devices such as a BSC or safety centrifuge cups. Other primary barriers should be used as appropriate such as splash shields, face protection, gowns, and gloves.

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

IX.2.1 BSL-2 Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.
6. All procedures are performed carefully to minimize the creation of splashes or aerosols.
7. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.
8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.
9. An insect and rodent control program is in effect.

IX.2.2 BSL-2 Special Practices

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.
2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (*e.g.*, immunization) may enter the laboratory.
3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.
4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (*e.g.*, hepatitis B vaccine or TB skin testing).
5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional

serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
7. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.
8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
    b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    c. Syringes that re-sheathe the needle, needleless systems, and other safety devices are used when appropriate.
    d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.
9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.
10. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is

finished, and especially after overt spills, splashes, or other contamination by infectious materials. Prior to removal from the facility contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained (see Appendix H).
12. Animals not involved in the work being performed are not permitted in the lab.

IX.2.3 BSL-2 Safety Equipment (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:
   a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.
   b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.
2. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.
3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (*e.g.*, cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.
4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the

glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

IX.2.4 BSL-2 Laboratory Facilities (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).
2. Consider locating new laboratories away from public areas.
3. Each laboratory contains a sink for handwashing.
4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.
5. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.
6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.
7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' air flow parameters for containment.
8. An eyewash station is readily available.
9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

IX.3 Biosafety Level 3 (BSL-3)

All work to be conducted with agents assigned to Risk Group 3 must be approved in advance by the Institutional Infection Prevention Committee (IIPC).

BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by inhalation. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by scientists experienced in working with these agents. *Mycobacterium tuberculosis*, St. Louis encephalitis virus, and *Coxiella burnetii* are representative of the microorganisms assigned to this level. Primary hazards to personnel working with these agents relate to autoinnoculation, ingestion, and exposure to infectious aerosols.

At Biosafety Level 3 more emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community, and the environment from exposure to potentially infectious aerosols. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features such as access zones, sealed penetrations, and directional airflow.

IX.3.1 BSL-3 Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.
2. Persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.
3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.
5. Policies for the safe handling of sharps are instituted.
6. All procedures are performed carefully to minimize the creation of aerosols.
7. Work surfaces are decontaminated at least once a day and after any spill of viable material.
8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.
9. An insect and rodent control program is in effect.

IX.3.2 BSL-3 Special Practices

1. Laboratory doors are kept closed when experiments are in progress.
2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. No minors should be allowed in the laboratory.
3. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (*e.g.*, immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.
4. When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.
5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (*e.g.*, hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.
6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be periodically collected, depending on the agents handled or the function of the laboratory.
7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.
8. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural changes.
9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard

microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.
    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
    b. Only needle-locking syringes or disposable syringe-needle units (*i.e.*, needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
    c. Syringes that re-sheathe the needle, needleless systems, and other safe devices are used when appropriate.

    Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.
11. All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.
12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials.
    a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and

posted.

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

13. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
14. All potentially contaminated waste materials (*e.g.*, gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse.
15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained (see Appendix H).
16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

IX.3.3 BSL-3 Safety Equipment (Primary Barriers)

1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.
2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.
3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.
4. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III biological safety cabinet.
5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (*e.g.*, respirators, face shields) and physical containment devices (*e.g.*, centrifuge safety cups or sealed rotors) are used.
6. Respiratory and face protection are used when in rooms containing infected animals.

IX.3.4 BSL-3 Laboratory Facilities (Secondary Barriers)

1. The laboratory is separated from areas that are open to unrestricted traffic flow

within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

2. Each laboratory room contains a sink for handwashing. The sink is hands-free or automatically operated and is located near the room exit door.
3. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.
4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.
5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.
6. All windows in the laboratory are closed and sealed.
7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (*i.e.*, autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.
8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.
9. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration

should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

10. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (*e.g.*, an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.
11. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).
13. An eyewash station is readily available inside the laboratory.
14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.
16. Additional environmental protection (*e.g.*, personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

X. Decontamination and Spills

X.1. Definitions

- **Sterilization:** the act or process, physical or chemical, that destroys or eliminates all forms of life, especially microorganisms.
- **Decontamination:** reduction of all organisms and the destruction of pathogenic organisms in or on a material so that material is no longer considered to be capable of transmitting disease.
- **Disinfection:** the act of destroying or irreversibly inactivating specific viruses, bacteria, or pathogenic fungi, but not necessarily their spores, on inanimate surfaces. Most disinfectants are not effective sterilizers.
- **Antiseptic:** a substance that prevents or arrests the growth or action of microorganisms either by inhibiting their activity or by destroying them. The term is used especially for preparations applied to living tissue.

X.2. Evaluation

The initial risk assessment for any project should include an evaluation of the processes and/or agents to be used to ensure that the biohazardous materials involved in the research are inactivated during spill cleanup, before cleaning equipment for re-use, and before final disposal.

The OSHA Bloodborne Pathogens Standard requires that all equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. The standard also requires decontamination of contaminated work surfaces after completion of procedures, immediately or as soon as feasible after any overt contamination of surfaces or any spill of potentially infectious material, and at the end of the work shift if the work surface has become contaminated. All reusable equipment shall be decontaminated immediately or as soon as feasible after visible contamination.

For any infectious material adequate precleaning of surfaces is important for any disinfection or sterilization procedure. Ten minutes of exposure to a disinfectant is not adequate to disinfect objects that have narrow channels or other areas that can harbor microorganisms. **Alcohols**, 70%, for example, are effective for killing HBV but are not recommended for this purpose because of their rapid evaporation and the consequent difficulty of maintaining proper contact times. Alcohols have been removed from many laboratories because they are

flammable. Alcohol should be maintained only in small volumes and may be desirable as an adjunct to skin disinfection.

Chlorine compounds are widely used disinfectants in the laboratory. An inexpensive, broad-spectrum disinfectant for use on bench tops and similar surfaces can be prepared by diluting common household bleach (5.25 % sodium hypochlorite solution [some cut-rate brands might not contain this much hypochlorite]) to obtain at least 500 ppm of free available chlorine. A 1:100 dilution of commercial bleach produces a solution containing 500 ppm free chlorine (approximately 1% bleach solution) that is satisfactory for general disinfection of surfaces. A 1:10 dilution of commercial bleach (10%) that produces a solution containing 5000 ppm of free chlorine can be used to disinfect spills. The use of higher concentrations of bleach in chemical fume hoods, and the autoclaving of materials that have been treated with bleach solutions, should be reserved for significant contamination.

High concentrations of bleach solutions should not go into an autoclave.

Make the solution fresh each day; discard unused portions down the sink drain and then flush with fresh water. Be aware that chlorine compounds may corrode metals, especially aluminum.

Formaldehyde is an OSHA-regulated chemical that is a suspect carcinogen, so its use as a disinfectant or chemical sterilant is not recommended.

Iodophors that are registered with the EPA may be effective hard-surface decontaminants when used per manufacturer's instructions, but iodophors formulated as antiseptics are not suitable for use as disinfectants.

Phenolics that are registered with the EPA may be effective hard-surface decontaminants when used per manufacturer's instructions.

Quaternary ammonium compounds are low-level disinfectants and are not recommended for spills of human blood, blood products, and other potentially infectious materials.

X.3. Sterilization

Unless the facility is permitted by the Ohio EPA to treat infectious waste, all terminal treatment is incineration. Consequently, all treated or untreated biohazards (*i.e.*, infectious waste) should be placed in a burn box. See Appendix F. Consult OEHS for assistance.

The sterilization process (steam autoclaving, ethylene oxide processing, dry heat, etc.) must be validated, and the validation documented. Liquid "cold" sterilants may be used to sterilize equipment that will not withstand the heat of steam or the chemical reactivity of ethylene oxide processing.

The sterilization process must also be monitored at least weekly (or a quality-control run completed if the autoclave is used less often than weekly) with biological indicators (spore strips, time/temperature charts, etc.), and records of monitoring kept for review.

OEHS personnel can assist in the development of an appropriate validation and monitoring process.

X.3.1. Steam Sterilization

Steam sterilization (autoclaving) is the primary means of sterilization at the University. The following points must be kept in mind when steam sterilization is to be used:

- **#** Materials affected (*e.g.*, denatured or melted) by heat will be destroyed by this method of sterilization;
- **#** Steam must reach the material for a prescribed period of time (adequate sterilization time) to ensure sterilization. **Containers must be open to steam penetration, or water must be placed in the container before placing in the sterilizer.**
- **#** Use extreme caution when opening the autoclave following the sterilization cycle. Live steam can cause serious injury. Malfunctioning autoclaves can fill with superheated water that will be released when the autoclave is opened.

X.4. Disinfection

An integral part of the biosafety program is the identification of appropriate disinfectants or decontaminating agents. Such materials are to be kept readily available in the use-dilution required.

The disinfectant and the disinfection process must be validated, and the validation documented.

Personnel must be trained in the appropriate use of the approved disinfectant.

OEHS personnel can assist in the development of an appropriate validation and monitoring process.

Disinfectants must always be used in accordance with the manufacturer's recommendations. **Failure to follow the manufacturer's recommendations can result in the failure of the disinfectant to perform as expected.**

Tables X.1-X.4 present some useful information concerning some commonly used disinfectants.

X.4.1. Disinfection Hazards

Disinfectants are potentially hazardous chemicals and should be handled with care. Check the manufacturer's Material Safety Data Sheet (MSDS) before use.

Personnel should be informed of the hazards associated with disinfectant use and provided with appropriate PPE to minimize exposure under use conditions.

Appropriate disposal requirements must be specified for each disinfectant used.

X.5. Spills and Spill Cleanup

Spills of biohazardous materials may constitute a significant health hazard if not handled in an appropriate manner. All personnel working with biohazardous materials must be trained in the specific cleanup and disinfectant procedures to be used for their particular laboratory. Personnel must also be informed of the handling and disposal of contaminated clothing and personal protective devices. All of this information is included in the Safety Plan developed by the PI.

A biological spill shall be followed by prompt action to contain and clean up the spill. When a spill occurs, warn everyone in the area and call for assistance as needed. The degree of the risk involved in a spill depends on the volume of the material spilled, the creation of infectious aerosols, the concentration of organisms in the material spilled, the hazard of the organisms involved, the route of infection of the organisms, and the diseases caused by the organisms.

Table X.1. Contact Time in Minutes for Some Disinfectants

Category	Dilution	Contact Time	
		Lipovirus	Broad Spectrum
Quaternary Ammonium cmpds. (l)	0.1 - 2.0%	10	Not effective
Phenol cmpds. (l)	1.0 - 5.0%	10	Not effective
Chlorine cmpds. (l)	500 ppm*	10	30
Iodophor cmpds. (l)	25-1600 ppm	10	30
Ethanol (l)	70-85%	10	Not effective
Isopropyl alcohol (l)	70-85%	10	Not effective
Formaldehyde (l)	0.2-8.0%	10	30
Glutaraldehyde (l)	2.0%	10	30
Ethylene oxide (g)	8-23 g/ft^3	60	60
Paraformaldehyde (g)	0.3 g/ft^3	60	60

l = liquid; g = gas

* Commercially available chlorine bleach is 5.25% chlorine (52,500 ppm). A dilution of 1 to 100 will yield a 525-ppm solution that is suitable for disinfecting purposes.

Table X.2. Irritant Types of Some Common Disinfectants

Category	Dilution	Skin	Eye	Resp.
Quaternary ammonia cmpds. (l)	0.1-2.0%	Yes	Yes	No
Phenolic cmpds. (l)	1.0-5.0%	Yes	Yes	No
Chlorine cmpds. (l)	500 ppm	Yes	Yes	Yes
Iodophor cmpds. (l)	25-1600 ppm	Yes	Yes	No
Ethanol (l)	70-85%	No	Yes	No
Isopropyl alcohol (l)	70-85%	No	Yes	No
Formaldehyde (l)	0.2-8.0%	Yes	Yes	No
Glutaraldehyde (l)	2.0%	Yes	Yes	No
Ethylene oxide (g)	8-23 g/ft^3	Yes	Yes	Yes
Paraformaldehyde (g)	0.3 g/ft^3	Yes	Yes	Yes

Spills of biological agents can contaminate areas and lead to infection of laboratory workers. Prevention of exposure is the primary goal in spill containment and cleanup, exactly as in chemical spills. In evaluating the risks of spill response, generation of aerosols and droplets is a major consideration. Spills often result in aerosol formation. If there is a danger of aerosol formation, especially if the agent involved requires containment at Biosafety Level 2 or higher, personnel must:

1. Leave the laboratory immediately;

2. Close doors and decontaminate clothing (as necessary);
3. Note the time of the spill;
4. Post the area to prevent others from entering;
5. In case of large spills notify Spill Response personnel by calling the facility emergency number (2-1284 or 2-2121 or 911 after hours);
6. OEHS and Employee Health Services must be notified promptly in case of overt or potential exposures to biohazardous materials.

Table X.3. Some Use Parameters of Some Common Disinfectants

Disinfectant	**Concentration of active ingredient**	**Temperature EC**	**Relative Humidity %**	**Contact time (minutes)**
Ethylene oxide (g)	40-800 mg/l	35-60	30-60	105-240
Paraformaldehyde (g)	0.3 g/ft^3	>23	>60	60-180
Quaternary ammonium cmpds.	0.2-1.0%			10-30
Phenolic compounds	0.2-3.0%			10-30
Chlorine compounds	0.1-5.0%			10-30
Iodophor compounds	0.47%			10-30
Alcohol (ethyl or isopropyl)	70-85%			10-30
Formaldehyde (l)	4-8%			10-30
Glutaraldehyde	2%			10-600

Table X.4. Effectiveness of Some Common Disinfectants

Disinfectant	Vegetative bacteria	Bacterial spores	Lipo viruses	Hydro philic viruses	Tub-ercle baci-lli	HIV	HBV
Ethylene oxide	+	+	+	+	+	+	+
Paraformalde-hyde (g)	+	+	+	+	+	+	+
Quaternary ammonium cmpds.	+		+			+	
Phenolic compounds	+		+	"	+	+	"
Chlorine compounds	+	"	+	+	+	+	+
Iodophor compounds	+		+	"	+	+	"
Alcohol (ethyl or isopropyl)	+		+	"		+	"
Formaldehyde (l)	+	"	+	+	+	+	+
Glutaraldehyde	+	+	+	+	+	+	+

+ denotes very positive response; ± denotes less positive response; a blank denotes a negative response or not applicable.

Under no circumstances should anyone attempt to reenter the laboratory for at least thirty (30) minutes (or longer depending upon the ventilation rate of the laboratory).

Supervisors or PIs must develop as part of the laboratory Safety Plan and communicate to

laboratory workers and occupants an appropriate spill cleanup plan and disinfectant procedure for the specific types of biohazardous agents used in their laboratories. OSHA's standard covering hazardous waste operations and emergency response (HAZWOPER) mandates that all employees receive at least awareness training in dealing with spills and releases. This training must include the recognition of releases of hazardous materials, mechanisms that have been developed by the laboratory for reporting them to appropriate supervision, and steps that should be taken for the employee's own safety.

Documentation must be available to ensure that the disinfectant being used is appropriate for the conditions of use and the agents in question.

X.5.1. Generic Spill Cleanup Plans

As part of the laboratory Safety Plan, each laboratory must have a spill cleanup plan detailing specific disinfectants and procedures for that laboratory. Cleanup of any spill requires the use of appropriate personal protective equipment (*i.e.*, laboratory coat, shoe covers, gloves, and possible respiratory protection). To comply with OEPA regulations, all spills of infectious materials greater than one gallon or one cubic foot must be reported to OEHS. The following procedures should serve as a guide for the development of specific procedures for the laboratory Safety Plan.

X.5.1.1. Small Spills

A spill is generally considered to be small if it is easily contained, has not generated infectious aerosols, and is not considered to be a significant threat to the personnel in other areas of the building.

1. Wear gloves and a laboratory coat or gown. Heavyweight, puncture-resistant utility gloves, such as those used for housecleaning and dishwashing, are recommended;
2. Do not handle sharps with the hands. Clean up broken glass or other sharp objects with sheets of cardboard or other rigid, disposable material. If a broom and dustpan are used, they must be decontaminated later;
3. Avoid generating aerosols caused by sweeping;
4. Absorb the spill. Most disinfectants are less effective in the presence of high concentrations of organic material. Absorb the bulk of the liquid before applying disinfectants. Use appropriate spill kit material or disposable inert absorbent material such as paper towels or gauze.

An appropriate disinfectant should then be applied to the absorbent material;

5. The disinfectant should be left in contact with the spilled material for a sufficient period of time to allow the disinfectant to penetrate the material and kill any infectious agents present. This is usually 15 to 30 minutes, but the length of time must be documented for the particular agents in use in the laboratory;
6. After the disinfectant has been in contact with the spill for the designated period of time, the entire spill should be cleaned up and all cleanup materials placed in a biohazard waste container;
7. Disinfect the spill site using an appropriate disinfectant, such as household bleach solution. Flood the spill site or wipe it down with disposable towels soaked in the disinfectant;
8. Absorb the disinfectant or allow it to dry;
9. Rinse the spill site with water;
10. Dispose of all contaminated and cleanup materials properly (into a burn box).

X.5.1.2. Large Spills

A spill is considered to be large if it is difficult to contain within the laboratory or the facility, and/or it constitutes a significant health hazard. This type of spill may require special assistance in controlling and clean up. In the event of a large spill of biohazardous material, laboratory personnel are to:

1. Leave the laboratory immediately, close the doors and post a "Do Not Enter" sign on the entrances to the laboratory. Note the time of the spill on the door of the laboratory;
2. Remove contaminated clothing and place in a bag or container for decontamination. The bag should be marked with a biohazard symbol;
3. Notify **Spill Response** Personnel by calling the facility emergency number **2-1284** or **2-2121** or **911** after hours;
4. Remain in the area to provide information regarding the size of the spill and the materials spilled to the Spill Response Team.

X.5.1.3. Biological Spill on a Person

If a biological material is spilled onto a person, emergency response is based on the hazard

of the biological agent spilled (including the ability of the organism to penetrate intact skin), the amount of material spilled, and whether significant aerosols were generated. If aerosol formation is believed to have been associated with the spill, a contaminated person shall leave the contaminated area immediately. If possible, he or she should go to another laboratory so that hallways and other public areas do not become contaminated.

Contaminated clothing is removed and placed in red or orange biohazard bags for disinfecting. Contaminated skin shall be thoroughly flushed with water and washed with a disinfectant soap. Showering may be appropriate, depending on the extent of the spill.

For Risk Group 2 and Risk Group 3 pathogens, the employee must report to University Employee Health immediately for evaluation.

X.5.1.4. Biological Spill in a Centrifuge or Other Equipment

A biological spill in a centrifuge has the potential for producing large volumes of aerosols. On becoming aware that a spill may have occurred within a centrifuge or other piece of equipment, turn off the equipment, warn others in the area, notify the principal investigator, leave the area allowing time for aerosols to settle, and decontaminate following the principles described above.

XI. Biological Waste Disposal

Laboratory waste may be potentially hazardous (infectious, radioactive, or toxic chemicals) and must be handled appropriately to prevent possible harm to personnel and/or the environment. Certain wastes are regulated and must be handled according to prescribed methods. All applicable rules and regulations of local, state, and federal agencies are to be followed in the handling, treatment, and disposal of biomedical waste. See specifics in Appendix F.

XI.1. Responsibility

It is the responsibility of the laboratory supervisor/PI to identify the classes of waste that are generated in the laboratory and to ensure that the appropriate methods of waste disposal are followed. This information must be included in the laboratory Safety Plan.

It is the responsibility of each laboratory employee to ensure that he/she follows the proper method of waste disposal.

XI.2. Requirements

Waste must be segregated on the basis of potential hazard.

All infectious waste will be handled, treated, and disposed of in accordance with Appendix F, University Guidelines for Disposal of Infectious Waste.

XII. Ordering, Receiving, Shipping and Movement of Biohazardous Materials

State and federal agencies may supersede this section. The federal government has rules regarding selected Risk Group 3 and 4 pathogens that would make the institution responsible for certifying that biohazardous agents ordered by individuals at the University will be used in accordance with the stated research objectives of the orderer. The State of Ohio is considering some limitations also.

The transport of biohazardous materials is regulated by a number of government agencies. Air transport is regulated by the International Air Transport Association (IATA). It is imperative that personnel are aware of the applicable regulations and comply with them. **Failure to comply could result in the confiscation and destruction of the material with concomitant loss of valuable research time.**

Personnel at OEHS are trained in the appropriate packing and shipping of hazardous materials.

Supervisors and/or PIs must be aware of the approved mechanisms for packing, shipping, and importation of biohazardous agents and are responsible for ensuring compliance with all applicable regulations. They should contact OEHS for information regarding shipping or receiving of biohazardous materials.

Supervisors and/or PIs should contact OEHS for clarification of any questions concerning the necessary permit for the transport or importation of biohazardous materials.

No University employee may transport any biohazardous material on a common carrier (*i.e.*, airline, bus line, train, etc.).

Movement of biohazardous material on campus must be completed in a manner that takes into account the potential risk of the agent being moved. The biohazard agent must:

- be enclosed in a **primary vessel** contained within a secondary vessel;
- have a **closed secondary vessel**, marked with the biohazard symbol, and marked with the name of the agent contained within the primary vessel;
- be **completely absorbed** by an absorbent material packed into the secondary vessel should the primary vessel be broken;
- have a secondary vessel constructed in such a manner that there will be no release into the environment of the agent in the case that the primary vessel becomes broken or

leaks.

Inappropriate transport of biohazardous materials constitutes a violation of the University's Biohazard Policy and will be dealt with accordingly.

XII.1. Applicable Regulations

1. U. S. Department of Health and Human Services: **42 CFR 71**;
2. U. S. Department of Transportation: **49 CFR 172** and **173**;
3. U. S. Postal Service: **39 CFR 111**;
4. U. S. Department of Health and Human Services: **42 CFR 72**;
5. International Air Transport Association, IATA, "Dangerous Goods Regulations", 37th Edition, Effective January 1, 1996 or later editions.

42 CFR 72 is the implementation of Section 511 of Public Law 104-132, *The Antiterrorism and Effective Death Penalty Act of 1996*, which requires the Secretary of Health and Human Services to regulate the transfer of select agents.

The rule is designed to:

- establish safeguards when certain agents are to be transported;
- collect and provide information concerning the location where certain potentially-hazardous agents are transferred;
- track the acquisition and transfer of these specific agents; and
- establish a process for alerting the appropriate authorities if an unauthorized attempt is made to acquire these agents.

! Registration of Facilities

The University must register prior to transferring or receiving a select agent (see below) as being equipped and capable of handling the covered agent at BSL-2, BSL-3 or BSL-4 levels. A responsible facility official is one who is authorized to transfer or receive selected agents on behalf of the facility. Registration includes:

- a statement indicating that the applicant laboratory(ies) are equipped and capable of handling agents at BSL-2, 3 or 4 (as described in *Biosafety in Microbiological and Biomedical Laboratories (3rd Edition)*.);
- inspection of the facility by CDC;
- issuance of a registration number to each facility;
- payment of a fee;

- follow-up inspections.

! Verification Procedures

The provider must verify with the responsible facility official that:

- the requesting facility retains a valid, current registration;
- the requestor is an employee of the requesting facility;
- the proposed use of the agent is correctly identified by the requestor.

If the provider has any suspicion about the request, then the party must notify CDC immediately.

! Transfer of Select Agents to Other Sites

- Receive a copy of CDC form EA-101 specifying:
  - Name of requestor and requesting facility;
  - Name of requesting facility's responsible official;
  - Requesting facility's registration number;
  - The name of the agent(s) being shipped;
  - The proposed use of the agent(s);
  - The quantity shipped (number of containers and amount per container; and
  - Significantly more information concerning the laboratory(ies) in which the work will be done.
- The form must be signed by the transferor and the requestor and by the responsible facility officials at both the requesting and transferring facilities;
- The transferring agent must verify the following before shipment:
  - Requesting facility has a valid, current registration;
  - That the requestor is an employee of the requesting facility;
  - That the proposed use of the agent(s) is correctly indicated on form EA-101.
- Transfer the agents complying with applicable shipping regulations;
- Receive confirmation of shipment delivery from requesting facility's responsible official telephonically or electronically within 36 hours of receipt and be provided with a completed paper copy or facsimile transmission of the EA-101 within 3 days. Provide CDC with a copy of the EA-101 within 24 hours of notification of receipt.

! Receipt of Select Agents from Other Sites

- C Fill out form EA-101 giving information and signatures as above;
- C Give confirmation of shipping delivery to requesting facility's responsible official telephonically or electronically within 36 hours of receipt and provide with a completed paper copy or facsimile transmission of the EA-101 within 3 days;
- C When the agent is consumed or destroyed, the responsible facility official must notify CDC, using form EA-101, keeping a copy of the form for five years.

! Recordkeeping

- C Retain a copy of EA-101 for five (5) years after shipment or five (5) years after the agent(s) is(are) consumed or properly disposed, whichever is longer;
- C The facility must retain records for five (5) years concerning the destruction of the agent, the quantity destroyed, the date of destruction, and the persons responsible for destruction;
- C CDC must be notified of the destruction or complete consumption of the agent(s);
- C It is advisable to retain use and consumption records to account for supplies of toxins, and to maintain records pertaining to storage, consumption and disposal of the agent(s);
- C For intrafacility transfers, the facility must keep records including the name and location of the recipient; the amount of agent transferred; and the date transferred (keeping these records for five years after the disposal or destruction of the agent.

! Overview

- C Prudent laboratory practices suggest the storing of select agents such that unauthorized and unqualified persons cannot gain access to them and such that the responsible person can account for quantities stored. Prudent practices also suggest that storage be secure, including controlled access to the storage area and storage containment;
- C Select agents are to be destroyed on site;
- C Laboratories in which select agents are to be used must be inspected prior to ordering the agent(s); all laboratories in which select agents are in use are subject to search at any time by the Institutional Biosafety Officer, his designee, or the IIPC;
- C All agents will be received at 1314 Kinnear Road and transferred to the appropriate laboratory. Shipping of agents will be from 1314 Kinnear Road. This is the facility address;
- C False statements on the EA-101 form are a violation of Title 18, United States

Code, Section 1001 (individual offenders are subject to imprisonment for not more than five years and a fine as provided in Section 3571(b) of Title 18). Other violations of the final rule **42 CFR 72** can include imprisonment for up to one year and a fine;

- C Possession of the select agents is not a violation of **42 CFR 72**; but possession of a "biological agent or toxin ... for use as weapons" as defined in Title 18 of the USC may subject the possessor to other criminal penalties;
- C The CDC does not intend to release the information gained under this act to the public under the Freedom of Information Act. Ohio statutes probably allow dissemination of the information held by the University, however;
- C Additional special requirements for handling toxins subject to this part must be met and are found in **29 CFR 1450**, "Occupational Exposure to Hazardous Chemicals in Laboratories";
- C The effective date for these measures is April 15, 1997.

! List of Select Agents

C **Viruses**

1. Crimean-Congo hæmorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley Fever virus
8. South American Hæmorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid # 1, Rift Valley Fever virus strain MP-12, Venezuelan Equine Encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

C **Bacteria**

1. *Bacillus anthracis*
2. *Brucella abortus, B. melitensis, B. suis*
3. *Burkholderia (Pseudomonas) mallei*

4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Exemptions: vaccine strains as described in **Title 9 CFR, part 78.1** are exempt.

C **Rickettsiae**

1. *Coxiella burnetti*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

C **Fungi**

1. *Coccidioides immitis*

C **Toxins**

1. Aurin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at LD_{50} for vertebrates > 100 nanograms per kilogram body weight are exempt. National standard toxins are required for biologic potency testing as described in **9 CFR 113** are exempt.

C **Recombinant organisms/molecules**

1. Genetically modified microorganisms or genetic elements from organisms in the above list, shown to produce or encode for a factor associated with a disease;
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed above, or their toxic subunits.

Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed above that are not known to acquire the trait naturally is prohibited by the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, if such acquisition could compromise the use of drug to control these disease agents in humans or veterinary medicine.

Anyone currently using or wanting to use a "selected agent" must notify the Institutional Biosafety Officer immediately.

Highlights of the IATA regulations mentioned above include:

a. **Definition**: ***Dangerous Goods*** are articles or substances that are capable of posing a significant risk to health, safety or to property when transported by air and those goods or articles that are presently classified according to these regulations;

b. **Classification**: ***Infectious substances*, 3.6.6.1, Division 6.2**, are allocated by criteria developed by the World Health Organization and belong to **UN 2814** or **UN 2900** and include viable micro-organisms including a bacterium, virus, rickettsia, parasite, fungus, or a recombinant, hybrid or mutant, that are known or reasonably believed to cause disease in humans or animals;

c. **Compliance**: An air shipper must comply fully with the dangerous goods regulation, **1.3.1**, including making special arrangements, **1.3.3.1**. Before shipping, the shipper must make advance arrangements with the person receiving the shipment, assure that the shipment can be shipped without delay, arrange with the shipping service to ensure expeditious carriage and notify the recipient of the shipping details;

d. **Packaging**: Infectious material (solid or fluid) must be contained in **UN Class 6.2/93** package for air shipping. Use only package materials approved by **UN**

2814 to ship infectious materials;

e. **Packing**: The shipper is responsible for all aspects of the packing of dangerous goods in compliance with the shipping regulations Packing Group II or medium danger;

f. **Air Bills**: The statement "prior arrangements as required by the IATA Dangerous Goods Regulations **1.3.3.1** have been made must appear in the " Additional handling information section." An additional charge for infectious materials will be added to regular priority overnight shipping charges.

6. Import and export of etiologic agents of human disease requires a permit issued by the Centers for Disease Control and is regulated by **42 CFR 71.156.**

7. Importation of animal infectious agents, animals, and plants is restricted and regulated by the U. S. Department of Agriculture.

XIII. Accident and Incident Reporting

Rapid and accurate reporting of accidents and incidents involving occupational exposures to biohazardous agents is important in identifying potentially hazardous operations and procedures. Furthermore, identification of exposures to biohazardous agents allows personnel to be treated for the agent and minimizes the potential for actually contracting a disease associated with the agent.

- Report all accidents involving human contamination and occupational illnesses to supervisory personnel, to the appropriate administrative unit (department, division, etc.), to OEHS and to the University Employees Health Service (UEHS). An acceptable report must be completed.

- An investigation of any incident or accident may be performed in accordance with University policy.

- Compare Chapters X and XIV for more reportable incidents.

XIV. University Employee Health Program

The initial risk assessment (Safety Plan) for any project must include an evaluation of the appropriate medical surveillance, prophylactic measures (*e.g.*, immunizations) possible treatment options, and post exposure follow-up requirements for the biohazardous agent. This portion of the Safety Plan is performed by the supervisor/PI in conjunction with University Employee Health Services (UEHS) and OEHS. The requirements for routine medical surveillance, prophylaxis, and post-exposure treatment and follow-up are dictated by the project risk assessment. All employees at risk to exposure to biological agents because of their job duties are to automatically be enrolled in a Medical Surveillance Program (MSP) as per University policy. MSPs provide a means to evaluate the success of workplace intervention strategies (*e.g.*, personnel protective equipment or engineering controls) and are successful in significantly reducing the frequency and severity of workplace injury and/or illness.

XIV.1 General Requirements

- **Exposure** resulting in a cut, abrasion, puncture wound or any exposure contaminating an existing skin injury must be treated immediately by washing the wound with soap and water (antibacterial soap preferred). The exposed employee must be evaluated by medical personnel, which means immediate referral to University Employee Health or to the Emergency Department of the University Hospitals after hours. The same is especially true if the organism involved has the capability of penetrating intact skin;
- **Hepatitis B virus vaccine** is available to all personnel who have contact with or use human-sourced materials as part of their job. Those with potential exposure to human blood and/or body fluids must meet the specific requirements for HBV immunization (*cf.*, OSHA Bloodborne Pathogen Standard, **29 CFR 1910.1030**);
- **Effective vaccines,** if available, are required for personnel working specifically with the infectious agents for which there is vaccine protection. Personnel are required to take that vaccine as a condition of employment or must demonstrate an active immunity to the agent in question. Consult with University Employee Health for specifics;
- **Report known exposures** to infectious agents or other biologically hazardous material to a supervisor and be evaluated for possible treatment by medical personnel;
- **Pregnant women** should contact University Employee Health personnel to discuss the ramifications of working with biohazardous agents during pregnancy;
- **Immune-compromised individuals** should consider the consequences of working with biohazardous agents and are encouraged to seek consultation with University Employee Health.

XV. Biosafety in Animal Research

XV.1. General

Laboratory animal facilities (vivaria) are an extension of the research laboratory and **all requirements for work with biohazardous agents and toxic chemicals in the research laboratory are applicable to work in the animal facility.**The Biosafety Level (facilities, practices, and operational requirements) recommended for working with biohazardous agents *in vivo* and *in vitro* are comparable. All animal work at the University shall be in compliance with all applicable standards and regulations as noted earlier in this *Manual* as well as the *Guide for the Care and Use of Laboratory Animals* (1996 revision) and the Laboratory Animal Welfare Regulations (**9 CFR Subchapter A, Parts 1, 2 and 3**). All research involving animals is subject to review by the Institutional Laboratory Animal Care and Use Committee (ILACUC).

The PI, in consultation with University Laboratory Animal Resources (ULAR), ORRP and OEHS is responsible for developing a Safety Plan for work with all animals to be used in the experimentation. This Safety Plan must include appropriate engineering controls, work practices and personal protective equipment to protect all personnel from the recognized hazards associated with the work.

All animal research involving biohazardous agents will be completed at the appropriate biosafety level indicated for the biohazardous agent being used as assigned by the Institutional Biosafety Officer or the IIPC.

Supervisors and PIs must evaluate work done with animals and, in addition to ensuring compliance with applicable animal research regulations, must ensure that all personnel (research as well as ULAR) will be adequately protected from exposure to biohazardous agents associated with the animal research.

The PI must notify the attending ULAR veterinarian at least three working days in advance of the exposure of animals that reside in a ULAR vivarium to biohazardous agents or toxic chemicals. A working day is defined as a day during which University offices are open and excludes weekends and holidays. In the interest of safety, ULAR reserves the right to euthanatize animals exposed to biohazardous agents or toxic chemicals without appropriate notification.

All carcasses from animals intentionally infected for research purposes must be disposed of

as infectious (biohazardous) waste in accordance with Appendix F. Bedding and waste from such infected animals must also be disposed of in accordance with the same section of this *Manual*.

XV.2. Laboratory Animal Dander Allergy (LADA)

It is important to minimize exposures that could result in sensitization of animal-care and laboratory-research personnel. Engineering control of animal facilities, adequate work procedures and the use of appropriate personal protective equipment minimize exposure to laboratory animal dander.

- **!** Allergic reactions to laboratory animal dander are common among personnel working with laboratory animals;
- **!** Personnel should be made aware of the signs and symptoms of laboratory animal dander allergy (LADA);
- **!** Personnel exhibiting any of the signs of LADA must report to University Employee Health for further evaluation and/or treatment.

XV.3. Zoonoses and Arthropodoses

Researchers working with lab animals must recognize the possibility of naturally-infected animals capable of transmitting those infections to lab personnel (zoonoses). This is particularly true of non-human primates, but it is possible with other lab-animal species. Research work also occurs with arthropods (members of the phylum *Arthropoda*, which includes the classes *Insecta, Arachnida, Pentastomida,* and *Crustacea*), and laboratory workers should be aware of the risks in working with these species, the extent to which the arthropods may or may not have been infected with agents, and the extent to which exposure to both infected or uninfected arthropods can impact health and well-being.

Personnel working with lab animals and arthropods must be made aware of the diseases that may infect these animals and that may be transmitted to humans and the methods of transmission (*i.e.*, aerosol for Tuberculosis, bites/scratches for Cercopithecine herpesvirus 1 [*Herpes virus simiae*], stings, etc.).

PIs working with animals or species that can cause injury or disease in man due to bites (snakes, ticks, mites, etc.) or touch (some amphibians and fish) or other methods of transfer of venoms, poisons, etc., to humans must work with University Employee Health, ORRP and OEHS to develop an appropriate plan to ensure reporting of possible exposures and provide for medical evaluation, treatment, and follow-up of personnel exposed to such agents.

XV.4. Vertebrate Animal Biosafety Level Criteria

Institutional management must provide facilities and staff and establish practices that reasonably assure appropriate levels of environmental quality, safety, and care for experimental animals. As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with biohazardous agents *in vivo* and *in vitro* are comparable. The animal room, however, is not the laboratory, and can present unique problems. In the laboratory, hazardous conditions are caused by personnel or the equipment that is being used. In the animal room, the animals themselves can introduce new hazards. Animals may produce aerosols, and they may also infect and traumatize animal handlers by biting and scratching.

Ideally, facilities for laboratory animals used for studies of infectious or noninfectious disease should be physically separate from other activities such as animal production and quarantine, clinical laboratories, and especially from facilities that provide patient care. Animal facilities should be designed and constructed to facilitate cleaning and housekeeping. Traffic flow to minimize the risk of cross contamination should be considered in the plans. A "clean/dirty hall" layout is useful in achieving this. Floor drains should be installed in animal facilities only on the basis of clearly defined needs. If floor drains are installed, the drain trap should always contain water or a suitable disinfectant.

These recommendations describe three combinations of practices, safety equipment, and facilities for experiments on animals infected with agents that produce, or may produce, human infection. These three combinations provide increasing levels of protection to personnel and to the environment, and are recommended as minimal standards for activities involving infected laboratory animals. These three combinations, designated Animal Biosafety Levels (ABSL) 1-3, describe animal facilities and practices applicable to work on animals infected with agents assigned to corresponding Risk Groups 1-3. ABSL-4 and BSL-4 work is currently inappropriate at OSU.

Facility standards and practices for invertebrate vectors and hosts are not specifically addressed in standards written for commonly used laboratory animals. "Laboratory Safety for Arboviruses and Certain Other Viruses of Vertebrates", prepared by the Subcommittee on Arbovirus Laboratory Safety of the American Committee on Arthropod-Borne Viruses, serves as a useful reference in the design and operation of facilities using arthropods.

XV.5. Animal Biosafety Level 1 (ABSL-1)

XV.5.1. ABSL-1 Standard Practices

1. Access to the animal facility is limited or restricted at the discretion of the laboratory or animal facility director;
2. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility;
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in animal rooms. Persons who wear contact lenses in animal rooms should also wear goggles or a face shield;
4. All procedures are carefully performed to minimize the creation of aerosols;
5. Work surfaces are decontaminated after use or after any spill of viable materials;
6. Doors to animal rooms open inward, are self-closing and are kept closed when experimental animals are present;
7. All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers;
8. An insect and rodent control program is in effect.

XV.5.2. ABSL-1 Special Practices

1. The laboratory or animal facility director limits access to the animal room to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when work is in progress. In general, persons who may be at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal room;
2. The laboratory or animal facility director establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., immunization) may enter the animal room;
3. Bedding materials from animal cages are removed in such a manner as to minimize the creation of aerosols, and are disposed of in compliance with applicable institutional or local requirements;
4. Cages are washed manually or in a cage washer. Temperature of final rinse water in a mechanical washer should be $180EF;
5. The wearing of laboratory coats, gowns, or uniforms in the animal facility is recommended. It is further recommended that laboratory coats worn in the animal facility not be worn in other areas;
6. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, are required to read and to follow instructions on practices and procedures.

XV.5.3. ABSL-1 Safety Equipment (Primary Barriers)

Special containment equipment is not required for animals infected with agents assigned to Risk Group 1.

XV.5.4. ABSL-1 Facilities (Secondary Barriers)

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping;
2. A handwashing sink is available in the animal facility;
3. If the animal facility has windows that open, they are fitted with fly screens;
4. Exhaust air is discharged to the outside without being recirculated to other rooms, and it is recommended, but not required, that the direction of airflow in the animal facility is inward.

XV.6. Animal Biosafety Level 2 (ABSL-2)

XV.6.1. ABSL-2 Standard Practices

1. Access to the animal facility is limited or restricted at the discretion of the laboratory or animal facility director;
2. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility;
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in animal rooms. Persons who wear contact lenses in animal rooms should also wear goggles or a face shield;
4. All procedures are carefully performed to minimize the creation of aerosols;
5. Work surfaces are decontaminated after use or after any spill of viable materials;
6. Doors to animal rooms open inward, are self-closing and are kept closed when experimental animals are present;
7. All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers;
8. An insect and rodent control program is in effect.

XV.6.2. ABSL-2 Special Practices

1. The laboratory or animal facility director limits access to the animal room to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when work is in progress. In general, persons who may be at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal room;
2. The laboratory or animal facility director establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., immunization) may enter the animal room;
3. When the biohazardous agent(s) in use in the animal room requires special entry provisions (e.g., the need for immunizations and respirators) a hazard warning sign, incorporating the universal biohazard symbol, is posted on the access door to the animal room. The hazard warning sign identifies the biohazardous agent(s) in use, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates the special requirement(s) for entering the animal room;
4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing);
5. When appropriate, considering the agents handled, baseline serum samples from animal care and other at-risk personnel are collected and stored. Additional serum samples may be collected periodically, depending on the agents handled or the function of the facility. The decision to establish a serologic surveillance program must take into account the availability of methods for the assessment of antibody to the agent(s) of concern. The program should provide for the testing of serum samples at each collection interval and the communication of results to the participants;
6. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures;
7. Appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures and the exposure evaluation procedures are provided to laboratory personnel. Personnel receive annual updates, or additional training as necessary for procedural or policy changes;
8. Contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels require a high degree of precaution. Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible;
    a. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of

infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving;

b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate;

c. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

1. Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping;
2. Cages are appropriately decontaminated, preferably by autoclaving, before they are cleaned and washed. Equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with biohazardous materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility;
3. Spills and accidents that result in overt exposures to biohazardous materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained;
4. Only those animals involved in the work being performed are permitted in the lab.

XV.6.3. ABSL-2 Safety Equipment (Primary Barriers)

1. Biological safety cabinets, other physical containment devices, and/or personal protective equipment (e.g., respirators, face shields) are used whenever procedures with a high potential for creating aerosols are conducted. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, intranasal inoculation of animals, and manipulations of high concentrations or large volumes of biohazardous materials;
2. Appropriate face/eye and respiratory protection is worn by all personnel entering animal rooms housing nonhuman primates;

3. Laboratory coats, gowns, or uniforms are worn while in the animal room. This protective clothing is removed before leaving the animal facility;
4. Special care is taken to avoid skin contamination with biohazardous materials; gloves are worn when handling infected animals and when skin contact with biohazardous materials is unavoidable.

XV.6.4. ABSL-2 Animal Facilities (Secondary Barriers)

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping;
2. A handwashing sink is available in the room where infected animals are housed;
3. If the animal facility has windows that open, they are fitted with fly screens;
4. If floor drains are provided, the drain traps are always filled with water or a suitable disinfectant;
5. Exhaust air is discharged to the outside without being recirculated to other rooms, and it is recommended, but not required, that the direction of airflow in the animal facility is inward.

XV.7. Animal Biosafety Level 3 (ABSL-3)

XV.7.1 ABSL-3 Standard Practices

1. Access to the animal facility is limited or restricted at the discretion of the laboratory or animal facility director;
2. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility;
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use are not permitted in animal rooms. Persons who wear contact lenses in animal rooms should also wear goggles or a face shield;
4. All procedures are carefully performed to minimize the creation of aerosols;
5. Work surfaces are decontaminated after use or after any spill of viable materials;
6. Doors to animal rooms open inward, are self-closing and are kept closed when experimental animals are present;
7. All wastes from the animal room are appropriately decontaminated, preferably by autoclaving, before disposal. Infected animal carcasses are incinerated after being transported from the animal room in leakproof, covered containers;
8. An insect and rodent control program is in effect.

XV.7.2. ABSL-3 Special Practices

1. The laboratory director or other responsible person restricts access to the animal room to personnel who have been advised of the potential hazard and who need to enter the room for program or service purposes when infected animals are present. Persons who are at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal room. Persons at increased risk may include children, pregnant women, and persons who are immunodeficient or immunosuppressed. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the facility;
2. The laboratory director or other responsible person establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific requirements (e.g., for immunization) may enter the animal room;
3. The biohazardous agent(s) in use in the animal room requires special entry provisions (e.g., the need for immunizations and respirators) and a hazard warning sign, incorporating the universal biohazard symbol, is posted on the access door to the animal room. The hazard warning sign identifies the biohazardous agent(s) in use, lists the name and telephone number of the animal facility supervisor or other responsible person(s), and indicates the special requirement(s) for entering the animal room;
4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing);
5. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and to follow instructions on practices and procedures;
6. Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes;
7. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments are restricted in the laboratory for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware should be substituted for glassware whenever possible;
    a. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be

carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container, preferably containing a suitable disinfectant, for transport to a processing area for decontamination, preferably by autoclaving;

b. Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate;

c. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, according to any local, state, or federal regulations.

8. Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping;
9. Cages are autoclaved or thoroughly decontaminated before bedding is removed or before they are cleaned and washed. Equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility;
10. Spills and accidents that result in overt exposures to biohazardous materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained;
11. All wastes from the animal room are autoclaved before disposal. All animal carcasses are incinerated. Dead animals are transported from the animal room to the incinerator in leakproof-covered containers;
12. Only those animals involved in the work being performed are permitted in the lab.

XV.7.3. ABSL-3 Safety Equipment (Primary Barriers)

1. Personal protective equipment is used for all activities involving manipulations of biohazardous materials or infected animals;

a. Wrap-around or solid-front gowns or uniforms are worn by personnel entering the animal room. Front-button laboratory coats are unsuitable. Protective gowns should be appropriately contained until

decontamination or disposal;

b. Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal;
c. Appropriate face/eye and respiratory protection is worn by all personnel entering animal rooms housing nonhuman primates;
d. Boots, shoe covers, or other protective footwear, and disinfectant footbaths are available and used when indicated.

2. Physical containment devices and equipment appropriate for the animal species are used for all procedures and manipulations of infectious materials or infected animals;
3. The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in partial containment caging systems, such as open cages placed in ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnets, or other equivalent primary containment systems.

XV.7.4. ABSL-3 Animal Facilities (Secondary Barriers)

1. The animal facility is designed and constructed to facilitate cleaning and housekeeping, and is separated from areas that are open to unrestricted personnel traffic within the building. Passage through two sets of doors is the basic requirement for entry into the animal room from access corridors or other contiguous areas. Physical separation of the animal room from access corridors or other activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility;
2. The interior surfaces of walls, floors, and ceilings are water resistant so that they may be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate fumigation or space decontamination;
3. A foot, elbow, or automatically operated handwashing sink is provided in each animal room near the exit door;
4. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and a HEPA filter;
5. If floor drains are provided, they are protected with liquid traps that are always filled with water or disinfectant;
6. Windows in the animal room are non-operating and sealed;
7. Animal room doors are self-closing and are kept closed when infected animals are present;
8. An autoclave for decontaminating wastes is available, preferably within the animal facility. Materials are transferred to the autoclave in a covered leakproof container

whose outer surface has been decontaminated;

9. A non-recirculating ventilation system is provided. The supply and exhaust components of the system are balanced to provide for directional flow of air into the animal room. The exhaust air is discharged directly to the outside and clear of occupied areas and air intakes. Exhaust air from the room can be discharged without filtration or other treatment. Personnel must periodically validate that proper directional airflow is maintained;
10. The HEPA-filtered exhaust air from Class I or Class II biological safety cabinets or other primary containment devices is discharged directly to the outside or through the building exhaust system. Exhaust air from these primary containment devices may be recirculated within the animal room if the device is tested and certified at least every 12 months. If the HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged to the outside through the building exhaust system, it is connected to this system in a manner (e.g., thimble unit connection) that avoids any interference with the performance of either the cabinet or building exhaust system.

XVI. IBCC Policy Statements

The Institutional Biosafety Coordinating Committee is charged with:

- ensuring that biosafety measures are developed in a coordinated fashion, implemented, and enforced by the appropriate committee or administrative unit;
- ensuring that researchers, students, University employees, and the public are protected;
- ensuring that the University has in place procedures to ensure compliance with relevant biosafety regulations;
- communicating the University's policies to the committees and administrative units that have responsibility for implementing and enforcing them and, when appropriate, to the University community;
- ensuring that appropriate training is in place for researchers, students, and staff members involved in research or educational activities;
- serve as a body of appeal for biosafety situations that cannot be resolved by other standing committees.

The Institutional Biosafety Coordinating Committee, cognizant of its charge, has adopted the following policies:

XVI.1. Biohazard Violation Policy

Willful violation of prudent safety practices (as described in this manual and references) is a violation of University policy and will be dealt with accordingly.

The following steps will be conducted after a University department (unit) is advised of a potential violation (the information can come from within the department, from the Office of Research Risks Protection (ORRP), the Office of Environmental Health and Safety (OEHS), or from some other University department or unit). In all cases the actions taken will be done so in a *timely manner* that, as used in this context, means with dispatch. The seriousness of the potential violation will indicate the rapidity with which action is to be taken. **Any potential violation involving the potential for personal injury or harm to individuals (*i.e.*, an emergency) must be dealt with immediately!**

1. It is the responsibility of the department chair to monitor and address safety practices. The department chair is notified of the reported violation. Once the department chair becomes aware of a significant or repeat violation or any violation that leads to injury or exposure, it must be reported to ORRP immediately if ORRP has not already been notified. The ORRP will convene a committee consisting of the department chair, the department biosafety officer, the Institutional Biosafety Officer (IBO), an ORRP representative, and the chair(s) of the committee(s) having jurisdiction over the research, that will ask the department chair to conduct an investigation or may conduct its own investigation of the alleged violation. If the department chair feels that the matter can be handled totally within the department (with input from the Institutional Biosafety Officer), the chair may do so, reporting to the committee formed by ORRP. In any case, the report from the chair must be received by ORRP within twenty-four (24) hours in the case of an emergency or within one week in other cases;

2. In those cases in which the department chair cannot resolve the situation or the committee convened by ORRP in ' **XVI.1.1** is not satisfied with the resulting situation, investigation/inspection by ORRP in cooperation with the Institutional Biosafety Officer, the department biosafety officer (or designee of the department chair), and the chair(s) of any involved committee(s) (Institutional Infection Prevention Committee, Institutional Laboratory Animal Care and Use Committee, Institutional Biosafety Committee, Institutional Biosafety Coordinating Committee) will be conducted;

1. A report concerning the investigation made in ' **XVI.1.2** will be made to the chairs of the appropriate committee(s), the Institutional Biosafety Officer, the department biosafety officer and the department chair. In the case of a perceived violation, a memo stating the required correctional steps will be issued with the concurrence of ORRP, the IBO and the chair(s) of the appropriate committee(s);

4. If there is no or incomplete compliance by the Principal Investigator (PI), then a **"stop work"** order will be issued by the IBO in cooperation with ORRP and the chair(s) of the appropriate committee(s). In consultation with the Vice President for Research (VP Research), consideration of withdrawal of research funds by The Ohio State University Research Foundation (OSURF) will be explored. In addition, and in consultation with the department chair, the PI may be locked out of his/her laboratory. The PI will be notified of the appeal processes available to her/him;

5. Appeals from the PI will be forwarded to the appropriate committee(s). The committee(s) will forward their findings to the VP Research who will determine if the committee has

acted appropriately. The decision of the VP Research will be forwarded to the PI;

6. In case of an adverse finding, the PI must take appropriate actions to correct the violation or may appeal the violation to the IBCC, that will contact a number of recognized experts to receive input and make a report of the experts= opinions to the VP Research, who will review the opinions and make a determination in the matter;

1. The findings of the VP Research will be final. Continued violation will be considered a violation of University policy and be dealt with accordingly.

XVI.2 Additional Requirements for Receiving and Sending Select Agents

Summary: The United States Congress has promulgated Public Law 104-132, "The Antiterrorism and Effective Death Penalty Act of 1996". Section 511 of Public Law 104-132, enacted on April 24, 1996, requires that the Department of Health and Human Services regulate the transfer and shipment of select agents. Consequently, the Centers for Disease and Prevention have finalized rules entitled " Additional Requirements for Facilities Transferring and Receiving Select Agents". These rules are in addition to previous regulations for packaging, labeling and transporting select agents shipped in interstate commerce. This final rule places additional shipping and handling requirements on facilities that transfer or receive select agents (listed in the rule and in Chapter 12 of this manual) that are capable of causing substantial harm to human health.

Policy: The Institutional Biosafety Coordinating Committee of The Ohio State University recognizes the implications and seriousness of the regulations. Consequently, the following policies and procedures will be in effect as of April 1, 1997:

1. The Institutional Biosafety Officer (IBO), Office of Environmental Health and Safety is designated as the "Responsible Facility Official". The IBO will be responsible for the following:

   - registering the University "facility" for transfer/receipt of the select agents;
   - providing University employees transferring or receiving select agents with registration documentation;
   - assuring that all transfer/receipt requirements are met;
   - verifying that facilities and personnel meet the minimum biosafety requirements applicable to the select agents being transferred/received;

- verifying that all disposal requirements are met;
- maintaining appropriate records; and
- providing the IBCC with periodic status reports.

2. All University employees transferring or receiving select agents shall:

   - review final rule **42 CFR 72**, Additional Requirements for Facilities Transferring or Receiving Select Agents;
   - complete appropriate registration documentation as provided by the IBO;
   - verify that facilities and personnel meet the minimum biosafety requirements applicable to the select agents being transferred/received;
   - meet appropriate disposal requirements for the select agents; and
   - maintain all records detailing transfers or receipts for five years.

3. The Institutional Biosafety Coordinating Committee shall:

   - assure that all requirements for compliance with this rule have been met;
   - review periodic reports from the IBO;
   - enforce this policy consistent with existing IBCC rules; and
   - review appeals for registrations that have been denied.

XVI.3. Movement of All Animals Exposed to Human Pathogens or Toxic Chemicals Within or Outside of Vivaria

Summary: Laboratory Animals are sometimes purposely infected with biohazardous agents or injected with or exposed to toxic chemicals as part of the research project of which they are a part. It is important to recognize the potential health effects that might result from uncontrolled transfer of these animals outside of the rooms in which the research is performed. To limit exposure to

animals and reduce as much as possible the risks to humans and the spread of diseases to which animals have been exposed or the toxic effects of the chemicals involved in the research, the Institutional Biosafety Coordinating Committee adopts the following policy concerning the movement of all animals exposed to human pathogens or toxic chemicals.

Policy: Movement outside of the assigned space of any animal(s) (alive or dead) infected with or exposed to pathogens (recombinant or otherwise) of Risk Group $ 2, or any animal(s) (alive or dead) exposed to or injected with toxic chemicals, or equipment contaminated with animal material from such animals, is prohibited except when the animal(s)/material is (are) confined to a sealed cage or approved container (microisolator cage or similar). The Risk Group assessment is made by the Institutional Biosafety Officer (IBO) or the Institutional Infection Prevention Committee (IIPC). Appropriate cages will be made available on a first-come, first-served basis by the University Laboratory Animal Resources (ULAR). Violation of this policy is covered in ' **XVI.1.** of this manual.

XVI.4. Risk Group Level Assignments for *Pfiesteria* spp., *Pfiesteria*-like, and *Microcystis* spp. Dinoflagellates

Summary: Because of fish kills in North Carolina and the Chesapeake Bay, research funds are becoming available for the study of the potential culprits, *Pfiesteria piscida. Pfiesteria* spp. are dinoflagellates (order Dinoflagellata). Dinoflagellates are generally placed under the broad heading of “algae”. Some of these protists are the cause of red tides. While the toxins from the red tides arise from the breakup of the organisms after their death, *Pfiesteria* acts differently in that it releases its toxins into water to stun the fish so that the organism can then feed upon the fish.

Characterization of the toxins from *Pfiesteria* proceed. Symptoms from exposure range from effects on mental concentration (aerosol-derived toxin?) to skin lesions (direct contact).

Policy: Because of the potential for transfer of the toxins as aerosols or gas, the Institutional Biosafety Coordinating Committee of The Ohio State University directs that *Pfiesteria* spp. and *Pfiesteria*-like dinoflagellates be treated as agents in Risk Group 3. Researchers planning to use these organisms in their research are required to do so in a BSL-3 facility or in a Class II-B2 biosafety cabinet in a BSL-2 facility. A written risk assessment of the proposed study including containment, training and appropriate personal protective equipment must be prepared and forwarded to the Institutional Biosafety Officer or the Institutional Infection Prevention Committee and approved prior to the commencement of the research. Violation of this policy is covered in ' **XVI.1.** of this manual.

Summary: *Microcystis* spp. are naturally occurring in Lake Erie. Each of the six known species of *Microcystis* produces toxins known as "microcystins". The entity has been associated with bird and fish kills. High levels of microcystins are known to cause liver damage. Low levels of the toxins over prolonged periods promote tumor growth in the liver. Acute exposure to humans can result in gastrointestinal disturbances.

Policy: Because of the potential human exposures during work at Lake Erie to University personnel, the Institutional Biosafety Coordinating Committee deems *Microcystis* spp. to be in Risk Group 2. Laboratory work with the organism will proceed accordingly. Human exposure during field work will proceed only after a written risk assessment of the study that addresses appropriate training and personal protective equipment and training. This risk assessment must be received by the Institutional Biosafety Officer or the Institutional Infection Prevention Committee and approved prior to the commencement of the field research activities. Violation of this policy is covered in ' **XVI.1.** of this manual.

XVII. Phone Numbers of Note

911	**Ambulance**
911	**Fire**
911	**Police**
_____	**Department Biosafety Officer**
_____	**Department Chair**
292-1284	**Institutional Biosafety Officer**
292-1284	**Office of Environmental Healthand Safety**
688-3234	**Office of Research Risks Protection (General)**
688-3234	**Office of Research Risks Protection (Biosafety Matters)**
_____	**Principal Investigator/Research Director**
292-1284	**Spill Response Team [911 after hours]**
293-8146	**University Employee Health**

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Appendix B. Biohazard Registration Form

Principal Investigator: _____

Phone Number: _____

Emergency Phone: _____

Campus address where agent is kept: _____

_____

Name of biohazard agent: _____

Individuals and affiliations of those involved in research with or handling of the agent:

_____

_____

_____

_____

_____

_____

_____

_____

Send completed form via Campus Mail to:

Dr. Cecil R. Smith, Jr.
Institutional Biosafety Officer
Room 210
1314 Kinnear Road

Appendix C. Assignment of Biological Agents to Risk Groups

The Principal Investigator is responsible for ensuring that appropriate precautions are taken for the Risk Group of an agent. Those agents not listed in Risk Groups (RGs) 2, 3, and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed. Agents not on this list may be assigned to Risk Groups by the Institutional Biosafety Coordinating Committee, the Institutional Infection Prevention Committee, or the Institutional Biosafety Officer. If the agent is not on this list, the Principal Investigator must contact the Institutional Biosafety Officer for information concerning the Risk Group assignment of that agent. In no case will a Risk Group assignment in this list be lowered without the permission of the IBCC, IIPC, or IBO.

I. Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis*, *Escherichia coli*-K12, and adeno-associated virus types 1 through 4.

II. Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease that is rarely serious and for which preventative or therapeutic interventions are *often* available.

A. RG2 Bacterial Agents including Chlamydia

Acinetobacter baumannii (formerly *Acinetobacter calcoaceticus*)
Actinobacillus
Actinomyces pyogenes (formerly *Corynebacterium pyogenes*)
Aeromonas hydrophila
Amycolata autotrophica
Archanobacterium hæmolyticum (formerly *Corynebacterium hæmolyticum*)
Arizona hinshawii, all serotypes
Bacillus anthracis
Bartonella henselæ, B. quintana, B. vinsonii
Bordetella including *B. pertussis*
Borrelia recurrentis, B. burgdorferi
Burkholderia (formerly *Pseudomonas*) except those in RG3
Campylobacter coli, C. fetus, C. jejuni
Chlamydia psittaci, C. trachomatis, C. pneumoniæ
Clostridium botulinum, Cl. chauvœi, Cl. hæmolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
Corynebacterium diphtheriæ, C. pseudotuberculosis, C. renale
Dermatophilus congolensis
Edwardsiella tarda

Erysipelothrix rhusiopathiæ
Escherichia coli: all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7
Hæmophilus ducreyi, H. influenzæ
Helicobacter pylori
Klebsiella: all species except *K. oxytoca* (RG1)
Legionella including *L. pneumophila*
Leptospira interrogans: all serotypes
Listeria
Moraxella
Mycobacterium (except those in RG3) including *M. avium* complex, *M. asiaticum, M. bovis* BCG vaccine strain, *M. chelonei, M. fortuitum, M. kansasii, M. lepræ, M. malmœnse, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiæ, M. szulgai, M. ulcerans, M. xenopi*
Mycoplasma except *M. mycoides* and *M. agalactiæ* that are restricted animal pathogens
Neisseria gonorrhœæ, N. meningitidis
Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis
Rhodococcus equi
Salmonella including *S. arizonæ, S. cholerasuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S.paratyphi,* A, B, C, *S. typhi, S. typhimurium*
Shigella including *S. boydii, S. dysenteriæ,* type 1, *S. flexneri, S. sonnei*
Sphærophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus including *S. pneumoniæ, S. pyogenes*
Treponema pallidum, T. carateum
Vibrio choleræ, V. parahemolyticus, V. vulnificus
Yersinia enterocolitica

B. RG2 Fungal Agents

Blastomyces dermatitidis
Cladosporium bantianum, C. (Xylohypha) trichoides
Cryptococcus neoformans
Dactylaria galopava (Ochroconis gallopavum)
Epidermophyton
Exophiala (Wangiella) dermititidis
Fonsecæa pedrosoi
Microsporum
Paracoccidioides braziliensis
Penicillium marneffei
Sporothrix schenckii
Trichophyton

C. RG2 Parasitic Agents

Ancylostoma human hookworms including *A. duodenale, A. ceylanicum*
Ascaris including *Ascaris lumbricoides suum*
Babesia including *B. divergens, B. microti*
Brugia filaria worms including *B. malayi, B. timori*
Coccidia
Cryptosporidium including *C. parvum*
Cysticercus cellulosæ (hydatid cyst, larva of *T. solium)*
Echinococcus including *E. granulosis, E. multilocularis, E. vogeli*
Entamœba histolytica
Enterobius
Fasciola including *F. gigantica, F. hepatica*
Giardia including *G. lamblia*
Heterophyes
Hymenolepis including *H. diminuta, H. nana*
Isospora
Leishmania including *L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruvania, L. tropica*
Loa loa filaria worms
Microsporidium
Nægleria fowleri
Necator human hookworms including *N. americanus*
Onchocerca filaria worms including *O. volvulus*
Plasmodium including simian species, *P. cynomologi, P. falciparum, P. malariæ, P. ovale, P. vivax*
Sarcocystis including *S. sui hominis*
Schistosoma including *S. hæmatobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi*
Strongyloides including *S. stercoralis*
Tænia solium
Toxocara including *T. canis*
Toxoplasma including *T. gondii*
Trichinella spiralis
Trypanosoma including T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense, T. cruzi
Wuchereria bancrofti filaria worms

D. RG2 Viruses

Adenoviruses, human¢ all types

Alphaviruses (Togaviruses)¢ Group A Arboviruses
Eastern equine encephalitis virus

Venezuelan equine encephalitis vaccine strain TC-83
Western equine encephalitis virus

Arenaviruses
Lymphocytic choriomeningitis virus (non-neurotropic strains)
Tacaribe virus complex
Other viruses as listed in *BMBL*

Bunyaviruses
Bunyamwera virus
Rift Valley fever virus vaccine strain MP-12
Other viruses as listed in *BMBL*

Calciviruses

Coronaviruses

Flaviviruses (Togaviruses)¢ Group B Arboviruses
Dengue virus serotypes 1, 2, 3, and 4
Yellow fever virus vaccine strain 17D
Other viruses as listed in *BMBL*

Hepatitis A, B, C, D, and E viruses

Herpesviruses¢ except Herpesvirus simiæ (Monkey B virus) (RG4)
Cytomegalovirus
Epstein Barr virus
Herpes simplex types 1 and 2
Herpes zoster
Human herpesvirus types 6 and 7

Orthomyxoviruses
Influenza viruses types A, B, and C
Other tick-borne orthomyxoviruses as listed in *BMBL*

Papovaviruses
All human papilloma viruses

Paramyxoviruses
Newcastle disease virus
Measles virus
Mumps virus
Parainfluenza viruses types 1, 2, 3, and 4
Respiratory syncytial virus

Parvoviruses
Human parvovirus (B19)

Picornaviruses
Coxsackie viruses types A and B
Echoviruses¢ all types
Polioviruses¢ all types, wild and attenuated
Rhinoviruses¢ all types

Poxviruses¢ all types except Monkeypox virus (see RG3) and restricted poxviruses including Alastrim, Smallpox, and Whitepox

Reoviruses¢ all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)

Rhabdoviruses
Rabies virus¢ all strains
Vesicular stomatitis virus¢ laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow

Togaviruses (see Alphaviruses and Flaviviruses)
Rubivirus (rubella)

III. Risk Group 3 (RG3) Agents

RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available.

A. RG3 Bacterial Agents Including Rickettsia

Bartonella
Brucella including *B. abortus, B. canis, B. suis*
Burkholderia (Pseudomonas) mallei, B. pseudomallei
Coxiella burnetii
Francisella tularensis
*Mycobacterium bovis (*except BCG strain, see Risk Group 2 (RG2)), *M. tuberculosis*
Pasteurella multocida type B¢ Abuffalo@ and other virulent strains
Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. tsutsugamushi, R. typhi (R. mooseri)
Yersinia pestis

B. RG3 Fungal Agents

Coccidioides immitis (sporulating cultures; contaminated soil)

Histoplasma capsulatum, H. capsulatum var. duboisii

C. RG3 Parasitic Agents

None

D. RG3 Viruses and Prions

Alphaviruses (Togaviruses)¢ Group A Arboviruses
- Semliki Forest virus
- St. Louis encephalitis virus
- Venzuelan equine encephalitis virus (except the vaccine strain TC-83, see RG2)
- Other viruses as listed in *BMBL*

Arenaviruses
- Flexal
- Lymphocytic choriomeningitis virus (LMC) (neurotropic strains)

Bunyaviruses
- Hantaviruses including Hantaan virus
- Rift Valley fever virus

Flaviviruses (Togaviruses)¢ Group B Arboviruses
- Japanese encephalitis virus
- Yellow fever virus
- Other viruses as listed in *BMBL*

Poxviruses
- Monkeypox virus

Prions
- Transmissible spongioform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents) (see *BMBL* for containment instructions)

Retroviruses
- Human immunodeficiency virus (HIV) types 1 and 2
- Human T cell lymphotropic virus (HTLV) types 1 and 2
- Simian immunodeficiency virus (SIV)

Rhabdoviruses
- Vesicular stomatitis virus

IV. Risk Group 4 (RG4) Agents

RG4 agents are likely to cause serious or lethal human disease for which preventive or

therapeutic interventions are *not usually* available.

A. RG4 Bacterial Agents

None

B. RG4 Fungal Agents

None

C. RG4 Parasitic Agents

None

D. RG4 Viral Agents

Arenaviruses
- Guanarito virus
- Lassa virus
- Junin virus
- Machupo virus
- Sabia

Bunyaviruses (Nairovirus)
- Crimean-Congo hæmorrhagic fever virus

Filoviruses
- Ebola virus
- Marburg virus

Flaviruses (Togaviruses)¢ Group B Arboviruses
- Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

Herpesvirus (alpha)
- Herpesvirus simiæ (Herpes B or Monkey B virus or Circopithecine herpesvirus 1)

Hemorrhagic fever agents and viruses as yet undefined

Paramyxoviruses
- Equine morbillivirus

V. Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work.

A containment level appropriate for RG1 human agents is recommended for their use, For agents that are infectious to human cells, e.g., amphotrophic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Baculoviruses

Herpesviruses
- Herpesvirus ateles
- Herpesvirus saimiri
- Marek's disease virus
- Murine cytomegalovirus

Papovaviruses
- Bovine papilloma virus
- Polyoma virus
- Shope papilloma virus
- Simian virus 40 (SV40)

Retroviruses
- Avian leukosis virus
- Avian sarcoma virus
- Bovine leukemia virus
- Feline leukemia virus
- Feline sarcoma virus
- Gibbon leukemia virus
- Mason-Pfizer monkey virus
- Mouse mammary tumor virus
- Murine leukemia virus
- Murine sarcoma virus
- Rat leukemia virus

Appendix D. rDNA Preliminary Review Form

Recombinant DNA
Institutional Biosafety Committee Date _____
The Ohio State University

Note: Please look at Question C.4. before proceeding. If any response from C.4.a. through j. is Ayes@, do not complete this form. A Memorandum of Agreement (MUA) must be completed. Call 8-8457 to obtain the MUA form.

Principal Investigator _____ _____
Typed Name Signature
Academic Title _____ Phone No. _____
Campus Address _____ Department _____
Project Title _____
_____
_____
OSURF Project No. _____ Location: Building _____
Room Number(s) _____

A. Has this project previously been reviewed by the IBC under a different OSURF number?
[ ] Yes [ ] No. If yes, indicate the protocol number:_____

B. Give a one sentence description of the project as it relates to the *NIH Guidelines.*

C. For each experiment (1, 2, 3, etc.) give:
1. The source of the DNAs (what organisms?):

2. The nature of the inserted sequence (gene for what?; promoter for what?; transposable element?; etc.):

3. Hosts and vectors (*E. coli* K-12 system, *Saccharomyces* system, insect cells, plasmids, cosmids, phages, elephants, donkies, etc.):

4. Are any of the following genes, viruses, factors, or conditions involved? [Yes or no]:

_____ a. deliberate transfer of drug resistance into organisms that do not acquire them naturally? (Except for approved host-vector systems that contain antibiotic resistance markers).
_____ b. deliberate transfer of recombinant DNA into humans?
_____ c. genes that produce vertebrate toxins with LD_{50} < 100 ng/kg of body weight?
_____ d. using human or animal pathogens as vector-host systems?
_____ e. human or animal pathogen DNA cloned into non-pathogenic prokaryote or lower eukaryote?
_____ f. using infectious animal or plant DNA or RNA viruses in tissue culture or using defective viruses when a helper is present?
_____ g. altering an animal genome by recombinant DNA or testing viable rDNA-modified organisms in whole animals?
_____ h. genetic engineering of plants by rDNA methods or use of plants with microorganisms or insects containing rDNA?
_____ I. experiments involving more than 10 liters of culture?
_____ j. deliberate release of rDNA-modified plants or animals into the environment?

D. Do you expect this research to lead to field trials of genetically-altered organisms? [ ] Yes [ ] No. If yes, when do you expect to begin field trials?

E. Please indicate if any or all of your experiments are exempt from full-committee review and cite the section(s) of the *NIH Guidelines* that establish this exemption.

Appendix E. Outline of *NIH Guidelines* Involving Recombinant DNA Molecules

This outline is based upon the latest amended guidelines issued in May 1998. Complete guidelines are available on the World Wide Web at http://www.nih.gov/od/orda.

Section I: Scope of *NIH Guidelines*

I-A: Purpose: the purpose of the *NIH Guidelines* is to specify practices for construction and handling : (i) recombinant deoxyribonucleic acid (DNA)molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

I-A-1: Some experiments require NIH approval.

I-A-1-a: The deliberate transfer of recombinant DNA or DNA or RNA derived from rDNA into human subjects (human gene transfer) requires submission to FDA and NIH/ORDA prior to initiation (see Appendix M).

I-B: Definition of recombinant DNA molecules (rDNA) . . . (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i).

Synthetic DNA segments that are likely to yield potentially harmful polynucleotide or polypeptides are considered equivalent to their natural DNA counterpart. If not expressed as biologically active component *in vivo*, experiments are exempt from IBC review.

I-C: *NIH Guidelines* apply to all rDNA research at institutions receiving NIH funds.

I-D: Institutions must ensure that rDNA research complies with *NIH Guidelines.*

Section II: Safety Considerations

II-A-1: Initial risk assessment based on Risk Group (RG) of agent used. Agents' RG's defined according to pathogenicity in healthy humans. RG1 = RG's = RG4. RG's of many pathogens listed in Appendix B.

II-A-2: RG's do not take into account possible increased susceptibility of individuals. Personnel may need medical surveillance to ascertain fitness to perform certain activities.

II-A-3: Risk assessment of experiment should involve many factors: virulence, pathogenicity, dose, stability, route of spread, communicability, operations, quantity, prophylaxis availability, and gene product effects.

The IBC must approve the risk assessment and the biosafety containment level for rDNA experiments in Section III-A, B, C and D.

Exotic plant and animal pathogens of domestic livestock are restricted and may require special laboratory design.

II-B: Physical containment levels for Biosafety Levels 1 to 4 are given in Appendix G. Biological containment levels are given in Appendix I. Plant biosafety levels are given in Appendix P. Actual containment levels necessary for experiments need to be assessed by many considerations beyond just the RG specified in Appendix B.

Section III: Experiments Covered by the *NIH Guidelines*

III-A: Experiments That Require IBC approval, RAC Review and NIH Director's and IBC Approval Before Initiation

A-1-a: Deliberate transfer of drug resistance traits to microorganisms that don't acquire them naturally.

III-B: Experiments That Require NIH/ORDA and IBC Approval Before Initiation

B-1: Cloning of toxins having LD_{50} < 100 ng/Kg body weight.

III-C: Experiments That Require IBC Approval and IRB Approval and NIH/ORDA Registration Before Initiation

C-1: Experiments involving the deliberate transfer of rDNA or DNA or RNA derived from rDNA into one or more human subjects

III-D: Experiments requiring IBC approval before initiation

D-1: Experiments using RG2-4 or restricted agents as host-vector systems

1-a: Risk Group 2 (RG2) agent: BSL-2 containment;

1-b: Risk Group 3 (RG3) agent: BSL-3 containment;

1-c: Risk Group 4 (RG4) agent: BSL-4 containment;

1-d: Restricted agent: Case by case review by NIH/ORDA, USDA permit required with plant or animal pathogen.

D-2: Experiments in Which DNA from Risk Group 2, Risk Group 3, Risk Group or Restricted agents is cloned into non-pathogenic prokaryote or lower eukaryote.

2-a: RG 2 or 3 at BSL-2; RG 4 at BSL-2 if shown defective, or BL-4 if not defective. IBC may approve level BSL-1 for certain experiments. Many experiments in this category do not fall under these *Guidelines.*

D-3: Experiments involving use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper in tissue cultures systems.

3-a: RG 2 virus or defective virus + helper: BSL-2;

3-b: RG 3 virus or defective + helper: BSL-3;

3-c: RG 4 virus or defective + helper: BSL-4;

3-d: Infectious or defective restricted poxviruses + helper: case by case, determined by NIH/ORDA review;

3-e: Not covered above: BSL-1.

D-4: Experiments Involving whole animals.

4-a: rDNA from any source (except >2/3 virus RNA or DNA) to non-human vertebrate: BSL-1. Must be shown that the virus DNA used does not lead to infection. USDA permit required for plant or animal pathogens.

4-b: For experiments using rDNA, or DNA or RNA derived therefrom, in animals, not covered in III-C-1 or III-C-4-a, containment set by IBC.

D-5: Experiments Involving Whole Plants

5-a-e: Experiments involving rDNA-transformed plants or associated organisms that have potentially harmful effects upon the environment must be conducted at more stringent containment than BL1-P.

D-6: Experiments involving more than 10 liters of culture. Containment determined by IBC.

Note: NIH guidelines no longer apply to the deliberate release of organisms containing rDNA into the

environment. Currently, other federal agencies such as USDA and EPA regulate these experiments. **IBC approval is still required.**

III-E: Experiments That Require IBC Notice Simultaneously With Initiation

E-1: Formation of rDNA molecules containing no more than 2/3 of the genome of eukaryotic virus (no helper) propagated in tissue culture: BL-1.

E-2: Experiments involving whole plants.

E-3: Experiments involving transgenic rodents

III-F: Exempt Experiments (fall outside of the *Guidelines*)

F-1: rDNA not in organisms or viruses.

F-2: rDNA entirely from single non-chromosomal or viral source.

F-3: rDNA entirely from a prokaryotic host including its plasmids and viruses when propagated in that host or closely related strain or transferred by established physiological means.

F-4: DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but not viruses) when propagated in that host or closely related strain of the same species.

F-5: rDNA consisting entirely of segments from different species that exchange DNA through known physiological processes. Lists of these exchangers are established by NIH and appear in Appendix A of the *Guidelines.*

F-6: Those not posing a significant risk to health or the environment as determined NIH. Listed in Appendix C.

Section IV. Roles and Responsibilities

IV-A: Policy: Safe conduct involving rDNA experiments depends on individual conducting experiment.

IV-B: General information.

IV-B-1: Each institution must:

B-1-a: Establish policies

B-1-b: Establish IBC

B-1-c: Appoint Institutional Biosafety Officer

B-1-d: Appoint person with knowledge of plants, plant pathogens, or plant-pest containment principles

B-1-e: Appoint person with expertise in animal containment principles

B-1-f: IBC must have expertise on hand or consultants available when human gene therapy experiments are done. Need to follow all aspects of Appendix M.

B-1-g: Assist and ensure compliance with *NIH Guidelines*

B-1-h: Ensure appropriate training of IBC

B-1-i: Determine necessity for health surveillance of personnel involved in rDNA experiments. Must be available for large-scale or animal BL3 experiments.

B-1-j: Report significant problems, violations of *Guidelines*, or specific research-related accidents to NIH/ORDA.

IV-B-2: IBC

B-2-a: Membership

IV-B-3: Biological Safety Officer

Appendix F. Infectious Waste Guidelines

F.1 Infectious Waste Generation and Treatment

The Ohio State University, as required by Ohio Administrative Code (OAC) **Section 3745-27**, is registered with the Ohio Environmental Protection Agency (OEPA) as a large-quantity generator of infectious waste. Faculty and staff who generate infectious waste must comply with OEPA regulations. For generators of infectious waste (faculty, staff, students, etc.) the following pages contain information dealing with these regulations. Individual PIs/Supervisors are responsible for assuring compliance with infectious regulations including:

1. identification and segregation;
1. proper packaging;
2. proper treatment;
3. personnel training;
4. spill and containment plans; and
5. contingency plans.

It is the PI's/Supervisor's responsibility to notify the Institutional Infection Prevention Committee, OEHS, and ORRP of their activities and to comply with OEPA regulations. Assistance is available from OEHS to help develop and implement procedures consistent with the regulations.

Individuals who choose to treat their own infectious waste must register with OEHS at **292-1284** and their laboratory/facility will be audited quarterly by OEHS and a representative of OEPA.

F.2 Definitions of Infectious Waste

1. Cultures and stocks of infectious agents (human pathogens) and associated biologicals, including, without limitation, specimen cultures, cultures and stocks of infectious agents, wastes from production of biologicals and discarded live and attenuated vaccines;

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 handled;

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;

4. Waste materials from the rooms of humans, or the enclosures of animals, that have been isolated because of diagnosed communicable diseases that are likely to transmit infectious agents. Such waste materials from the rooms of humans do not include any wastes of patients who have been placed on blood and body fluid precautions under the Universal Precaution System established by the Centers for Disease Control and Prevention in the Public Health Service of the United States Department of Health and Human Services, except to the extent specific wastes generated under the Universal Precaution System have been identified as infectious wastes by rules referred to in **§ F.2.8** below;

5. Human and animal blood specimens and blood products that are being disposed of, except that "blood product" does not include patient care waste such as bandages or disposable gowns that are lightly soiled to the extent that the generator of the wastes determines that they should be managed as infectious wastes. Bandages, gowns, or other waste materials generated in the diagnosis, treatment, or immunization of humans or animals that, when held vertically, drip or exude blood or body fluids are said to be saturated and will be considered an infectious waste;

6. Contaminated carcasses, body parts, and bedding of animals that were intentionally exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals, and carcasses and bedding of animals otherwise infected that may present a substantial threat to public health if improperly handled;

7. Sharp wastes used in the treatment or inoculation of human beings or animals or 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 rule referred to as "sharp infectious waste" or "sharps";

8. Any other waste material generated in the diagnosis, treatment, or immunization of humans or animals, in research pertaining thereto, or in the production or testing of biologicals that represent a substantial threat to public health when improperly managed.

F.3 Packaging and Disposal of Untreated Infectious Waste

For the packaging and disposal of infectious waste the Ohio Administrative Code Section **3745-27-30** requires the following:

F.3.1 Material

1. Red bags or biohazard bags, biohazard shipping boxes, and sharps containers;

2. All material in **§ F.3.1.1** except sharps containers are available at no charge from OEHS. Sharps containers are available through the Medical Stores. Call **292-1284** for delivery of the bags and boxes.

F.3.2 Packaging

1. Separate infectious from noninfectious waste at the point of generation;

2. Place infectious waste other than sharps in securely closed red bags or plastic bags labeled with the international biohazard symbol. Place bags in a biohazard box and tape shut. Label the biohazard box with your room number and building;

3. Place all sharp infectious waste and all unused discarded hypodermic needles, syringes, and scalpel blades in a sharps container (*i.e.*, any rigid plastic, sealable container labeled "sharps" and displaying the international biohazard symbol). Bag, box and label as in **§ F.3.2.2**.

F.3.3 Disposal

1. Call OEHS at **292-1284** for pick-up of packaged infectious waste.

2. Generators of infectious waste may discharge untreated liquid or semi-liquid infectious wastes consisting of blood, blood products, body fluids, and excreta into the sanitary sewer system (**OAC 3745-27-30-C**).

F.3.4 Spills

1. All individuals who use biohazardous substances must record in a log all spills or accidents involving infectious waste. For spills in quantities greater than one gallon

or which involve exposure of laboratory personnel, OEHS must be notified;

2. All individuals who use biohazardous substances must develop and implement a spill-containment and clean-up procedure. The procedure must be readily available to persons likely to handle infectious waste;

3. Sections F.7 and F.8 are provided to meet these requirements. Modifications of procedures must be forwarded to OEHS for review and comments.

F.4 Treatment By Incineration

Those who wish to treat infectious waste onsite by incineration must comply with **OAC 3745-27-32.** In the past, infectious waste (primarily animal carcasses and bedding) had been incinerated at Wiseman Hall, Biological Sciences or Goss Laboratory. These incinerators are not permitted by the Ohio Environmental Protection Agency to burn infectious waste. Administrative units responsible for these incinerators have been notified that all incineration of infectious waste must cease immediately. Infectious waste currently treated at one of these locations should be packaged according to instructions provided above in **F.3**. Contact OEHS at **292-1284** for further assistance.

F.5 Treatment by Steam Sterilization

Those who wish to treat infectious waste onsite using steam sterilization must also comply with **OAC 3745-27-32.**

F.5.1 Operational Requirements

1. Autoclaves must operate at a minimum temperature of 121EC or 250EF with a minimum of 15 pounds per square inch pressure;

2. Autoclaves shall operate within the specified temperatures and pressures for one-half hour or longer, depending upon the load size;

3. Autoclaves shall operate with a maximum-registering thermometer, except for fast exhaust loads;

4. The following must be available at the site:

    a. a copy of the OSU Infectious Waste Permit must be posted at the site;

b. the autoclave's manufacturer's specifications and maintenance records;

c. infectious waste containment and clean-up procedures;

d. a contingency plan in the event the autoclave is out of service;

e. quality control procedures;

f. standard operating procedures; and

g. emergency telephone numbers and responders.

5. Each package of waste in a load shall have heat-sensitive tape or equivalent to indicate temperature conditions.

F.5.2 Standard Operating Procedures (SOPs)

The SOPs shall address the following items: time, temperature, pressure, type of infectious waste, type of container, closure of container, loading pattern, maximum load quantity, and liquid content.

F.5.3 Quality Controls

1. All autoclaves shall:

   a. be calibrated quarterly;

   b. be tested with *Bacillus stearothermophilus* each week the autoclave is utilized for treatment of infectious waste; and

   c. have a log maintained containing: date, time cycle started, time cycle completed, operator, type of waste, temperature of maximum registering thermometer, and post-treatment reading of temperature sensitive tape.

2. have a permanent record of temperature graphs maintained.

F.5.4 Spill Containment- See F.7

F.5.5 Disposal

Treated infectious waste (except sharps) can be placed in the general refuse. All treated materials must be double bagged with the outside bag being opaque. No visible red bags or biohazard bags are permitted.

F.6 Chemical Treatment

Chemical treatment of infectious waste also requires complying with **OAC 3745-27-32.**

The Ohio Environmental Protection Agency has only approved chemical treatment of infectious waste categorized as cultures. Therefore, chemical treatment of any other category of infectious waste must be approved by the Director OEPA or an alternate approved-treatment method used.

F.6.1 Approved Chemical Treatment Solutions

1. Chlorine compounds, specifically hypochlorite or chlorinated isocyanurates, used at a strength of 15% (v/v) diluted with solvent; and

2. Chemicals registered with the U.S. EPA as virucidal, bactericidal, fungicidal, parasiticidal, or sporicidal.

F.6.2 Procedures

1. All cultures must remain submerged in chemical sterilant for a minimum of 10 minutes or for a period of time as described by the manufacturer;

2. All treatment solutions shall be mixed immediately prior to use and discarded after use;

3. Excess chemical shall be decanted prior to disposal of treated cultures.

F.6.3 Disposal

1. Treated liquid cultures can be put into the sanitary sewer system;

2. Treated cultures consisting of solids should be double-bagged and can be placed into the general refuse.

F.6.4 Spill and Containment Procedures - See F.7

F.6.5 Quality Control

Maintain logs with the following information: type of waste, volume, treatment chemical, concentration, and contact time.

F.7 Spill Containment and Clean-up Procedures

According to **OAC 3745-27-32**, all treatment facilities shall keep a spill containment and clean-up kit within the vicinity of any storage area, loading/unloading areas, decontamination areas, and treatment areas where infectious wastes are managed. The location of the kits shall provide for rapid and efficient clean up of spills anywhere within these areas.

F.7.1 Spill Kit Materials

1. Absorbent;

2. One gallon approved chemical disinfectant (bleach);

3. Red bags or bags labeled with the biohazard symbol;

4. Impermeable and disposable overalls (preferably tyvek total body coveralls);

5. Gloves (heavy neoprene or latex);

6. Goggles (can be reusable); and

7. Rigid plastic container for sharps.

** Spill Kits can be purchased from OEHS for a nominal fee. ***

F.7.2 Clean-up Procedures

1. A copy of the clean-up procedures is provided later in this section;

2. More specific or detailed clean-up procedures can be prepared by the generator.

F.7.3 Spill Log

1. A copy of the spill log is also provided;

2. Spill logs must be maintained for five years;

3. All spills greater than one gallon or which involve exposure of laboratory personnel must be reported to OEHS immediately and those spills of volume greater than one cubic foot must be reported to OEHS and to the Director of OEPA within 48 hours.

F.8 Contingency Plan

In accordance with **OAC 3745-27-32** and **35**, a contingency plan must be available at treatment sites. In the event that sites which treat infectious waste cannot meet the storage requirements described below or are experiencing a malfunction in treatment processes, the contingency plan shall be implemented.

F.8.1 Storage

1. Store infectious waste in a manner that maintains the integrity of packing;

2. Maintain waste in a nonputrescent state, using refrigeration or freezing if necessary;

3. Lock outside storage to prevent unauthorized access;

4. Designate and label storage areas by posting biohazard warning signs;

5. Store infectious waste in a manner that affords protection from animals;

6. No infectious waste may be stored more than 14 days;

7. No more than seven times the treatment facility's total maximum daily throughput capacity shall be stored for treatment.

CONTINGENCY PLAN

Emergency Coordinator: _____ Telephone: _____

Alternate Coordinator: Dr. Cecil Smith, OEHS Telephone: 292-1284

1. If you cannot comply with the storage requirements set forth, the following contingency plan shall be implemented:

   d. Notify your Emergency Coordinator;

   e. Call OEHS and request red bags, biohazard boxes, and sharps containers as needed for packing infectious waste at your treatment location;

   f. Following packaging of infectious waste, OEHS will arrange for offsite incineration.

2. Listing of emergency telephone numbers in addition to the Emergency Coordinator.

a.	Campus Police Dispatcher	**292-2525**
b.	OEHS Chemical/Infectious Waste Management	**292-1284**
c.	OEHS Main Office	**292-1284**
d.	OEPA Central District Office	**771-7505**
e.	Emergency Number	**911**
f.	Columbus Health Department	**645-7676**

CONTACTS: _____ Dr. Cecil Smith, AVP

_____ 1314 Kinnear Road

_____ Tel: 292-1284/292-2525

F.9 INFECTIOUS WASTE SPILL CONTAINMENT AND CLEAN-UP PROCEDURE

In accordance with **OAC 3745-27-30**, the following containment and clean-up procedures are to be implemented in the event of an infectious waste spill.

F.9.1 Directions

1. Open the spill kit;

2. Put on the (1) Tyvek total body coveralls over normal work clothes, (2) the latex gloves and (3) the goggles;

3. If this is a liquid spill, contain it by covering with absorbent pads;

4. Put up barrier tape at the spill site and limit access to authorized personnel;

5. Place contaminated absorbent and other contaminated solids into the red bags in the spill kit. Seal the bag with the enclosed ties and place in a second bag. Sharps (needles, blades, or broken glass) should be placed in the rigid container labeled sharps;

6. Cover contaminated surfaces with absorbent pads and soak with disinfectant (bleach) in the spill kit. Allow the bleach to stand on the contaminated surface for a minimum of ten (10) minutes;

7. Place the decontamination pads in a red bag. Use additional absorbent pads to soak up excess liquid, if necessary;

8. Remove the Tyvek coveralls and gloves and put them into the same red bag. Seal the bag with the enclosed ties and place into a second red bag. Seal the second bag. Put into a biohazard box;

9. Disinfect the goggles with the disposable alcohol pads in the spill kit. Put the goggles back into the spill kit.

NOTES

1. Complete the spill log and return address on the log sheet;

2. If you require assistance or have questions, contact the Office of Environmental Health and Safety at **292-1284** or the police dispatcher at **292-2525** after working hours.

INFECTIOUS WASTE SPILL REPORT

A spill report is required under **OAC 3745-27-30(A)(10)** for any spill that is greater than or equal to one cubic foot in volume. Complete this report and return to the address listed below.

Date and Time of Spill: _____

Date of Report: _____

Location of Spill: _____

Employee(s) Involved in Clean-up: _____

_____

Waste Spilled: _____ Estimated Quantity: _____

Describe Clean-up Procedure: _____

_____

_____

Summary of Events Causing Spill (If Known): _____

_____

_____

_____ _____ _____

Printed Name Signature Date

Mail Completed Report To:
Dr. Cecil Smith
Office of Environmental Health and Safety
Room 210
1314 Kinnear Road, CAMPUS

Appendix G. World-Wide Web Site Addresses

The Ohio State University:

Office of Environmental Health and Safety
Source for MSDSs and other safety matters.
University Radiation Safety Committee
http://www.ehs.ohio-state.edu

Office of Research Risks Protection
Includes Institutional Infection Prevention Committee (IIPC), Institutional Laboratory Animal Care and Use Committee(ILACUC), Institutional Biosafety Committee (Recombinant DNA) (IBC), Institutional Biosafety Coordinating Committee (IBCC).
http://www1.rf.ohio-state.edu

College of Biological Sciences
Thanks to Jeremy Smith
http://www.biosci.ohio-state.edu/

Other University Sites:

Michigan State University Office of Radiation, Chemical and Biological Safety (ORCBS). Refers to other Big-Ten safety sites:
http://www.orcbs.msu.edu/imagemap/imagemap.cgi$patchmap.gif2

Stefan=s Biosafety Resource Page
An unbelievable number of URLs all in one place
http://www.orcbs.msu.edu/biological/resource.htm

Other Sites:

American Society for Microbiology
http://www.asmusa.org

Agency for Toxic Substances and Disease Registry
http://atsdr1.atsdr.cdc.gov:8080/cx.html

FDA http://www.fda.gov/fdahomepage.html

NIH http://www.nih.gov

NIOSH http://www.cdc.gov/niosh/homepage.html

OSHA http://www.osha.gov

Searchable Federal Register (from 1995) and CFR Site (searchable Code of Federal Regulations (CFR))
http://www.access.gpo.gov/su_docs/aces/aces140.html

What Do I Do Now?

Now that you have the *Biosafety Manual*, how do you proceed? The first question you must answer is whether you are using one of the "select agents" named in Chapter XII. If the answer is "yes", you must notify the Institutional Biosafety Officer immediately.

To carry out research using biohazards your laboratory is required to have at least two programs extant:

1. the OSHA Hazard Communications Standard (Worker's Right-to-Know); and
2. the OSHA Laboratory Standard (Occupational Exposure to Hazardous Chemicals in the Laboratory).

The latter requires the implementation of a Chemical Hygiene Plan. Depending upon the biohazards in use, you may also be required to implement the OSHA Bloodborne Pathogens Standard.

The are a number of sources of information you may wish to use. The first is your college's OSHA Coordinator, whose job is to help acquaint you with and comply with OSHA Standards and University Safety Policies. Another source is the *Safety Management Guidebook*. The *Guidebook* is available from your OSHA Coordinator or the Office of Environmental Health and Safety (OEHS). You should get to know your OSHA Coordinator as that person has a vested interest in helping you comply with State and Federal Laws and University policies. The information presented in this *Biosafety Manual* is just the beginning.

1. Use the **Hazard Communication (HACOM)** boilerplate (available from OEHS) to establish your own program for your laboratory. Consult OEHS concerning training components and the *Guidebook* for more details.
2. Use the **Bloodborne Pathogens Standard** boilerplate (available from OEHS) to implement the standard for your laboratory. Contact OEHS concerning training components and the *Guidebook* for more details.
3. Use the **Chemical Hygiene** boilerplate as part of implementing the **Laboratory Standard** in your laboratory. Contact OEHS concerning training components and the *Guidebook* for more details.
4. Complete the **Laboratory Compliance Audit**.
5. Finish the **Risk Assessment Guidelines** for your laboratory.
6. Determine what Personal Protective Equipment will be necessary for working in your laboratory.
7. Contact University Employee Health and establish a Medical Surveillance Program for your laboratory workers. The MSP will include the appropriate checkups for the PPE necessary for your laboratory.
8. Notify OEHS or ORRP of the biohazardous materials used in your laboratory.
9. Make the appropriate changes in your laboratory as dictated by the Laboratory Compliance Audit, the *Biosafety Manual*, the *Guidebook*, and state and federal laws.
10. Go forth and do good things in compliance with University policies.

Risk Assessment Checklist

Query	Response
Have you and the University established a work environment committed to compliance and safety? Have you and the University communicated your expectations for safety and compliance to your staff and students? Does the work environment encourage employees to raise safety and compliance issues? Is there a published discipline policy for safety violations and are workers aware of it? Is it being followed?	Insist upon University compliance with federal, state and local regulations. Work with your college's OSHA Coordinator and departmental biosafety officer to establish a safe and compliant workplace.
Are resources adequate to perform and maintain control over the proposed research?	Obtain adequate resources prior to doing the work. Work may not be done if adequate resources are not available.
Does the risk assessment include events from similar work completed previously? Is there a need to increase the frequency of laboratory audits due to the nature of the work being proposed?	Utilize all factors in the development of your risk assessment. Increase the frequency of internal laboratory audits if necessary.
Are prudent practices employed in your laboratory? Have you analyzed the work habits of your workers and found them to be adequate for the hazards they face? Is there a need to discuss the number of hours worked in light of the hazards posed by the new agent(s)? Have you reviewed any "stop work" orders given by you to your workers to determine whether any shortcomings have been overcome? Do you encourage self-examination of work habits on a regular basis by your workers? Does your staff appreciate the need to consider "safety first" in approaching daily assignments?	Rethink the manner in which work is done. Adopt prudent practices for your laboratory. Regularly review the work habits of your staff and address shortcomings. Do not allow workers to spend an excessive number of continuous hours in the laboratory performing research involving hazards without breaks from the work. Encourage regular self-examination of work habits. Adopt a "safety first" attitude in your laboratory.
Are all of your workers enrolled in a Medical Surveillance Program (MSP)? Have you informed University Employee Health about	Contact University Employee Health and create, with their assistance, an appropriate Medical Surveillance Program for your

Query	Response
the use of the new agent(s) and discussed the implications of that use on the MSP? Have you consulted with University Employee Health on the efficacy of preventive medicine measures (prophylaxis, serum banking, etc.) and other concerns involving the use of the new agent(s)?	workers. Inform University Employee Health about the existence of new agents in the laboratory so that the MSP can be appropriately modified. Consult with University Employee Health concerning the possibility of preventive medicine measures as they might apply to the new agent(s).
Is appropriate signage in place on your laboratory? If you are using a ULAR vivarium, have you notified the ULAR veterinarian in writing at least two working days prior to the use of the new agent(s)?	Read the section in the *Institutional Laboratory Biosafety Manual* about appropriate signage or check with Office of Environmental Health and Safety concerning the signage. Notify the University Laboratory Animal Resources veterinarian in writing at least two working days before use of a biohazardous agent or toxic chemical in a University Laboratory Animal Resources vivarium.
Will the proposed work involve a biohazardous agent?	See Chapter I of the *Institutional Laboratory Biosafety Manual* for the definition of "biohazard." Read on in this document.
What is the nature of the biohazard?	Toxin, bacterium, virus, prion, arthropod, animal, venom, etc.?
What are the hazards associated with the use of the new agent(s)? Have you contacted your departmental biosafety officer, the Institutional Biosafety Officer, or the Chair of the Institutional Infection Prevention Committee concerning the potential hazards associated with working with the new agent(s)? Have specific procedures to minimize the potential hazards been implemented?	Complete a literature search to determine the hazards. Contact University sources to determine the potential hazards involved. Employ procedures to minimize exposure to the new agent(s).
What is the appropriate hazard class associated with the agent? Can you comply with the appropriate "Special Practices" section of the *Institutional Laboratory*	BSL-1, BSL-2, BSL-3, ABSL-1, ABSL-2, ABSL-3. See Chapters IX and XV and Appendix C of the *Institutional Laboratory Biosafety Manual*.

Query	Response
Biosafety Manual when using the agent(s)?	
Will special containment issues arise because of the nature of the biohazard? Have you addressed them? Have the appropriate engineering controls necessary for the use of the agent(s) been installed before work begins?	Any special considerations must be addressed before work begins. Install the appropriate engineering controls before beginning work.
Has your staff been apprised of the new research and the implications thereof? Has your staff been adequately trained in previous efforts, or do you need to revamp training methods to deal with the proposed research? Will special training be required because of the nature of the biohazard? Have the training issues been addressed? Have your workers been trained in the appropriate safety procedures? Have you maintained the appropriate training documentation? Have new safety procedures generated by the existence of the new agent(s) been tested to see that workers are comfortable with the new requirements? Do supervisors adequately observe new employees and difficult, unique or new operations?	Hold a staff meeting to inform staff of the new work. Rework your training methods to deal with the new requirements posed by the new agent(s). Contact specialists to provide input concerning risks and any special training needed. Provide training time for all workers to be involved with the new agent(s). Maintain adequate training records. Test the workability of new Standard Operating Procedures before exposing workers to the agent(s). Ensure that proper supervision of workers occurs, including new hires and supervisors.
Will permits or special permission be necessary to acquire or work with the agent(s)? Have they been applied for? Have you complied with University policies concerning the ordering, receiving, shipping and movements of new agents?	Check with the departmental biosafety officer, the Institutional Biosafety Officer, the Chair of the Institutional Infection Prevention Committee or Office of Research Risks Protection. Complete the permit forms and remit them after receiving appropriate signatures from University officials. Check with the *Institutional Laboratory Biosafety Manual* for guidance.

Query	Response
If the use of laboratory animals is involved, has ULAR been contacted and consulted concerning space, containment, etc? Have you discussed with ULAR, Office of Research Risks Protection and Office of Environmental Health and Safety the necessary animal husbandry and safety issues involved in the use of the new agent(s) in the vivarium?	Contact ULAR and notify them of your plans. Ensure that available space and containment vehicles are available for the planned work. Work with ULAR, Office of Research Risks Protection and Office of Environmental Health and Safety to see that all workers are adequately protected when in the room with animals treated with the new agent(s).
Will the use of the agent(s) in your research result in the production of hazardous or infectious waste? Has waste disposal been factored into your risk plan?	Refer to the *Institutional Laboratory Biosafety Manual* for information. Contact Office of Environmental Health and Safety concerning the handling and disposal of hazardous or infected waste.
Will additional or different Personal Protective Equipment (PPE) be required because of the use of the new agent(s)? Is the new PPE available before work commences? Have your workers been trained in the use and care of the new PPE? Do supervisors check periodically to ensure that the appropriate PPE is worn and used correctly? Are appropriate records kept? Have you considered the maintenance and replacement of PPE?	Acquire the required PPE. Work may not begin if required PPE is not available. Contact Office of Environmental Health and Safety for training requirements on PPE. For respirators, individuals must visit University Employee Health for a pulmonary fitness exam prior to fit testing by the Office of Environmental Health and Safety. Have supervisors check regularly that appropriate PPE is worn and used correctly. Keep appropriate records concerning PPE.
Will new decontamination supplies be necessary due to the use of the new agent(s)? Are there supplies on hand? Are new spill instructions necessary and in place due to the use of the new agent(s)?	Provide the new decontamination supplies before work commences. Obtain the MSDSs for the supplies and follow instructions. If appropriate decontamination supplies are not available, work may not begin. Produce new spill instructions if necessary.
Is new equipment (Biological Safety Cabinets, hoods, Bioclean units, cages, laboratory equipment, etc.) necessary for the use of the new agent(s)? Is the new equipment available and, if necessary, certified?	Order new equipment in time for it to arrive before work is planned to commence. Equipment that requires certification must be certified before work can begin.

Query	Response
Do you need to consider a change in security in your laboratory (vivarium) associated with the use of the new agents?	Some agents require specific security arrangements. Check with the Institutional Biosafety Officer for assistance.
Have you registered the biohazardous agent with Office of Research Risks Protection or Office of Environmental Health and Safety?	Fill out Appendix D of the *Institutional Laboratory Biosafety Manual* and submit it to Office of Research Risks Protection or Office of Environmental Health and Safety.
Is your present Safety Desk Book adequate to cover the new agent(s)? If not, have you begun to update the Safety Desk Book? Have you reviewed the appropriate parts of the *Institutional Laboratory Biosafety Manual* covering the use of the new agent(s)?	Update your Safety Desk Book if necessary. Read the *Institutional Laboratory Biosafety Manual* for information. Contact your departmental biosafety officer, Institutional Biosafety Officer, the Institutional Infection Prevention Committee Chair, or Office of Research Risks Protection for assistance.
Have the appropriate standing oversight committees been contacted in sufficient time to adequately perform their oversight duties (Institutional Infection Prevention Committee, ILACUC, IBC, IRBs, Radiation Safety Committee, etc.)? Has a Safety Plan been prepared and submitted to the Institutional Infection Prevention Committee? Has a literature and colleague search revealed any surprising factors about the new agents(s) that should be included in your Safety Plan?	Since work on the project cannot begin without approval of all the appropriate oversight committees involved, submit protocols or Safety Plans in time for adequate review. Include all salient information in your Safety Plan.
Are you planning to use one of the “select agents” specified in Chapter XII?	Notify the Institutional Biosafety Officer immediately.

Laboratory Safety Audit

Date:_____

Instructions:

1. Follow these instructions on each page:

    - Indicate Y (yes), N (no) or NA (not applicable) in the second column
    - Answer all questions
    - List, explain, and/or clarify responses in the third column.

2. If there is insufficient space on the form for all of the required information:

    - Include the information on a separate page
    - Add it to this document
    - Indicate on the form that there is additional information on the following page.

3. You will need to review/update your policies and procedures in the following situations:

    - When you add new tasks and procedures that affect occupational exposure
    - When you change or modify tasks and procedures that affect occupational exposures
    - On an annual basis otherwise.

    Make sure that you are in compliance with every item you check or date in this audit.

Work Practice/Engineering Controls

The following work-practice/engineering controls are in place	**Yes / No / NA**	**Comments/Explanations**
1. *Handwashing* sinks are available for staff use in work areas where exposure to biohazards (including blood and body fluids) can occur.		
1a. Handwashing sinks are used for disposal of biohazards (If yes, explain).		
2. In instances where *handwashing facilities* are *not* readily available, antiseptic hand cleansers and clean towels or towelettes are available. (Method used?)		
3. *Handwashing* is required in the following instances: ∗ If hands become contaminated with biohazards. ∗ When gloves are removed. Is this policy being followed? (If not, please explain.)		
4. Are *recapping of sharps* and bending or breaking of needles prohibited under all circumstances? (If not see 4a.)		
4a. Needles must be recapped in the procedures listed.		
4b. Method of recapping is: ∗ With one-handed scoop (passive recapping) ∗ A recapping device is used. ∗ Other. (Describe method.)		
5. *Leak-proof, puncture-resistant sharps containers,* with appropriate labels or color coding, are readily available for disposal of used sharps. (If not, please explain.)		
6. Are there any *reusable* sharps used in the lab? (Please list.)		
6a. *Reusable sharps* that are contaminated with blood or other infectious materials are stored and processed in a way that does not require employees to reach by hand into the containers where these sharps have been placed.		

7. *Handling of sharps:* After use, all sharps (needles, scalpels, capillary pipettes, slides, cover slips, disposable pipettes, and other sharps) are placed in appropriate puncture-resistant containers for reprocessing or disposal. Employees have been trained in these procedures and have been instructed not to overfill containers.		
8. *Eating, drinking, applying cosmetics, and handling contact lenses* is prohibited in work areas where there is any risk of occupational exposure. Employees have been informed of this rule and are in compliance.		
9. Mouth pipetting is prohibited in the laboratory.		
9a. Mechanical pipetting devices are available in the laboratory.		
10. *Storage of food and drink* is prohibited in places where biohazards are kept. This applies to freezers, shelves, cabinets, countertops, and benchtops. Employees have been informed of this rule and are in compliance.		
11. *Specimen handling: Leakproof primary containers* are used for all specimens.		
11a. *All specimens* (biohazards) are placed in leak-proof secondary containers with fill material capable of absorbing all liquids during transport. Requisitions are attached to the outside of the secondary container.		
11b. When *packages* that contain biohazards are shipped from the laboratory to another mailing address, they are appropriately packaged and a biohazard label is affixed to the outside of the package.		
12. *Equipment* that becomes contaminated with biohazards is decontaminated immediately or as soon as possible.		

12a. *Equipment* is also inspected before it is repaired or shipped and decontaminated if possible. If it cannot be decontaminated before repair or shipment, staff has been instructed to attach a biohazard label that clearly identifies the site(s) of contamination.		
13. *Regulated waste: Closable leak-proof containers* with the appropriate color coding (red bag), or labeling, are available.		
13a. *Bulk body fluids* (urine, vomitus, feces, etc.) are disposed of down the sanitary sewer.		
13b. *Containers of biohazards* are placed in biohazard waste containers for incineration or other approved disposal.		
13c. *Laboratory specimens* are disposed of in biohazard bags in leak-proof containers with tight-fitting covers.		
13d. *Laboratory specimens* are autoclaved before disposal when applicable.		
13e. If autoclaves are used for treatment of waste, they are monitored with biological indicators on a regular basis. (Define how often.)		
13f. *Tissues, organs, and other body parts* are placed in biohazard waste containers and sent for incineration or other approved disposal.		
14. *Other solid waste* (gloves, dressings, etc.) is placed in sturdy, plastic bags that are tightly closed for transport.		
15. Procedures that can cause splashing, spraying, or splattering of any solutions that might contain the biohazard (blood, body fluids, etc.) are performed in a biological safety cabinet (BSC) or behind an appropriate protective shield. (List procedures.)		
15a. BSCs are inspected on and annual basis.		

16. Written laboratory biological/infection control safety policies are available and employees know where they are kept.		
16a. The Laboratory or Hospital Exposure Control Plan (OSHA Bloodborne Pathogen Standard) is available and employees know where it is kept and have received appropriate training and prophylaxis.		
16b. Copies of other OSHA Standard documents (HAZCOM, Lab Standard) are available and employees know where they are kept and have received appropriate training.		

Personal Protective Equipment

The following fluid-resistant personal protective equipment (PPE) is available to employees free of charge:	**Yes / No / NA**	**Comments/ Explanations**
1. *Disposable gloves*, in appropriate sizes and materials, are available for all workers *at risk of exposure* for use at their discretion or as required,		
1a. Are gloves worn: ∗ When touching surfaces contaminated with the biohazard? ∗ When touching fluids containing or contaminated with the biohazard? ∗ When handling items that might be contaminated with the biohazard? ∗ When dealing with animals?		
2. *Hypoallergenic gloves and liners* are available to workers who are allergic to latex gloves.		
3. *Utility gloves* are available when indicated. They are checked before use and replaced as necessary.		
4. Is *face protection* needed?		

4a. If face protection is needed/required, the type(s) of face protection available are as follow (indicate all that apply): ∗ Mask with glasses with solid side shields ∗ Mask and goggles ∗ Mask with splash shield ∗ Chin-length face shield ∗ Other (specify).		
5. Is *protective body clothing* required?		
5a. Type(s) of protective body clothing available (indicate all that apply): ∗ Gowns ∗ Laboratory coats ∗ Tyvac coveralls ∗ Aprons ∗ Other (specify).		
6. Is footwear and headgear required?		
6a. Type(s) of footwear and headgear available (indicate all that apply): ∗ Surgical caps/hoods ∗ Shoe covers ▪ Short ▪ Knee-high ∗ Other (specify).		
7. Is reusable *protective clothing* being reprocessed by either of the following?: ∗ Hospital laundry services ∗ Outside laundry services (if an outside laundry service is used, provide the following information: name of service; address; items processed by service; whether the service meets OSHA standards) ∗ Group provides own laundry service (provide indicators used to verify sanitization of laundry)		
8. Are *respirators* required?		
8a. Those employees requiring respirators have required pulmonary function test and are trained and fit-tested.		

9. The PPE mentioned above is available in all work areas where needed and is maintained on a regular basis.		

Housekeeping

	Yes / No / NA	Comments/Explanations
1. Employees decontaminate work surfaces with appropriate disinfectant immediately after completion of procedures, after their work shift, and as soon as feasible after contamination by a biohazardous material.		
2. *Liquid spills.* *Broken glass*: Staff has been instructed never to pick up by hand any broken glassware that might be contaminated.		
2a. A brush, dust pan, forceps and/or tongs are available for picking up broken glassware.		
2b. Are the following procedures used for spill cleanup? ∗ Soak up material with absorbent material ∗ Decontaminate the area with an appropriate disinfectant ∗ Dispose of contaminated materials appropriately ∗ Other (specify)		
3. Disinfectant is ready and available for use at all times. List the disinfectants used in the laboratory and the portions of the laboratory in which they are utilized.		
4. *Laundry*: Staff has been instructed to consider all used items as potentially infectious and to wear appropriate PPE when handling used laundry.		
4a. Staff has been instructed to handle contaminated laundry as little as possible.		

4b. Staff has been instructed to place laundry directly into the standard laundry bag.		
4c. Staff has been instructed to double bag as necessary to prevent leakage.		
5. *Biohazard warning signs* are used to identify the following contaminated materials: * Containers used to store or transport contaminated materials * Containers used to store or transport regulated waste * Refrigerators and freezers holding potentially infectious material are marked with biohazard labels.		
5a. Biohazard warning signs are posted on laboratory entrances		
5b. Biohazard labels are placed on generally accessible equipment (telephones, computer terminals, etc.) that is used by personnel wearing gloves. No one is to use this equipment without wearing gloves.		

Exposures

	Yes / No / NA	**Comments/Explanations**
1. Do staff know what to do if they sustain percutaneous exposure via nonintact skin or mucocutaneous exposure?		
1a. Is a written protocol available for exposure follow-up, *i.e.*, part of the Exposure Control Plan/House Infectious Control Manual?		

Exposure Determination/Training/Vaccine Compliance

	Yes / No / NA	Comments/Explanations
1. Have you received and reviewed the Bloodborne Pathogens Program compliance summary for documentation of exposure determination, training and vaccine compliance?		
1a. Have you taken steps to ensure compliance for all your employees?		

Information and Training

	Yes / No / NA	Comments/Explanations
1. Are you familiar with the location and contents of the following items?:		
∗ Biohazard inventory		
∗ Chemical Hygiene Plan		
∗ Chemical hygiene poster		
∗ Right-to-Know Center		
∗ Chemical inventory		
∗ Material Safety Data Sheets		
∗ Emergency response guide		
2. Has laboratory safety/health training been provided and documented?		

Standard Operating Procedures

Procurement	Yes / No	Comments
1. When procuring chemicals do you consider the following factors?: ∗ Potential hazards of the chemicals ∗ Selecting the least hazardous chemicals for the procedure ∗ Ensuring that all chemical containers are properly labeled		

Distribution	Yes / No	Comments
2. To reduce accidents during transport, do you use the following safety procedures? ∗ Use a transport vessel or secondary container with absorbent? ∗ Follow the least-trafficked routes? ∗ Wear correct PPE as indicated for transport?		
Storage	**Yes / No**	**Comments**
3. Do you?: ∗ Understand and follow appropriate storage of chemicals so as to not mix incompatible chemicals? ∗ Store chemicals according to hazard class? ∗ Avoid storing chemicals in an open area or under walkways? ∗ Store chemicals in areas appropriate for storage?		
4. Do you know the reason(s) that you need to store chemicals according to hazard class?		
5. Do you know the reason it is not a good idea to store chemicals in a chemical fume hood?		
Disposal	**Yes / No**	**Comments**
6. Do you comply with the University's Waste Policy?		
7. If not, how do you dispose of hazardous waste in the laboratory?		
Potentially High-Risk Procedures	**Yes / No**	**Comments**
8. Do you perform any of the following procedures in your laboratory? ∗ Weigh/prepare stock solutions ∗ Handle concentrated acids/bases ∗ Pressurization activities ∗ Rinsing with solvents ∗ Heat/cool chemicals ∗ Use reactive chemicals ∗ Handle particularly hazardous substances (toxic, highly toxic, carcinogens, flammable, etc.)		

9. If yes, list the safety precautions you take.		
Particularly Hazardous Substances	**Yes / No**	**Comments**
10. Do you maintain an up-to-date inventory of particularly hazardous substances?		
11. When are the following safety controls necessary, if working with particularly hazardous substances ?: ∗ Establish a designated work area ∗ Use containment devices ∗ Establish waste-removal procedures		
High-Risk Protocols	**Yes / No**	**Comments**
12. Are you aware that these activities require prior approval ?: ∗ Work with severely/extremely toxic inhalation hazards, both inside and outside of containment devices ∗ Work with highly reactive/unstable compounds		

Controlling Exposures

Hazard Potential	**Yes / No**	**Comments**
1. Do you work with highly volatile chemicals and/or finely divided powders?		
2. If yes, are you aware of the hazard potential? List.		
Control Measures	**Yes / No**	**Comments**
3. Do you use any of the following engineering controls ?: ∗ Chemical fume hood (is it certified for this use?) ∗ Other local exhaust ventilation		
4. Does your chemical fume hood have a performance indicator?		
5. If yes, do you know how to use and interpret the chemical fume hood indicator?		

6. Do you know how to inform the maintenance department when the hood is outside its normal operating mode?		
7. Do you keep supplies at least four (4) inches away from the hood face?		
8. Do you maintain the hood sash height as low as possible?		
Personal Protective Equipment: Respiratory Protection	**Yes / No**	**Comments**
9. Do any procedures in the laboratory require the use of respiratory protection?		
10. Have the necessary individuals undergone the appropriate physical examinations, training and respirator fit testing?		
Gloves	**Yes / No**	**Comments**
11. Do you use a glove permeability chart to select the most appropriate glove material to wear for specific procedures?		
12. Do you remove gloves in the following situations ?: * Answering the phone * Opening laboratory doors * Leaving the laboratory environment		
13. Do you wash your hands after taking gloves off?		
14. Do you double glove when appropriate?		
Laboratory Coat and Gown	**Yes / No**	**Comments**
15. Do you remove you laboratory coat or gown when leaving the laboratory environment?		
Eye/Face Protection	**Yes / No**	**Comments**
16. Have provisions been made for an emergency eye-wash station within 100 feet from every area of the laboratory in which hazardous chemicals and/or biohazards are used?		

17. Do you know the proper type of eye and face protection to use for a specific procedure?		

Exposure Determination

	Yes / No	Comments
1. What would you do if your or any member(s) of your staff developed the following symptoms ?: * Skin/eye irritation * Chemical intoxication * Skin rashes * Diarrhea * Symptoms consistent with exposure to the biohazard(s) being used in the laboratory		
2. Do you use your sense of smell to assess chemical concentrations?		
3. Do you know what the threshold limit values (TLVs) and permissible exposure limits (PELs) are for the chemicals you use? Do you understand how these values should be used when undertaking the risk assessment of the chemicals used in the laboratory?		
4. Do you know that the Office of Environmental Health and safety is available to assess work practices and conduct air monitoring for hazardous chemicals?		
5. Do you know that you are entitled to an evaluation of your laboratory environment any time you have a concern about work with biohazards or hazardous chemicals?		
Chemical/Biohazard Spill Response	**Yes / No**	**Comments**
6. Do you know what procedures to follow when you have a biohazard or chemical spill in your area?		

Medical Consultation

	Yes / No	Comments
1. Are you aware that all individuals working with biohazards or hazardous chemicals should be enrolled in a medical surveillance plan tailored to the moiety(ies)to which you might be exposed?		
2. Are you aware that you are entitled to a medical examination under the following circumstances ?: * If you develop signs or symptoms of exposure to the biohazard or chemicals with which you work * If you are present during a chemical spill, leak, explosion, or accidental release * If you are present during the spill or accidental release of a biohazard * If you are exposed to a chemical above its regulated level		

Exposure Control

I) BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

A) PURPOSE

This plan is established to provide a coordinated program of education, vaccination, Universal Precautions, and exposure follow up to minimize or eliminate workplace exposure to hepatitis B, Human Immunodeficiency Virus (HIV) and other bloodborne pathogens.

B) Scope

This plan applies to all occupation exposures to blood or other potentially infectious materials within the facilities of The Ohio State University Medical Center.

C) DEFINITIONS

1) **Employees**: University Medical Center Employees, employees of subcontractors or independent contractors working within facilities of OSUMC
2) **Students**: All students with potential exposure to bloodborne pathogens who are enrolled in clinical programs of The OSU and other affiliated schools.
3) **Healthcare Workers**: All employees, staff, faculty and students whose work activity allow potential exposure to bloodborne pathogens or other potentially infectious materials.

D) PREVENTION OF EXPOSURE TO BLOOD AND BODY FLUIDS

1) **Universal Precautions** will be followed by all healthcare workers to prevent contact with blood or other potentially infectious materials by providing barriers between the individual and infectious materials.
2) **Engineering and work practice controls** shall be used to eliminate or minimize exposure. General controls are applicable to all work areas and include: accessible handwashing facilities, controlled disposal of contaminated sharps, separate storage for food/drink and infectious materials, and protected transport of properly labeled specimens. Specific controls will be determined by individual departments and listed in the departmental infection control policies. These controls shall be reexamined and maintained or replaced on a regular schedule to ensure their effectiveness.
3) **Personal Protective Equipment (PPE)** shall be provided by the hospital where there is a potential for exposure. Equipment includes, but is not limited to, gloves (vinyl, latex, or heavy-duty rubber), gowns (fluid resistant or fluid proof), face shields or protective eyewear with side-shields, and resuscitation bags or other ventilation devices. Appropriate protective equipment functionally must:
    a **Prevent passage** of blood or other potentially infectious materials through to the employee's clothing, skin, eyes, mouth, or mucous membranes

under normal conditions of use and for the duration of time that the protective equipment will be used.

b Be available in appropriate sizes that are **readily accessible** at the worksite or issued to employees. Hypoallergenic gloves, or other similar alternatives, shall be readily accessible to employees who are allergic to the gloves normally provided.

c **Be in working condition** with repair or replacement as needed to maintain equipment effectiveness at no cost to the worker.

4) The worksite shall be **maintained in a clean and sanitary condition**.
5) Infectious waste disposal shall follow Hospital's Policy #1-04-12.
6) **Communications of hazards** to worker.

a All workers with occupational exposure must participate in a training program at no cost to the employee and during working hours.

- All new workers must attend an orientation program
- Training is to be provided at the time of initial assignment to tasks where occupational exposure may take place.
- All workers with occupational exposure must receive training at least annually

b The training and orientation programs will contain at a minimum the following elements:

- Accessible copy of OSHA Standard.
- An explanation of the contents of the OSHA Standard.
- An explanation of the epidemiology and symptoms of bloodborne diseases.
- The Bloodborne Pathogens Exposure Prevention Control Plan and the means of obtaining a copy of the written plan.
- Appropriate methods for recognizing tasks or activities that may involve exposure to blood or other potentially infectious materials.
- Use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices and personal protective equipment.
- Types, proper use, location, removal, handling, decontamination, and disposal of PPE.
- Basis for selection of PPE.
- Hepatitis B vaccine, including it efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination are offered free of charge to hospital employees.
- Appropriate actions to take and person s to contact in an emergency involving blood or other potentially infectious materials.
- The procedure to follow in an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available.
- The post-exposure evaluation and follow-up that is provided following and exposure incident.

- An explanation of required signs and labels and/or color coding to identify infectious materials.

E) HIV RESEARCH LABORATORY

HIV research laboratories shall comply with regulations as stated in OSHA Standard and the institution exposure control plan.

F) HEPATITIS B VIRUS (HBV)

1) Hepatitis B vaccinations are required for all non-immune new healthcare workers with anticipated occupation exposure to blood or body fluids.
2) Hepatitis B vaccine is recommended for current healthcare workers with anticipated exposure. The employer shall provide vaccination.
3) Refusal of Hepatitis B vaccine after counseling requires that the employee have a hepatitis B core antibody test performed and sign a vaccine waiver statement. The employee is counseled annually until vaccinated.

G) EXPOSURE RISK

1) Job classifications in which all hospital employees have occupational exposure to blood and body fluids are available in the Medical Center Epidemiology Department and Employee Health Services.
2) Examples of tasks and procedure performed by healthcare workers in which occupational exposures may occur:
   a Cultivation of Human Immunodeficiency Virus.
   b Invasive procedures - disruption of vascular tissues or channels.
   c Laboratory examinations - body fluids or blood.
   d Laundry - handling items contaminated with blood or body fluids.
   e Maintenance of facilities - particularly disposal systems.
   f Needle manipulations.
   g Physical examinations/manipulations - moist lesions, nonintact skin, or mucous membranes.
   h Surgery - disruption of vascular tissues, open body cavity.
   i Transportation of patient tissue, fluids, or blood.
   j Vaginal obstetrical deliveries.
   k Vascular access procedures.
   l Removal or disposal of patient waste.

H) **SIGNIFICANT WORK EXPOSURE**

A significant exposure is defined as direct contact with mucous membranes (eyes, nose, mouth) or broken skin or traumatic contamination with the blood, semen, vaginal secretions, or spinal fluid, synovial fluid (joint, tendon), pleural fluid (lung), peritoneal fluid (abdomen), pericardial fluid (heart), or amniotic fluid from another person.

I) POST EXPOSURE MANAGEMENT

1) **Wash break in skin** or contaminated area with soap and water, or flush exposed mucous membranes with water. Remove contaminating material immediately, or as soon as feasible.
2) Medical Center employees **complete** the "Employee's and Supervisor's Report of Injury/Occupational Disease" **form**. Others complete the "Report of Significant Exposure to Blood and Body Fluids" **form**.
3) **Report as** soon as possible to Employee Health Services or Medical Center Epidemiology.
   a Refer exposures of hospital employees and faculty to Employee Health Services (UHC 2A).
   b Refer exposures of non-employees (independent contractors, subcontractors, community safety and emergency workers, students and others) to the Epidemiology Department (Doan N-055).
4) **Post exposure evaluation and follow-up**.
   a Following a report of an exposure incident, the exposed individual will be offered the opportunity for a confidential follow-up by Employee Health (medical center employees and faculty), or Student Health Center (students). The following will be included:
      - The source individual's blood shall be collected and tested as soon as feasible after consent is obtained to determine HBV and HIV infectivity. (See hospital policy 03-11, Management of HIV Infection in the Health Care Facility). If the source individual is already known to be infected with HBV or HIV, testing need not be repeated.
      - If the exposed individual consents to baseline blood collection but does not give consent for HIV serologic testing, the sample shall be preserved for 90 days. If, within 90 days, the individual elects to have the sample tested, testing shall be done as soon as feasible.
      - Results of the source individual's testing shall be made available to the exposed healthcare worker. The individual shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
   b Exposure follow-up
      - Health service including counseling and evaluation of reported illnesses. Post exposure prophylaxis will be provided when medically indicated as recommend by the U. S. Public.
5) **Healthcare Professional's Written Opinion**
   a Within 15 days of the completion of the evaluation, the healthcare worker shall be provided with a copy of the evaluating healthcare professional's written opinion. The written opinion shall be limited to:
      - Whether hepatitis B vaccination is indicated and if the employee has received such vaccination.
      - That the healthcare worker has been informed of the results of the evaluation.

- That the healthcare worker has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment.

b All other findings or diagnoses shall remain confidential and shall not be included in the report.

J) MEDICAL RECORD KEEPING FOR EMPLOYEES

1) An accurate record shall be maintained in EHS for each employee with occupational exposure.
2) The record shall include:
   a The employee's name and social security number.
   b The employee's hepatitis B vaccination status including the dates of all hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination.
   c All results of examinations, medical testing, and follow-up.
   d Copy of the healthcare professional's written opinion with a copy of the information provided to the health care professional.
3) All medical records **are confidential** are not disclosed or reported without the individual's express written consent to any person within or outside the workplace except as required by law.
4) Records will be maintained for at least the duration of employment plus 30 years.

K) PROCEDURE FOR EVALUATION OF CIRCUMSTANCES SURROUNDING EXPOSURE

1) The manager/supervisor must ensure that the healthcare worker uses appropriate PPE unless the manager/supervisor shows that the worker temporarily and briefly declined to use PPE when, under rare and extraordinary circumstances, it was the worker's professional judgment that in the specific instance its use would have prevented the delivery of healthcare or public safety services or would have posed an increased hazard to the safety of the worker or co-worker.
2) When a healthcare worker makes this judgment, the circumstances are to be investigated by the manager/supervisor and documented in order to determine whether changes can be instituted to prevent such occurrences in the future. Documentation of the circumstances, investigation, and corrective action is to be recorded on the Incident Report Form. (See hospital policy 2-04-05)

L) SPECIMENS AND CONSULTS

1) All patient specimens are to be collected in appropriate container and **securely closed to prevent leakage.** The external surfaces of containers shall be disinfected if contaminated.
2) Prior to transport, specimens are to be placed into plastic bags labeled with the biohazard symbol.
3) Specimens are not to be sent to the laboratory in syringes with needles attached.

M) RESTRICTIONS FOR WORK AREAS WITH THE LIKELIHOOD OF OCCUPATIONAL EXPOSURE

1) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.
2) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or other potentially infectious materials are present.
3) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

N) ENVIRONMENTAL

1) **HOUSEKEEPING** The worksite shall be maintained in a clean and sanitary condition. All potentially contaminated reusable hospital and patient care furniture and equipment shall be decontaminated on a regularly scheduled basis or as soon as feasible upon visible contamination.
2) **WASTE DISPOSAL** Certain items must routinely be handled as infectious waste: all liquids, all non-sterile laboratory wastes, all sharps, and all pathologic wastes. (See Hospitals' Hazardous Waste Disposal Procedure 02-04-12). In addition, items contaminated with large amounts of blood or body fluids from any patient shall be discarded as infectious waste (e.g. linen savers from an incontinent patient with severe diarrhea, dressings from a patient with large amounts of purulent drainage).
3) **SHARPS** Sharp objects shall be handled in such a manner to prevent accidental cuts or punctures during procedures, when cleaning used instruments, and during disposal.
    a Broken glassware that may be contaminated shall not be picked up directly with hands. It shall be cleaned using mechanical means, such as a brush and dustpan, tongs, or forceps.
    b All sharps must be removed from procedure trays and placed in appropriate puncture resistant containers for transport.
    c Disposable sharps must be discarded **intact** immediately after use into an upright, impervious needle disposal box that is readily accessible. The needle box shall be routinely replaced and not allowed to overfill. Contaminated needles and sharps shall **not** be bent, broken, reinserted into their original sheath, removed or unnecessarily handled unless the manager can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure. Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed procedure.
    d All disposable sharps must be discarded as hazardous waste. When moving containers of contaminated sharps from the are of use, the containers shall be closed immediately prior to removal or replacement to prevent spillage or protrusions of contents during handling, storage, transport, or shipping.

e If leakage is possible, the container shall be placed in a secondary closed container that is constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping, and labeled with a biohazard symbol or color coded.

f Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be puncture resistant, red or labeled with a biohazard symbol, closable and leakproof on the sides and bottom.

g All reusable trays must be secured in a clear biohazard bag at the point of use. All instrument sets in ridged containers must be closed at the point of use for transport.

h Sharps, instruments and containers that are contaminated with blood or other potentially infectious material shall be handled in a manner that will minimize the risk of percutaneous injury to the employees. Barrier attire including heavy puncture resistant gloves must be worn for the decontamination process.

4) **REUSABLE PATIENT CARE EQUIPMENT** After use, items contaminated with blood or body fluids should be disinfected prior to removal from the patient care area or placed in a appropriately labeled plastic bag for transport to the cleaning areas. All reusable equipment and supplies must be disinfected between patient usages. Special procedure trays should be separated into component parts and handles appropriately. (Some components can be discarded; others may need to be sent to the laundry or central services for reprocessing.) Equipment that may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. Such equipment will be appropriately labeled stating which portions of the equipment remain contaminated.

5) **LINEN** Soiled linen should be handled as little as possible, with minimum agitation, to prevent microbial contamination of the environment. Linen should never be placed on the floor. All soiled linen is to be placed in blue plastic linen bags. When the bag is approximately two-thirds full, it is to be closely secured and placed in the designated area for pick-up. Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in the location of use.

6) **CONTAMINATED WORK SURFACES** Work surfaces contaminated with blood or body fluids shall be cleaned up promptly with an approved hospital disinfectant solution (e.g. alcohol, Wexcide) or a freshly prepared 1:10 dilution of bleach. Gloves must be worn when cleaning up all contaminated work areas.

7) **EMERGENCY EQUIPMENT** The need for emergency mouth-to-mouth resuscitation should be minimized. Mouth pieces, resuscitation bags, or other ventilation devices are available on resuscitation carts. They must also be strategically located and available for use in areas where the need for resuscitation is predictable.

8) **PATIENTS' PERSONAL ITEMS** Personal clothing soiled with blood or body fluids should be bagged and sent home to be washed with a detergent and, if possible, hot water and bleach. In areas equipped with washers and dryers, such as psychiatry and rehabilitation units, each patient's clothing should be washed separately. Any other personal items contaminated with blood or body fluids should be disinfected, discarded, or bagged and sent home for cleaning.
9) **EMPLOYEE'S PERSONAL ATTIRE** If personal attire (uniforms or street clothes) becomes contaminated with blood or body fluids, the employee should not take this clothing home. The employee is to obtain clean scrub attire form the Scrub Dispensing Room, RH S-540M or CHRI 722. (If scrub-dispensing room is closed, contact the SPD, or nursing supervisor.) Contaminated personal clothing should be (1) placed in a plastic bag, (2) labeled with the date and employee's name and ID number, and (3) taken to the Supervisor of Linen Services, DN 050 (if unavailable, contact Supervisor of Central Sterile Supply) who will send the clothing to a commercial facility. Supervisors are to work with employees who repeatedly contaminate their clothing to reduce the frequency of contamination of clothing.
10) **DISHES** All patients may receive reusable meal trays and dishes. Any dishes that are obviously contaminated should be disinfected prior to removal from the patient's room or cubicle. A disposable meal tray may be ordered for any patient at the discretion of the nurse.
11) **PROTECTIVE COVERINGS** Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper use to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overly contaminated or at the end of the workshift if they may have become contaminated during the shift.

O) COMMUNICATION OF HAZARDS

1) Warning labels shall be affixed to containers of regulated waste, refrigerators, and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials.
2) Labels shall include the following legend:

3) These labels shall be predominantly fluorescent orange or orange-red with lettering or symbols in a contrasting color.
4) Labels shall either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Red bags or red containers may be substituted for labels.

5) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted form the labeling requirements.
6) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment, or disposal are exempted from the labeling requirement.
7) Regulated waste that has been decontaminated need not be labeled or color-coded.

II) TUBERCULOSIS CONTROL PLAN

A) INTRODUCTION

Active tuberculosis cases have increased 18% in the United States between 1985 and 1993. The increase is largely attributable to relapse tuberculosis in geriatric populations, spread of tuberculosis in homeless and prison populations and the association of tuberculosis with individuals infected with Human Immunodeficiency Virus (HIV). Outbreaks of multi-drug resistant tuberculosis (MDRTB) with transmission to healthcare workers have occurred with failure to properly isolate patients and failure to complete appropriate treatment regimes. Tuberculosis control programs continue to be successful where they are appropriately implemented.

B) PURPOSE

This plan is established to provide a coordinated program of education, tuberculosis surveillance (skin testing), exposure follow-up, and environmental control to minimize acquisition of tuberculosis in the workplace.

C) SCOPE

This plan applies to all patient care settings within the facilities of The Ohio State University Medical Center. The plan was designed and implemented by The Medical Center Epidemiology Department and approved by the Infection Control Committee.

D) PREVENTION OF EXPOSURE TO INFECTIOUS MATERIAL

1) Healthcare providers must maintain a high level of suspicion for pulmonary or laryngeal tuberculosis and take appropriate actions.
   a **A diagnosis of TB** should be considered in any patient with a persistent cough (>2 weeks duration) or other signs compatible with TB (see definition of suspected case).
      - Groups of individuals with a higher risk of TB: medically underserved populations, homeless, current or past prison inmates, injecting drug users, elderly, foreign born persons from areas with a high prevalence of TB, and contacts to persons with active TB.
      - Groups with a higher risk of reactivation of latent TB to active disease: HIV infection, silicosis, status-post gastrectomy or jejuno-ileal bypass surgery, =10% below ideal body weight, chronic renal failure, diabetes mellitus, immunosuppression, some malignancies, persons

infected within the last two years, young children (=5 years of age), and persons with primary TB lesions on chest x-ray.

b **Diagnostic measures** should be instituted among suspect patients. These include history, physical examination, PPD, chest x-ray, and microscopic examination and culture of three consecutive morning sputum's or other appropriate specimens.

c Clinical Microbiology Laboratory Services

- Acid fast stains are performed STAT and 5 days a week on concentrated sputa submitted for Mycobacterial Culture. During evening hours and on weekend days, AFB stains are performed by the pathology house staff and reviewed by the pathologist on call.
- Drug susceptibility testing is performed on all initial isolates, on all subsequent specimens submitted more than one month apart, and on special request of the physician.

2) Patients or visitors with a "cough"

a Should be encouraged to cover their cough.

b Tissues should be made available as needed.

c Healthcare providers who are in close contact with patients who are non-compliant with covering their coughs should wear a surgical mask if the patient has a productive cough, hemoptysis, or is suspected of having active TB.

d Known or suspected TB patients in waiting areas should be

- Segregated from others.
- Kept waiting a minimal time.
- Required to wear a surgical mask.

3) **Special respiratory isolation** prevents contact of other individuals with aerosolized particles containing *M. tuberculosis.*

a Uses for all in-patients with known or suspected (refer to suspected case definition) pulmonary or laryngeal TB. Priority should be given to placing all cases of multi-drug resistant in negative airflow rooms.

b A private room with negative air pressure is required.

- Doors to patient rooms and anteroom must be kept closed.
- Negative air pressure rooms are located on Doan 11 West (6 rooms) and SICU (8 rooms).

c Rooms must be posted with a **Special Respiratory** Isolation Sign. Signs are kept in areas with negative airflow and copies are available through Medical Center Epidemiology.

d Patients must stay in room except when traveling to necessary procedures.

e Only personnel who have completed annual respiratory protection training may enter the room.

f The number of individuals entering the room should be limited to that necessary to provide patient care.

g Mask

- Everyone entering the room must wear a particulate respirator. The mask should be applied to produce a tight face fit by molding the nosepiece to the individuals nose.

- If the patient must travel within the facility, the patient must wear a surgical mask.
- Particulate respirators must be readily accessible at the entrance to the room.
- Masks must be changed if it becomes moist, obviously soiled with blood or body fluids, difficult to breathe through or otherwise provides an ineffective barrier.

h The absence of AFB in adequate sputum specimens collected on 3 separate days indicates an extremely low risk for transmission and isolation can be discontinued.

4) Engineering Controls

a Environments for patient care/testing should provide adequate air exchanges and air quality to remove or dilute infectious TB droplets nuclei.

b Adequate air circulation (a minimum of 6 air changes per hour) and fresh air renewal is recommended for all patient waiting areas and patient examination and care/testing areas.

c Negative air pressure and controlled air disposal are required for rooms used to

- House patients with tuberculosis
- Induce sputum
- Perform bronchoscopy, pulmonary function test
- Give inhalation medication treatments

d Monitoring of negative pressure rooms.

- Rooms should be routinely check and documented at least monthly by Facilities Engineering personnel.
- Rooms occupied by patients with suspected or confirmed tuberculosis should be monitored and documented at least daily.
- Copies of all documentation should be sent to Medical Center Epidemiology.

5) The worksite shall be maintained in a clean and sanitary condition. All disinfectants shall be tuberculocidal as well as bactericidal, fungicidal and viricidal.

6) **Communication of Hazards** to Workers with potential exposure to TB.

a Employees must participate in educational programs.

- At the time of initial assignment.
- The need for additional training should be reevaluated at least yearly.

b The training and education program will contain at a minimum the following elements:

- Risk factors for TB disease.
- Cause and transmission of TB.
- Signs and symptoms of TB.
- Distinction between TB disease and TB infection.

- Isolation requirements to include site-specific protocols, purpose, proper selection, fit, use and limitations of masks and engineering controls in use in their employee's work area.
- Skin Test Surveillance requirements including purpose and interpretation of PPD.
- Skin testing, significance of skin test conversion.
- Routine testing
- Post-exposure evaluation and follow-up
- Tuberculosis preventive therapy.
- Tuberculosis treatment including the role that directly observed therapy plays in preventing the emergence of multi-drug resistant strains of TB.

E) TUBERCULIN SKIN TESTING

1) Tuberculin skin testing is recommended for persons with:
   a Suspected clinical tuberculosis.
   b Recent contact with persons known to have or suspected of having clinically active TB.
   c HIV infection.
   d Abnormal chest x-ray suspicious for remote tuberculosis except when excluded by medical history.
   e Other medical conditions that increase the risk of TB.
   f High risk of recent TB infection.
2) Two stage testing and controls
   a Two stage PPD skin testing should be performed for individuals =30 years of age who have not been tested within 5 years.
   b Candida, mumps, or tetanus controls should be performed for individuals suspected of being anergic responders.
3) All new OSU employees, students with anticipated patient contact, and hospital volunteers must be demonstrated to be free of tuberculosis prior to initiation of patient contact.
   a All new employees are required to have a tuberculin skin test unless there is a documented history of a previous positive.
   b A previous TB immunization (BCG) does not alter the requirement except that an initial first strength test may be used if there is a history of a previous reaction.
   c A tuberculosis free chest radiograph or a **documented** history of tuberculosis treatment is required for skin test positive individuals.
4) For skin test negative individuals, an annual tuberculin skin test
   a **Required** for all healthcare workers (including employees, resident and attending physicians, students, trainees, and volunteers with more than 10 hours per month patient contact) who have potential exposure to TB through patient contact or laboratory exposure.
   b **Recommended** for all other employees.
   c **Semiannual** testing is **required** for those with highest likelihood of exposure to TB. This includes personnel who have patient contact in the

Infectious Disease Unit, Emergency Department, Pulmonary Functions Laboratory, Prison Unit, Pulmonary Division, Infectious Disease Division, and Thoracic Surgery Division.

5) Skin test positive individuals
   a Should be evaluated annually for any symptoms suggestive of TB.
   b Routine chest x-rays are not required for asymptomatic employees.

F) POST EXPOSURE MANAGEMENT

1) Recommended for identified source contacts:
   a Medical history
   b Tuberculin skin test at 8 weeks if previous negative skin test with the last year.
   c Tuberculin skin test following exposure and again at 8 weeks if sin test reactivity is unknown or previous testing remote.
   d Contacts with known positive skin tests are recommended that have a clinical evaluation that may include a chest radiograph at 3 months.
2) Evaluation and management of Healthcare workers or students.
   a All Healthcare personnel should seek medical consultation if symptoms of TB develop at any time regardless of exposure history.
   b OSU employees should consult or inform Employee Health Services.
   c Students should consult or inform Student Health.
   d Non-OSU employees should inform Medical Center Epidemiology.
   e Potential infectious individuals will be removed from duty until tuberculosis is excluded or the healthcare worker is on therapy and documented to be non-infectious.

G) TUBERCULOSIS PREVENTIVE THERAPY

1) Preventive therapy should be considered and may be recommended for individuals who have not previously been treated and who present:
   a With initial intermediate PPD reaction of =10mm and who:
      - Are <35 years of age
      - Are from medically underserved, deprived socioeconomic, migrant or transient populations.
      - Are residents of long term care facilities or institutions
      - Are foreign born from high prevalence countries.
   b With initial intermediate PPD reaction of =5mm and who:
      - Is HIV infected or otherwise immunocompromised.
      - Have or may have had recent contact with active TB cases.
      - Demonstrate X-ray medical finding suggestive of old TB.
      - Have other medical conditions increasing susceptibility to active TB.
   c With initial intermediate PPD reaction of =15mm and who are:
      - =35 years of age.
      - Not included in other categories above.
   d As recent converters regardless of previous therapy who demonstrate an increase in intermediate PPD reaction within a two year period or less, amounting to:

- =10mm if <35 years of age,
- =15 mm if =35 years of age,
- =5mm if in risk groups described in #2.

e As anergic responders regardless of previous therapy and who have significant contact with clinically active TB cases.

2) The usual preventive therapy for adults is oral isoniazid 300mg daily.
   a Duration of therapy is 12 months for persons with HIV infections and persons with abnormal X-rays consistent with old healed TB.
   b Other persons should receive a minimum of 6 months of therapy.
   c For persons likely infected with MDRTB-TB alternative multi-drug preventive therapy regimens should be considered.

H) TUBERCULOSIS THERAPY FOR ACTIVE DISEASE

1) Initial treatment usually consists of four drugs: Isoniazid (INH), rifampin, pyrazinamide, and either ethambutol or streptomycin.
2) Ethambutol or streptomycin may be discontinued if susceptibility to Isoniazid and rifampin is demonstrated.
3) The continuation phase should consist of Isoniazid and rifampin for 16 weeks.
4) Assistance in development of treatment regimes is available through consultation with Infectious Disease or Pulmonary Medicine.
5) In order for any regime to be effective, adherence to the regimen must be assured. The most effective method of assuring adherence is the use of directly observed therapy following discharge. This should be coordinated with the public health department.

I) EXPOSURE EVALUATION

1) The Microbiology Laboratory notifies the Medical Center Epidemiology Department of all positive AFB smears and positive cultures for *M. tuberculosis.*
2) Healthcare workers should contact the Epidemiology Department any time there is a possible exposure.
3) Epidemiology personnel will determine if follow-up is necessary.
   a Whether the source patient was appropriately isolated and the time that isolation procedures were initiated.
   b Names of individuals what were involved in the care or diagnosis of the source patient, prior to initiation of isolation.
4) Follow-up
   a Employee Health Services (EHS) are notified of all employees who were exposed. EHS then contacts the exposed individual to arrange appropriate follow-up. Medical Center Epidemiology is notified of the follow up results.
   b Exposed students are referred to Student Health Services.
   c All other exposed healthcare providers are notified of their exposure, given instructions for follow-up, and advised to seek consultation with at physician.

- Medical Center Epidemiology will notify physicians of their patients exposed to healthcare workers or other patients with tuberculosis.

Universal Precautions

I) PERSONAL HYGIENE

A) DEFINITON

Protective measures primarily within the responsibility of each individual, which promote and limit the spread of infectious disease, especially those that are transmitted by direct contact

B) **PROTECTIVE MEASURES** of personal hygiene include:

1) Keeping the body clean.
2) Practice good handwashing.
3) Limiting personal items: do not share drinking cups, eating utensils, towel, handkerchiefs, combs, brushes, or other personal items.
4) Avoiding exposure to individuals with communicable disease.
5) Covering nose and mouth when coughing and sneezing.

II) UNIVERSAL BLOOD AN BODY FLUID PRECAUTIONS (See also Blood and Body Fluids Exposure Control Plan)

A) INTRODUCTION

For many years, isolation procedures have been one of the primary means of preventing the spread of infectious conditions. It is now widely recognized that many patients have undiagnosed infectious diseases for which health care workers must take precautions. Colonized body fluids often serve as a reservoir for antibiotic resistant microorganisms that can also be transmitted to other patients on the hands of personnel. **ALL** healthcare workers must consider the blood and body fluids from **ALL** patients as potentially infectious and take precautions to prevent transmission of disease to themselves and other patients. Universal Blood and Body Fluid Precautions provide a consistent approach to managing the blood and body fluids of **ALL** patients and are essential for the prevention of transmission of infectious agents. Universal precautions serve to prevent transmission from staff to patient, as well as from patient to staff.

B) DISEASE TRANSMISSION

Spread of disease within a hospital requires three elements: a source of the infecting organism, a susceptible host, and a means of transmission for the organism.

1) **SOURCE**. The source of the infectious agent my be patients, personnel, or visitors. The source may include people with acute disease, those in the incubation period of the disease, or persons colonized with the infectious agent but having no apparent disease. Another source of infection can be a person's own endogenous flora (autogenous infection). Other potential sources are inanimate objects in the environment that have become contaminated, including equipment and medications.
2) **HOST**. Patient's resistance to pathogenic microorganisms may vary greatly. Some persons may be immune to or able to resist colonization by an

infectious agent; others exposed to the same agent may establish a commensal relationship with the infectious organism, and become asymptomatic carriers; still others may develop clinical disease. Persons with diabetes mellitus, lymphoma, leukemia, neoplasia, granulocytopenia, or uremia and those treated with certain antimicrobials, corticosteroids, irradiation, or immunosuppressive agents may be particularly prone to infection. Age, chronic debilitating disease, shock, coma, traumatic injury, or surgical procedures also make a person more susceptible.

3) **TRANSMISSION**. Microorganisms are transmitted by various routes, and the same microorganism can be transmitted by more than one route. For example, varicella zoster (chickenpox) virus can spread by either the airborne route (droplet nuclei) or by direct contact. There are four routes of transmission; contact, airborne, vehicle, and vectorborne.
   a **Contact** transmission, the most important and frequent means of transmission of nosocomial infections, is divided into three subgroups: direct, indirect, and droplet contact.
      - Direct contact involves direct physical transfer between a susceptible host and an infected person or colonized person. This can occur when hospital personnel turn patients, give baths, change dressings, or perform other procedures requiring direct personal contact. Direct contact can also occur between two patients, one serving as the source of infection and the other as a susceptible host.
      - Indirect contact involves personal contact of the susceptible host with a contaminated intermediate object, usually inanimate, such as bed linens, clothing, instruments, or dressings.
      - Droplet contact refers to the brief passage of infectious agents through the air when the source and the susceptible host are relatively near each other, as a result of coughing, sneezing, or talking. It involves contact with the conjunctive, nose, or mouth of a susceptible person from a source who has clinical disease or is a carrier of the organism. This is considered "contact" transmission rather than airborne since droplets usually travel no more than three feet.

   b **Airborne** transmission occurs by dissemination of either droplet nuclei (residue of evaporated droplets that may remain suspended in the air for long periods of time) or dust particles in the air containing the infectious agent. Organisms carried in this manner can be widely dispersed by air currents before being inhaled by or deposited on the susceptible host.

   c The **vehicle** route applies to diseases transmitted by a contaminated inanimate vehicle which serves as the vector for transmission of the agent to multiple people. This route usually applies to diseases transmitted through food (e.g. salmonellosis), water (e.g. legionellosis), drugs (e.g. bacteremia resulting from infusion of a contaminated infusion product), or blood (e.g. Hepatitis B or C).

   d **Vectorborne** transmission refers to disease transmission by arthropods and is of greater concern in tropical countries (e.g. mosquito-transmitted malaria). It is of little significance in hospitals in the United States.

C) RESPONSIBILITIES FOR CARRYING OUT PRECAUTIONS

1) All personnel (faculty, staff, students) are responsible for complying with Universal Precautions as well as specific isolation procedures and for tactfully calling observed infractions to the attention of offenders. Physicians should observe the proper isolation precautions at all times; they must teach by example. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of those substances.
2) Patients and visitors also have a responsibility for complying with these precautions. The appropriate measures must be explained to the patient, the patient's family, and visitors.
3) Infractions of the isolation protocols, by some are sufficient to negate the conscientious efforts of others.

D) **HANDWASHING**: The most important means of controlling the transmission of microorganisms is by effective handwashing.

1) Wash hands:

- After using the restroom.
- Before handling food and eating.
- After contact with hair, eyes, mucous membranes and wounds.
- Before and after giving patient care.
- After touching organic material.
- After handling contaminated equipment.
- Before handling dressings or touching open wounds.
- Before and after performing invasive procedures.
- Before preparing medications.

2) Method for effective handwashing:

- Keep hands and clothing away from the sink surface, turn on the water and regulate flow and temperature.
- Avoid splashing water on clothing.
- Wet hands and lower arms under running water. Keep hands and forearms lower than the elbows during washing. (Hands are the most contaminated parts to be washed. Water flows from least to most contaminated areas.)
- Apply soap.
- Wash hands, using plenty of lather and friction for 15-30 seconds. Friction and rubbing mechanically loosen and remove dirt and transient bacteria.
- Interlace fingers and rub palms and backs of hands with circular motion to ensure that all surfaces are cleansed.
- If areas under fingernails are soiled, clean with fingernails of other hand or orangewood stick.
- Do not tear or cut skin under or around nails.

- Rinse hands and wrists thoroughly, keeping hands down and elbows up. (Rinsing washes away dirt and microorganisms.)
- Dry hands thoroughly, wiping from fingers down to wrists and forearms.
- Discard paper towel in proper receptacle.
- Turn off faucet with a clean, dry paper towel. (Wet towels and wet hands allows transfer of pathogens by capillary action.)

III) PERSONAL PROTECTIVE EQUIPMENT

A) Personal protective equipment is to be worn by all personnel when having contact with blood or body fluids from **all** patients.

B) Personal protective equipment will be considered **appropriate** only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's clothes, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. Scrub uniforms do not prevent the passage of blood or other potentially infectious materials and are not considered personal protective equipment.

C) Personal protective equipment shall be **available** in the appropriate sizes and readily accessible at the worksite or issued to employees. The hospital shall clean, launder, and dispose of required personal protective equipment at no cost to the employee. The hospital shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

D) All personal protective equipment shall be **removed** prior to leaving the work area. When personal protective equipment is removed it shall be placed in an appropriately designated are or container for storage, washing, decontamination, or disposal.

1) Gloves. In general, there are three distinct reasons for wearing gloves; provide protection against infectious microorganisms, reduce the likelihood that personnel with transmit their own endogenous microbial flora to patients; reduce the possibility that personnel will become transiently colonized with microorganisms that can be transmitted to other patients.

a Gloves shall be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients. They must also be worn when handling items or surfaces soiled with blood or body fluids and for performing venipuncture and other vascular access procedures. While gloves reduce the incidence of contamination of hands, they cannot prevent injuries caused by sharp instruments.

b **Hypoallergenic gloves**, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

c When gloves are indicated for patient care, sterile or non-sterile, depending on the purpose for use, should be worn. There are no reported

differences between the barrier effectiveness of vinyl or latex gloves. The type of glove selected should be appropriate for the task being performed. The following guidelines are recommended:

- Use sterile gloves for procedures involving contact with normally sterile areas of the body or sterile procedures.
- Use examination gloves for procedures involving contact with mucous membranes and for other patient care or diagnostic procedures that do not requires the use of sterile gloves.
- Disposable (single use) gloves, such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as barrier is compromised.
- **Do NOT** wash or disinfect sterile or examination gloves for reuse. Washing may cause "wicking" , i.e. the enhanced penetration of liquids though undetected holes in the glove. Disinfecting agents may cause deterioration.
- Use general-purpose utility gloves (rubber household gloves) for housekeeping chores and for instrument cleaning or decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracking, or discolored, or if they have punctures, tears, or other evidence of deterioration.

d Gloves must be changed after contact with each patient. Used gloves shall be discarded into an appropriate trash receptacle. Gloves shall be changed after contact with a patient's excretions or secretions, and clean gloves reapplied if patient care has not been completed. Environmental surfaces are not to be touched with contaminated gloves.

e Gloves shall be worn when cleaning or disinfecting environmental surfaces contaminated with blood or body fluids.

2) **Protective Clothing.** Gowns and similar protective attire are indicated if clothes are likely to be soiled with the blood or body fluids of any patient.

a Appropriate protective clothing shall be worn in occupational exposure situations. The type and characteristics will depend upon the task an degree of exposure anticipated.

b If the garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

c Gowns shall be worn only once and discarded into an appropriated container.

3) Masks and Protective Eyewear.

a Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

b Masks are recommended to prevent transmission of infectious agents through airborne routes. Masks protect the wearer from inhaling large-

particle aerosols (droplets) that are transmitted by close contact and small-particle aerosols (droplet nuclei) that remain suspended in the air and travel longer distances.

c When masks are indicated, they shall cover both the nose and the mouth. Masks become ineffective when moist; therefore, they shall be used only once and discarded into an appropriate receptacle. Masks shall not be lowered around the neck and reused. When it is necessary to wear masks for extended periods of time, they must be changed at least every hour, or more frequently if they become moist. When removing the mask, only the ties or elastic band should be touched because the filtering area may be highly contaminated.

d Non-disposable protective eyewear contaminated with blood or body fluids shall be washed with a germicidal disinfectant. Disposable protective eyewear shall be discarded into an appropriate receptacle.

4) Surgical Caps and Shoe Covers

Surgical caps or hoods and/or fluid resistant shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g. autopsies, orthopedic surgery).

5) Eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

IV) ASEPSIS

A) Definitions

1) Is intended to break the infection chain (consists of: infectious agent, reservoir, portal of exit from the reservoir, means or mode of transmission, portal entry into host and susceptible host).
2) **Medical asepsis** (or clean technique) consists of techniques used to reduce the number of microorganisms and help reduce or prevent their spread.
3) **Surgical asepsis** (or sterile technique) is the elimination of microorganisms from an area.

B) GUIDELINES FOR SURGICAL ASEPSIS

1) **Should be used in the following situations:**
   a When there will be an intentional break in the patient skin.
   b When there is an open wound.
   c When a sterile body cavity must be entered.

2) Handling sterile objects and fields

   a There should be a minimal number of people in a room during a sterile procedure.
   b Equipment and supplies used are sterile.
   c A sterile object remains sterile only when touched by another sterile object.
   d A sterile object or field out of the range of vision or held below a person's waist is contaminated.

- Never turn your back on a sterile tray or leave unattended.
- Cover a sterile tray with a sterile towel or drape when leaving a room.

e A sterile object or field becomes contaminated by microorganisms transported through the air.

- Avoid activities that create air currents.
- Avoid talking, coughing, sneezing, or laughing when working with sterile equipment.
- Never reach over a sterile field.
- When opening sterile packages, hold items or pieces of equipment, without touching surfaces, as close as possible to the sterile field.

f A sterile object or field becomes contaminated by capillary action when a sterile surface comes into contact with a wet contaminated surface.