Illinois State University

Institutional Biosafety Guidelines

For the use of rDNA and Potentially Infectious Material

Created by Environmental Health and Safety
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POLICY AND PROCEDURES MANUAL FOR

THE INSTITUTIONAL BIOSAFETY PROGRAM

1. Introduction

The purpose of the Illinois State University Biosafety Program is to protect the faculty, staff, and students from exposure to biohazardous materials. Illinois State University is taking precautionary measures to guard against the release of biohazardous materials that may harm humans, animals, plants, or the environment. The Institutional Biosafety Committee (IBC) develops, reviews, and updates guidelines describing standard procedures for the use of biohazards. IBC also wants to protect the integrity of experiments being conducted at the University. The Institutional Biosafety Committee will see that the proper training resources are available along with making sure that medical surveillance, hazard identification, and recordkeeping are being utilized in the laboratories. The IBC will review resources within the laboratory for safety compliance. They have the responsibility of reviewing, approving, and surveilling all research protocols at Illinois State University. That involves the use of recombinant DNA (rDNA), genetically altered organisms (GMO's) and biohazardous agents including infectious agents to humans, plants, and animals in accordance with NIH and CDC requirements. All research will be reviewed by Research & Sponsored Programs that involve biohazards, regardless of its source of financial support. The research must be approved by the IBC and must conform to the IBC policies and procedures.

2. When IBC is Needed

The Institutional Biosafety Committee affects everyone at the University. It evaluates the risks to the health and safety of the faculty, staff, students, or visitors. The IBC plays a large role for the scientists who conduct research that utilizes rDNA or potentially infectious agents at risk groups and biosafety levels 1-4. It also affects scientists doing non-rDNA or non-infectious agent research to ensure that the type of work being performed in the laboratory meets institutional requirements.

3. Definitions

- **Aerosols-** Colloids of liquid or solid particles less than 10 microns in diameter suspended in gas.
- **Autoclave-** A device designed to sterilize equipment or biological waste using heat, steam, and pressure within a chamber.
- **Biological Agents-** Infectious agents and recombinant DNA molecules.
- **Biohazardous Agent-** A pathogen capable of replication and capable of causing diseases in humans, animals, or plants. Biohazardous agent refers to the agent itself while biohazardous material refers to material that harbors the biohazardous agents.
- **Biological Waste-** Laboratory waste means any of the following:
    - Human or animal specimen cultures from medical and pathology laboratories.
    - Cultures and stocks of infectious agents from research and industrial laboratories

    - Waste from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis and Contagious Ecthyma, as identified by the department, and culture dishes and devices used to transfer, inoculate, and mix cultures
- **Biological Barrier-** An impediment (naturally occurring or introduced) to the infectivity and/or survival of a biohazardous agent.
- **Biological Safety Cabinet-** A device enclosed on three sides, top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user.
- **Biosafety Level-** Laboratory practices, techniques, safety equipment and laboratory facilities appropriate for the operations performed and the hazards posed by the particular biohazard material. The National Institutes of Health (NIH) and the Centers for Disease Control (CDC) define four levels of biosafety and four levels of animal biosafety in the Health and Human Services Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, May 1993. This publication recommends biosafety levels for work with particular microorganisms. Biosafety levels of specific agents are listed in the "Biosafety Levels for Infectious Agents and Infected Animals."
- **Bloodborne Pathogens-** Pathogenic microorganisms that are present in human and other primate blood and can cause diseases in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV), and the Human Immunodeficiency Virus (HIV).
- **Clinical Laboratory-** Workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.
- **Containment-** The confinement of a biohazardous agent that is being cultured, stored, manipulated, transported, or destroyed in order to prevent or limit its contact with people and/or the environment. Methods used to achieve this include physical and biological barriers and inactivation using physical or chemical means.
- **Decontamination-** The removal or neutralization of toxic agents or the use of physical or chemical means to remove, inactivate, or destroy living organisms on a surface or item so that the organisms are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- **Diagnostic Specimen-** Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, tissue fluids being analyzed for purposes of diagnosis. (CDC Interstate Shipment of Etiologic Agents)
- **Disinfection-** A process by which viable biohazardous agents are reduced to a level unlikely to produce disease in healthy people, plants, or animals.
- **Engineering Controls-** Controls (e.g., sharps containers, self-sheathing needles) that isolate or remove a hazard from the workplace.
- **Exposure Incident-** Contact with blood or other potentially infectious materials that result from the performance of an employee's duties.
- **HEPA filter-** High Efficiency Particulate Air Filter; a disposable extended pleated-medium, dry type filter with (1) rigid casing enclosing the full depth of the pleats (2) minimum particulate removal of 99.97 percent for thermally generated monodisperse dioctyl phthalate (DOP) smoke particles with a

diameter of 0.3 um and (3) maximum pressure drop of 1.0 in wg when clean and operated at rated airflow capacity.

- **Inactivation-** Any process that destroys the ability of a specific biohazardous agent to self-replicate.
- **Infectious Agent-** An organism (virus, rickettsia, bacteria, fungus, protozoan or helminth) that is capable of producing infection or disease in humans or animals.
- **Infectious Waste-** Solid waste that contains pathogens with sufficient virulence and in sufficient quantity that exposure of a susceptible human or animal to the solid waste could cause the human or animal to contract an infectious disease.
- **Interstate Traffic-** The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country. NOTE: Interstate shipping is interpreted to include intrastate shipping. (CDC Interstate Shipment of Etiologic Agents)
- **Laminar Airflow-** Unidirectional airflow through the work area often referred to as (1) turbulence-free airflow; (2) steady unidirectional micro turbulence flow; or (3) mass air flow.
- **Mixed Waste-** Waste that contains a combination of hazardous constituents. For example, waste that is contaminated with biohazardous, radioactive, and chemical substances is considered mixed waste.
- **Medical waste-** A medical waste is defined as any:
    - Biohazardous laboratory waste, such as specimen or microbiological cultures, stocks of infectious agents, live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;
    - Liquid blood, including fluid blood, fluid blood products, containers or equipment containing blood that is fluid;
    - Sharps, including syringes, needles, blades, intact or broken Pasteur pipettes, other broken glass items such as blood tubes and vials, acupuncture needles, intact and fragmented teeth and root canal files;
    - Contaminated animals, including animal carcasses, body parts and bedding materials that the attending veterinarian knows to be or suspects of being contaminated with infectious agents know to be pathogenic for humans;
    - Surgical specimens, including human or animal parts or tissues removed surgically or by autopsy that the attending physician, surgeon, or dentist knows to be or suspects of being contaminated with infectious agents known to be pathogenic for humans;.
    - Isolation waste, highly communicable diseases, waste contaminated with human or animal excretion, exudates, or secretions.
- **NIH-** National Institutes of Health.
- **Occupational Exposure-** Reasonably anticipated skin, eyes, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

- **Office of Recombinant DNA Activities (ORDA)-** The office within the NIH responsible for reviewing experimental activities related to recombinant DNA.
- **OSHA-** Occupational Safety and Health Administrations.
- **Other Potentially Infectious Materials (OPIM)-** Materials in addition to human blood that may be capable of transmitting bloodborne pathogens. These include:
    - The following human bodily fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental settings, any bodily fluid that is visibly contaminated with blood, and all bodily fluids in situations where it is difficult or impossible to differentiate between bodily fluids.
    - Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
    - HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medial or other solutions as well as human cell cultures not shown to be free of bloodborne pathogens.
    - Blood, organs, or other tissues from experimental animals infected with HIV or HBV.
- **Parenteral-** Piercing mucous membrane or the skin barrier through events such as needlesticks, human bites, cuts, and abrasions.
- **Pathogen-** Any biohazardous agent that is capable of producing disease in healthy people, plants, or animals.
- **Personal Protective Equipment (PPE)-** Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.
- **Personal Protection-** Techniques or devices designed to eliminate or significantly reduce employee risk.
- **Physical Barrier-** Any equipment, facilities, or devices (e.g., fermenters, factories, filters, thermal oxidizers) that are designed to achieve containment or exclusion.
- **Plenum-** An enclosure for flowing gases in a biosafety cabinet in which the static pressure at all points is relatively uniform.
- **Pleural Fluid-** Fluid from lung tissue
- **Post-exposure follow up-** In the case of an exposure incident, the mandatory course of action taken by the employer to provide medical services (i.e. medical assessment, vaccination, source testing, baseline testing, counseling) to the exposed worker in order to reduce the risk of infection.
- **Production facility-** Facility engaged in industrial scale, large volume, or high concentration production
- **Recombinant DNA Advisory Committee (RAC)-** The public advisory committee that advises the Director of the NIH on recombinant DNA matters.
- **Recombinant DNA (rDNA)-** Defined as either:
    - Molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or
    - DNA molecules that result from the replication of those described in above definition.

- **Research Laboratory-** A laboratory producing or using research-laboratory-scale volumes or concentrations
- **Sharps-** Instruments, tools, or items that have rigid, acute edges, protuberances, or corners capable of cutting, piercing, ripping or puncturing such as syringes, blades, and broken glass. Items that have the potential for shattering or breaking are also considered sharps.
- **Sterilize-** The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
- **Synovial fluid-** Fluid from the joints such as the knees or elbows.
- **Universal Precautions-** An approach to infection control that treats all human blood and certain body fluids as if known to be infectious for HIV, HBV, and other bloodborne pathogens
- **Work Practice Controls-** Controls that reduce the likelihood of exposure to bloodborne pathogens by altering the manner in which a task is performed.

4. Responsibilities

a. Research & Sponsored Programs (RSP)

The Research & Sponsored Programs office is responsible for the submission and management of projects with funding sources external to the University. The RSP has been designated as the office to prepare, review, and negotiate all grants and contracts for externally sponsored projects. They are also responsible for contract negotiation and approval of institutionally initiated projects, such as those handled by the Extended University. The office manages pre-award sponsored project activities of Illinois State University. RSP ensures compliance with all institutional, state, and federal regulations, including human subjects and animal care. Further, they provide guidance and support to the University community on externally sponsored research opportunities and sponsored projects award administration. The primary intent of the review is to determine whether a proposal fulfills legal and policy requirements for sponsored projects.

b. Environmental Health & Safety (EHS)

The Environmental Health & Safety office is responsible for compliance with all applicable health and safety regulations. EHS is to maintain up-to-date records of current health and safety standards and provide information to the University upon request. The records would cover accidents, fire incidents, job related injuries, radiation exposure, biohazardous exposure and other records as required by law. Recommendations would also be given for corrective action and forwarded to the respective colleges, divisions, or departments. Training assistance is available along with inspections, consultations, and emergency response. The Environmental Health & Safety office interprets laws and regulations and provides assistance to departments in achieving regulatory compliance and developing proactive strategies. EHS works to prevent or minimize injuries and illnesses through the recognition, evaluation,

and control of potential hazards arising from University activities. EHS also has the responsibility of monitoring and providing services in conformity with the procedures and standards set forth in the Biosafety Manual.

c. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee is composed of no fewer than five members who are responsible for review, approval, and surveillance of all teaching and research projects involving the use of biohazardous agents and rDNA. The members of the IBC are selected so that they collectively have experience and expertise in: recombinant DNA and infectious agents technology; the capability to assess the safety of the research experiments; and, the capability to assess any potential risk to the public or the environment. Additionally, two members will represent the health and environmental interests of the surrounding community and have no affiliation with ISU other than membership on the IBC. The members are appointed for a term of three years.

The IBC shall review and approve rDNA and potentially infectious agent projects in accordance with the NIH/CDC requirements along with OSHA. A "protocol" is the document to be submitted to the IBC for its review and approval of potential research projects. The Committee assures that such activities and related facilities are in compliance with applicable University procedures and external guidelines and regulations. The IBC is responsible for recommending University procedures on the use of biohazardous agents and rDNA. They also advise the University on matters related to biosafety, reviewing, and approving proposed uses of biohazardous agents, and advising EHS in carrying out the Biosafety Program. The IBC has additional responsibilities such as the following:

- Notifying the Principal Investigator of the results of the IBC's review and decisions
- Lowering/raising containment levels for certain experiments
- Setting containment levels
- Annual review of rDNA/infectious agents research to ensure compliance
- Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA and infectious agent research

d. Biological Safety Officer (BSO)

The Institutional Biological Safety Officer is a member of the Institutional Biosafety Committee and is responsible for facilitating the operations of the Biosafety Program. The BSO is also responsible for assuring that the use of biological agents conforms to the University procedures and applicable governmental regulations, and for referring the IBC matters requiring its review and approval. Other responsibilities of the BSO include the following:

- Ensuring thorough periodic inspections that laboratory standards are rigorously followed

- Reporting to the IBC all significant problems with and violations of the guidelines and all significant research-related accidents and illnesses of which the BSO becomes aware unless the BSO determines that the PI has already done so
- Ensuring that each laboratory has emergency plans for dealing with accidental spills and personnel contamination, and investigating research laboratory accidents
- Providing advice on laboratory security
- Providing technical advice to the PI and the IBC on research safety procedures

e. Department Chair

The Department Chair is responsible for reviewing and approving the completed protocol that is being proposed by the Principle Investigator. The Department Chair is responsible for the general safety of the faculty, staff, and students working with biological agents in his/her jurisdiction. Additional responsibilities of the Department Chair include the following:

- Ensure that prior to initiation of work, each PI using a biological agent files the appropriate registration form(s).
- Mutually responsible, with the PI, for informing the IBC of work involving biological agents and reporting accidents or incidents involving such agents to the Biological Safety Officer.
- Determines that appropriate facilities and safety equipment are available for proposed research or instruction involving biological agents.
- Mutually responsible, with faculty members supervising the teaching laboratories or field sites, for informing students of proper precautions and safety procedures to be taken when working with biological agents and assuring that those precautions are taken.
- Signature for initial and annual Memorandum of Understanding and Agreement (MUA) and registration to ensure that the laboratories are in compliance.

f. Principle Investigator (PI)

On behalf of Illinois State University, the Principle Investigator is responsible for full compliance with the NIH/CDC Guidelines and OSHA in the conduct of rDNA and potentially infectious agents. As overall guidelines of responsibility, the PI shall conform to but not limited to:

- Instructing and training staff in the practices procedures for dealing with accidents.
- Supervising the safety performance of their staff to ensure they follow safe practices and techniques.
- Informing the staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccination or serum collection when necessary.
- Making available to the laboratory staff copies of the manuals and procedures that describe the potential biohazards and the necessary precautions.
- Making available a copy of the Biosafety Manual. The University's Biosafety Manual that contains biosafety standards from NIH, CDC, and other regulations. The manual also includes

information about the specific hazards of each class of biohazardous agents. The manual must be available in every relevant laboratory on campus.

- Maintaining written documentation for all training activities, which includes the review of protocols by all laboratory personnel.
- Investigating and reporting, in writing to the BSO and the IBC, any significant problems or incidents pertaining to the operation and implementation of containment practices and procedures.
- Correcting conditions that may result in the release of biological agents.
- Ensuring the integrity of the physical containment (e.g., biosafety cabinet) and the biological containment (e.g. purity, genotypic and phenotypic characteristics).
- Making available a copy of CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* 4th edition if the laboratory is working with infectious material.
- Making available a copy of NIH *Guidelines for Research Involving Recombinant DNA Molecules* if the laboratory is working with rDNA.
- Ensuring compliance with NIH and CDC guidelines.

g. Lab Workers/Students/Participants

In order to reduce laboratory hazards and to promote an increased awareness for worker safety, it is the responsibility of the lab workers, students, and other participants to abide by the following:

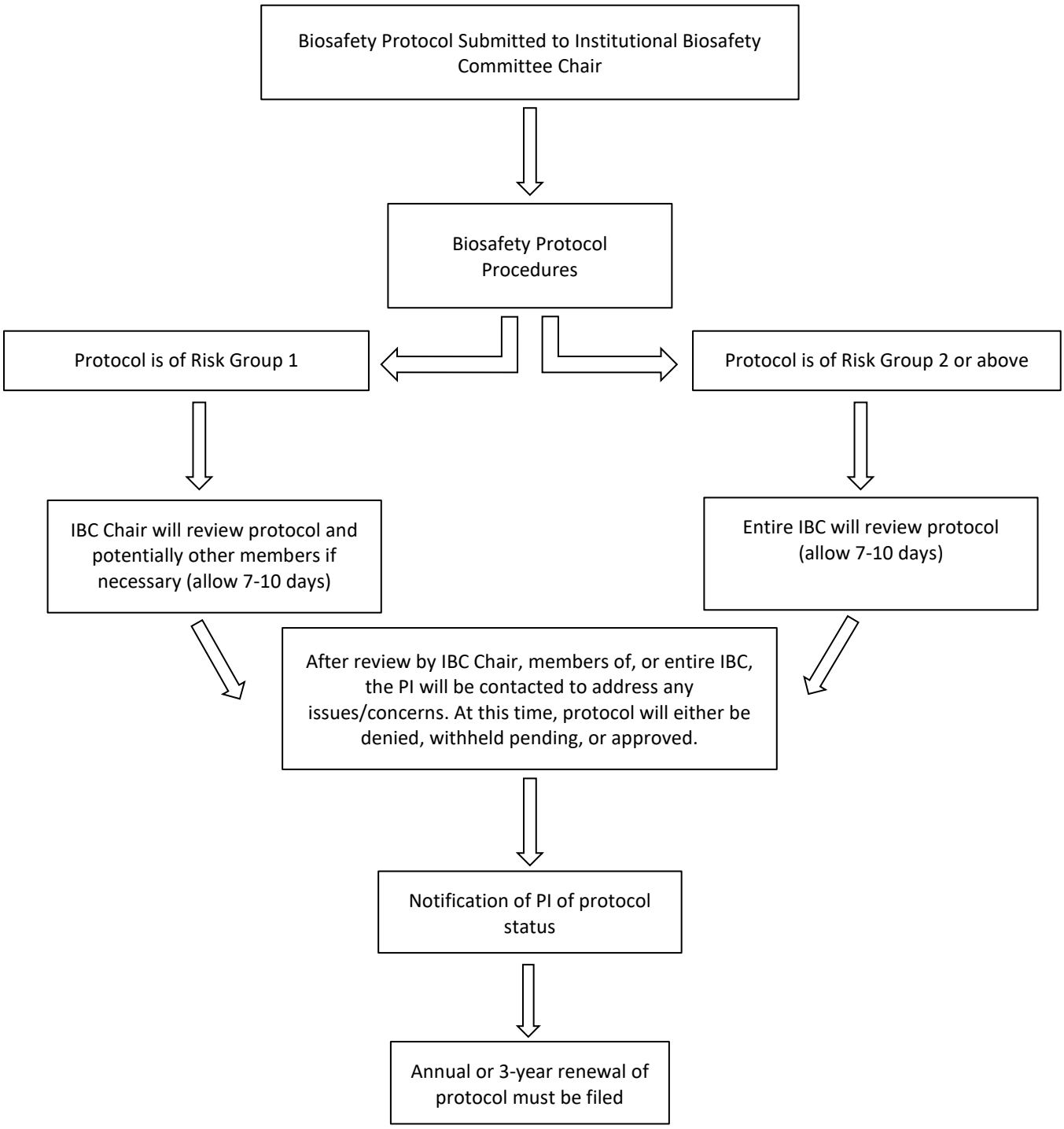
A. Read and understand the submitted protocol
B. Read and understand all applicable sections of the Biosafety Manual
C. To abide by the procedures in approved protocols established by the PI and RSP
D. To be adequately trained in microbiological techniques and practices
E. To report any adverse events, such as a work-related injury or exposure to the PI

5. Protocol Submission Process

The protocol submission process is first initiated by submission of the grant proposal, dissertation, thesis, or any other research or teaching that involves rDNA or potentially infectious agents to the Research & Sponsored Programs. During the review of the protocol, the RSP will determine whether it should be submitted to the IBC for further review. If the research falls under IBC supervision, the IBC will be contacted, and the PI will be contacted to obtain more information regarding specifics of the research. If review is necessary and the research is designated at a risk group 2 or above, it is then brought before the IBC for discussion. If the protocol is a risk group of 1, it will only be reviewed by the Institutional Biological Safety Chair for completeness. The IBC will take the proper steps to make sure all health and safety issues are addressed. When all requirements are met the IBC or IBC Chair will approve or disapprove the protocol and notify the principal investigator within 7-10 days. Once the protocol has been approved, it is subject to renewal; If the rDNA or infectious agent is exempt, it is subject to renewal in three years unless changes are

made to the approved protocol. Each laboratory is subject to a one-time registration unless conditions in the lab change.

Biosafety Protocol Submission Procedures



a. IBC Review

The Institutional Biosafety Committee will review the Protocol for Use and the MUA to determine if the proposed project is adequate and in compliance with NIH/CDC/OSHA Guidelines and regulations. The review will consist of but not limited to:

- An overall assessment of the proposed research to determine if any conditions would prohibit the research from being initiated. This would include the type of DNA molecules, the host and vectors, the nature of the inserted DNA sequences, etc. Ensure that authorization and containment levels have been received from NIH for experiments not presently authorized in the NIH Guidelines.
- An assessment of the containment levels proposed to ensure that the levels are sufficient for the type of research being conducted.
- An assessment of the procedures, practices, training, and facilities. Besides reviewing the proposal and questioning the PI, a physical inspection will be conducted. The BSO/IBC Chair or designee would audit/inspect the facility with the PI. The BSO/IBC Chair or designee will certify in writing the findings to the IBC. The IBC will meet to discuss the review and vote on accepting or rejecting the proposed research. The review of the lab audit/inspection will be forwarded to the PI.

b. Requirements on Submission of Protocol

The protocol is subject to IBC approval if recombinant DNA, an infectious material, or if microbiological agents are being used regardless of whether exempt or nonexempt. Required paperwork must be completed in order to proceed with any research and in order to receive any monetary rewards. The IBC will be notified by either the PI or RSP when such research is being conducted. The IBC will require **a Protocol for Use of recombinant DNA** and/or **Infectious Agents** form to be completed. The PI is also required to sign the **Memorandum of Understanding and Agreement (MUA)** that is attached to the registration document. This information must be completed before initiation of a project involving rDNA or biohazardous material. The review of the protocol will be delayed if the required paperwork is not received or not fully completed. This is also when a laboratory inspection will be initiated for compliance and safety issues. Whenever a sponsored project is using rDNA or infectious agents, grant monies will not be released until IBC approval is in place.

i. Protocol Amendment

If a protocol that has already been approved is modified in any way, the PI must submit an **Amendment Form** to the IBC. The Amendment Form must state any change and the reasoning for doing such when deviation from the original protocol takes place. This form must be completed before the change is to take place. After IBC reviews the change in the protocol, the status of the protocol will be relayed directly to the PI.

ii. Renewal of Protocol

A periodic review of the protocol is required by NIH guidelines. The review of such protocols will take place annually for all research projects that involve the use of potentially infectious agents or rDNA at all biosafety levels. The renewal will include the **Annual Registration Form** and a new **MUA.** The MUA covers a variety of information and therefore the IBC will assume that each entry has been completed.

The renewal of the protocol will be due on June 15 (or some other summer date to avoid holiday rush) of each calendar year following initial approval. The IBC will have these recent documents on file. The Annual Registration and MUA will cover all proposals through the year if multiple proposals are submitted and approved as long as each protocol is listed.

iii. Memorandum of Understanding and Agreement (MUA)

The **Memorandum of Understanding and Agreement** is to make sure all requirements are being met based on CDC/NIH guidelines along with the University policies and OSHA. Signing of the MUA transfers responsibility to the principal investigators and stating that all requirements have been met when dealing with rDNA and potentially infectious agents. The MUA is completed upon protocol registration and annually thereafter until the protocol has been officially terminated. The IBC will review all initial and annually submitted MUAs; confirm, where applicable, that exempt status is appropriate for certain rDNA work; and consider approval for those MUAs that are complete, and which provide for safe handling of potentially biohazardous materials under the appropriate Biosafety Levels. For those protocols that do fall under the exempt status, the MUA must be completed every three years instead of annually.

The IBC will send out a reminder on November 1 of every calendar year to remind PI's about the completion of the MUA and the Annual Registration. The MUA along with Annual Registration must be submitted by January 1 of the following year to continue with the research protocol. There will be a three-week window for when all such protocol MUAs must be submitted to the IBC. After the third week of January, any remaining PI's that have not submitted the required forms will result in suspension or possible termination of the protocol until forms are in and it has gone to the IBC for review. The MUA will cover all proposals through the year if multiple proposals are submitted and approved. Any protocol that has been submitted and approved to the IBC between March 1 through May 31 of a calendar year is exempt from filing the MUA.

iv. Termination of Protocol

If a protocol is no longer using rDNA or potentially infectious agent, then the IBC requests for the investigator(s) to terminate the protocol. The termination will allow the IBC to put the protocol in a non-active file. This will also allow the IBC to remain up to date and discontinue further inspections, registrations, and MUAs from those laboratories that no longer require IBC supervision. If the PI should leave the University, he or she should file an amendment to terminate or transfer the protocol. **The Amendment of Protocol** form will need to be submitted to the IBC to officially terminate the protocol.

v. Transferring a Protocol

If the principal investigator decides at some point during the research of an approved proposal to transfer his/her status to another PI, an Amendment of Protocol form must be filed with the IBC. The

former principal investigator is required to sign off on the protocol acknowledging the transfer. The new principal investigator will now be recognized as the individual responsible for the research. By transferring the protocol, the IBC will require that a new MUA be filed. If there have been any changes in the approved protocol, then the changes can be documented on the amendment form for IBC review. The Amendment of Protocol will need to be filed with the IBC. The new PI will be informed by the IBC on the status of the transfer or amendment of the protocol.

6. Risk Assessment

The risk assessment is performed in order to assign the appropriate containment level. The risks associated with biological agents need to be assessed when these agents are used for diagnostic, teaching, research, or other purposes. The responsibility for assessing the risks associated with biological agents or obtaining an initial assessment lies with the investigator and is based on the risk group of an agent. The assessment helps to reduce the risk of handling the materials plus provide protection for workers and the environment. Factors that are considered in the assessment are virulence, pathogenicity, infectious dose, environmental stability, transmission, communicability, operations, quantity of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. The risk assessment seeks to determine both the probability of particular risks and the consequence if that risk does occur.

The risk assessment is to be performed by the principal investigator before the initiation of each protocol. The IBC will confirm the determined risk group(s) to be appropriate for the proposed protocol during the review process. The risk assessment is to be evaluated based on the Protocol for Use of Infectious Agents and the Protocol for Use of rDNA. The following must also be considered when determining the potential risk involved:

- Decontamination methods
- Personnel training
- Waste handling
- Special equipment requirements
- Safety procedures to be followed for proper containment

The risk groups can be located in the NIH guidelines, CDC, and American Biological Safety Association. For further guidance on risk assessment contact Environmental Health & Safety (Grant Lee at 309-438-8039).

a. NIH Risk Group (RG) Classification

- **Risk Group 1 (RG1)-** Agents are not associated with disease in healthy adult humans (low individual & community risk)
- **Risk Group 2 (RG2)-** Agents are associated with human disease, which is rarely serious, and for which preventive or therapeutic interventions are often available (moderate individual risk, limited community risk)

- **Risk Group 3 (RG3)-** Agents are associated with serious or fatal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)
- **Risk Group 4 (RG4)-** Agents are likely to cause serious or fatal human disease for which preventive or therapeutic interventions are not usually available (high individual risk & high community risk)

After determination of the proper Risk Group, the Biosafety Level can be determined. As a general rule, Risk Group 1 research falls under Biosafety Level 1.

b. Exemption

The following recombinant DNA molecules are considered exempt from the NIH Guidelines. An initial registration of the research is required and every three years it is to be reregistered with the Institutional Biosafety Committee. (Use the NIH Guidelines for specific sections)

- Those that are not in organisms or viruses.
- Those that consist entirely of DNA segments from a single non chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
- Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
- Those that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the Recombinant DNA Advisory Committee (RAC) after appropriate notice and opportunity for public comment (see Section IV-C-1-b- (1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions Under Section III-F-5--Sub lists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.
- Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-6 for other classes of experiments, which are exempt from the NIH Guidelines.
- Cloning of all other DNA in E. coli K12, S. cerevisiae, and B. subtilis host-vector systems
- Introduction into cultured cells of any recombinant DNA containing less than half of a eukaryotic viral genome.

7. Containment

Containment is used in describing safe methods for managing biological agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, persons outside the laboratory, and the environment to potentially hazardous agents. The three elements of containment include: laboratory practice and technique, safety equipment, and facility design.

The proper containment is located by identification of the risk group and the appropriate biosafety level. The biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed. They are also based on the potential hazards imposed by the agents used and for the laboratory function and activity. As a general rule, a biosafety level should be used that matches the highest Risk Group (RG) classification of the organism involved.

a. Laboratory Practice & Technique

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

Each PI should identify specific hazards that will or may be encountered, and consider practices and procedures needed to minimize or eliminate risks. Personnel should be advised of special hazards and are expected to follow the required practices and procedures.

b. Safety Equipment (Primary Barriers)

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

c. Facilities Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect those working inside and outside the laboratory and to protect people or animals in the community from infectious agents that may be accidentally released from the laboratory. Facilities must commensurate with the laboratory's function and the recommended biosafety level for the agent manipulated. The three facility designs are the basic laboratory, the containment laboratory, and the maximum containment laboratory. The

secondary barrier(s) needed will depend on the risk of transmission of specific agents. Secondary barriers in laboratories include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave) and handwashing facilities.

Laboratories at Illinois State University must be annually inspected by the Biological Safety Officer/Institutional Biological Safety Chair or his designee and found to be compatible with the appropriate biosafety level containment for the biohazards in use as defined by NIH, CDC, OSHA, and the University guidelines.

8. Biosafety Levels (BSL)

There are four biosafety levels (BSL) that have been established by NIH and CDC to ensure safety when working with biohazardous agents. The Institutional Biosafety Committee requires that the principal investigator identify the biosafety level appropriate for the agent(s) for which he/she is proposing to work with. The biosafety level depends on the Risk Group to which a biohazardous agent and its uses belong. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Each BSL consists of combinations of laboratory practices and techniques, safety equipment and laboratory facilities, specifically appropriate for the operations performed, documented, or suspected routes of transmission of infectious agent, and for the laboratory function or activity. The biosafety levels were created to represent the conditions under which the agent ordinarily can be safely handled. There are four resources that are considered to determine as to what precautions are recommended. The four areas are: infectious agents, biohazards in plants, biohazards in animals, and rDNA.

When requesting approval from the IBC to use a particular agent(s), it is important to recognize that the PI is agreeing to ensure the integrity of physical containment of these agents by complying with the requirements and precautions.

a. *Physical Containment Levels*

Safety Guideline	BSL1	BSL2	BSL3	BSL4
Laboratory personnel must wash their hands after handling cultures, after removing gloves and before leaving the laboratory	Y	Y	Y	Y
Eating, drinking, smoking and application of cosmetics is prohibited	Y	Y	Y	Y
Personnel must be familiar with basic biosafety procedures, including this manual	Y	Y	Y	Y
Personnel should wear safety glasses or face shields if possibility of splashes and aerosols exist	Y	Y	Y	Y
Pipetting by mouth is prohibited	Y	Y	Y	Y
All laboratory procedures should be performed to minimize aerosol generation or release	Y	Y	Y	Y
Work surfaces must be decontaminated at least daily, after each use for infrequent users, and after any spill of viable materials	Y	Y	Y	Y
Sharps must be placed in specially designed puncture and leak proof sharps containers and disposed of appropriately as medical or regular	Y	Y	Y	Y
Laboratories must be kept neat; good housekeeping procedures must be in place and in regular use	Y	Y	Y	Y
All contaminated liquid or solid waste is decontaminated before disposal by and approved decontamination method or disposed of appropriately	Y	Y	Y	Y
Insect and rodent control programs are instituted	Y	Y	Y	Y
Laboratory contains a sink for hand washing	Y	Y	Y	Y
Laboratories are designed for ease of decontamination (e.g. no carpets, sealed surfaces, no unreachable areas, etc.)	Y	Y	Y	Y
Bench tops are impervious to water, moderate heat and chemicals	Y	Y	Y	Y
Laboratory furniture must be secured, spaces between benches, cabinets, and equipment must be accessible for decontamination	Y	Y	Y	Y
Laboratory Windows that can be opened must be fitted with fly screens	Y	Y	Y	Y

Laboratory coats or gowns and gloves must be provided in BSL 1 and provided and worn at BSL 2-4	Y	Y	Y	Y
Access to laboratory is limited or restricted during experiments	Y	Y	Y	Y
Laboratory personnel require specific training in handling of pathogenic materials	Y	Y	Y	Y
The universal biohazard symbol must be posted on the access door to the laboratory	Y	Y	Y	Y
Decontamination at site away from laboratory are placed in a durable leak-proof container	Y	Y	Y	Y
Autoclaves are required for waste treatment prior to disposal as non-biohazardous waste	Y	Y	Y	Y
Autoclave quality Control program is required for used specified above	N	Y	Y	Y
Materials (e.g. plants, animals, clothing) not involved in the experiment are not permitted in laboratory	N	Y	Y	Y
Biological safety cabinets are required and must be certified annually-if aerosol is created at BSL 1, then BSC must be used	N	Y	Y	Y
Safety centrifuge cups are required	N	Y	Y	Y
Spills & accidents that result in overt exposure to organisms containing rDNA molecules are immediately reported to IBC and NIH/OBA	N	Y	Y	Y
No materials or equipment can leave the building unless they have been autoclaved or decontaminated	N	Y	Y	Y
Immunization and/or serological testing for agents to be handled may be required	N	Y	Y	Y
All laboratory procedures must be performed in a properly certified biological safety cabinet that has been assessed for the proper BSL	N	Y	Y	Y
Laboratory requires controlled entry, unidirectional air flow and other special design features	N	N	Y	Y
Windows must be closed and sealed	N	N	Y	Y
Autoclaves must be located inside the facility	N	N	Y	Y
Access is through an airlock system	N	N	Y	Y
Two sets of doors for entry	N	N	Y	Y
Persons under 16 years of age shall not enter laboratory	N	N	Y	Y
Laboratory doors are kept closed when experiments are in progress	N	N	Y	Y
Molded surgical masks or respirators are used in rooms containing experimental animals	N	N	Y	Y
Vacuum lines are protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps	N	N	Y	Y
Hypodermic needles and syringes are used only for parenteral injections and aspiration of fluids	N	N	Y	Y
Duct exhaust air ventilation system is provided	N	N	Y	Y
Laboratory animals are housed in class III cabinets or partial containment caging system	N	N	Y	Y
Exhaust air from HEPA filter is properly discharged	N	N	N	Y
Personnel shower each time they exit facility	N	N	N	Y
Biological materials are to be packaged accordingly and removed through a disinfectant dunk tank, fumigation chamber, or an airlock	N	N	N	Y
Street clothing is removed, laboratory clothing provided & decontaminated prior to laundering or disposal	N	N	N	Y
System is setup for medical surveillance of those entering or existing laboratory	N	N	N	Y
All penetrations in these structures and surfaces are sealed	N	N	N	Y
Minimize horizontal surface area on which dust can settle	N	N	N	Y
Foot, elbow, or automatically operated hand washing sink is provided near entrance door	N	N	N	Y
Central vacuum systems do not serve areas outside facility	N	N	N	Y
If water fountains are provided, they are foot operated outside of laboratory	N	N	N	Y
Windows are breakage resistant	N	N	N	Y
Access doors are self-closing and locking	N	N	N	Y
Double-doored autoclave is provided for decontamination	N	N	N	Y
All liquid effluent are decontaminated by heat treatment	N	N	N	Y
An individual supply and exhaust air ventilation system is provided	N	N	N	Y
A specially designed suit area may be provided in the facility, personnel shall wear a one-piece positive pressure suit that is ventilated by a life support system	N	N	N	Y

b. Infectious Agents

The Center for Disease Control and Prevention has established the guidelines for containment at certain biosafety levels when an infectious material is being used in the laboratory. The purpose of containment is to reduce or eliminate the exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The three elements of containment include: laboratory practice and technique, safety equipment, and facility design. Agent specific containment levels need to be sought out in the CDC-NIH guidelines.

Table 1. Summary of Recommended Biosafety Levels for Activities in Which Infectious Agents are Present

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials. PPE: protective laboratory coats, gloves, face protection as need	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmissions; disease may have serious or lethal consequences	BSL-2 practice plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Class I or II BSCs or other physical containment devices used for all open manipulations of agents. PPE: protective lab clothing, gloves, respiratory protection as needed	BSL-2 plus: Physical separation from access corridors Self-closing, double-door access Exhausted air not recirculated Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: Clothing change before entering Shower on exit All material decontaminated	All procedures conducted in Class III BSCs **OR** Class I or II BSC **in combination with** full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems

		on exit from facility		Other requirements outlined in the text

c. *Vertebrate Animals*

The biosafety levels of vertebrate animals are comparable to the infectious agents. However, some unique problems may occur in the animal room. The activities of the animals themselves can present new hazards. The animals may generate aerosols, they may bite and scratch, and they may be infected with a zoonotic disease. The designated Animal Biosafety Levels (ABSL-N) that are provided below show increasing levels of protection to personnel and to the environment.

Table 2. Summary of Recommended Biosafety Levels for Activities in Which Experimentally or Naturally Infected Vertebrate Animals Are Used

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in human adults	Standard animal care and management practices, including appropriate medical surveillance programs	As required for normal care of each species	Standard animal facility No recirculation of exhausted air Directional air flow recommended Hand washing sink recommended
2	Associated with huma disease Hazard: percutaneous exposure, ingestion, mucous membrane exposure	ABSL-1 practices plus: Limited access Biohazard warning signs Sharps precautions Biosafety manual Decontamination of all infectious wastes and of animal cages prior to washing	ABSL-1 equipment plus primary barriers: containment equipment appropriate for animal species PPE: laboratory coats, gloves, face and respiratory protection as needed	ABSL-1 facility plus: Autoclave available Hand washing sink available in the animal room Mechanical cage washer used
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious health effects	ABSL-2 practices plus: Controlled access Decontamination of clothing before laundering Cages decontaminated before bedding removed	ABSL-2 equipment plus: Containment equipment for housing animals and cage dumping activities Class I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols	ABSL-2 facility plus: Physical separation from access corridors Self-closing, double door access Sealed penetrations

		Disinfectant foot bath as needed	PPE: appropriate respiratory protection	Sealed windows Autoclave available in facility
4	Dangerous/exotic agents that pose high risk of life-threatening disease; aerosol transmission, or related agents with unknown risk of transmission	ABSL-3 practice plus: Entrance though change room where personal clothing is removed, and laboratory clothing is put on, shower on exiting All wastes are decontaminated before removal from the facility	ABSL-3 equipment plus: Maximum containment equipment (i.e., Class III BSC or partial containment equipment **in combination with** full body, air supplied, positive pressure personnel suit) used for all procedure and activities	ABSL-3 facility plus: Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems

d. Plants

The 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 biosafety levels of plants (BSL-P) are to supersede the *Physical Containment* of rDNA.

e. Arthropods

Arthropods pose a variety of threats not only to the individuals who work with them, but also when considering the potential escape from a laboratory setting. Some arthropods are vectors of infectious human diseases and special precautions must be taken. To minimize the risk of potential hazards, guidelines have been established for both infected and uninfected arthropods being used in the laboratory setting. The American Biological Safety Association has established containment guidelines to set a minimum standard for university practice. Lab specific training regarding potential hazards relating to arthropods needs to also be addressed.

9. General Guidelines for the Laboratory

When work with a biological agent(s) is performed, appropriate steps must be taken to protect personnel and the environment. Personal protective equipment, good personal hygiene, biological safety cabinets (BSCs), proper disinfection and proper disposal play an important role in protecting lab personnel and the environment.

It is the responsibility of the principal investigator to identify potential biohazards and to specify safe practices and procedures. Awareness is the most fundamental role when working in a laboratory. All laboratory personnel must therefore be informed of the potential hazards and trained in safe handling techniques along with other necessary training. The service personnel and cleaning staff of ISU, who enter the facility, must also be informed of the hazards that might be encountered. The following ISU Biosafety Manual

demonstrates the **minimum requirements** for all research, diagnostic, production facilities, or teaching laboratories that handle recombinant DNA, infectious material, or microbiological agents.

The general guidelines are applied to all labs working with the above to establish good laboratory practices. The good laboratory practices are to minimize hazards associated with scientific work. Consult the NIH/CDC manual for further guidelines.

a. Safe Practices

The following safety practices have been established as a guide to minimize hazards in the laboratory setting:

- The Biosafety Manual must be available for all staff and its requirements followed; it will be reviewed and updated regularly.
- Personnel must receive training on potential hazards associated with work involved and the necessary precautions to take**.** **See Training Section.**
- Protective laboratory clothing (lab coats or gowns) must be worn and properly fastened by all personnel working in the laboratory of a BSL2 and above. BSL1 must have protective laboratory clothing provided and advised to use it to prevent contamination. Protective clothing must not be worn in public areas.
- Suitable footwear with closed toes and heels and preferable with non-slip soles must be worn in all laboratory areas. Bare legs are not acceptable when working with corrosives, reactive, toxic materials easily absorbed by the skin, radioactive or infectious materials.
- Eating, drinking, smoking, storing of either food or utensils, applying cosmetics, and inserting or removing contact lenses are not permitted in the working area of any laboratory. Long hair must be tied back or restrained. Oral pipetting is prohibited.
- Hands must be washed before leaving the laboratory and at any time after handling materials known or suspected to be contaminated, even when gloves have been worn.
- The laboratory must be kept neat and clean. Work surfaces must be decontaminated with a suitable disinfectant at the end of the day and after any spill of potentially dangerous material.
- All contaminated or infectious liquid or solid material must be sterilized before disposal or re-use.
- Extreme caution must be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should either not be recapped or should be capped using the “scoop” methods. They should be promptly placed in a puncture-resistant container and a pick-up form from EHS should be filled out for removal.
- All technical procedures should be performed in a manner that minimizes the creation of aerosols and splashes.
- Do not use chipped or cracked glassware.
- Use guards and shields where possible.
- Know appropriate procedures for emergencies, including the location and operation of all emergency equipment.

- When working with hazardous materials, it is advised to have a second person nearby, or, at minimum, surveillance by telephone contact.
- Use hazardous chemicals in a chemical fume hood, whenever possible.
- Maintaining an inventory of chemicals is recommended.
- Every lab that has an exposure to hazardous substances needs to make available an emergency shower and eyewash station. If not located in the lab, it must be within 10 seconds of reach.
- Have a **Chemical Hygiene Plan** developed (for the labs that contain chemicals), placed in the lab, and familiarized with all employees.
- Each person involved should know what to do if loss of electricity were to occur.
- Each laboratory is to have the proper ventilation for the proper BSL being used. See **Fume Hoods** and **Laboratory Equipment.**
- REPORT ALL ACCIDENTS, EVEN IF THEY DO NOT RESULT IN INJURY, TO THE PRINCIPAL INVESTIGATOR, LABORATORY SUPERVISOR AND EHS IMMEDIATELY.

Universal Precautions:

Laboratories often handle specimens without full knowledge of the material's diagnosis; these specimens may contain infectious agents. To minimize exposure, observe universal precautions when handling **any** biological specimen. Consider **all** specimens to be infectious and treat these materials as potentially hazardous.

IMPORTANT:

Never underestimate the hazards associated with a laboratory. If you are unsure about what you are doing, get assistance. Do not use unfamiliar chemicals, equipment, or procedures alone.

b. Laboratory Equipment

A general understanding of laboratory equipment and how it works is essential to working safely in the laboratory. Provided is a list of equipment and the proper use of It.

i. Biological Safety Cabinet

Biological safety cabinets (BSCs) are among the most effective and most commonly used primary containment devices in laboratories working with infectious agents. The BSC is designed to capture and contain infectious particulates or aerosols generated within the BSC and exhaust them through a HEPA filter. Although biological safety cabinets surround the immediate workspace involving an agent, they do not provide complete containment (i.e., aerosols can escape). Therefore, careful work practices are essential when working with agents that require a BSC. Since HEPA filters are ineffective against gaseous chemicals, volatile chemicals should not be used in BSCs; most BSCs recirculate a percentage of the exhausted air. Biological safety cabinets are also subject to certification and inspection when they are newly installed, after filter or motor replacement, after being moved and annually.

ii. Autoclave

An autoclave is a steam sterilizer that is used for biohazardous laboratory waste. In order to dispose of infectious laboratory waste (petri dishes, pipettes, culture tubes, glassware, etc.), the waste must be autoclaved for 30 minutes at 121°C (minimum 15 psi). The autoclave is a type of decontamination that is either done by gravity displacement or a pre-vacuum method. The effectiveness of decontamination by steam autoclaving depends upon various loading factors that influence the temperature to which the material is subjected and the contact time. Particular attention must be given to packaging, including the size of containers and their distribution in the autoclave. Containers must be arranged in a manner that permits free circulation of steam. All processed items must have heat-sensitive tape, or other acceptable method (such as commercially available strips or vials of *Bacillus* species endospores or thermocouples), attached to confirm proper sterilization. Once the cycle has been completed, the waste can then be disposed of either as solid waste (regular trash) or medical waste. A Standard Operating Procedure **(SOP)** must be located at each autoclave that states the proper procedures to use for proper decontamination. The autoclaves are to be inspected every month for adequate sterilization by a *Bacillus stearothermophilus* test (spore test). An annual inspection of the thermometer for accurate calibration shall also take place. A log must be maintained by the department. The log, calibration results, and *Bacillus stearothermophilus* test must be kept on file for 3 years by the department. The **Autoclave Log** must include:

- The date and time of autoclaving
- The person conducting the autoclaving
- The material and amount being autoclaved
- Maximum temperature attained
- Maximum pressure attained
- If verification spores or heat/pressure tape were used
- Lab location

iii. Centrifuges

Improper centrifuge use can result in the generation and release of hazardous aerosols. Follow these guidelines for proper centrifuge use:

- Make sure the lid is on and secured before operating the centrifuge.
- Always balance the load in the centrifuge. If you are not filling the entire centrifuge rack, position the tubes opposite one another. If you have an odd number of samples, use an empty tube with enough water to equal the weight.
- If vibration occurs, stop the centrifuge, and check the load balances. Never operate an unbalanced centrifuge; this could result in breaking the centrifuge tube(s) and generating hazardous aerosols.
- Keep the rotors and buckets clean, and promptly clean breakages or spills.

iv. Refrigerators

Follow these guidelines for proper laboratory refrigerator use:

- Flammable liquids must be stored in explosion-proof refrigerators.
- Refrigerators must be labeled prominently to indicate whether they are suitable for storage of flammable liquids.
- Never place food or beverages in a refrigerator where chemicals, radioactive or biohazardous materials are stored.
- Refrigerators containing biohazardous materials must be labeled "biohazardous." The biohazardous agent must be identified on the label.

v. Glassware

Follow these guidelines for proper laboratory glassware use:

- Inspect all glassware before use. Discard broken, cracked or chipped glassware.
- Fire-polish all cut-glass tubing and rods before use.
- When inserting glass tubes or rods into stoppers, be sure the diameter of the tube is compatible with the diameter of the stopper; lubricate the glass with water or glycerol; and wear heavy gloves and insert the glass tube carefully with a twisting motion.
- Dispose of broken glassware in an appropriate "broken glass" container, not the ordinary trash.

vi. vi. Compressed Gas Cylinders

Compressed gas cylinders can present a dual hazard in the laboratory because the contents are under pressure and may contain hazardous materials. The following guidelines must be followed for proper use:

- Compressed gas cylinders, empty or full, must be chained in place or otherwise secured at all times.
- Cylinder caps must be in place except when the cylinder is in use.
- Do not transport gas cylinders without the cylinder cap in place and an appropriate dolly with a securing strap.
- Cylinder and delivery valves should be closed when not in use (especially true for poisonous, flammable, or corrosive gases).

c. *Laboratory Security*

All laboratories must adopt laboratory security practices to minimize opportunities for unauthorized entry into laboratories and storage areas, and the unauthorized removal of infectious materials from their facility. Security requirements for facilities handling infectious agents become more stringent as the risk and biosafety levels increase. A protocol for reporting and investigating security incidents (e.g. missing infectious substances, unauthorized entry) should also be addressed. The following are offered as guidelines for laboratories using biological agents or toxins capable of causing serious or fatal illness to humans or animals.

- Recognize that laboratory security is related to but different from laboratory safety.
- Control access to areas where biologic agents or toxins are used and stored.

- Know who is in the laboratory area.
- Know what materials are being brought into the laboratory area.
- Know what materials are being removed from the laboratory area.
- Have an emergency plan.
- Have a protocol for reporting incidents.
- Maintaining a **Chemical Inventory** in research laboratories and teaching laboratories is recommended.

10. Decontamination

Decontamination includes both sterilization (the complete destruction of all microorganisms, including bacterial spores) and disinfection (the destruction of specific types of microorganisms). It is the responsibility of all laboratory workers to ensure the effective use of these decontaminants for waste disposal; removing materials, equipment, and samples from containment zones; laundry; decontaminating surfaces and rooms; and spills of infectious materials. Failure in the decontamination procedure can result in occupational exposure to infectious agents and/or the unintentional release of agents from a containment facility. The choice of decontaminate is determined by the nature of the material to be treated. This may include, but is not limited to, laboratory cultures, stocks, clinical specimens, laboratory equipment, sharps, protective clothing, and other items that have come into contact with infectious materials. The laboratory bench tops and surfaces are to be decontaminated after any spill of potentially infectious materials and at the end of the working day. A specific written SOP must be developed for each lab for proper decontamination methods. The employees must be trained in all decontamination procedures specific to their activities and should know the factors affecting the effectiveness of the treatment procedure. Proper decontamination can be done using the following:

a. Autoclave

Infectious laboratory wastes (petri dishes, pipettes, culture tubes, glassware, etc.) can be effectively decontaminated in either a gravity displacement or pre vacuum autoclave. For the autoclave process to be effective, sufficient temperature, time, and direct steam contact are essential. See Autoclave under laboratory equipment.

b. Radiation

Microwave radiation is not widely used in containment facilities. Like autoclaving, heat is the critical factor for eliminating viable microorganisms. Ultraviolet radiation should not be relied upon as the sole method of decontamination for materials removed from containment facilities. UV can be effective in reducing airborne and surface contamination providing the lamps are properly cleaned, maintained, and checked to ensure that the appropriate intensity is being emitted.

c. *Chemical Disinfectant*

Chemical disinfectants are used for the decontamination of surfaces and equipment that cannot be autoclaved. This includes specimen containers and other items removed from containment, spills of infectious materials, laboratories, animal cubicles and other rooms, and is also used for other items from which heat treatment is not feasible. The choice of chemical disinfectant depends on the target organism to be removed and the characteristics of the area to be cleaned. One characteristic to consider is the resistance of the microorganisms itself. Use the following table to aid in the selection of disinfectants:

Table 3. Disinfectant Activity

Disinfectants			**Practical Requirements**			**Inactives**				
Type	Category	Use Dilution	Contact time (min.) *Lipovirus Spectrum*	Temp. (°C)	Relative Humidity (%)	Vegetative Bacteria I.e. *E. coli*	Lipo-virus I.e. *hantavirus*	Non-Lipid Viruses I.e. *rhinovirus*	Myco-bacteria I.e. Mycobacterium *tuberculosis*	Bacterial Spores I.e. *Bacillus subtilis*
Liquid	Quaternary Ammonium Compounds	0.1%-2.0%	10	NE		+	+			
	Phenols	1.0%-5.0%	10	NE		+	+	B		
	Chlorine	500 ppm*	10	30		+	+	+	+	+
	Iodophor	25-1600 pmm*	10	30		+	+	+		
	Alcohol Ethyl	70%-85%	10	30		+	+	B		
	Alcohol Isopropyl	70%-85%	10	30		+	+	B		
	Formaldehyde	0.2%-8.0%	10	30		+	+	+	+	+
	Glutaraldehyde	2%	10	30		+	+	+	+	+
Gas										
	Ethylene Oxide	8-23g/ft3	60	60 37	30	+	+	+	+	+
	Paraformaldehyde	0.3g/ft3	60	60 >23	60	+	+	+	+	+

NE=not effective B=Variable results dependent on virus *=Available Halogen (1:100)

- **Mycobacteria-** Any of the genus of nonmotile aerobic acid-fast bacteria that include numerous saprophytes and the pathogens causing tuberculosis and leprosy
- **Vegetative Bacteria-** A single celled microorganism that is able to reproduce
- **Nonlipid virus-** Small non-enveloped viruses
- **Lipovirus-** medium-sized enveloped virus
- **Bacterial spore-** Single celled microorganism that is in a dormant state

11. Emergency Spill Procedures

Spills will inevitably occur in the lab and staff should be properly trained to recognize the hazards associated with the spill, to mitigate the spill within their ability, and to notify response authorities where necessary. Initial response to a spill shall always be to evacuate the immediate area until the scope of the hazard has been assessed. All spills shall be contained and cleaned up by those properly trained and equipped to work with potentially concentrated infectious materials/chemicals as soon as feasible. All spills or accidents that result in an exposure incident shall immediately report to the PI or other responsible persons. All lab staff must be trained to recognize hazardous conditions associated with spills in the laboratory. Lab supervisors are responsible for ensuring that their staff has received this training. Additional training shall be provided to those that will be expected to respond to and mitigate hazardous spills. This training shall include an assessment of what type of spill there is, special precautions to take, proper PPE to use during clean up, proper clean up procedures, and when to evacuate and call for help. A wide variety of spill response kits are available that are designed for response to minor spills. EHS can offer guidance in kit selection. All spills of infectious, biological, radioactive, and chemical need to be recorded in the Spill Log. The spill log is to be maintained by the PI in case of future dilemma.

a. *Spills of Infectious Material*

If the spill is of an infectious material, leave the area immediately and evacuate the room. Allow sufficient time for the aerosol created to settle before re-entering the room. Upon leaving the room, be sure to remove all contaminated clothing. Place the contaminated clothing in the receptacle for autoclaving. Before re-entering the lab, don all necessary protective clothing required for dealing with a spill. Follow the procedures below for dealing with small spills:

- Wear gloves
- Cover spill with paper towels and disinfectant
- Allow sufficient contact time
- Pick up towels and put in biohazard bag
- Wipe spill area again with disinfectant
- WASH HANDS

*ALWAYS ATTEND TO INJURED PEOPLE BEFORE ATTENDING TO THE SPILL

b. *Spills of Biological and Radioactive Material*

Spills of biological and radioactive materials are handled similarly to the spills of infectious agents. The Environmental Health and Safety office (438-8325) should be notified to determine the radioisotope cleanup procedure and will assist in the cleanup. It is important to first determine if anyone has been contaminated. All contaminated clothing needs to be removed and the contaminated skin then washed with soap and water. The lab should be evacuated, especially if an

aerosol was generated. Bleach must **not** be used on iodinated materials. Follow the procedures below, in addition to the above procedures, for dealing with small spills:

- Use procedures outlined in the **Radiation Safety Guidelines**
- Monitor your hands, footwear, etc. and the area for residual radioactive contamination, decontamination procedures may need to be repeated if necessary

All spills of any nature must be recorded in the **Spill log** and maintained by the PI, which will be viewed upon annual inspection. The description must include:

- The type and quantity of spill
- The time and date it happened
- Names of individuals involved in the spill and cleanup
- Nature and extent of any injuries or property damage

All major spills must be reported to the PI. A major spill is one in which:

- Hazardous materials contact skin, eyes, etc.
- A break in the skin occurs
- The spill splashes over an area larger than one foot in diameter
- The extent of the spill is undetermined
- The spill involves an aerosol
- The spill is > 500mL

*If assistance is needed in clean-up or to report injury contact EHS (438-8325)

12. Hazardous & Biohazardous Waste

Hazardous and biohazardous waste has specific guidelines for proper disposal. A hazardous waste is classified as ignitable, corrosive, reactive and toxic. These terms are defined below.

Ignitable

- Liquids with flash point below 140°F
- Solids, under STP, may cause fire through friction, absorption of moisture or spontaneous chemical changes
- Certain ignitable compressed gases
- Oxidizers

Corrosive

- Any aqueous solution with a pH of less than or equal to 2 or greater than or equal to 12.5 or any liquid that will corrode steel faster than one-quarter inch per year.

Reactive

- Normally unstable and readily undergoes violent change without detonating

- Reacts violently or forms a potentially explosive mixtures with water
- Generates toxic gases, vapors or fumes when mixed with water
- Cyanide- or sulfide-bearing waste that can generate toxic gases, vapors or fumes when exposed to a pH between 2 and 12.5
- Capable of detonation or explosive reaction if subjected to a strong initiating source or heat under confinement
- Readily capable of detonation or explosive decomposition or reaction at STP

Toxic

- A solid waste is one that contains any of the toxic heavy metals, pesticides or organics that can pose risk to the health.

Waste that contains infectious materials and waste that may be harmful to humans, animals, plants, or the environment is considered biohazardous. Examples of biohazardous waste include the following:

- Waste from infectious animals that includes animal tissues or carcasses
- Bulk human blood or blood products
- Microbiological waste (including pathogen-contaminated disposable culture dishes, and disposable devices used to transfer, inoculate, and mix pathogenic cultures)
- Pathological waste
- Sharps
- Hazardous rDNA and genetic manipulation products
- Waste from production of bacteria, viruses, spores, discarded live and attenuated vaccines

Hazardous and biohazardous waste must be disposed of properly. Hazardous waste must be disposed of through Environmental Health & Safety. Biohazardous waste can be disposed of as regular trash after it has been rendered non-infectious by proper decontamination. If you are unsure of how to dispose of any material, view the Waste Decision Tree or contact EHS at 309-438-8039. All bloodborne pathogenic material must be incinerated and removed by the designee. If questions regarding bloodborne pathogen disposal arise, view the Waste Decision Tree or contact EHS at 309-438-8039.

13. Specimen Transport & Packaging

Blood or other potentially infectious materials (OPIM) must be placed in a container, which prevents leakage during the collection, handling, processing, storage, and transport of the specimen. The container used for this purpose shall be labeled with a **Biohazard Sign** that is fluorescent orange or orange red, which is in accordance with the requirements of the OSHA standard. The container must also identify the content being transported. Any specimens, which could puncture a primary container, will be placed within a secondary container that is puncture resistant. Only properly trained personnel are responsible for transporting treated biological waste to the dumpster or incinerator. Properly trained technical personnel may handle untreated biohazardous waste. Use of trash receptacles for untreated biohazardous waste is prohibited. The specimens for shipping must meet DOT/USPS (Department of Transportation/U.S. Post Office) requirements. Hazardous goods shipments **must** be properly packaged, marked, labeled, and identified with the appropriate paperwork

(shipping papers). **All** outgoing shipments of hazardous materials, including biological, must be coordinated through EHS. Below is useful information that you should browse if you find yourself having to ship hazardous materials by any mode of transportation (car, truck, air, boat, etc.). Contact EHS for assistance in preparing a package for shipment (438-8039).

- Transportation Regulations- http://www.access.gpo.gov/nara/cfr/waisidx_01/49cfrv2_01.html
- NIH Guidelines - http://www4.od.nih.gov/oba/RAC/guidelines_02/Appendix_H.htm

14. Hazard Communication

Communication of hazards is a top priority for Illinois State University. With proper communication, exposure to chemicals, infectious material, and other hazardous material can be eliminated or reduced. At initial hire, proper training must be performed to communicate all information. Universal precautions must be followed at all times when dealing with bloodborne pathogens and OPIM.

a. *Communication to Employees*

The Occupational Safety and Health Administration (OSHA) requires that employers, such as the University, have a Right to Know Program or **Hazard Communication Program.** The Right to Know Law requires that an employer's program provide a means for identifying a hazard and communicating appropriate information to employees. The **EHS website** gives details on the program. The Right to Know Program requires the following:

- Employee training (including recognition of signs of exposure)
- Labeling procedures
- MSDS for chemicals at each workplace
- Instructions on how to read and interpret the MSDS
- Chemical inventory reporting procedures
- Recordkeeping requirements
- Emergency response procedures

*PI(s) are responsible for conveying this information to all lab workers under their supervision

When an employee is working with infectious agents or other potentially infectious material, the principal investigator is required to communicate the potential hazards to the employee. The supervisor of applicable laboratories that are exposed to Potentially Infectious Materials are required to develop an Exposure Control Plan, which will help communicate the hazards of bloodborne pathogens

An SDS is normally associated with chemicals, however; an SDS for infectious agents is highly applicable for relaying important information to workers. If an infectious agent is used in a laboratory, an SDS is required to

be available to all students and employees. Health Canada has been a great source to provide SDSs for infectious agents.

Each occupationally exposed employee **(see Appendix A)** must be given information and training at no cost to the employee, during working hours, the time of initial assignment, and at least once a year thereafter. Additional training is needed when existing tasks are modified or new tasks that involve occupational exposure to bloodborne pathogens affect the employee's exposure. The person conducting training must be knowledgeable about the subject and the information provided must be appropriate in content and vocabulary. The hazard communication must consist of the following elements:

- How to obtain a copy of the regulatory text and an explanation of its contents
- Information on the epidemiology, symptoms of, and transmission of bloodborne disease
- Explanation of the exposure control plan and how to obtain a copy
- Information on how to recognize tasks that might result in occupational exposure
- Explanation of the use and limitations of work practice, engineering controls, and PPE
- Information on the types, selection, proper use, location, removal, handling, decontamination, and disposal of Personal Protective Equipment (PPE)
- Information on HBV immunization such as safety, benefits, efficacy, methods of administration, and availability
- Information on who to contact and what to do in an emergency
- Information on how to report an exposure incident and on post-exposure evaluation and follow-up
- Information on warning labels, and signs, where applicable, and color-coding
- Question and answer session on any aspect of the training

b. Labels & Signs

Warning labels shall be affixed: to containers of regulated waste; refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials. Biohazard signs must be posted at entrances to all biosafety levels. The labels shall be fluorescent orange or orange-red or predominately so, with lettering and symbols in a contrasting color. Red bags or red containers may be substituted for labels. An emergency contact form must also be placed in each laboratory. See the following links for the proper sign:

Biosafety Level 1 door sign	**Emergency Contact Form**
Biosafety Level 2 door sign	**Biohazard labels**
Biosafety Level 3 door sign	**NFPA Diamond**

15. HIV/Hepatitis

Hepatitis B has been one of the most frequently occurring laboratory-associated infections. Laboratory workers are recognized as a high-risk group for acquiring such infections. Those who are infected with HBV are at risk of infection with hepatitis D virus. HDV is defective and requires the presence of HBV for replication. Hepatitis C infections can also occur in the laboratory. Hepatitis A and E are usually found among animal handlers. The agents may be present in feces, saliva, and blood of infected humans and nonhuman primates. The ingestion of feces, stool suspensions, and other contaminated materials are the primary hazard to laboratory personnel.

The hepatitis B vaccination shall be made available to employees who are potentially exposed and those who are known to be exposed. The vaccination will be made available to employees in **Appendix A** within 10 working days of the initial assignment. If declining to receive the offered vaccination, the individual must sign a **Hepatitis B Declination Form**. This form must be retained by the supervisor. If the individual later decides to accept the vaccination, it shall be provided at that time. Only acceptable circumstances for not providing this vaccination are that:

- The individual has previously received the complete hepatitis B vaccination series
- Antibody testing has revealed that the individual is immune
- The vaccination is not recommended for medical reasons

The Human Immunodeficiency Virus (HIV) is a virus that has no known cure or immunization that can prevent seroconversion to the virus. HIV causes acquired immunodeficiency syndrome (AIDS), a severe life-threatening illness that suppresses the body's immune system and can impede neurological functions. All possible precautions must be taken when working with human blood or tissue, semen, vaginal secretions, or breast milk.

Universal precautions must always be used. Consider all specimens to be infectious and treat these materials as potentially hazardous. All exposures/accidents/incidents should be reported to the supervisor. If medical treatment or compensation for medical bills or lost wages is anticipated, the CMS Early Intervention packet must be completed. **(See Accident/Incident/Exposure reporting)**

Hepatitis B vaccine is administered through:

Illinois State University — Phone: (309) 438-8655

Student Health Services — (309) 438-2498 (TDD)

Campus Box 2540 — Fax: (309) 438-3689

Illinois, IL 61790-2540

16. Accident/Incident/Exposure Reporting

All individuals who are considered compensated employees of the University, including graduate assistants, teaching assistants, RA's and student workers are required to notify the supervisor of accidents, incidents, and exposures to hazardous material. The supervisor must maintain a **Sharps Injury Log** for all accidents/incidents involving a sharp as soon as possible. The log is to be kept by the supervisor of the lab and will be viewed upon annual inspection. An **Employee Accident/ Incident Report** is also required to be filled out by the supervisor for risk assessment. If further reporting is requested contact EHS for an Accident Report.

Percutaneous (needle stick, cut or puncture) or mucous membrane (splash to eye, nasal mucosa, or mouth) exposure to body fluids or has a cutaneous exposure to blood when their skin is chapped, abraded, or otherwise, non-intact, the source patient shall be contacted and informed of the incident and tested for HIV and HBV infections after consent is obtained. The employee shall be clinically evaluated, by medical facility of choice, as soon as possible. A copy of the **Exposure Control Plan** should accompany the individual to the medical facility of choice and a supervisor is recommended to accompany the employee also.

Post-exposure prophylactic treatment, when medically indicated; counseling; and evaluation of reported illnesses is provided by Student Health Services or designated health care provider and documented in the individual's medical records. The Student Health Services (SHS) will give a medical review and a professional opinion. At this point, depending on the medical review, SHS may refer individuals to another health care clinic if necessary. All findings or diagnoses shall remain confidential and shall not be included in the written report.

17. Training

Training is essential to communicate proper worker safety issues. The only way to prevent potential injury is to train each individual who will be involved with any type of hazardous operation. Training not only reduces injury, but also increases worker efficiency. All training must be given at least at initial hire. Some training must be given annually and/or when a condition/duty changes. The PIs are responsible for ensuring that the training is performed for all lab workers under their supervision. The training must be documented and will be reviewed at the annual audit/inspection. To help make an evaluation of what training is needed see the chart below and page 13 of this manual.

JOB CHARACTERISTICS	TRAINING REQUIREMENTS								
Does your job involve the use of the following?	General Lab Safety Training Outline	Lab Specific Recombinant DNA Infectious Agents	Emergency Action/Fire Safety	IACUC Contact RSP 438-8451	Respiratory Protection Contact EHS 438-8325	Bloodborne Pathogens	Hazard Communication Lab Standard 29CFR1910.1450	Radiation Safety	X-Ray Safety

Research Animals	X	X	X	X	X*				
Arthropods	X	X	X						
Infectious Agents	X	X	X		X*				
Bloodborne Pathogens	X	X	X			X			
Recombinant DNA	X	X	X						
Chemicals	X	X	X		X*		X		
Radioactive Material or Other Radiation								X	X

a. Lab Safety (General & Lab Specific)

General laboratory safety procedures need to be communicated in a formal training session by the laboratory supervisor. The emphasis on proper laboratory safety needs to be addressed. It is required to identify all hazards and communicate the appropriate safety information to employees upon initial hire. Laboratory-specific safety must also be addressed. Each biosafety level must have its proper containment communicated. Competent supervisors, who are experienced in working with agents designated at different biosafety levels, must communicate and/or make available at least the following:

- Understanding the factors affecting disinfection
- Understanding the primary and secondary barriers
- Protocols to describe potential biohazards and precautions to be taken
- Procedures for dealing with accidents
- Emergency spill and/or exposure
- Appropriate emergency contacts
- Explanation of signs and labels and/or color coding that is required
- Information on the types, basis for selection, proper use, location, removal, handling, decontamination, and disposal of PPE
- Decontamination procedures
- Recognition of signs of exposure

- Labeling procedures
- SDS for chemicals and infectious agents at each workplace
- Instructions on how to read and interpret the SDS
- Chemical inventory reporting procedures
- Recordkeeping requirements
- Accident/incident reporting
- Housekeeping

b. *Emergency Action Plan/Fire Prevention*

The Emergency Action Plan (EAP) must be reviewed with each new employee at initial hire and if the plan changes at any point. It is important to communicate to employees the proper route of escape in the case of an emergency. If there are ten or fewer employees, the plan may be communicated orally. More than ten employees must have the plan in writing. An **Emergency Action Plan** can be downloaded from the EHS web site and filled out for your specific location. If there are any questions relating to the EAP, contact EHS. Emergency contact numbers must be located in near proximity to the telephone of every lab. The following web site can help aid in the training process: https://ehs.illinoisstate.edu/safety/fire/

The following are to be addressed accordingly:

- Emergency escape procedures and emergency escape route assignments
- Procedures to be followed by employees who remain to operate critical plant operations before they evacuate
- Procedures to account for all employees after emergency evacuation has been completed
- Rescue and medical duties for those employees who are to perform them
- The preferred means of reporting fires and other emergencies
- Names or regular job titles of persons or departments who can be contacted for further information or explanation of duties under the plan

c. *Bloodborne Pathogen Training*

All employees who have occupational exposure to human blood, human blood components, and products containing blood from humans are required by OSHA (29 CFR 1910.1030) to have proper training at initial assignment and annually thereafter. All employees listed in **Appendix A** are to be offered the Hepatitis B Vaccine within 10 days of the initial hire. If the employee declines the immunization, a **Hepatitis B Vaccine Declination Form** must be obtained and kept on file by the supervisor of the laboratory. The supervisor of the lab is required to have written an Exposure Control Plan and make it readily available to all employees. The **Bloodborne Pathogens/Infectious Waste Exposure Control Plan** is available for more information and must be reviewed by each applicable employee. This manual must be located and available to all employees if they are being occupationally

exposed. Environmental Health & Safety can aid in training and development of the Exposure Control Plan (309) 438-8325. Training must cover the following topics:

- The OSHA standard for Bloodborne Pathogens (1910.1030 - Bloodborne pathogens. | Occupational Safety and Health Administration (osha.gov)
- Epidemiology, symptoms, and modes of transmission of bloodborne diseases
- Information on Hepatitis B Vaccine, including its efficacy, safety, method of administration, the benefits of being vaccinated, and that employees will be offered the vaccination series free of charge
- Post-exposure follow-up procedures
- Information on the types, basis for selection, proper use, location, removal, handling, decontamination, and disposal of PPE
- Control methods
- Explanation of signs and labels and/or color coding that is required
- The Exposure Control Plan
- Procedures which might cause exposure to blood or OPIM at ISU

d. Teaching Laboratories

Instructors in teaching laboratories should provide specific training for the hazards expected to be encountered in the laboratories where hazardous procedures are utilized. Because of the brevity of courses, the large number of students involved, and the detail and length of the Training Form, it is recommended that each instructor use the **Teaching Laboratory Training Form** to document the training of the particular elements required for their course. Both the student and the instructor should sign the training form. This form is to be retained by the PI and must be available upon audit/inspection.

18. Records/ Required Documentation

Each laboratory is required to maintain a set of records that are applicable to that lab. Training records shall be maintained for 3 years after the employee/student is terminated or no longer working in the lab. The hepatitis B vaccination status must be maintained for the duration of employment plus 30 years. The sharps log(s) must be maintained for 5 years following the end of the year to which they relate if it involves an infectious agent containing human blood. If the sharps log does not contain a bloodborne pathogen it must be maintained for 3 years. The following items must be available to each employee:

- Emergency Contact Form
- Exposure Control Plan (If exposure to bloodborne pathogens)
- Chemical Hygiene Plan (If lab contains chemicals)
- Biosafety Manual (Labs dealing with rDNA/infectious agents)
- Emergency Action Plan/Fire Prevention Plan

- OSHA bloodborne pathogen standard (where applicable)
- Copy of CDC/NIH booklet *Biosafety in Microbiological and Biomedical Laboratories (BMBL),* 4th edition and/or NIH *Guidelines for Research Involving Recombinant DNA Molecules*
- SOP (Accident reporting, spill clean-up, decontamination, PPE) if different from Biosafety Manual

19. Annual Audit/Inspection

Each calendar year there will be an audit/inspection to ensure compliance. The annual audit/inspection will be held in the spring of each year following the initial protocol approval time period. A one-time inspection of all research labs will be conducted. Once this is completed, an assessment will be made by the IBC Chair/BSO to determine whether a specific lab will need to continue the annual inspection beyond protocol submission and exemptions. All laboratories, which conduct research that deal with infectious agents or recombinant DNA that are not exempt, will be inspected on an annual basis. A reminder will be sent to all applicable labs to notify of the upcoming audit/inspection. This will communicate the need to have all necessary documentation ready for the annual inspection. A **MUA** and an **Annual Renewal of Protocol** will need to be completed by the principal investigator conducting experiments involving infectious agents or rDNA along with any other necessary documentation. If a protocol has been submitted on or after October 1 of the previous year, then the PI is exempt from re-filing the MUA and Annual Registration Form. Laboratories shall be inspected in accordance with the procedures set forth below.

- During laboratory inspections, a laboratory representative should be present to observe and provide additional information and clarification.
- At the close of each laboratory audit/inspection, an exit interview highlighting the issues, which were identified in the laboratory, shall take place.
- Laboratory audit/inspection results shall be provided within ten working days of completion of a particular laboratory's review.
- Summary results by department shall be distributed to the respective administrative department.

Each identified concern shall be corrected in accordance with the corrective action dates listed in the laboratory's audit/inspection form. Each department shall ensure that corrective action plans have been implemented or are in process prior to the time frame listed on the Review Summary. Safety concerns identified during the initial laboratory inspection shall be corrected and re-evaluated during a follow-up inspection within 90 days. All concerns shall be tracked until corrective actions have been completed. The **Biosafety Audit/Inspection Form** must be available upon initial inspection.

20. Liability for Noncompliance

All NIH-funded and non-NIH-funded projects involving rDNA techniques must comply with the NIH guidelines. Non-compliance may result in suspension, limitation, or termination of financial assistance for the non-compliant NIH-funded research project and also of NIH funds for other recombinant DNA research at the institution.

The failure to follow these guidelines or to adhere to good scientific integrity could result in some or all of our research endeavors being suspended or other consequences, similar to the ones that have occurred at several prominent institutions over the past year including St. Louis University, University of California, Ohio State University and many others. Non-compliance with the Institutional Biosafety Program, which includes CDC, NIH, and OSHA, will have several immediate and long-term consequences. Those unable to conform to both the specifics and spirit of this manual must refrain from any biohazardous activity. Until all aspects of this manual are met, EHS will not approve the protocol request. If failure to continue compliance occurs, assets may be frozen by RSP.

Redundancy in enforcement, just as in containment, is needed because individuals may unconsciously develop unsafe practices or fail to recognize unsafe conditions. For this reason, all PIs and others supervising or overseeing biohazardous activities are expected to closely inspect the work, work practices and work conditions of subordinates and expeditiously correct any unsafe conditions and/or practices observed.

21. Forms

- ***A. Protocol for Use of rDNA***
- ***B. Protocol for Use of Infectious Agents***
- ***C. Memorandum of Understanding and Agreement (MUA)***
- ***D. Sharps Injury Log***
- ***E. Biosafety Audit/Inspection Form***
- ***F. Amendment of Protocol***
- ***G. Hepatitis B Vaccine Waiver***
- ***H. Autoclave Recording Log***
- ***I. Chemical Inventory***
- ***J. Emergency Contact Form***
- ***K. Annual Renewal of Protocol***
- ***L. Teaching Laboratory Training Form***
- ***M. Training Completion Form***
- **N. *Spill Log***
- **O. *Training Chart***
- **P. *Biosafety Level 1 door sign***
- **Q. *Biosafety Level 2 door sign***
- **R. *Biosafety Level 3 door sign***
- **S. *Biohazard Labels***
- **T. *NFPA Diamond***
- **U. *Waste Decision Flow Chart***
- **V. *Biohazard Spill Kit***
- **W. *Emergency Action Plan***

***It is highly advised to keep a laboratory notebook for all required documents to make the audit/inspection quicker and to keep track of paperwork

22. Miscellaneous Information

Environmental Health and Safety

Chemical Hygiene

Radiation Safety

IACUC

Environmental Waste

Acknowledgements

This document has been written according to National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), and also Occupational Safety and Health Administration (OSHA) regulations. Illinois State University must adhere to these guidelines as a minimum standard. The University guidelines may deviate from the regulations but only in a manner that may be more stringent than the regulations.

This manual, and the forms associated with the manual, has been created with ideas and concepts from various universities, colleges, and institutions integrated into it. Some of the concepts and ideas came from the following:

- *University of Kentucky*
- *Auburn University*
- *Medical College of Georgia*
- *Office of Health and Safety (CDC)*
- *Health Canada (Population and Public Health Branch)*
- *Iowa State University*
- *Colorado State University*
- *Princeton University*
- *Medical University of South Carolina*
- *University of Minnesota*
- *University of Texas at San Antonio*
- *Texas A&M University*
- *Harvard University*
- *University of Victory*
- *University of Chicago*
- *University of Pennsylvania*
- *Arizona State University*
- *North Carolina State University*
- *University of Virginia*
- *Yale University*
- *University of California-San Diego*
- *Ohio State University*

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)

Department of Transportation (DOT)

USPHS 42 CFR Part 72 - Interstate Shipment of Etiologic Agents

DOT 49 CFR PART 173 - Transportation of Etiologic Agents

American Biological Safety Association (ABSA)