Major Revisions to the 2014 Institutional Laboratory Biosafety Manual

Section	Revision
II.5 – Institutional Biosafety Coordinating Committee (IBCC)	Deleted section; the following wording was added to the new Section II.5 – President and Vice Presidents: "As needed, an ad-hoc committee may be formed to consider policy implications for the university of emerging technologies and processes that have a biosafety component. This committee will work with the standing university committees and administrative units with responsibilities for biosafety issues in research and teaching to provide advice to the Vice President for Research." The remaining sections were renumbered in part II.
II.9 – Principal Investigators and Supervisors	Renumbered to section II.8; updated the link for the Biohazard Incident Reporting Policy; added "Post Animal Hazard Safety Protocols on applicable door when using hazardous agents for the duration specified on the form."
V – Biohazard Signs and Tags	OASIS forms changed to "Animal Hazard Safety Protocol (AHSP)"
VI.3.2 – Use of Biological Safety Cabinets	Updated title of NSF/ANSI Standard 49 to "Biosafety Cabinetry: Design, Construction, Performance, and Field Certification"
IX.5.1 – Generic Spill Procedures	Added "recombinant and synthetic nucleic acids" to "The biological spill kit should contain supplies to clean up any spill of biological origin, including plant, animal or human material and recombinant or synthetic nucleic acids, both infectious and non-infectious."
XII – Accident and Incident Reporting	Reporting Responsibilities #2 – updated links to "rDNA / Biohazard Incident Report Form" and "Animal Bite / Exposure Report Form"
XII – Accident and Incident Reporting	Clarified that #2 under Reportable Incidents and Timelines is for human gene therapy adverse events only.
XIII.1 – Occupational Health Program	Clarified that anyone with the potential for direct or indirect contact with animals or other hazardous agents must enroll in the program
XIV – IBCC Policy Statements	Delete section from manual; IBCC is referenced in Section II.5 as an Ad Hoc committee and will no

Major Revisions to the 2014 Institutional Laboratory Biosafety Manual

	longer be a standing committee; Charter and policies removed from manual
Appendix B	Delete current Appendix B (Charter of IBCC); rename remaining Appendices
Old Appendix D (New Appendix C)	Added information on how to request waste supplies (EHS Online)

General Comments:

- Recombinant DNA (rDNA) has been changed to “recombinant or synthetic nucleic acid” throughout the document to be in line with the revised NIH Guidelines.
- Employee Health Services has been changed to “University Health Services” throughout the document

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 Public Employment Risk Reduction Program which has adopted Occupational Safety and Health Administration (OSHA) standards. The University is also committed to complying with current safety regulations and guidelines as issued by the United States Departments of Health and Human Services and Agriculture, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

This biosafety manual provides university-wide safety guidelines, policies, and procedures for the use and manipulation of biohazards and recombinant and synthetic nucleic acid molecules. Although the implementation of these procedures is mainly the responsibility of the Principal Investigator (PI), success in biosafety depends upon the combined efforts of everyone in the laboratory. Planning for and implementation of biological safety must be part of every laboratory activity in which biohazard materials are used. The purpose of the University's overall biological safety plan is to ensure the safe handling of biohazardous materials in any work performed under University aegis and to thereby protect personnel, research outcomes and the environment.

The biosafety program consolidates the compliance programs for the Public Employment Risk Reduction Program adoption of the OSHA Hazard Communication Standard (29 CFR 1910.1200), the OSHA Occupational Exposure to Hazardous Chemicals in the Laboratory (29 CFR 1910.1450), the OSHA Occupational Exposure to Bloodborne Pathogens Standard (29 CFR 1910. 1030), the NIH's *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines)* and the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (5th edition). Additionally, the Institution's *Safety Management Guidebook* provides University

procedures for medical surveillance, sharps injuries, and working alone that are to be followed by principal investigators and laboratory personnel.

This *Institutional Laboratory Biosafety Manual* applies to all OSU faculty, staff, hosted visitors, students, participating guests and volunteers, contract laborers, supplemental personnel and employees of firms working at locations where the University has management control of specific biohazards.

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) that can cause disease in humans, animals or plants. Work with some experimental animals and arthropods 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 react or may become allergic.

II. Responsibilities

The basic safety principle is that **all injuries are preventable**. **Management**, from the university President to the Principal Investigator/Supervisor, has a responsibility to encourage the university's 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. OEHS personnel are involved in the development of safety practices and procedures for the university. They also provide guidance to personnel in safety matters through consultation. The unit also has the responsibility of ensuring, through the auditing of laboratory facilities and work practices, that the work of the university is completed in a safe and environmentally sound manner.

OEHS has institutional responsibility for the disposal of radioactive materials, hazardous chemicals and infectious wastes. Training in specific areas of safety concerns is provided by OEHS personnel, including those associated with the collection and disposal of biological wastes.

Use, possession and transfer of select agents and toxins at the university must be in accordance with federal regulations. Select agents and toxins are biological agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or a threat to animal or plant products. The Office of Environmental Health and Safety oversees the use, possession and transfers of select agents and toxins to ensure compliance with federal regulations. Appendix B contains additional information on select agents and toxins. Questions about select agents and toxins should be directed to the Responsible Official (RO) or the Alternate Responsible Official

(ARO) at 614-292-1284.

II.2. Office of Responsible Research Practices (ORRP)

The Office of Responsible Research Practices (ORRP), a unit of the Office of Research, provides support for review committees, many of which are federally mandated, including a Biomedical Institutional Review Board (IRB), a Cancer IRB, a Behavioral and Social Sciences IRB, the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC) The Office of Responsible Research Practices also supports the institution by promoting ethical conduct of research and educating OSU students, faculty, and staff regarding research regulations. Copies of application forms, information on policies and procedures, and Statements of Assurance can be obtained through the ORRP website (http://orrp.osu.edu/).

II.3. Institutional Biosafety Officer (IBO)

The Institutional Biosafety Officer (IBO) is responsible for the development, implementation and direction of the comprehensive biological safety program at the institution. The biosafety program includes work with human tissues, fluids, cells or cell cultures, recombinant or synthetic nucleic acids, transgenic plants/animals, infectious agents, work with animals known to be vectors of zoonotic diseases, gene transfer, xenotransplantation, etc. This individual serves as the Institutional Biosafety Officer as defined by the *NIH Guidelines* and thereby serves on the Institutional Biosafety Committee. The membership of this committee reviews and approves protocols involving the use of biohazards, recombinant or synthetic nucleic acid and gene transfer. The IBO assists investigators and staff with all matters related to biosafety. The IBO audits laboratories and work practices for compliance with university policies and procedures.

II.4. Institutional Biosafety Committee (IBC)

The Ohio State University is committed to the safe, legal, and ethical use of biologically-derived hazardous materials. Acting as the agent for the university in such matters, the Institutional Biosafety Committee acts to assure that activities involving recombinant or synthetic nucleic acid molecules and biohazards meet the legal and ethical requirements for the responsible use of these agents, that safety levels are appropriately classified, and that work is performed in accordance with good safety practices. Additionally, the committee membership works to establish policies and make recommendations to the university regarding such activities, maintain and promote an open and cooperative relationship with investigators and other university committees, and educate the university community concerning the regulatory requirements of biosafety.

The IBC reviews all aspects of research involving recombinant or synthetic nucleic acid molecules, vectors, and host cells that cannot be classified as human or animal biohazards. The committee also has responsibility for traditional research activities that utilize biohazards and for recombinant or synthetic nucleic acid projects that include biohazards (including mammalian viral vectors, pathogenic organisms, and the use of human blood, tissues, body fluids, cells, blood products, human stem cells and other potentially infectious materials). All human gene transfer protocols and those animal gene transfer protocols not exempted from review by the *NIH Guidelines* and potential dual use research of concern is also reviewed by the IBC.

The IBC retains the authority to refuse permission for a principal investigator to work with specific biological agents if, in the opinion of the committee, public health or the environment would be compromised by granting such use.

II.5. President and Vice Presidents

The university President and Vice Presidents encourage a climate of

compliance with federal, state and local regulations and support an ongoing commitment to this compliance.

As needed, an ad-hoc committee may be formed to consider policy implications for the university of emerging technologies and processes that have a biosafety component. This committee will work with the standing university committees and administrative units with responsibilities for biosafety issues in research and teaching to provide advice to the Vice President for Research.

II.6. 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.7. 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 the conduct or work practices of PIs and/or other personnel in the department;

- **Ensure the compliance of principal investigators** and other supervisory personnel with federal, state, and local regulations and university policies applicable to the department's work, including enrollment of individuals in the

Occupational Health program. 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, OEHS, the department safety officer and the appropriate university standing committee.

II.8. 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, research protocols/safety plans are prepared and submitted to the IBC for review, and laboratories are submitted to periodic inspections. PIs are responsible for maintaining good working order of equipment in their laboratories (including the appropriate certification of biological safety cabinets, [BSCs] required annually or whenever 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 implementation of measures to eliminate or control workplace hazards;

- **Ensure** that all laboratory personnel, maintenance personnel and visitors who may be exposed to any biohazard be informed in advance of their potential risk and the behavior required to minimize that risk;

- **Correct deficiencies** noted during the periodic laboratory inspection and respond in writing with the corrective action and date of implementation, to OEHS within the required time period;

- **Submit a research protocol (Safety Plan)** covering the use of biohazard agents for review and approval by the Institutional Biosafety Committee before laboratory work commences and submit the laboratory to periodic inspections by a representative of Environmental Health and Safety;

- **Submit** any significant changes in the research protocol to the IBC for review and approval;

- **Ensure** any research projects covered by the *NIH Guidelines* that require prior agency approval before initiation, be reviewed by the IBC before seeking or obtaining agency approval.

- **Encourage regular self-assessment inspections** by employees in order 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 concerning laboratory shortcomings in good faith will be protected from retaliatory actions based on such filings;

- **Ensure that all individuals in the laboratory** know how to access the ***Institutional Laboratory Biosafety Manual*** available on the OEHS website and maintain a written acknowledgment of understanding by these individuals;

- **Ensure training** of all individuals involved in the handling and

disposal of biohazard agents and that all training records are maintained as directed by the standards;

- **Create** and foster an environment in the laboratory that encourages open discussion of biosafety issues, problems, and modifications of procedures;

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

- **Ensure the participation** of all personnel in a Medical Surveillance Program (i.e. Occupational Health Registry). EHS should be informed of all biohazard agents used in the laboratory;

- **Ensure** that all accidents and biohazard exposures are reported as required under OSU policy in a timely manner to the Institutional Biosafety Officer and the Chair of the Institutional Biosafety Committee. The Biohazard Incident Reporting policy and forms can be found at http://orrp.osu.edu/ibc/osuibcpolicies/incidentreporting/.

- **Notify** the Institutional Biosafety Officer if a laboratory-acquired infection is known or suspected;

- **Stop any 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 which include hazardous materials (consult with the animal vivarium supervisor for more information);

- **Develop** (with the Institutional Biosafety Officer) plans for handling emergencies (accidental spills, fires, riots, etc.);

- **Ensure that the animal vivarium supervisor is notified** via the eProtocol system at least three working days before animals under the care of ULAR staff are treated with biohazardous agents. Consultation with ULAR and OEHS personnel may be needed to ensure the risks and required PPE (personal protective equipment) are understood by all individuals involved. Post Animal Hazard Safety Protocols on applicable door when using hazardous agents for the duration specified on the form

II.9. 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, the Institutional Biosafety Committee (IBC), or OEHS.

Each employee is expected to be conscientious in assuming personal safety responsibility from the 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 the chair of the IBC;

- **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.11. 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.

III. Risk Assessment and Research Protocols

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 biological, toxic, flammable, reactive, explosive and/or radioactive 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 safety officers, the chair of the Institutional Biosafety Committee, the Institutional Biosafety Officer, and/or 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 biohazard materials requires the proper **risk classification of the material**, the **risk modification of the manipulations of the material**, the **environmental risks associated with the material**, and the **laboratory requirements for containment associated with those risks**. Agents of Risk Group 1 or 2 can usually be assessed in consultation with the departmental safety officer but still require the submission of a research protocol to the IBC. It is required that PIs submit a research protocol for approval by the Institutional Biosafety Committee for the use of Risk Group 3 agents prior to the beginning of the research. Agents of Risk Group 3 require submissions for approval of research protocols and are best managed by early consultation with the BSL-3 Advisory Committee, the Institutional Biosafety Committee, the Institutional Biosafety Officer, and Environmental Health and Safety (OEHS) personnel.

Established, ongoing research or development initiatives should be evaluated annually 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 research protocol. New initiatives that increase the risk profile of the laboratory must be accompanied by appropriate changes in the laboratory's research protocol (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 research protocol is approved and 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 and engineering controls) required and the appropriate handling of spills. It is the Principal Investigator's responsibility to make sure that all training is completed at the required intervals by their laboratory personnel. Be aware that while allowing unpaid volunteers (both minors and adults) to work in the laboratory is a department level policy, if allowed all volunteers must take all of the required safety training prior to beginning work in the laboratory.

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.

Information pertaining to the assignment of agents to risk groups may be found in Appendix B of the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines)* and Section VIII of the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*, 5th Ed.

This method of Risk Group (RG) 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 (5th 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.

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

Risk Group 1 (RG1)	Agents not associated with disease in healthy human adults
Risk Group 2 (RG2)	Agents associated with human disease that is rarely serious and for which preventative or therapeutic interventions are *often* available. **All** human source material (including blood, human cell lines and other potentially infectious materials) are considered RG2.
Risk Group 3 (RG3)	Agents 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 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).

III.3. Research Protocol

The **research protocol** is a project-specific biological safety plan for research and teaching laboratories or common facilities shared by more than one of these activities. In each laboratory/facility, the PI/supervisor must specify the safety practices/procedures to be used in the laboratory and is responsible for the implementation of the plan. Approved practices

must be based on the risk assessment for that laboratory/project and must comply with accepted national standards. A research protocol for the containment of Risk Group 2 and 3 infectious agents and any work with recombinant or synthetic nucleic acid molecules must be submitted to the IBC prior to implementation (work with agents of RG 4 is not permitted at the university). The research protocol 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 *Biosafety in Microbiological and Biomedical Laboratories* (5th Edition), in *Physical and Biological Hazards of the Workplace*, in similar references, or by contacting the Institutional Biosafety Officer, the IBC, or EHS personnel.

- **Bloodborne Pathogens Standard (OSHA) [29 CFR 1910.1030]:** laboratory use of human or animal blood, blood components, or tissues;

- **Containment requirements/engineering controls:** for biosafety level (BSL) 2 or 3, biosafety cabinets, storage requirements, transport containers, personal protective equipment (PPE) (*i.e.*, hoods, eye protection, gloves, gowns, respirators, etc.), spill management and waste disposal;

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

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

- **Specific safety training requirements:** all laboratory personnel (including the Principal Investigator) must be

trained on the specific standard operating procedures to be used in the research; personnel must also be informed according to Public Employment Risk Reduction Program regulations (i.e. OSHA regulations) of the 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 annually required education: standard operating procedures, bloodborne pathogens training for blood or body fluid exposure prevention, respirator training, safe animal handling, hearing conservation, laboratory chemical hazards, etc.;

- **Training records:** protocols for recording and maintaining records of initial personnel training and the annually required yearly exposure-prevention education programs must be established and in place.

III.4. 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 Chemical Hygiene Plans and 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;
- Chemical Hygiene Plan;
- Departmental Emergency Plans;
- Radiation Safety Information;
- Annual Chemical Inventory;

- Annual Biohazardous Agent Inventory (if available);
- Safety Data Sheets (Safety Data Sheets) or access thereto;
- Bloodborne Pathogens Exposure Control Plan;
- Approved Research Protocols (IBC, IRB and IACUC) and Annual Reviews;
- Personal Protective Equipment (PPE) hazard assessment;
- Respirator Records (Respirator Plan) plus records of examinations and Fit Test Reports);
- Training Documentation.

Boilerplates of some of the elements of the Safety Desk Book may be found at the OEHS website at www.ehs.osu.edu.

III.6. Select Agents

The use, possession or transfer of select agents at the University requires prior approval by the Responsible Official. For additional information on select agents please see Appendix C of this document or contact the RO or ARO at 614-292-1284.

IV. Recombinant and Synthetic Nucleic Acids, Gene Transfer and Transgenic Organisms

IV.1. Introduction

Recombinant and synthetic nucleic acids are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids, (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2) above.

All work with recombinant and synthetic nucleic acid molecules must be registered with the ORRP and, if the research is not exempt from full committee review under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH* Guidelines), also approved by the IBC. Investigators must understand that the poor wording used in the *NIH Guidelines i.e.,* "exempt from the *NIH Guidelines*", means only that the work need not be approved by the IBC. Good laboratory practices and containment procedures are to be followed by all individuals using recombinant and synthetic nucleic acids at The Ohio State University. Exempted research is also subject to inspection by the Institutional Biosafety Officer or other OEHS personnel.

All Principal Investigators intending to use recombinant and synthetic nucleic acid molecules shall notify the IBC by submitting an electronic research protocol (e-Protocol) according to the nature of the research. All recombinant and synthetic nucleic acid research falls into the six classes below:

- Experiments that require IBC approval, RAC review, and NIH director approval before initiation
- Experiments that require NIH/OBA and IBC approval before initiation
- Experiments that require IBC and IRB and RAC review before research participant enrollment

- Experiments that require IBC approval before initiation
- Experiments that require IBC notice simultaneous with initiation
- Exempt experiments.

Experiments involving the generation of recombinant and synthetic nucleic acids require, at a minimum, registration with the Institutional Biosafety Committee (IBC). Some experiments also require approval of the IBC. The *NIH Guidelines* are applicable to all research conducted at or sponsored by an institution that receives funds from the National Institutes of Health for recombinant and synthetic nucleic acid research. The University is required to monitor all recombinant and synthetic nucleic acid research. Compliance is required 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 prior approval by NIH. The rest come under the jurisdiction of the OSU 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 recombinant and synthetic nucleic acid research at the University is exempt from full committee review. But even the research that is exempted from full committee review must be registered and 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 of genetically-engineered organisms into the environment, their use as drugs or food products, and human gene-therapy protocols may be regulated by the USDA, EPA and FDA. The IBC may not have the sole authority to approve research in these areas and researchers may need to obtain permission from the federal agencies in addition to the IBC.

All protocols involving the generation of recombinant and synthetic nucleic acid molecules for human gene transfer must be approved by

the IBC prior to the enrollment of the first human subject.

Investigators who use transgenic plants or animals must submit a recombinant and synthetic nucleic acid protocol and submit it via e-Protocol to the IBC. The IBC will review the form to determine if IBC approval of the experiments is necessary.

IV.2. Institutional Biosafety Committee (IBC)

An Institutional Biosafety Committee (IBC) is required at all institutions that receive funding from the National Institutes of Health (NIH). The IBC is composed of researchers, administrators, OSU staff, and community members. The committee meets as needed to review research protocols and advise the University on matters of recombinant and synthetic nucleic acid safety or biosafety matters. Different subcommittees of the IBC review recombinant and synthetic nucleic acid experimentation, biohazard research, and gene transfer experiments. All recombinant and synthetic nucleic acid and gene transfer protocols are approved by the full committee. All recombinant and synthetic nucleic acid research at The Ohio State University (OSU), regardless of funding source, must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules and must be registered with the OSU IBC.

The OSU IBC is further charged with reviewing and approving research conducted with human, plant, or animal pathogens. This review is conducted pursuant to the Centers for Disease Control and Prevention (CDC)/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* (currently in 5th edition, February 2007).

The OSU IBC in conjunction with the Office of Environmental Health and Safety also provides guidance to the OSU research community regarding proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials. The Office of Responsible Research Practices (ORRP) will also provide assistance with IBC registrations and applications.

Additional information is provided at the ORRP Biosafety web page (http://orrp.osu.edu/ibc/about/) under the Investigator Guidance link. This site provides detailed descriptions of IBC registration requirements and the IBC review process.

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.
5. Ensure that all recombinant and synthetic nucleic acid waste is appropriately decontaminated prior to disposal.

V. 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 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 at the end of this section.

- The University requires that the universal biohazard symbol be used to designate the presence of materials defined as biohazard (see Chapter I of this document);
- All laboratories must display room signs signifying the biohazards present, an emergency contact and phone number, and the necessary precautions to be taken when entering or working in the area (room signs [Fig 5.1] may be requested through EHS by using the "Room Sign Request Form" found on the OEHS website) ;
- **PIs are responsible for ensuring that hazard signs are posted and are current and accurate;**
- When using experimental animals cared for by University Laboratory Animal Resources (ULAR) staff, the PI must give a minimum of three days' notice via the e-Protocol online system, to the animal vivarium supervisor before exposing or treating the animals with biohazardous agents or hazardous chemicals so that ULAR staff can prepare for appropriate animal husbandry. A working day is defined as a "day" during which University offices are open and excludes weekends and holidays. The PI or laboratory staff should confirm the appropriate signage is posted at the animal room level as indicated on the OSU Animal Hazard Safety Protocols (AHSP) prior to initiating hazardous work. The AHSP is provided to the PI and ULAR supervisors have access to the signage. A

research protocol for the use of the particular agent as prepared by the PI must be submitted to the IBC and the research protocol must receive IBC approval before the research can begin.

Fig 5.1

THE OHIO STATE UNIVERSITY

OSU Stadium

PI
Dr. Brutus Buckeye

Emergency Contacts
Rose Bowl: 614-xxx-xxx
Urban Meyer: 614-xxx-xxx

IN EMERGENCY: Firemen may enter: Call office of Radiation Safety 2-1284 or University Police 2-2121. Radiation Safety Emergency Pager: 614-240-0705

Designated Area Lab ☒

Access limited to authorized personnel only

No Food or Drink

VI. Containment

The term **containment** is used to describe safe methods for managing biohazard agents in the laboratory environment. The 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 hazard agents and prevent the escape of these agents into the outside environment.

Research or teaching activities involving biohazard agents of RG 2 or higher can only be conducted with prior approval of the IBC. The elements of a safety plan have been discussed previously. The NIH/CDC manual *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) (5th Edition) provides guidance for the appropriate containment of biohazard work. The biosafety levels are based on the probability of occupationally-acquired infections resulting from the handling of specific agents in the laboratory.

CDC describes four biosafety levels (BSLs) which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations conducted, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity. The recommended biosafety level for an organism represents the conditions under which the agent can be ordinarily handled safely. When specific information is available to suggest that virulence, pathogenicity, antibiotic resistance patterns, vaccine and treatment availability, or other factors are significantly altered, more (or less) stringent practices may be specified.

Biosafety Level 1 is appropriate for work done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. It represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing.

Biosafety Level 2 is applicable to work done with a broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Agents can be used safely on the open bench, provided the potential for producing splashes or aerosols is low. Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures or ingestion of infectious materials. Procedures with high aerosol or splash potential must be conducted in primary containment equipment such as biosafety cabinets. Primary barriers such as splash shields, face protection, gowns and gloves should be used as appropriate. Secondary barriers such as hand washing and waste decontamination facilities must be available.

Biosafety Level 3 is applicable to work done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious and potentially lethal infection. Primary hazards to personnel working with these agents (i.e., *Mycobacterium tuberculosis*, *St. Louis encephalitis virus* and *Coxiella burnetii*) include auto-inoculation, ingestion and exposure to infectious aerosols. Greater emphasis is placed on primary and secondary barriers to protect personnel in adjoining areas, the community and the environment from exposure to infectious aerosols. For example, all laboratory manipulations should be performed in biological safety cabinets or other enclosed equipment. Secondary barriers include controlled access to the laboratory and a specialized ventilation system to prevent the release of infectious agents in the event an accidental release occurs in the laboratory.

Biosafety Level 4 is applicable for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. Agents with close or identical antigenic relationship to Biosafety Level 4 agents should also be handled at this level. Primary hazards to workers include respiratory exposure to infectious aerosols, mucous membrane exposure to infectious droplets and auto-inoculation. The facility is generally a separate building or a completely isolated zone within a complex with

specialized ventilation and waste management systems to prevent the release of viable agents to the environment. All manipulations of potentially infected materials and isolates pose a high risk of exposure and infection to personnel, the community and the environment. Isolation of aerosolized infectious materials is accomplished primarily by working in a Class III biological safety cabinet or a full-body, air-supplied positive pressure personnel suit.

Vertebrate Animal Biosafety Levels

There are four animal biosafety levels (ABSLs), designated Animal Biosafety Level 1 through 4, for work with infectious agents in mammals. The levels are combinations of practices, safety equipment and facilities for experiments on animals infected with agents that produce or may produce human infection. In general, the biosafety level recommended for working with an infectious agent in vivo and in vitro is comparable.

Animal Biosafety Level 1 is suitable for work involving well characterized agents that are not known to cause disease in healthy human adults, and that are of minimal potential hazard to laboratory personnel and the environment.

Animal Biosafety Level 2 is suitable for work with those agents associated with human disease. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.

Animal Biosafety Level 3 is suitable for work with animals infected with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease.

Animal Biosafety Level 4 is suitable for addressing dangerous and exotic agents that pose high risk of like threatening disease, aerosol transmission, or related agents with unknown risk of transmission.

Complete descriptions of all Biosafety Levels and Animal Biosafety Levels are outlined in the NIH/CDC manual *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) (5th Edition). **The *BMBL***

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 for confirmation of university requirements.

Research at the university is limited to Biosafety Levels 1, 2 or 3. Infectious materials must be clearly identified and stored in such a manner as to preclude accidental exposure. This normally includes double containment and labeling of the storage freezer/refrigerator/liquid nitrogen tank.

VI.1.Laboratory-acquired Infections

A number of infectious agents have been documented as causes of laboratory-acquired infections. Included in the list are bacterial, viral, chlamidial and rickettsial, and parasitic organisms.

VI.2. Laboratory Practices

The most important element of containment is strict adherence to standard microbiological practice and techniques. Persons working with biohazard agents or infected materials shall be aware of potential hazards and shall be trained and proficient in the practices and techniques required for safe 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.

VI.3.Safety Equipment (Primary Barriers)

Safety equipment includes personal protective equipment, biological safety cabinets, sealed, leak proof 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.

VI.3.1. 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.

CDC and NIH have published a document 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. This document is available as Appendix A of the NIH/CDC manual *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*) (5th Edition).

VI.3.1.1. Class I BSCs

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 used specifically 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, prior to the exhaust fan.

VI.3.1.2. Class II (Types A1, A2, B1, and B2) BSCs

Class II BSCs provide personnel, environmental and product

protection. Airflow is drawn around the operator into the front grille of the cabinet providing personnel protection. In addition, the downward laminar flow of 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 to the cabinet workspace, back into the laboratory (Class II Type A1 and A2 BSCs) or ducted out of the building (Class II Type B1, B2, and A2 BSCs). A Class II Type A2 BSC may optionally be installed such that air re-circulates back into the room or is ducted outdoors. Under the new NSF/ANSI 49 Standard, no newly installed Type A cabinet may be directly ducted to the building's exhaust system; thimble exhaust connections should be used to connect all new installations of Type A BSCs to the building exhaust system.

HEPA filters are effective at trapping particulates and infectious agents, but not at capturing volatile chemicals or gases. Only Class II Type B2 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 ONLY be used with minute amounts of volatile chemicals as long as the re-circulating vapors do not present a problem in the work. The same is true of Class II Type A2 cabinets that are vented to the outdoors (with the exception that this type of cabinet re-circulates 70% of the air back to the cabinet); when the Type A2 cabinet is vented back into the room, it should NOT be used with toxic chemicals.

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.

VI.3.1.3. Class III BSCs

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.

VI.3.1.4. Horizontal Laminar Flow "Clean Benches"

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 ONLY. They can be used for certain clean activities, such as dust-free assembly of sterile equipment or electronic devices. These benches should not 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 or as a substitute for a chemical hood.

VI.3.1.5. Vertical Laminar Flow "Clean Benches"

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.

VI.3.1.6 Biological Safety Cabinets vs. Chemical Fume Hoods

Biological Safety Cabinets (BSCs) and Chemical Fume Hoods (CFHs) are not interchangeable. BSCs and CFHs are different equipment designed for different applications. BSCs are for working with biological materials and CFHs are for use when working with hazardous chemicals.

There are two main differences between chemical fume hoods and biosafety cabinets. Chemical fume hoods have inward airflow, offering personnel protection only. Biological safety cabinets, on the other hand, have both inward and downward airflow, allowing for both

personnel and product protection (clean work environment). The second difference is that a chemical fume hood has no HEPA filtration on the exhaust offering no environmental protection, where a biological safety cabinet has HEPA filters on both the supply and the exhaust which provides both product and environmental protection.

It is important to understand the differences between these two types of equipment. If you have questions as to which type of equipment you should be using for your research, please contact Environmental Health and Safety for assistance.

VI.3.2. Use of Biological Safety Cabinets

Biological safety cabinets with the potential to be used to protect workers from hazardous biological agents shall be tested and certified after installation and before use, any time they are moved, when major repairs are performed and at least annually. According to NSF/ANSI Standard 49, prior to repair or replacement of components located in contaminated plenums, prior to relocation and in some cases prior to recertification, BSCs should be gas decontaminated by a qualified contractor. The PI shall provide annual certification records for each biosafety cabinet under that individual's control. Testing shall meet the criteria in **NSF/ANSI Standard 49 - 2012 Biosafaety Cabinetry: Design, Construction, Performance, and Field Certification, Annex F.** 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 (below are a list of activities that are prone to aerosol formation);
    - Centrifugation
    - Vigorous shaking and mixing
    - Pipetting
    - Grinding
    - Aspiration/washing
    - Injection
    - Sonication
    - Working with materials under pressure
- 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 biological safety cabinet before beginning work;
    - Demonstrate proficiency in working in the BSC;
    - **No modifications may be made to any BSC without first contacting the Institutional Biosafety Officer.**

Open flames are not permitted to be used in BSCs. The flame creates turbulence which disrupts the pattern of HEPA-filtered air being supplied to the work surface. In addition, the heat from the continuous flame may damage the supply and/or exhaust HEPA filters, requiring replacement of the filters.

Biosafety cabinets are designed for a single operator. Never work with two or more people at a time in ***any*** BSC, regardless of manufacturer, model or size. Multiple users will cause air disruptions and potentially destroy the containment capabilities of the BSC, possibly creating personnel, product or environmental protection issues.

Any procedure specific exemption or waiver from this policy must be submitted to the Institutional Biosafety Officer and/or the Institutional Biosafety Committee Chair for review and approval prior to commencement.

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 biological safety cabinet. Contact the Institutional Biosafety Officer for assistance when selecting a new biosafety cabinet.

Additional information on BSCs can be found in the “Biological Safety Cabinets” online training available on the OEHS training website.

VI.3.3. Other Safety Equipment

Leak proof containers for the processing, transporting or storage of etiologic agents are also safety equipment. An example of a leak proof container is the safety centrifuge cup/rotor that is designed to prevent the 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 to contain the agents, animals, or materials during manipulation. PPE is covered in more detail in Chapter VII 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.

Appropriate safety equipment must be considered when performing a risk assessment for a particular project. The Institutional Biosafety Officer, OEHS, and/or the IBC must be consulted when additional containment devices are determined to be necessary.

- ***WARNING***: **Chemical fume hoods and laminar-flow clean-air benches (both vertical and horizontal) are *not* to be used for work with biohazard materials.**

VI.4.Facility Design (Secondary Barriers)

Secondary barriers not only protect the environment within the facility, but also 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 should be inspected annually by OEHS

staff and found to be in compliance 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 RG 3 or Biosafety Level 3 must be approved by the IBC before being initiated.

VI.4.1. The Basic Laboratory

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 (especially those that produce aerosols). Conventional laboratory designs are adequate.

VI.4.2. The Containment Laboratory

The Containment Laboratory has specialized 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 Biosafety 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.

VI.4.3. The Maximum Containment Laboratory

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.

VI.5.Recombinant and Synthetic Nucleic Acid Biosafety Levels

Laboratory-scale recombinant and synthetic nucleic acid 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 or Synthetic Nucleic Acid 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 recombinant and synthetic nucleic acid production (≥ 10 liters) must be approved by the IBC. The appropriate level of containment will be determined by the IBC at the time of review of the protocol.

VII. Personal Protective Equipment

VII.1. Regulations

Working safely in a laboratory requires having the proper containment equipment and engineering controls, wearing appropriate Personal Protective Equipment (PPE), using proper work practices, knowing safety information for the materials and equipment used, and following safety instructions and laboratory protocols. Some labs contain more than one type or category of hazardous material. The protective equipment and work practices in such a lab are those that provide protection against the most hazardous agent.

The appropriate use of personal protective equipment (equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers) minimizes the potential for exposure to biohazard, toxic, and corrosive agents.

The Ohio Public Employment Risk Reduction Program has adopted the Occupational Safety and Health Administration standard (**29 CFR 1910.132**) covering the availability and use of PPE. According to the standard, the PI shall assess the workplace to determine if hazards are present, or are likely to be present, that necessitate the use of PPE. If such hazards are present, or are likely to be present, the PI shall:

- Offer the employee with the potential to exposure, types of PPE that will protect them from the hazards identified in the hazard assessment;

- Communicate the selection decisions to each employee;

- Select PPE that properly fits each employee; and

- Educate the employee on proper use of PPE

The PI is responsible for ensuring that each person using PPE knows when PPE is necessary, what PPE is necessary, how to properly don, doff, adjust and wear the PPE, what the limitations of the PPE are, and the proper care,

maintenance, useful life and disposal of the PPE. The PI shall verify that each affected person has received and understood the required training through a written certification that contains the person's name, the date(s) of the training, and that identifies the subject of the certification.

The PI must verify in writing that the required workplace hazard assessment has been performed by identifying the workplace evaluated, the person certifying that the assessment has been performed, and the date(s) of the hazard assessment. The document must identify itself as a certification of hazard assessment. The PPE hazard assessment should be kept as part of the Chemical Hygiene Plan.

VII.2. General Comments

Some protection is provided by ordinary clothing and glasses. However, one must dress sensibly for laboratory work. Laboratory-provided clothing protects the clothing underneath. It is the responsibility of the lab worker to use special protective clothing and equipment when they are required for safety. Protective wear may include laboratory coats, wrap around gowns, masks, coveralls, aprons, gloves, shoe covers, eye protection, and respirators. It is necessary to select the garments and fabric used based upon the nature of the hazardous agent.

The PI must provide or ensure provision of appropriate PPE to each employee who is subject to occupational exposure to human blood or other potentially biohazard material. The PPE is provided at no cost to the employee.

The PI must either directly or through delegation ensure that each employee uses PPE when warranted. Aprons, laboratory coats, gloves, and other protective clothing, preferably made of chemically inert material, shall be readily available. Laboratory coats are essential to protect street clothing from biological aerosols or chemical splashes and spills, vapors, or dusts.

PPE shall be provided in a sanitary and reliable condition and shall be cleaned regularly to avoid spreading contamination.

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 Safety Data Sheet for incompatibility.

PPE must be repaired or replaced as needed to maintain effectiveness.

Eyes are very vascular and can quickly absorb many chemicals. Regulations require the use of protective eye and face equipment where there is a reasonable probability that their use can prevent injury. Safety glasses with side shields are required for everyone entering the laboratory when hazardous agents are in use. Eye protection is not interchangeable among employees and shall be provided for each individual unless disinfected after use.

Safety glasses with clear side shields are adequate protection for general lab use. Goggles shall be worn when there is danger of splashing chemicals or biologicals or flying particles (such as when chemicals are poured or glassware is used under elevated or reduced pressure). A face shield (or face shield with goggles) offers maximum protection (for example, with macaque monkeys, or vacuum systems that may implode).

Corrective lenses in spectacles do not in themselves provide sufficient protection for working in the lab. Regulations require that persons whose vision requires corrective lenses, and who are required to wear eye protection, shall wear goggles over their eyeglasses, prescription safety glasses, or goggles with prescription lenses. Persons who wear contact lenses in laboratories must also wear appropriate eye protection.

Unprotected skin should be protected whenever possible. Suitable clothing shall be worn in the laboratory. Street clothing may absorb liquid spills that might otherwise contact skin. Shorts are not appropriate clothing for the laboratory. Long sleeves protect arms; long sleeves shall fit snugly when working around moving machinery. Wool affords more protection from flash burns or corrosives than cotton or synthetic fabrics. Some synthetic fabrics may increase the severity of injury in the case of fire. Cotton is less

prone to static electricity build up than nylon or other synthetics.

The wearing of substantial leather shoes in the lab protects against chemical splashes or broken glass. The wearing of sandals or other open-toed footwear is prohibited. Cleaning up spills on floors may require extra protection such as rubber boots or plastic shoe covers. Steel-toed shoes should be used when handling heavy items such as gas cylinders or heavy equipment components.

Gloves must be worn when it is reasonably anticipated that hand contact with blood or other potentially infectious materials, mucous membranes, or non-intact 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 (non-disposable 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.

For certain protocols and projects, additional PPE such as respiratory protection may be required. Respirator selection is based upon the hazard and the protection factor required. ***Personnel who require respiratory protection must contact University Health Services for medical evaluation and clearance, and Environmental Health and Safety for fit testing and training, prior to using a respirator.***

Personal hygiene is extremely important to individuals working in a lab. Contamination of food, beverages, or smoking materials is a potential route of exposure to toxic chemicals or biological agents through ingestion. Laboratory personnel shall not prepare, store, or consume food or beverages, pipette by mouth, smoke, apply cosmetics, or handle contact

lenses in the lab.

Hand washing is a primary safeguard against inadvertent exposure to toxic chemicals or biological agents. Individuals should always wash their hands before leaving the lab, even if using gloves. Wash hands after removing protective clothing, before leaving the lab, and before eating, drinking, smoking, or using the restroom. Individuals should wash their hands periodically during the day at intervals dictated by the nature of the work being completed. Wash with soap and running water, with hands held downwards to flush the contaminants off the hands. Turn the tap off with a clean paper towel to prevent recontamination and dry hands with clean towels.

Confine long hair and loose clothing when in the lab to keep them from catching fire, dipping into hazards, or becoming entangled in moving machinery. Avoid the wearing of finger rings and wristwatches that may become contaminated, react with chemicals, puncture or tear gloves, or be caught in moving parts or equipment.

Remove laboratory coats and gloves before leaving the lab and entering public spaces (i.e elevators and restrooms) to prevent spreading contamination to other areas.

VIII. Biosafety Laboratory Practices and Equipment

All laboratory personnel shall engage in good microbiological laboratory practices 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, smoking, handling contacts or applying cosmetics.

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, eyewashes or exits at any time, for any reason.

All hazardous materials, including biological, chemical and radioactive materials, should be secured when unattended, to protect from unauthorized access, misuse or removal.

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

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:

VIII.1.1. BSL-1 Standard Microbiological Practices

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 laboratory. Food is stored outside the laboratory 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, leak-proof 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 must 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.

VIII.1.2. BSL-1 Special Practices

None

VIII.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. However, if BSCs are used (i.e. tissue culture) they must be tested and certified annually.

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 latex gloves should be

available (i.e. nitrile gloves).

4. Protective eyewear should be worn to conduct procedures in which splashes of microorganisms or other hazardous materials is anticipated. Persons who wear contact lenses in laboratories should also eye protection.

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

1. Laboratories should have doors for access control.

2. Each laboratory contains a sink for hand washing.

3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not permitted.

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.

VIII.2. Biosafety Level 2 (BSL-2)

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:

VIII.2.1. BSL-2 Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory. Laboratory doors should remain closed when working with BSL2 materials.

2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, applying cosmetics and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory in cabinets or refrigerators designated and used for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.

5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.

6. Perform all procedures to minimize the creation of splashes and/or aerosols.

7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with an appropriate disinfectant.

8. An effective integrated pest management program is required.

VIII.2.2. BSL-2 Special Practices

1. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

2. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.

3. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), emergency telephone number, and required procedures for entering and exiting the laboratory.

4. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.

5. Institutional policies and procedures describing the collection and storage of serum samples from at-risk personnel must be followed.

6. A laboratory-specific biosafety manual/research protocol must be prepared and adopted as policy. The manual must be available and accessible.

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. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce the risk of sharps injuries.

Precautions, including those listed below, must always be taken with sharp items. These include:

a. Careful management of needles and other sharps are of primary importance.

b. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes or otherwise manipulated by hand before disposal. If re-capping is deemed necessary, Standard Operating Procedures shall be followed for using recapping sheaths or the one-handed method only.

c. Used disposable needles and syringes 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.

e. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs or forceps.

f. Plasticware should be substituted for glassware whenever possible.

9. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage or transport within a facility.

10. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes or other

potential contamination. Spills involving infectious materials must be contained, decontaminated and cleaned up by staff properly trained and equipped to work with infectious material.

11. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor.

12. Animals and plants not associated with the work being performed are not permitted in the laboratory.

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

1. Properly maintained biological safety cabinets(preferably Class II), 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 pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.

b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups

2. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be manipulated outside the BSC or containment device.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab must be worn while working with hazardous materials. Remove protective clothing before

leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately. PPE should not be taken home by personnel for laundering. If sent off-site for laundering, PPE should be properly bagged and the laundry facility notified of any potential hazards.

4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Wear two pairs of gloves, when appropriate. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory. Alternatives to latex gloves should be available.

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

1. Laboratory doors should be self-closing and have locks in accordance with institutional policies.

2. Each laboratory contains a sink for hand washing. The sink may be manually, hands-free or automatically operated and located near the exit door.

3. The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.

4. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.

5. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning. Chairs used in laboratory work must be covered with a non-porous material that can easily be cleaned and decontaminated with an appropriate disinfectant.

6. BSCs must be installed so that fluctuations of the room air

supply and exhaust air do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions (i.e. supply air diffusers).

7. An eyewash station must be readily available.

8. Vacuum lines should be protected with an in-line filter. Liquid disinfectant traps may be required, and if glass traps are used, must be stored in appropriate secondary containment.

9. There are no specific requirements on ventilation systems. 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.

10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to the manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection, depending on the type of BSC.

11. A method for decontaminating all laboratory wastes should be available in the facility. At OSU, all infectious waste, including liquid infectious waste, must be collected and disposed of in a biohazard box and sent off-site for incineration.

VIII.3. Work with Human or Animal Tissues

Human blood, blood products, cells and cell lines, body fluids and tissues are listed as potentially hazardous biological materials. Animal tissues may also be contaminated with biohazardous materials. Biosafety Level 2 practices and procedures must be followed when handling human blood, blood products, cells and cell lines (including established cell lines), body fluids and tissues and animal tissues because of

the infectious agents that they may contain. Biosafety Level 2 practices and procedures are consistent with the concept of "Universal Precautions" that require all specimens of human blood, blood products, body fluids and tissues to be treated as if they are infectious. The federal regulation, the Occupational Exposure to Bloodborne Pathogens (29 CFR 1910.1030), adopted by the Ohio Public Employment Risk Reduction Program, mandates a series of engineering and work practice controls, training, and Hepatitis B vaccination to control the health risk to employees resulting from occupational exposure to human blood and other potentially infectious materials that may contain human pathogens.

VIII.4. Biosafety Level 3 (BSL-3)

A complete description of Biosafety Level 3 can be found in the BMBL 5th edition. Specific BSL3 practices and procedures for work at the university are described in the BSL3 facility safety manuals.

IX. Decontamination and Spills

IX.1. Definitions

- **Sterilization:** the act or process, physical or chemical, which 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.
    - o High Level Disinfectants kill all viruses and vegetative cells, but they may not kill endospores reliably.
    - o Intermediate Level Disinfectants destroy all vegetative cells including Mycobacteria, fungi and most, but not all viruses. They cannot kill endospores.
    - o Low Level (General Purpose) Disinfectants destroy vegetative bacteria, except Mycobacteria, fungi and non-enveloped viruses.
- **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.

IX.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 for 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 pre-cleaning 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. Alcohols 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. (Some bleach solutions available now contain about 1/3 more hypochlorite than the solutions mentioned above. Check to see what the concentration of chlorine in the bleach solution you are using.) 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 should be reserved for significant contamination.

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

Prepare a fresh solution of bleach 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. To help prevent corrosion after using the bleach solution, rewipe the surfaces with 70% ethanol.

Chlorine dioxide, either as a liquid solution or as a gas, can also be used for decontamination purposes. The liquid form (i.e. Clidox) is most commonly used as a 1:5:1 or 1:18:1 dilution (base:water:activator). Chlorine dioxide gas can be used for large equipment or space decontaminations.

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

Phenolics that are registered with the EPA may be effective hard-surface decontaminants when used per the manufacturer's instructions (i.e. Vesphene, Hil-Phene).

Quaternary ammonium compounds are low-level disinfectants and are not recommended for spills of human blood, blood products, and other potentially infectious materials (i.e. Conflikt, End-BacII).

The use of such chemicals requires that the laboratory have a current Chemical Hygiene Plan (29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories). Safety Data Sheets (SDSs) for the chemicals in use must be made available to the individuals in the lab, as well as training on special procedures for handling the chemicals.

IX.3. Sterilization

Unless the facility is permitted by the Ohio EPA to treat infectious waste, all terminal treatment is incineration. Consequently, **all pre-treated and untreated biohazards** (*i.e.*, infectious waste) shall be

placed in a burn box. See Appendix C. Consult EHS for assistance.

According to the OEPA, for terminal sterilization to be allowed, the sterilization process (steam autoclaving, 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.

Additionally, 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.

Since The Ohio State University has no autoclave licensed for terminal sterilization by the OEPA, individuals using autoclaves must still have their autoclaved waste prepared and sent off-site for incineration per the University contract. If an autoclave is being used for infectious waste pre-treatment, periodic monitoring of the effectiveness of the sterilization process is still recommended.

IX.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 allow 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. Steam can cause serious injury. Additionally, malfunctioning autoclaves can fill with superheated water that will be released when the autoclave is opened.

- Suggested sterilization cycle times:
    - 60 minutes @ 121°C & 15 PSI for decontaminating waste
        - Lengthen time for large or dense loads
    - 30 minutes @ 121°C & 15 PSI for sterilizing clean materials (i.e. glassware)
    - Use slow exhaust for liquids and fast exhaust for glassware

  Additional information can be found in the "Safe Use of Autoclaves" training, available on the EHS website.

IX.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. EHS 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.**

IX.4.1. Disinfection Hazards

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

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.

IX.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 should be included in a Standard Operating Procedure 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.

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.

IX.5.1. Generic Spill Cleanup Plans

As part of the laboratory Safety Plan, each laboratory must have a

biological spill kit and a spill cleanup plan detailing specific disinfectants and procedures for agents used in that laboratory. The biological spill kit should contain supplies to clean up any spill of biological origin, including plant, animal or human material and recombinant or synthetic nucleic acids, both infectious and non-infectious. 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.

A copy of the OEHS "Infectious Waste Spill Containment & Clean Up Procedure" can be obtained by contacting your OEHS Safety Representative. This procedure should be posted in all labs where working with or storing potentially infectious materials, including recombinant or synthetic nucleic acids.

IX.5.1.1. Spill Cleanup Procedures

The following procedures are to assist lab personnel with containment and cleanup of spills under specific circumstances.

Spill Contained Within a Biological Safety Cabinet (BSC)

- BSC must run during cleanup to contain aerosols & HEPA-filter exhaust air.
- Don appropriate personal protective gear before initiating cleanup.
- Initiate clean up as soon as possible using a 10% bleach solution or other EPA approved tuberculocidal disinfectant.
- If the spill is contained on a bench diaper, remove the contaminated bench diaper & discard as infectious waste.

- If the spill is on the work area surface, cover spilled material with disinfectant-soaked towels. Allow the appropriate contact time (30 minutes for bleach; other EPA approved tuberculocidal disinfectants follow manufacturer's recommendations) then remove the contaminated towels & discard as infectious waste.

- Wipe down the interior of the cabinet & any splatter on items within the cabinet with a disinfectant-soaked towel.

- Wipe down non-autoclavable materials with disinfectant. Allow the appropriate contact time (30 minutes for bleach; other EPA approved tuberculocidal disinfectants follow manufacturer's recommendations) with disinfectant before any items are removed from cabinet.

- Place items designated as contaminated used sharps in an appropriate infectious waste sharps container using tongs/forceps. Place other contaminated disposable materials used in the cleanup process in a biohazard bag. Process as infectious waste.

- Place contaminated re-usable items in autoclave bags, autoclavable pans with lids or wrap them in newspaper. Sterilize, preferably by autoclaving, and clean for re-use.

- If the cabinet has a catch basin beneath the work surface & the spill resulted in liquids flowing into this area, more extensive decontamination is required.

    1) Ensure the drain valve under the cabinet is closed.

    2) Pour disinfectant onto the work surface & through the front and rear grilles into the drain pan. Allow 30 minutes contact time.

    3) Absorb spilled fluid-disinfectant from work surface with paper towels & discard in biohazard bag.

4) Prepare to empty drain pan. Place disinfectant solution in a collection vessel. Attach flexible tubing to the drain valve. The tube should be of sufficient length to allow the open end to be submerged in the collection vessel to minimize aerosol generation.

5) Open the drain valve & empty the drain pan into the collection vessel containing disinfectant. Flush the drain pan with water & remove the flexible tubing. Manage contaminated materials as if they are infectious.

6) Remove protective clothing used during cleanup & dispose of as infectious waste. Wash hands when gloves are removed.

7) Notify Principal Investigator or supervisor. Consult with OEHS (614-292-1284) to determine whether gas decontamination of the cabinet and filters is necessary, especially if a high-risk agent or a major spill of a moderate-risk agent occurred.

8) Run BSC at least 10 minutes after cleanup, before resuming activity in the cabinet.

Outside the Cabinet, Inside the Laboratory

- If a spill occurs in a Biosafety Level 2 facility, outside the BSC, notify other individuals in the laboratory to evacuate.
- Exit the laboratory to the hallway, closing the door behind you.
- Remove any contaminated clothing (turn contaminated portion inward) & place it in an autoclave bag.
- Wash all exposed skin.

- Place signs on door(s) to the laboratory warning individuals who may want to enter that a spill occurred & access is denied.

- Allow aerosols to settle for at least 30 minutes before re-entering the laboratory.

  ** *If assistance is needed, contact* ***Spill Response Personnel*** *by calling the facility emergency number 614-****292-1284;*** *or 614-****292-2121*** *(from cell phone) or* ***911*** *(from campus phone) after hours and remain in the area to provide information regarding the size of the spill and the materials spilled to the responder(s).*

- Assemble supplies (disinfectant, sharps containers, towels, tongs, biohazard bags, etc.) before entering the laboratory.

- Don appropriate personal protective equipment (i.e. disposable gown, protective eyewear, gloves, shoe coverings & respiratory protection [if necessary]).

- Clean up spill with a 10% bleach solution or other EPA approved tuberculocidal disinfectant as follows:
  1) Surround spill area with disinfectant or diking material that is soaked in disinfectant.

  2) Place items designated as contaminated used sharps in an appropriate infectious waste sharps container. Place other disposable materials used in the cleanup process in a biohazard bag. Process as infectious waste.

  3) Place paper towels over the entire spill area to absorb the spill. Clean the area and dispose of the material as infectious waste.

  4) Apply disinfectant and allow the appropriate contact time (30 minutes for bleach; other EPA approved

tuberculocidal disinfectants follow manufacturer's recommendations) with the disinfectant to ensure adequate germicidal action.

5) Wipe down non-autoclavable materials with disinfectant.

6) Place contaminated re-usable items in autoclave bags, autoclavable pans with lids or wrap them in newspaper. Sterilize, preferably by autoclaving, and clean for re-use.

7) Remove protective clothing used during cleanup then place in a biohazard bag for autoclaving.

- Wash hands when gloves are removed.
- Notify Principal Investigator or supervisor & OEHS (614-292-1284)

Inside a Centrifuge

The potential for multiple infections from a single centrifuge accident is high. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge is operating at high speed. ***All opening of centrifuges must be performed slowly.***

Unsealed buckets:

- If a centrifuge tube breaks while the centrifuge is running, turn off motor. Allow the machine to be at rest for 30 minutes before opening. If breakage is discovered after the machine has stopped, re-close the lid immediately & allow the unit to be at rest for 30 minutes.
- Unplug centrifuge before initiating clean up.

- Don strong, thick, rubber gloves & other PPE before proceeding with clean up.
- Flood centrifuge bowl with a 10% bleach solution or other EPA approved tuberculocidal disinfectant. Place paper towels soaked in a disinfectant over the entire spill area. Allow the appropriate contact time (30 minutes for bleach; other EPA approved tuberculocidal disinfectants follow manufacturer's recommendations) with the disinfectant. Use mechanical means (such as forceps) to remove broken tubes & glass fragments. Place them in a sharps container for disposal as infectious waste.
- Remove buckets, trunnions & rotor then place in disinfectant for 24 hours or autoclave.
- Unbroken, capped tubes may be placed in disinfectant & recovered after appropriate contact time.
- Use mechanical means to remove remaining disinfectant soaked materials from centrifuge bowl & discard as infectious waste.
- Place paper towels soaked in a disinfectant in the centrifuge bowl & allow it to soak overnight, wipe down again with disinfectant, wash with water & dry. Discard disinfectant soaked materials as infectious waste.
- Remove protective clothing used during cleanup & place in a biohazard bag for autoclaving. Wash hands whenever gloves are removed.

<u>Sealed buckets (safety cups):</u>

- If breakage is suspected, remove the sealed bucket to a biological safety cabinet before opening.

- If breakage occurred, replace the cap on the safety cup loosely and autoclave.

Notify Principal Investigator or supervisor & OEHS (614-292-1284).

Outside the Laboratory; during Transport (on the OSU Campus)

The major emphasis should be on preventing spills during transport. All transport of infectious materials must be in a rigid, securely sealed, watertight primary container, which is contained within a second rigid, leak proof sealed container. Sufficient absorbent should be added to the second container to absorb contents in case of leakage from the primary container. The outer container must be labeled with the universal biohazard symbol.

If a spill occurs during transport, don gloves and initiate cleanup immediately with a 10% bleach solution or other EPA approved tuberculocidal disinfectant as follows:

- Surround spill area with disinfectant or diking material that is soaked in disinfectant.
- Place **contaminated used sharps** in an appropriate infectious waste sharps container.
- Place paper towels over the entire spill area to absorb the spill. Clean the area and dispose of the material as infectious waste.
- Apply disinfectant and allow the appropriate contact time (30 minutes for bleach; other EPA approved tuberculocidal disinfectants follow manufacturer's recommendations) with the disinfectant to ensure adequate germicidal action.

- Place all materials used in the cleanup process (including contaminated gloves) in a biohazard bag and process as infectious waste.

- Wash hands as soon as possible.

IX.5.1.2. 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 should 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 segregated as biohazard laundry 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. 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 environmental contamination. Certain wastes are regulated and must be handled according to approved 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.

All biohazard waste must be packaged, contained, and stored in a manner that protects and prevents the waste from release at any time. If storage is necessary, putrefaction and the release of infectious agents into the air must be prevented.

X.1. Responsibility

It is the responsibility of the PI/laboratory supervisor to identify the classes of wastes that are generated in the laboratory and to ensure that the appropriate methods of waste disposal are followed. Information regarding infectious waste disposal is covered under the Principal Investigator Assurances section of the IBC e-Protocol submission.

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

X.2. Requirements

Waste must be segregated on the basis of potential hazard.

All infectious waste will be handled, and disposed of in accordance with Appendix C, *Infectious Waste Guidelines*.

XI. Ordering, Receiving, Shipping and Movement of Biohazard Materials

The transport of biohazard material is regulated by a number of government agencies. It is imperative that personnel are aware of the applicable regulations and comply with them. The shipper of biohazard material is responsible for the proper classification, identification, packaging, labeling, and documentation of the shipped material. **Failure to comply could result in fines, the confiscation and destruction of the material and loss of valuable research time.**

XI.1. Applicable Regulations

The following is a list of regulations that control the shipping of hazardous materials:

1. U. S. Department of Health and Human Services (HHS) and United States Department of Agriculture (USDA): **42 CFR 73, 7 CFR 331, and 9 CFR 121** for select agents or toxins; **42 CFR 73** is the implementation of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002;* **7 CFR 331** and **9 CFR 121** are implementations of the *Agricultural Bioterrorism Protection Act of 2002* (Part of Title II of the *PHSBPRA*). The select agent list may be found in Appendix B of this manual.

2. U. S. Department of Transportation: **49 CFR 171 et seq.**;

3. *Technical Instructions for Safe Transport of Dangerous Goods by Air*, International Civil Aviation Organization (ICAO);

4. *Dangerous Goods Regulations,* International Air Transport Association, (IATA);

5. *Recommendations of the Committee of Experts on the Transportation of Dangerous Goods,* United Nations.

6. USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54 Etiologic agents, hosts, and vectors

XI.2 Shipments within the United States

The United States Department of Transportation (DOT) has issued regulations covering the intrastate, interstate, and foreign shipment of hazardous materials.

Shippers of dangerous goods must be trained (**49 CFR 172.700 *et seq.***) on the DOT regulations. Training must be documented and is required every three years. Individuals must comply with shipping regulations and certify that the shipped materials will arrive at their destination in good condition and will not present any hazards to humans or animals during the shipment. Commercial carriers will refuse to accept any packages that do not meet the regulations. Substantial fines, for both the individual and the University, may be incurred if an individual is not compliant.

Shipment or transfer of exempt amounts of select agent toxins (see Appendix B) falls under the DOT regulations for hazardous materials. **If shipping or transferring a non-exempt amount of select agent toxin, contact the University's Responsible Official at 614-292-1284.**

XI.3 International Shipments

If hazardous or infectious materials are being shipped internationally, the shipper must complete training on the *Dangerous Goods Regulations,* International Air Transport Association, (IATA). This training must be completed every two years, or whenever the regulations change, whichever comes first.

The U.S. Government actively regulates the use, import, export, and interstate transport of many microorganisms, toxins, vectors and other infectious substances and biological materials. In many cases a permit or license from the Department of Commerce, the Centers for Disease

Control and Prevention (CDC) and/or the Animal and Plant Health Inspection Service (APHIS) will be required. For specific information detailing current permit and licensing requirements by type of material see the "Import, Export and Transfer of Biological Materials Guide" on the EHS Biosafety webpage.

Material containing etiologic agents being imported into the United States must be accompanied by a U.S. Public Health Service importation permit. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package through the United States Public Health Service Division of Quarantine and release by U.S. Customs.

The USDA Animal and Plant Health Inspection Service (APHIS) also regulates the importation of certain plants, animals and animal products into the United States. Please visit the APHIS website (http://www.aphis.usda.gov/import_export/index.shtml) for more information on obtaining an APHIS permit.

The importer is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials according to Federal and International regulations. Shipping labels with the universal biohazard symbol, the address of the importer, the permit number, and the expiration date, are also issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs Service and U.S. Division of Quarantine Personnel of the package contents.

XI.4 Intracampus transport of biohazardous materials

Transportation of biohazard material on campus (including between laboratories) must be completed in a manner that takes into account the potential risk of the agent being moved. The biohazard material must:

- be enclosed in a **primary vessel** contained within a secondary

vessel;

- have a **closed, leak proof 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 biohazard material constitutes a violation of the University's Biohazard Policy and will be dealt with accordingly.

XII. Accident and Incident Reporting

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

- Report all accidents involving potential exposures to biohazard material and occupational illnesses to supervisory personnel, the appropriate administrative unit (department, division, etc.), the Institutional Biosafety Officer and Employee Health Services. An accident report form (available at www.ehs.osu.edu) must be completed and sent to Employee Health Services

- An investigation of any incident or accident may be performed in accordance with University and EHS policy (see Appendix E for more information).

- Additional information relating to biohazard/rDNA incident reporting requirements is available at: http://orrp.osu.edu/ibc/osuibcpolicies/incidentreporting/

The Ohio State University Recombinant DNA / Biohazard Research Incident Reporting Policy and Process

The Ohio State University is required to report certain incidents involving recombinant DNA or biohazard research to the National Institutes of Health. This policy outlines the information necessary to determine the nature and extent of the incident, as well as the appropriate reporting requirements and process.

Reporting Responsibilities

1. The University personnel involved will immediately report the incident to the Institutional Biosafety Officer, who will contact the Senior Director of Environmental Health and Safety, the Director of University Lab Animal Resources, the Chair of the Institutional Biosafety Committee and the Offices of Responsible Research Practices and Research Compliance as needed.

2. The Institutional Biosafety Officer and the Principal Investigator will collectively complete a rDNA / Biohazard Incident Report Form or an Animal Bite/Exposure Report Form, whichever is appropriate. The form will be completed in a timely manner as determined by the nature of the incident and agency reporting timelines. The report will be provided to the Institutional Biosafety Committee (IBC) for review.

3. Following review by the IBC and the University's Office of Research Compliance, the Chair of the IBC and Office of Responsible Research Practices will submit the final incident report with the Chair's signature to the respective federal agency on behalf of the university. Copies of the incident report will be provided to the University Office of Legal Affairs, the Associate Dean for Research of the College involved, and the Chair of the Department involved.

Reportable Incidents and Timelines

1. The following incidents should be reported immediately to the Principal Investigator, the Institutional Biosafety Officer, and the Chair of the Institutional Biosafety Committee:

   a. Spills or accidents in a BSL2 laboratory resulting in an overt exposure, injury or illness of personnel, including bites/exposures to animals intentionally infected with RG2 agents or potential zoonotic diseases.

   b. Spills or accidents in a BSL3 laboratory resulting in an overt potential exposure, injury or illness of personnel, including

bites/exposures to animals intentionally infected with RG3 agents or potential zoonotic diseases.

c. Release of a Risk Group 2 or 3 agent / genetic material from a primary containment device (e.g., biological safety cabinet, centrifuge, or primary container into the laboratory)

d. Spills or accidents that lead to personal injury or illness or breach of containment (e.g., aerosols released outside of containment, skin punctures with needles containing Risk Group 2 or 3 agents or genetic material from these agents).

e. Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.

2. The following timelines will be used for institutional incident reporting for human gene therapy adverse events to the agency:

    1. Section IV-B-2-b-(7) of the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) states that "…any significant problems, violations of the NIH Guidelines, or any significant research related accidents and illnesses" must be reported to the Office of Biotechnology Activities (OBA) <u>within 30 days</u>.

    2. Appendix G of the NIH Guidelines specifies that certain types of accidents / incidents (i.e., 1.a and 1.b) must be reported <u>immediately</u>. A follow-up report will then be submitted as needed.

    3. Appendix M-I-C-4-b of the NIH Guidelines specifies that <u>any serious adverse event that is fatal or life-threatening</u>, that is unexpected, and associated with the use of the gene transfer product <u>must be reported to the NIH OBA as soon as possible, but not later than 7 calendar days after the sponsor's initial</u>

receipt of the information (i.e., at the same time the event must be reported to the FDA).

Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening, must be reported to the NIH OBA as soon as possible, but not later than 15 calendar days after the sponsor's initial receipt of the information (i.e., at the same time the event must be reported to the FDA).

rDNA / BIOHAZARD INCIDENT REPORT FORM

1. List the name(s) of the employee(s) involved:

2. List the date, time and location in which the accidental exposure occurred:

3. As thoroughly as possible, describe the circumstances of the exposure incident:

4. List the biological agent / genetic material and route(s) of possible exposure (e.g. inhalation, subcutaneous, etc.):

5. What is the nature of the organism strain to which the employee has been exposed? (strain name and history, complete drug-resistance/susceptibility profile, any other information that might be pertinent to treatment):

6. List steps taken to evaluate employee's health, and action taken to prevent recurrence of a similar incident:

(Attach additional pages as necessary)
Employee Signature _____ Date _____
Principal Investigator Signature _____

Submit to Chair of the Institutional Biosafety Committee for review via the Office of Responsible Research Practices (fax number 614-688-0366).

ANIMAL BITE / EXPOSURE REPORT FORM
WILD CAUGHT & USDA SPECIES

(To be completed by employee and supervisor)

Employee's Name:
_____
Principal Investigator's Name
_____
Date of incident: _____Time of incident: _____AM/PM
Location of incident:

Animal species involved:

Describe the circumstances of the exposure incident:

Possible risks of exposure:

What first aid / medical attention was given to employee following exposure:

What action has been taken to prevent recurrence of a similar incident (if any):

(Attach additional pages as necessary)
Employee Signature _____ Date _____
Principal Investigator Signature _____
Submit completed form to the Institutional Biosafety Officer for review via fax at 614-292-6404.

XIII. Occupational Health Program

1. Overview

All individuals (i.e. faculty, staff, students, visiting scientists and volunteers) who work in lab animal facilities or have with the potential for direct or indirect contact with animals, human and/or animal tissues, biohazards, and hazardous chemicals must participate in the OSU Occupational Health Program. This program includes: identification and enrollment of personnel, hazard evaluations/ risk assessments, exposure controls, medical evaluations, and occupational health and safety training. The purpose and goal of the Occupational Health Program is to identify, evaluate, manage, and reduce potential health risks associated with work involving animals, biohazards, and hazardous chemicals.

Hazard assessments and medical surveillance are critical components of an effective occupational health program and involve the evaluation of health risks associated with an individual's occupational exposures, as well as an individual's current heath status. A comprehensive occupational medicine program is provided through University Health Services, The Ohio State University's Wexner Medical Center, OSU Student Health Services, or a designated contractor for regional sites. After reviewing an individual's information, a member of the Occupational Health team determines if a medical evaluation is necessary. During the medical evaluation, employees are counseled about exposure to hazardous agents that they may encounter in the course of their employment at The Ohio State University. Sources for additional information are given to the employee at that time. In many cases, an initial evaluation and risk assessment is all that is necessary. For some individuals, a clinical examination, vaccinations, and medical monitoring may be required as well.

2. Enrollment

Personnel shall enroll in the Occupational Health Program by

completing an online questionnaire at https://rf.osu.edu/secure/ochre. If an individual experiences a change in their health status or a change in their occupational exposure, he/she should update their information by updating relevant information at https://rf.osu.edu/secure/ochre. Personnel must update their occupational health registry information annually, or in the event of changes in health status or occupational exposures.

3. Medical Disclosures

Personnel that work with biohazards and have chronic medical conditions are asked to disclose these conditions to University Health Services (if unpaid students, Student Health Services). These conditions will be evaluated as part of the health evaluation. Some medical conditions and treatments can increase the severity or risk of an adverse health outcome resulting from occupational exposures.

4. Research Risk Assessment

Use of hazardous agents requires an approved Biosafety Research Protocol, Chemical Hygiene Plan and/or Radioactive Materials Application, which are reviewed and approved by the Institutional Biosafety committee (IBC), the Office of Environmental Health and Safety (OEHS), and/or the University Radiation Safety Committee (URSC) respectively. When completing the initial risk assessment for a biohazard research project, the PI 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 biohazard agent(s). This assessment is performed by the supervisor/PI in conjunction with University Health Services. The requirements for routine medical surveillance, prophylaxis, and post-exposure treatment and follow-up for work with biohazards are dictated by the risk assessment.

5. Vaccinations

Hepatitis B virus (HBV) vaccine is available free of charge to all employees who could reasonably anticipate exposures to human blood or other potentially infectious materials (e.g. human tissues, human cell lines, blood products, etc.) while performing their job duties. Employees with a potential for exposure to human blood or potentially infectious materials must be offered HBV immunization (*cf.*, OSHA Bloodborne Pathogen Standard, **29 CFR 1910.1030**).

When vaccinations are deemed necessary in the biohazard risk assessment, personnel may be required to receive a vaccine as a condition of employment or demonstrate an active immunity to the agent in question. Personnel should consult with University Health Services for specific information.

6. Routes of Exposure

Exposures can occur in research personnel via:

- Injections, including, but not limited to cuts, abrasions, puncture wounds or via contamination of an existing skin injury;
- Absorption through skin (failure to wear PPE/ properly use PPE), as well as splashes to mucous membranes (e.g. eyes, nose, mouth);
- Ingestion resulting from improper lab practices (e.g. eating/drinking in lab, failure to wash hands prior to exiting lab); and
- Inhalation

7. Reporting Exposures, Illnesses, or Injuries

Personnel experiencing any injury or illnesses related to occupational exposures must report the event to their supervisor or PI and University Health Services (614-293-8146), as well as submit an Employee Accident Report. Concerns or symptoms of allergies to lab animals should be reported as soon as they are noted. Known exposures to infectious agents or other biologically hazardous material (e.g. recombinant or synthetic nucleic acid molecules) must

be reported to PI/supervisor; University Health Services (614-293-8146); and to the Institutional Biosafety Officer (Environmental Health & Safety at 614-292-1284). If medical treatment is needed, personnel should go to University Health Services or Student Health Services. Student employees shall go to Employee Health Services and non-paid students to Student Health Services. Employee Health Services is located on the 2nd floor, McCampbell Hall at 1581 Dodd Dr. Student Health Services (614-292-4321) is located at 1875 Millikin Road. If medical treatment is needed after hours, personnel should report to the Wexner Medical Center Emergency Department. Personnel working at regional campuses shall go to the nearest Emergency Department for medical treatment. If personnel seek medical treatment in an Emergency Department, they must have an evaluation and complete an Employee Accident Report at University Health Services, Student Health Services or the regional site's designated contractor prior to returning to work.

8. Reproductive Hazards

Persons capable of and considering reproduction should consider the ramifications of working with chemical, biological, or radiological agents, or animals. Information that should be reviewed while considering whether precautions will be necessary include: Safety Data Sheets (SDS), the laboratory's Chemical Hygiene Plan and/or the biohazard risk assessment. Individuals who are concerned about potential reproductive hazards in the workplace may contact the Office of Environmental Health and Safety (614-292-1284) with questions on locating relevant safety information.

XIV. Animal Research Safety

XIV.1. General

A laboratory animal facility (vivarium) is 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 biohazard 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* (2010 revision) and the Laboratory Animal Welfare Regulations [Animal Welfare Act] (**9 CFR Subchapter A, Parts 1, 2 and 3**). All research involving animals is subject to prior review by the Institutional Animal Care and Use Committee (IACUC).

The PI, in consultation with University Laboratory Animal Resources (ULAR) and OEHS is responsible for developing a research protocol to be submitted to the IBC when conducting animal research involving biohazard agents. This research protocol 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 biohazard agents will be completed at the appropriate animal biosafety level indicated for the biohazard agent being used as assigned by the Principal Investigator and approved by the Institutional Biosafety Officer and the IBC.

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 hazardous agents associated with the animal research.

The PI must notify the animal vivarium supervisor via the e-Protocol system at least three working days before animals under the care of ULAR staff are treated with hazardous agents. For agents that do not require any additional handling or processing by ULAR notification in advance is not required. The PI is responsible for posting the Animal Hazard Safety Protocol (AHSP) at the lab, housing or procedure space for the duration of the hazard. 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 euthanize those animals exposed to biohazard agents or toxic chemicals if ULAR has not received the appropriate notification.

All animal carcasses, whether infectious or not, must be disposed of as infectious waste in accordance with Appendix C. Only bedding and waste from infected animals must be disposed of in accordance with the same section of this *Manual*.

Individuals working in vivaria must recognize that conscientious personal hygiene practices establish an important barrier to infection. All individuals handling animals must wear gloves. After handling animals, their secretions or excretions, individuals shall remove their gloves, wash their hands with disinfectant soap and water and then dry their hands. Protective clothing (lab coat, uniform or surgical gown) and other safety devices such as hearing protection, facemasks and safety glasses may be required when working with animals. Eating, drinking, storing food and/or drink, smoking, or applying cosmetics in animal rooms are prohibited. Individuals should keep their hands away from their mouths, eyes, noses, and hair after handling animals. Inadvertent self-contamination with pathogens is the primary cause of reported illnesses among laboratory workers. Individuals who are ill (especially with respiratory problems) should avoid working with animals. Individuals who have open wounds should also take additional care when working with animals.

XIV.2. Laboratory Animal Allergies

It is important to minimize exposures that could result in sensitization of animal-care and laboratory-research personnel to animal allergens. Engineering controls of animal facilities, adequate work procedures and the use of appropriate personal protective equipment can minimize exposure to laboratory animal urine, dander, fur, saliva, serum, etc.

- Allergic reactions to laboratory animals are common among personnel working with laboratory animals;
- Personnel should be made aware of the signs and symptoms of laboratory animal allergies;
- Personnel exhibiting any signs of hypersensitivity to laboratory animals (contact dermatitis, allergic conjunctivitis, allergic rhinitis, asthma) must report to Employee Health Services for further evaluation and/or treatment.

XIV.3. Zoonoses and Arthropodoses

Researchers working with lab animals must recognize the possibility of naturally-infected animals capable of transmitting those infections (zoonoses) to lab personnel. This is particularly true of non-human primates and farm animals, but it is possible with other lab-animal species. Research work also may involve exposure to 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. It is important to understand the extent to which the arthropods may or may not have been infected with agents, and 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 as well as the methods of transmission (*i.e.*, aerosol for Tuberculosis, bites/scratches/intimate contact for Cercopithecine herpesvirus 1 [*Herpes virus simiae*], Rocky Mountain Spotted Fever from tick bites, skin contact for ringworm and orf, etc.).

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

For more information on zoonotic diseases associated with laboratory animals, see the OSU OEHS Animal Research Safety website.

XIV.4. Vertebrate Animal Biosafety Level Criteria

Institutional management must provide appropriate facilities and staff and must 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 biohazard 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.

The following section describes the combinations of practices, safety equipment, and facilities for experiments on animals infected with agents that produce, or may produce, human infection. The 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 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 NOT conducted at OSU.

Facility standards and practices for invertebrate vectors and hosts are not specifically addressed in standards written for commonly used laboratory animals. *Arthropod Containment Guidelines*, prepared by the American Committee of Medical Entomology, serves as a useful reference in the design and operation of facilities using arthropods.

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

Animal Biosafety Level 1 is suitable for work involving well characterized agents that are not known to cause disease in healthy human adults, and present minimal potential hazard to personnel and the environment.

XIV.5.1. ABSL-1 Standard Microbiological Practices

1. The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergency situations.

Each project is subject to pre-approval by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biosafety Committee (IBC). Any special practices are approved at this time.

2. A safety manual specific to the animal facility is prepared or adopted in consultation with the animal facility director and appropriate safety professionals.

The safety manual must be available and accessible. Personnel are advised of potential hazards and are required to read and follow instructions on practices and procedures.

3. Supervisor must ensure that animal care, laboratory and support personnel receive appropriate training regarding their duties, animal husbandry procedure, potential hazards, manipulations of infectious agents, necessary precautions to prevent hazard or exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.).

Personnel must receive annual updates or additional training when procedures or policies change. Records are maintained for all hazard evaluations, employee training sessions and staff attendance.

4. Appropriate medical surveillance program is in place, as determined by risk assessment. The need for an animal allergy prevention program should be considered.

Facility supervisors should ensure that medical staff is informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, animal care and manipulations.

Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all personnel and particularly women of child-bearing age should be provided information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

Personnel using respirators must be enrolled in an appropriately constituted respiratory protection program.

5. A sign (AHSP) incorporating safety information must be posted at the entrance to the areas where infectious materials and/or animals are housed or are manipulated. The sign must include the animal biosafety level, general occupational health requirements, personal protective equipment requirements, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the animal areas. Identification of specific infectious agents is recommended when more than one agent is being used within an animal room. Depending on the agent, information may need to be posted for the study duration or simply during the innoculation of the animals.

Security-sensitive agent information should be posted in accordance with the institutional policy.

Advance consideration should be given to emergency and disaster recovery plans, as a contingency for man-made or natural disasters.

6. Access to the animal room is limited. Only those persons required for program or support purposes are authorized to enter the facility.

All persons including facility personnel, service workers, and visitors are advised of the potential hazards (natural or research pathogens, allergens, etc) and are instructed on the appropriate safeguards.

7. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.

Gloves are worn to prevent skin contact with contaminated, infectious and hazardous materials, and when handling animals.

Gloves and personal protective equipment should be removed in a manner that minimizes transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or are manipulated.

Persons must wash their hands after removing gloves, and before leaving the areas where infectious materials and/or animals are housed or are manipulated.

Eye and face and respiratory protection should be used in rooms containing infected animals, as dictated by the risk assessment.

8. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food/drink for human consumption should only be done in designated areas and

are not permitted in animal or procedure rooms.

9. All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.

10. Mouth pipetting is prohibited. Mechanical pipetting devices must be used.

11. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.

When applicable, laboratory supervisors should adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:

a. Needles and syringes or other sharp instruments are limited to use in the animal facility when there is no alternative for such procedures as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

b. Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible. If re-capping is deemed necessary, Standard Operating Procedures shall be followed for using recapping sheaths or the one-handed method only.

c. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.

e. Equipment containing sharp edges and corners should be avoided.

12. Equipment and work surfaces are routinely decontaminated with an appropriate disinfectant after work with an infectious agent, and after any spills, splashes, or other overt contamination.

13. Animals and plants not associated with the work being performed must not be permitted in the areas where infectious materials and/or animals are housed or are manipulated.

14. An effective integrated pest management program is required.

15. All wastes from the animal room (including animal tissues, carcasses, and bedding) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional, local and state requirements.

Decontaminate all potentially infectious materials before disposal using an effective method.

B. Special Practices

None required.

C. Safety Equipment (Primary Barriers and Personal

Protective Equipment)

1. A risk assessment should determine the appropriate type of personal protective equipment to be utilized.

2. Special containment devices or equipment may not be required as determined by appropriate risk assessment.

Protective laboratory coats, gowns, or uniforms may be required to prevent contamination of personal clothing.

Protective outer clothing is not worn outside areas where infectious materials and/or animals are housed or manipulated. Gowns and uniforms are not worn outside the facility.

3. Protective eyewear is worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials.

Persons who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates.

Persons having contact with the NHP should assess risk of mucous membrane exposure and wear appropriate protective equipment (e.g., masks, goggles, face shields, etc.) as needed.

4. Gloves are worn to protect hands from exposure to hazardous materials.

A risk assessment should be performed to identify the appropriate glove for the task and alternatives to latex gloves should be available.

Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.

Gloves must not be worn outside the animal rooms.

Gloves and personal protective equipment should be removed in a manner that prohibits transfer of infectious materials. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated waste.

Persons must wash their hands after handling animals and before leaving the areas where infectious materials and/or animals are housed or are manipulated. Hand washing should occur after the removal of gloves.

D. Laboratory Facilities (Secondary Barriers)

1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building. External facility doors are self-closing and self-locking.

Access to the animal facility is restricted.
Doors to areas where infectious materials and/or animals are housed, open inward, are self-closing, are kept closed when experimental animals are present, and should never be propped open. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

2. The animal facility must have a sink for hand washing. Sink traps are filled with water, and/or appropriate liquid to prevent the migration of vermin and gases.

3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors and ceilings) are water resistant.

It is recommended that penetrations in floors, walls and ceiling surfaces are sealed, to include openings around ducts, doors and door frames, to facilitate pest control and proper cleaning.

Floors must be slip resistant, impervious to liquids, and

resistant to chemicals.

4. Cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

Chairs used in animal area must be covered with a non-porous material that can be easily cleaned and decontaminated. Furniture must be capable of supporting anticipated loads and uses. Sharp edges and corners should be avoided.

5. External windows are not recommended; if present windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens. The presence of windows may impact facility security and therefore should be assessed by security personnel.

6. Ventilation should be provided in accordance with the *Guide for Care and Use of Laboratory Animals*. No recirculation of exhaust air should occur. It is recommended that animal rooms have inward directional airflow.

Ventilation system design should consider the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.

7. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites.

8. If floor drains are provided, the traps are filled with water, and/or appropriate disinfectant to prevent the migration of vermin and gases.

9. Cages are washed, preferably in a mechanical cage washer. The mechanical cage washer should have a final rinse temperature of at least 180°F.

10. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

11. Emergency eyewash and shower are readily available; location is determined by risk assessment.

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

Animal Biosafety Level 2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. ABSL-2 is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 requires that 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals and the manipulation of pathogenic agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations and husbandry procedures; and 4) procedures involving the manipulation of infectious materials, or where aerosols or splashes may be created, should be conducted in BSCs or by use of other physical containment equipment. Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Implementation of employee occupational health programs should be considered.

IX.6.1. ABSL-2 Standard Microbiological Practices

1. The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergency situations.

Worker safety and health concerns are addressed as part of the animal protocol review.

Prior to beginning a study animal protocols must also be reviewed and approved by the IACUC and the Institutional Biosafety Committee.

2. A safety manual specific to the animal facility is prepared or adopted in consultation with the animal facility director and appropriate safety professionals.

The safety manual must be available and accessible.

Personnel are advised of potential hazards, and are required to read and follow instructions on practices and procedures.

Consideration should be given to specific biohazards unique to the animal species and protocol in use.

3. Supervisor must ensure that animal care, laboratory and support personnel receive appropriate training regarding their duties, animal husbandry procedure, potential hazards, manipulations of infectious agents, necessary precautions to prevent hazard or exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.). Personnel must receive annual updates or additional training when procedures or policies change. Records are maintained for all hazard evaluations, employee training sessions and staff attendance.

4. Appropriate medical surveillance program is in place, as determined by risk assessment. The need for an animal

allergy prevention program should be considered.

Facility supervisors should ensure that medical staff is informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, animal care and manipulations.

Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all personnel and particularly women of child-bearing age should be provided information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

Personnel using respirators must be enrolled in an appropriately constituted respiratory protection program.

5. A sign incorporating the universal biohazard symbol must be posted at the entrance to areas where infectious materials and/or animals are housed or are manipulated when infectious agents are present. The sign must include the animal biosafety level, general occupational health requirements, personal protective equipment requirements, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the animal areas. Identification of specific infectious agents is recommended when more than one agent is being used within an animal room.

Security-sensitive agent information and occupational health requirements should be posted in accordance with the institutional policy.

Advance consideration should be given to emergency and disaster recovery plans, as a contingency for man-made or natural disasters.

6. Access to the animal room is limited. Only those persons required for program or support purposes are authorized to enter the animal facility and the areas where infectious materials and/or animals are housed or are manipulated.

All persons including facility personnel, service workers, and visitors are advised of the potential hazards (natural or research pathogens, allergens, etc.) and are instructed on the appropriate safeguards.

7. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.

Gloves are worn to prevent skin contact with contaminated, infectious and hazardous materials and when handling animals.

Gloves and personal protective equipment should be removed in a manner that minimizes transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or are manipulated.

Persons must wash their hands after removing gloves, and before leaving the areas where infectious materials and/or animals are housed or are manipulated.

Eye and face and respiratory protection should be used in rooms containing infected animals, as dictated by the risk assessment.

8. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should only be done in designated areas and are not permitted in animal or procedure rooms.

9. All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.

10. Mouth pipetting is prohibited. Mechanical pipetting devices must be used.

11. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. When applicable, laboratory supervisors should adopt improved engineering and work practice controls that reduce the risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:

a. Needles and syringes or other sharp instruments are limited to use in the animal facility when there is no alternative for such procedures as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

b. Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible. If re-capping is deemed necessary, Standard Operating Procedures shall be followed for using recapping sheaths or the one-handed method only.

c. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

d. Broken glassware must not be handled directly; it should be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.

e. Equipment containing sharp edges and corners should be avoided.

12. Equipment and work surfaces are routinely decontaminated with an appropriate disinfectant after work with an infectious agent, and after any spills, splashes, or other overt contamination.

13. Animals and plants not associated with the work being performed must not be permitted in the areas where infectious materials and/or animals are housed or are manipulated.

14. An effective integrated pest management program is required.

15. All wastes from the animal room (including animal tissues, carcasses, and bedding) are transported from the animal room in leak-proof containers for appropriate disposal in compliance with applicable institutional, local and state requirements.

Decontaminate of all potentially infectious materials before disposal using an effective method. All infectious waste at The Ohio State University is disposed of in biohazard boxes and sent off-site for incineration.

B. Special Practices

1. Animal care staff, laboratory and routine support personnel must be provided a medical surveillance program as dictated by the risk assessment, and administered appropriate immunizations for agents handled or potentially present, before entry into animal rooms.

When appropriate, a base line serum sample should be stored**.**

2. Procedures involving a high potential for generating

aerosols should be conducted within a biosafety cabinet or other physical containment device. When a procedure cannot be performed within a biosafety cabinet, a combination of personal protective equipment and other containment devices must be used.

Consideration should be given to the use of restraint devices and practices that reduce the risk of exposure during animal manipulations (e.g., physical restraint devices, chemical restraint medications, etc). All restraint devices must be reviewed and approved by the IACUC prior to use.

3. Decontamination is recommended for all potentially infectious materials and animal waste before movement outside the areas where infectious materials and/or animals are housed or are manipulated by an appropriate method (e.g. autoclave, chemical disinfection, or other approved decontamination methods). This includes potentially infectious animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse.

Consideration should be given to means for decontaminating routine husbandry equipment, sensitive electronic and medical equipment.

Materials to be decontaminated outside of the immediate areas where infectious materials and/or animals are housed or are manipulated must be placed in a durable, leak proof, covered container and secured for transport. The outer surface of the container is disinfected prior to moving materials. The transport container must contain a universal biohazard label.

Develop and implement an appropriate waste disposal program in compliance with applicable institutional, local and state requirements. Autoclaving of content prior to incineration is recommended.

4. Equipment, cages, and racks should be handled in manner that minimizes contamination of other areas.

Equipment must be decontaminated before repair, maintenance, or removal from the areas where infectious materials and/or animals are housed or are manipulated.

Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.

5. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the safety manual. All such incidents must be reported to the animal facility supervisor or personnel designated by the institution. Medical evaluation, surveillance, and treatment should be provided as appropriate and records maintained.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Properly maintained BSCs, personal protective equipment (e.g., gloves, lab coats, face shields, respirators, etc.) and/or other physical containment devices or equipment, are used whenever conducting procedures with a potential for creating aerosols or splashes. These include cage changes, necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, and intranasal inoculation of animals.

When indicated by risk assessment, animals are housed in primary biosafety containment equipment appropriate for the animal species, such as solid wall and bottom cages covered with filter bonnets for rodents, or larger cages placed in inward flow ventilated enclosures or other equivalent primary containment systems for larger animal cages.

Please note, OSU ULAR policy also requires all procedures, including cage changes, for animals housed in barrier or sterile housing, to be done in a functioning biosafety cabinet.

2. A risk assessment should determine the appropriate type of personal protective equipment to be utilized.

Disposable gowns or lab coats are removed before leaving the animal facility. Reusable clothing is appropriately contained and decontaminated before being laundered. Laboratory and protective clothing should never be taken home.

Gowns, uniforms, laboratory coats and personal protective equipment are worn while in the areas where infectious materials and/or animals are housed or manipulated and removed prior to exiting. Disposable personal protective equipment and other contaminated waste are appropriately contained and decontaminated prior to disposal.

3. Eye and face protection (mask, goggles, face shield or other splatter guard) are used for anticipated splashes/ sprays from infectious or other hazardous materials and when the animal or microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations of airborne particulates.

Persons having contact with the NHP should assess risk of mucous membrane exposure and wear appropriate protective equipment (e.g., masks, goggles, face shields, etc.) as needed. Respiratory protection is worn based upon risk assessment.

4. Gloves are worn to protect hands from exposure to hazardous materials. A risk assessment should be performed to identify the appropriate glove for the task and alternatives to latex gloves should be available.

Gloves are changed when contaminated, integrity has been compromised, or when otherwise necessary.

Gloves must not be worn outside the animal rooms.

Gloves and personal protective equipment should be removed in a manner that prohibits transfer of infectious materials.

Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated waste.

Persons must wash their hands after handling animals and before leaving the areas where infectious materials and/or animals are housed or are manipulated. Hand washing should occur after the removal of gloves.

D. Laboratory Facilities (Secondary Barriers)

1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building. External facility doors are self-closing and self-locking.

Access to the animal facility is restricted.

Doors to areas where infectious materials and/or animals are housed, open inward, are self-closing, are kept closed when experimental animals are present, and should never be propped open. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

2. A hand washing sink is located at the exit of the areas where infectious materials and/or animals are housed or are manipulated. Additional sinks for hand washing should be located in other appropriate locations within the facility.

If the animal facility has segregated areas where infectious materials and/or animals are housed or manipulated, a sink must also be available for hand washing at the exit from each segregated area.

Sink traps are filled with water, and/or appropriate liquid to prevent the migration of vermin and gases.

3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors and ceilings) are water resistant.

Penetrations in floors, walls and ceiling surfaces are sealed, to include openings around ducts, doors and door frames, to facilitate pest control and proper cleaning.

Floors must be slip resistant, impervious to liquids, and resistant to chemicals.

4. Cabinets and bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

Furniture should be minimized. Chairs used in animal area must be covered with a non-porous material that can be easily cleaned and decontaminated. Furniture must be capable of supporting anticipated loads and uses. Sharp edges and corners should be avoided.

5. External windows are not recommended; if present, windows should be sealed and must be resistant to breakage. The presence of windows may impact facility security and therefore should be assessed by security personnel.

6. Ventilation should be provided in accordance with the *Guide for Care and Use of Laboratory Animals*.[1] The direction of airflow into the animal facility is inward; animal rooms should maintain inward directional airflow compared to adjoining hallways. A ducted exhaust air ventilation system is provided. Exhaust air is discharged to the outside without being recirculated to other rooms.

Ventilation system design should consider the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process.

7. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas, to facilitate cleaning and minimize the accumulation of debris or fomites.

8. Floor drains must be maintained and filled with water, and/or appropriate disinfectant to prevent the migration of vermin and gases.

9. Cages should be autoclaved or otherwise decontaminated prior to washing. Mechanical cage washer should have a final rinse temperature of at least 180°F. The cage wash area should be designed to accommodate the use of high pressure spray systems, humidity, strong chemical disinfectants and 180°F water temperatures, during the cage/equipment cleaning process.

10. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

11. If BSCs are present, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.

HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper biosafety cabinet performance and air system operation must be verified. Correct performance of the BSCs should be recertified at least once a year.

All BSCs should be used according to manufacturer's recommendation, to protect the worker and avoid creating a hazardous environment from volatile chemical and gases.

12. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

13. An autoclave should be considered in the animal facility to facilitate decontamination of infectious materials and waste.

14. Emergency eyewash and shower are readily available; location is determined by risk assessment.

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

A complete description of Animal Biosafety Level 3 can be found in the BMBL 5th edition. Specific ABSL-3 practices and procedures for work at the University are described in the ABSL-3 facility safety manuals.

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Appendix B. Select Agents and Toxins

The Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) oversee the possession, use and transfer of select agents and toxins in the Unites States. Select agents and toxins are biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Select agents and toxins are listed in Table 1 of this appendix.

Select agent regulations require entities to implement many provisions, including without limitation, Department of Justice security risk assessments of all individuals who will access select agents; providing training to all staff with access to ensure safety and security while conducting research involving select agents or toxins; developing biosecurity, biosafety, and incident response plans; and maintaining records, e.g. select agent inventory and access records and training documentation. Certain individuals, referred to as restricted persons, cannot possess or have access to select agents or toxins. Personnel are subject to significant criminal and civil penalties for the inappropriate use, possession, or transfers of select agents and toxins.

The attenuated strains of select agents that are excluded from Select Agent Regulations can be found at http://www.selectagents.gov/exclusions.htm#hhsAgents. An excluded attenuated strain will be subject to the regulations if there is any reintroduction of factor(s) associated with virulence or other manipulations that modify the attenuation such that virulence is restored or enhanced.

Table 2 of this appendix lists the toxins, which are excluded from select agent regulations when the amount under the control of a principal investigator does not exceed, at any time, the amounts indicated in Table 2 of this appendix.

For additional information, contact the Responsible Official (RO) or Alternate Responsible Official (ARO) at the Office of Environmental Health & Safety at 292-1284. All select agent and toxin shipments to or from The Ohio State University require prior approval from the RO. The Ohio State University has designated the Responsible Official the authority and control to ensure compliance with Select Agent Regulations.

TABLE 1: SELECT AGENT AND TOXIN LIST
HHS SELECT AGENTS AND TOXINS
Abrin
Botulinum neurotoxins *
Botulinum neurotoxin producing species of *Clostridium* *
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus *
Francisella tularensis *
Lassa fever virus
Lujo virus
Marburg virus *
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing Any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associate coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses: Chapare Guanarito Junin Machupo Sabia
Staphylococcal enterotoxins A, B, C, D, E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses: Far Eastern subtype Siberian subtype

Kyasanur Forest disease virus Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus) *
Variola minor virus (Alastrim) *
Yersinia pestis *
OVERLAP SELECT AGENTS AND TOXINS
Bacillus anthracis *
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei *
Burkholderia psuedomallei *
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus
USDA SELECT AGENTS AND TOXINS
African horse sickness virus
African swine fever virus
Avian influenza virus
Classical swine fever virus
Foot-and-mouth disease virus *
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum
Mycoplasma mycoides
Newcastle disease virus [1]
Peste des petits ruminants virus
Rinderpest virus *
Sheep pox virus
Swine vesicular disease virus
USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae

Synchytrium endobioticum
Xanthomonas oryzae

* Denotes Tier 1 Agent

[1] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

Table 2. EXCLUDED TOXIN QUANTITIES

Toxin	**Permissible amount***
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, E)	5.0 mg
T-2 toxin	1000 mg
Tetrodotoxin	100 mg

Appendix C. Infectious Waste Guidelines

C.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;
2. proper packaging;
3. proper treatment;
4. personnel training;
5. spill and containment plans;
6. spill response;
7. spill reporting; and
8. contingency plans.

It is the PI's/Supervisor's responsibility to notify the Institutional Biosafety Committee, or OEHS 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 wish to treat their own infectious waste must register with OEHS at **614-292-1284**, obtain a treatment facility permit from OEPA and undergo quarterly laboratory audits by OEHS and a representative of OEPA. Records must be kept of all waste treatment and disposal. This includes treating liquid waste with bleach and disposing in the sanitary sewer.

C.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 managed;

3. Pathological wastes, including, without limitation, human and animal tissues, organs, and body parts, and body fluids and excreta that are contaminated with or are likely to be contaminated with infectious agents, removed or obtained during surgery or autopsy or for diagnostic evaluation provided that, with regard to pathological waste from animals, the animals have or are likely to have been exposed to a zoonotic or infectious agent;

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. Also included are waste materials from the rooms of patients who have been placed on blood and body fluid precautions under the Universal Precaution System established by the Centers for Disease Control and Prevention in the Public Health Service of the United States Department of Health and Human Services, if specific wastes generated under the Universal Precaution System have been identified as infectious wastes by rules referred to in **§ C.2.8** below;

5. Human and animal blood specimens and blood products that are being disposed of provided that with regard to "blood specimens and blood products" from animals, the animals were or were likely to have been exposed to a zoonotic or infectious agent. Blood products do not include patient care waste such as bandages or disposable gowns that are lightly soiled with blood or bodily fluids unless such wastes are soiled to the extent that the generator of the wastes determines that they should be managed as infectious wastes;

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

7. Sharp wastes used in the treatment, diagnosis, 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 the Public Health Council created in Section 3701.33 of the Revised Code, by rules adopted in accordance with Chapter 119 of the Revised Code, identifies as infectious waste after determining that the wastes represent a substantial threat to public health when improperly managed because they are contaminated, or likely to be contaminated with infectious agents.

C.3 Packaging, Storage and Disposal of Untreated Infectious Waste

To meet Ohio Administrative Code Section **3745-27-30** for the packaging, storage and disposal of infectious waste, OSU requires the following:

C.3.1 Material

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

2. All material in **C.3.1.1** except sharps containers are available at no charge from EHS, excluding the Medical Center operations. Contact Environmental Services in the Hospital for additional information. Sharps containers are available through the Medical Stores. For university locations, delivery of waste supplies can be requested by logging into the EHS Online secure web application.

C.3.2 Packaging

1. Assemble the infectious waste box provided by Environmental Health and Safety (OEHS) and ensure that all markings are oriented correctly with the “Up Arrows” pointed upward.

2. Tape all seams with sturdy packaging tape. **NOTE**: Masking tape is not acceptable.

3. Line the infectious waste box with the EHS provided red plastic infectious waste bag prior to placement of infectious waste materials into the container.

4. Place only infectious material or infectious contaminated materials in the infectious waste bags used to line infectious waste boxes.

5. Store liquid infectious waste in Department of Transportation (DOT) approved plastic containers or carboys prior to packaging for pickup. **NOTE**: Total liquid volume is not to exceed four (4) gallons.

6. Place liquid containing infectious waste containers in the bottom of lined infectious waste boxes to facilitate pickup and storage. **NOTE**: Total liquid volume is not to exceed four (4) gallons.

7. **Limit the total weight in the infectious waste boxes to 30 pounds.**

8. Seal the bag prior to sealing the box.

9. Seal the box securely with packaging tape.

10. Include the building name, room number and the name of the principal investigator or lab supervisor, waste request number on the top of the box.

11. Arrange for pickup of packaged infectious waste or to request storage containers or packaging materials via the EHS website (https://ehs.osu.edu/secure/apps

C.3.3 Storage

1. Lock outside storage areas containing infectious waste containers to prevent unauthorized access.

2. Designate infectious waste storage areas. Those storage areas that are not locked, shall be visibly labeled with a sign stating "Warning: Infectious Waste" and/or displaying the international biohazard symbol on all points of access.

C.3.4 Disposal

1. Request pick-up of packaged infectious waste via the EHS website (https://ehs.osu.edu/secure/apps).

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 as defined in Section 6111.01 of the Revised Code, unless the discharge is inconsistent with the terms and conditions of any permit for the system involved under Chapter 6111 of the Revised Code (**OAC 3745-27-30-C**).

C.3.5 Spills

1. All individuals who use biohazard 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 biohazard 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 C.7 and C.8 are provided to meet these requirements. Modifications of procedures must be forwarded to OEHS for review and comments.

C.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 **C.3**. Contact OEHS at **614-292-1284** for further assistance.

C.5 Treatment by Steam Sterilization

1. Those who wish to treat infectious waste onsite using steam sterilization must also comply with **OAC 3745-27-32** and be permitted by OEPA. Contact Environmental Health and Safety for more information.

C.6 Chemical Treatment

Chemical treatment of infectious waste also requires complying with **OAC 3745-27-32 and be permitted by OEPA**. Contact Environmental Health and Safety for information.

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.

C.7 Spill Containment and Clean-up Procedures

According to **OAC 3745-27-30**, spill containment and a clean-up kit shall be available in those areas designated in the Spill Containment and Cleanup Procedures. The location of the kits shall provide for rapid and efficient clean up of spills anywhere within these areas.

C.7.1 Spill Kit Materials

The kit shall include but is not limited to:

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.

8. First aid kit unless emergency care is available on the premises.

9. Boundary tape and other appropriate safety equipment.

C.7.2 Clean-up Procedures

1. A copy of the clean-up procedures is provided later in this section (see D.9);

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

C.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.

C.8 Contingency Plan

In accordance with **OAC 3745-27-32** and **35**, a contingency plan for treatment facilities 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.

C.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.

8. Contain and clean up any spill of infectious waste within a storage area using approved methods.

CONTINGENCY PLAN

Emergency Coordinator:

Telephone:

Alternate Coordinator: Michael St. Clair, EHS Telephone: 614-292-1284

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

    a. Notify your Emergency Coordinator;

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

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

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

    a. OSU Police Dispatcher: 911 from campus phone

    b. OEHS Chemical/Infectious Waste Management: **(614)292-1284**

    c. OEHS Main Office: **(614)292-1284**

    d. OEPA Central District Office: **(614)728-3778**

    e. Emergency Number: **911**

    f. Columbus Health Department: **(614)645-7417**

CONTACT: Michael St. Clair, 1314 Kinnear Rd; Tel: (614)292-1284

D.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.

INFECTIOUS WASTE SPILL CONTAINMENT AND CLEAN-UP PROCEDURE

Infectious waste spills must be contained and cleaned up immediately.

I. A spill kit containing absorbent material, bleach or another USEPA registered tuberculocidal disinfectant, biohazard bags, gloves, eye protection, and a biohazard sharps container must be accessible in the laboratory.

II. To use bleach as a disinfectant, a 1:10 dilution (minimum 10% sodium hypochlorite solution) of household bleach should be prepared immediately prior to use, with a minimum of 30 minutes contact time with the waste. If another USEPA registered tuberculocidal disinfectant is used, the manufacturer's recommendations for concentration and contact time should be followed.

1. Limit access to area to authorized personnel.

2. Open the spill kit.

3. Put on appropriate PPE (i.e. gloves, eye protection, coveralls).

4. Contain liquid spills by covering with absorbent pads. Place contaminated absorbent pads and other contaminated solids into a biohazard bag. Seal the bag by tying in a knot and place

into a second biohazard bag. Sharps (i.e. needles, blades or broken glassware) associated with the spill should be placed in a biohazard sharps container.

5. Clean the spill and cover contaminated surfaces with absorbent pads and soak with appropriate disinfectant (See II above). Allow the disinfectant to stand on the contaminated material for the minimum recommended contact time.

6. Place all materials used during the clean up process in a biohazard bag. Seal the bag by tying in a knot and place into a second bag. Place all biohazard bags into a biohazard burn box.

7. Disinfect all re-usable materials from the spill kit (i.e. goggles, dustpan, etc.) and put back into the kit. Replenish disposable items from the spill kit.

See the OSU Institutional Biosafety Manual for additional information on Decontamination and Spills
(http://ehs.osu.edu/manuals.aspx)

FOR ASSISTANCE OR QUESTIONS, CONTACT THE OFFICE OF ENVIRONMENTAL HEALTH & SAFETY AT 614-292-1284 OR THE OSU POLICE DISPATCHER AT 911 FROM A CAMPUS TELEPHONE, 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:
Michael St. Clair
Office of Environmental Health and Safety
Room 210
1314 Kinnear Road, CAMPUS

Appendix D. Accident / Incident Follow-Up Information

For severe or life threatening injuries to employees of The Ohio State University, call 911 (campus phone) or 614-292-2525 (cell phone) immediately. Also, promptly contact the Office of Environmental Health & Safety (OEH&S) at 614-292-1284 to report the injury.

For minor occupational injuries, the supervisor should direct the employee to University Health Services, located at McCampbell Hall, 2nd Floor, 1581 Dodd Dr., (614-293-8146).

For all injuries, the supervisor shall:

- Ensure that an OSU Employee Accident Report is completed and submitted to Employee Health Services; and,
- Investigate the incident to determine a root cause; and as appropriate, implement measures to prevent recurrence. Note: For assistance or if you have questions, contact the OSU Office of Environmental Health & Safety.

What is the purpose of accident / incident investigation?

Intent is prevention and correction (i.e., identify the root cause(s), not to assign blame)

Definitions

ACCIDENT: an undesired event that results in personal injury or property damage

INCIDENT: an unplanned, undesired event that adversely affects completion of a task

NEAR MISS: incidents where no property was damaged and no personal injury sustained, but where, given a slight shift in time or position, damage and/or injury easily could have occurred

When should you conduct an investigation?

All incidents whether a near miss or an actual injury-related event should be investigated. Near miss reporting and investigation enable identification and control of hazards before they cause a more serious incident. Accident/incident

investigations are tools for uncovering hazards that were either missed during earlier job hazard analyses or have managed to slip away from the controls planned for them. To be useful, an investigation needs to be done with the aim of discovering every contributing factor to the accident/incident in order to "fail-safe" the condition and/or activity to prevent reoccurrence.

While all accidents should be investigated, including accidents involving property damage only; the extent of the investigation shall be reflective of the seriousness of the accident.

When an accident results in a fatality or hospitalization of employees, promptly contact the Office of Environmental Health & Safety. In these situations, (except to the extent necessary to protect employees and the public) evidence at the scene of an accident shall be left untouched until the site has been inspected by health and safety officials.

Who should investigate?

The usual investigator for incidents is the supervisor in charge of the involved area and/or activity. The supervisor should be accountable for accidents in his/her area, should know the situation and the people involved best, has a personal interest in cause identification and can take immediate corrective action. The injured or impacted employee should be involved as the individual can clarify any uncertainties by providing details on what happened and why it occurred. Employee involvement in investigations will not only provide additional expertise and insight, but in the eyes of the workers, will lend credibility to the results. Employee involvement can enhance employee knowledge of potential hazards and the experience can make employees advocates of the importance of safety thus strengthening the safety culture of the organization.

OEH&S will assist with investigation of accidents involving fatalities, serious injuries or extensive property damage. Upon request, OEH&S will provide assistance investigating any accident, incident or near miss. OEH&S will review the investigation findings and recommendations.

The investigation report should answer six key questions

Six key questions should be answered: who, what, when, where, why and how. Fact should be distinguished from opinion and both should be presented carefully and clearly. The report should include thorough interviews with everyone with any knowledge of the incident. A good investigation is likely to reveal several contributing factors, and it probably will recommend several preventive actions.

Avoid the trap of laying sole blame on the injured employee. Even if an injured worker openly blames his/herself for making a mistake or not following a prescribed process; the accident investigator should not be satisfied that all contributing causes have been identified. The error made by the employee may not be the most important contributing cause. The employee who has not followed prescribed procedures may have been encouraged directly or indirectly by a supervisor or expected workload to "cut corners". The prescribed procedures may not be practical or even safe in the eyes of the employee. Sometimes where elaborate and difficult procedures are required, engineering redesign might be a better answer. In such cases, management error – not employee error – may be the most important contributing cause.

All supervisors and others who investigate accidents/incidents should be held accountable for describing causes carefully and clearly. Investigation reports should not include catch-phrases, such as "Employee did not plan job properly." While such a statement may suggest an underlying problem with this worker, it is not conducive to identifying all possible causes, preventions and controls. Certainly, it is too late to plan a job when the employee is about to do it. Further, it is unlikely that safe work will always result when each employee is expected to plan procedures alone.

Implications of accident investigations

Recommended preventive actions should make it very difficult, if not impossible, for the incident to recur. The investigative report should list all the ways to "fail-safe" the condition or activity. Considerations of cost or engineering should not enter at this

stage. The primary purpose of accident investigations is to prevent future occurrences. Beyond this immediate purpose, the information obtained through the investigation should be used to update and revise controls used to reduce hazards to employees. For example, the Job Safety Analysis should be revised and employees retrained to the extent that it fully reflects the recommendations made by an accident/incident investigation report. Implications from the root causes of the accident need to be analyzed for their impact on all other operations and procedures.

References:

Occupational Safety and Health Administration Fact Sheets: Accident/ Incident Investigations.

Occupational Safety and Health Administration: Accident/ Incident Investigation Tools and Tips.

APPENDIX E. Plant Biosafety

This appendix specifies physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant DNA-containing plants, plant-associated microorganisms, and small animals.

Plant-associated microorganisms include viroids, virusoids, viruses, bacteria, fungi, protozoans, certain small algae, and microorganisms that have a benign or beneficial association with plants, such as certain *Rhizobium* species and microorganisms known to cause plant diseases. The appendix applies to microorganisms which are being modified with the objective of fostering an association with plants.

Plant-associated small animals include those arthropods that: (i) are in obligate association with plants, (ii) are plant pests, (iii) are plant pollinators, or (iv) transmit plant disease agents, as well as other small animals such as nematodes for which tests of biological properties necessitate the use of plants. Microorganisms associated with such small animals (e.g., pathogens or symbionts) are included.

The principal purpose of plant containment is to avoid the unintentional transmission of a recombinant DNA-containing plant genome, including nuclear or organelle hereditary material or release of recombinant DNA-derived organisms associated with plants.

The containment principles are based on the recognition that the organisms that are used pose no health threat to humans or higher animals (unless deliberately modified for that purpose), and that the containment conditions minimize the possibility of an unanticipated deleterious effect on organisms and ecosystems outside of the experimental facility, e.g., the inadvertent spread of a serious pathogen from a greenhouse to a local agricultural crop or the unintentional introduction and establishment of an organism in a new ecosystem.

Plant containment levels BL1-P through BL4-P are designed to provide differential levels of biosafety for plants in the absence or presence of other experimental organisms that contain recombinant DNA.

For experiments in which plants are grown at the BL1 through BL4 laboratory settings, containment practices shall be followed as described in Chapter VI of this manual. These containment practices include the use of plant tissue culture rooms, growth chambers within laboratory facilities, or experiments performed on open benches.

Plant Biosafety Levels - The following information is taken from the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (2012).

Biosafety Level 1 - Plants (BL1-P)

Standard Practices (BL1-P)

Greenhouse Access (BL1-P)

Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, when experiments are in progress.

Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL1-P greenhouse practices and procedures. All procedures shall be performed in accordance with accepted greenhouse practices that are appropriate to the experimental organism.

Records (BL1-P)

A record shall be kept of experiments currently in progress in the greenhouse facility.

Decontamination and Inactivation (BL1-P)

Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Control of Undesired Species and Motile Macroorganisms (BL1-P)

A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and Federal laws.

Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Concurrent Experiments Conducted in the Greenhouse (BL1-P)

Experiments involving other organisms that require a containment level lower than BL1-P may be conducted in the greenhouse concurrently with experiments that require BL1-P containment, provided that all work is conducted in accordance with BL1-P greenhouse practices.

Facilities (BL1-P)

Definitions (BL1-P)

The term "greenhouse" refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all

immediately contiguous hallways and head-house areas, and is considered part of the confinement area.

Greenhouse Design (BL1-P)

The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended.

Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

Biosafety Level 2 - Plants (BL2-P)

Standard Practices (BL2-P)

Greenhouse Access (BL2-P)

Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Director, to individuals directly involved with the experiments when they are in progress.

Personnel shall be required to read and follow instructions on BL2-P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms.

Records (BL2-P)

A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility.

A record shall be kept of experiments currently in progress in the greenhouse facility.

The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Director, Institutional Biosafety Committee, NIH/OBA and other appropriate authorities immediately (if applicable). Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Documentation of any such accident shall be prepared and maintained.

Decontamination and Inactivation (BL2-P)

Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.

Control of Undesired Species and Motile Macroorganisms (BL2-P)

A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws

Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Concurrent Experiments Conducted in the Greenhouse (BL2-P)

Experiments involving other organisms that require a containment level lower than BL2-P may be conducted in the greenhouse concurrently with experiments that require BL2-P containment provided that all work is conducted in accordance with BL2-P greenhouse practices.

Signs (BL2-P)

A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area.

If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors.

If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Transfer of Materials (BL2-P)

Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed non-breakable container.

Greenhouse Practices Manual (BL2-P)

A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

Facilities (BL2-P)

Definitions (BL2-P)

The term "greenhouse" refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth.

The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas and is considered part of the confinement area.

Greenhouse Design (BL2-P)

A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil.

Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds)

Autoclaves (BL2-P)

An autoclave shall be available for the treatment of contaminated greenhouse materials.

Supply and Exhaust Air Ventilation Systems (BL2-P)

If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

Other (BL2-P)

BL2-P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macro organisms in a manner that satisfies the intent of the foregoing clauses.