STANDARD OPERATING PROCEDURES

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE

Kansas City University

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1. INTRODUCTION

These biosafety policies of the Kansas City University (the "**University**") regulate the use of recombinant DNA molecules and other biohazardous materials in both the research and teaching laboratories of the University. The aim of these policies is to ensure that such regulated materials are used safely and in compliance with the *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf (See Appendix H of this Policy) and the NIH and Center for Disease Control's (CDC), *Biosafety in Microbiological and Biomedical Laboratories, Edition 6* (*Biosafety Manual*) https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf (See Appendix G of this Policy). These policies are in place to protect students, faculty, staff, the public, and the environment from exposure, and resulting consequences, to recombinant DNA molecules and biohazardous material the University uses during research and teaching. The primary and overriding goal is safety, with the ancillary aim of doing so without unnecessarily hindering research and teaching activities.

1.1 Definitions

A. **Biohazardous Materials**: Any microorganism, or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: 1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; 2) deterioration of food, water, equipment, supplies, or material of any kind; or 3) harmful alteration of the environment. These include, but are not limited to: Certain bacteria, fungi, viruses, rickettsia, protozoa, parasites; recombinant products; toxins of biological origin; allergens; cultured human or animal cells and the potentially infectious agents these cells may contain; viroids and prions; other infectious agents as outlined in applicable laws, regulations and guidelines.

   Examples include all materials containing recombinant DNA; transgenic animals or plants; human, animal or plant pathogens; biological toxins (such as tetanus toxin); human blood and certain human body fluids; select agents; high consequence livestock pathogens and toxins; and human or primate cell cultures.

B. ***Biosafety Manual*:** NIH and Center for Disease Control's (CDC), *Biosafety in Microbiological and Biomedical Laboratories, Edition 6.* (Also See Appendix G of this Policy) https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf .

C. **Infectious Agent(s):** Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions.

D. ***NIH Guidelines:*** *National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (2019)* (See Appendix H of this Policy) https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

E. **Non-Biohazardous Materials:** Biological materials not usually infectious. Examples are non-pathogenic microorganisms, sub-viral agents, viruses, biomaterial unlikely to contain infectious agents, exempt recombinant DNA molecules under the *NIH Guidelines*, environmental samples unlikely to have infectious agents, and biologically-derived non-toxic molecules.

F. **Principal Investigator:** Encompasses both lead investigator of research project and instructors/course supervisors in teaching labs.

G. **Recombinant DNA:**

(i) Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or

(iii) molecules that result from the replication of those described in (i) or (ii) above. (*NIH Guidelines*, 2019).

Recombinant DNA molecules are considered biohazardous unless exempt from the *NIH Guidelines*. Examples are recombinant DNA formed by transfer of drug resistant trait to microorganisms that do not acquire the trait naturally; designed for use in human gene transfer; contains genes for the biosynthesis of toxic molecules lethal for vertebrates at a median lethal dose (LD50) of less than 100 ng/kg body weight; is designed for generating transgenic plants or animals; or contains infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus.

H. ****Note:** The terms "research" and/or "research activities" as used in this policy also encompass teaching and/or teaching activities at the University. Likewise, the terms "principal investigator(s)" and/or (PI(s)) encompasses, when applicable, instructor(s) for a teaching laboratory or teaching activity involving research.

1.2 Abbreviations

A. **APHIS:** Animal and Plant Health Inspection Service
B. **BSC:** Biological Safety Cabinet
C. **BSL:** Biosafety Level
D. **BSO:** Biological Safety/Biosafety Officer
E. **CDC:** Centers for Disease Control and Prevention
F. **DOT:** Department of Transportation
G. **HHS:** United States Department of Health and Human Services
H. **IBC:** Institutional Biosafety Committee

I. **IO:** Institutional Official (the EVPR)
J. **NIH:** National Institutes of Health
K. **OSP:** Office of Science Policy
L. **ORSP:** Office of Research and Sponsored Programs
M. **PI:** Principal Investigator
N. **rDNA:** Recombinant DNA
O. **USDA:** United States Department of Agriculture
P. **EVPR:** Executive Vice President for Research (also the IO)
Q. **ORC:** Office of Research Compliance

1.3 Materials and Activities Covered

All work with recombinant DNA, whether classified as exempt or non-exempt according to the *NIH Guidelines* and work with any biohazardous materials (See Section 1.1(A) of this Policy). Any research involving recombinant DNA molecules (See Section 1.1(G) of this Policy) must be registered with the University's IBC, regardless of whether such research is exempt under NIH Guidelines (See Section 13 of this Policy for IBC Procedures). **BSL-3 & 4 research is not currently allowed at the University.**

1.4 Roles and Responsibilities

Effective implementation of the University Biosafety Program requires the effective cooperation of several individuals and groups within the campus community. Individuals falling under these policies may fall into more than one category.

1.4.1Principal Investigators

The PI is vested with the primary responsibility for ensuring safe performance of research activities within a research or teaching lab on the University's campus**.** For teaching laboratories that are associated with courses, the designated instructor/lab supervisor shall have the same responsibilities as the PI.

The PI's **minimal** responsibilities are the following:

A. Reading and being knowledgeable of this policy and the procedures and guidelines contained within.
B. Being familiar with principles and procedures appropriate for the safe use of the specific recombinant DNA molecules and biohazardous materials used in his or her research and following/applying those principles and procedures.
C. Conducting a risk assessment and determining the appropriate biosafety level(s) for the materials to be used in his or her lab.
D. Using risk assessment to determine lab procedures, containment equipment, personal protective equipment, and facilities that are suitable for the biosafety level(s).

E. Making sure lab facilities are maintained, equipment is in safe working condition, and biohazard-warning signs are posted where appropriate, including lab entrances, and freezers, refrigerators, and any other containers holding recombinant DNA molecules or other biohazardous materials. Ensuring that animal rooms involving recombinant DNA-modified organisms used with animals have postings on the associated risks. For details on signage requirements, see Exposure Control Plan Section 6 (See Appendix C of this Policy), Hazard Communication Plan, and NIH Guidelines Appendices L-II-B-1-f, L-Ii-C-1-f, L-II-D-1-f, L-II-D-1-f, M-II-B-1-c, M-II-C-1-c, and M-II-D-1-c.

F. Determining the minimum Personal Protective Equipment for lab staff and ensuring personnel are trained on the proper use of PPE and are in fact properly using PPE. Supervising the safety performance of the lab staff, which includes monitoring Personal Protective Equipment compliance. See NIH Guidelines IV-B-7-e-(1) and NIH Guidelines Appendix G.

G. Consulting the *NIH Guidelines* that apply to the type of research to be conducted and indicating such on the protocol application for IBC review.

H. Prior to beginning recombinant DNA or Biosafety Level 1-3 research, submitting research protocols for review by, and registration with, the Institutional Biosafety Committee (See Section 13 of this Policy for IBC procedures), unless the research activities are authorized by the *NIH Guidelines* to the IBC simultaneously with beginning research (See Section III-E of the NIH Guidelines). PIs are also responsible for submitting to the IBC subsequent changes to such protocols.

I. Submitting protocol renewal and amendment forms (See Appendix G) as well as incident reports to the IBC as required (See Sections 13.6(c)(4) and 13.11(a)-(c) for more on incident reports).

J. Ensuring all lab personnel are appropriately trained for working with biohazardous materials and/or recombinant DNA, use of safety equipment, and the *NIH Guidelines*. This includes ensuring personnel have undergone the University's required training program as outlined in Appendix A of this Policy, as well as any additional lab-specific training needed to be in compliance with the *NIH Guidelines.* PIs are responsible for keeping records of training that individual personnel have undergone and submitting such to the IBC and ORSP. For laboratory specific training, there is a specific form for documenting lab-specific training, the PIs must ensure that the form is used for documentation includes information about (1) who was trained, (2) where they were trained, (3) the date of

training, (4) the content/subject/tasks of the training, (5) a signature by the PI who gave the training, (6) the signature of the individual who underwent the training, and (7) the role the trained individual will serve in the research project.

K. Prior to initiating research, making available to lab staff, (1) the protocols that describe the potential biohazards and the precautions to be taken, (2) instructing and training lab staff in (a) the practices and techniques required to ensure safety and (b) the procedures for dealing with accidents, and (3) informing lab staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

L. Supervising the safety performance of the lab staff to ensure that the required safety practices and techniques are employed.

M. Correct work errors and conditions that may result in the release of recombinant DNA materials.

N. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Manager(where applicable), Institutional Biosafety Committee, NIH/OSP, and other appropriate authorities (if applicable) (reports to NIH/ OSP shall be sent to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20817 or by email at NIHGuidelines@od.nih.gov Phone: 301-496-9838, 301- 496-9839 (fax).

O. Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

P. Complying with reporting requirements for gene transfer experiments conducted in compliance with the NIH Guidelines Appendix M-II – A to D; Appendix G-II-C-2-q, G-II-D-2-k, Reporting Requirements).

Q. Reporting newly identified select agents immediately to the IBC and/or Biosafety Officer.

R. Timely requesting collection of biohazardous waste.

S. Making available reference information on biological hazards and that research personnel knows how to use such references.

T. Knowing and implementing when required the proper procedures to use in the event of an emergency or spill/release.

U. Complying with shipping requirements for rDNA and biohazardous materials.

V. Reporting all significant violations, spills, releases, injuries or illnesses use of materials during research to the IBC and/or Biosafety Officer.

W. Reporting all exposures to biological agents or recombinant DNA, theft or loss of biohazardous material, and incidents that warranted emergency response to the IBC.

X. Cooperating with Annual Biosafety Inspections of the lab, including those by the Biosafety Officer.

1.4.2 Research Personnel

Research personnel are responsible for:

A. Completing all University requirements for approval to work in the lab and making sure all work performed in the lab complies with University policy, NIH, CDC, OSHA and any other guidelines the research activities fall under.

B. Learning and following the standard operating procedures for the lab. Familiarizing self with potential hazards, infectious agents being used, and emergency procedures.

C. Help keep the lab facility in good, operable condition.

D. Report to the PI all medical restrictions, reportable illnesses, and any potential exposure. Report all conditions that are irregular.

E. Follow the University training program as outlined in Appendix A of this Policy and as well as training from PI to ensure proficiency in appropriate microbiological practices.

F. Completing medical surveillance requirements, if applicable.

G. Following instructions given by PI regarding keeping the lab maintained and operating functionally.

1.4.3 Deans, Directors, and Department Heads

The Dean, Director or Department Head are responsible for:

A. Ensuring all persons under his or her jurisdiction have access to the University's biosafety manual.

B. Ensuring PI has taken required training for the research activity to be performed.

C. Ensuring availability of facilities are appropriate for containing biohazardous materials and sufficient to enable the PI to comply with University policies.

D. Ensuring the IBC reviews research activity involving biohazardous materials.

E. Ensuring accidents/incidents are Immediately reported to Biosafety Officer.

F. Ensuring all personnel who are eligible are assigned to occupational health program that is appropriate.

G. Assisting in eliminating known unsafe practices.

1.4.4 Institutional Biosafety Committee

The IBC is a committee appointed by the Chief Executive Office in coordination with the EVPR. See Section 13 of this Policy for procedural information regarding the IBC. The IBC's responsibilities include, but are not limited to:

A. Review research protocols involving recombinant DNA and materials that are biosafety level 2 (infectious agents, biological toxins, and other biohazardous materials) and higher (collectively referred to as "covered research activities) to ensure they comply with the *NIH Guidelines* and *The Select Agent Rule*, reviewing protocols for biosafety concerns, the *CDC Manual* and University policy.

B. Overseeing implementation of University biosafety procedures.

C. Independently assessing containment levels required by the *NIH Guidelines* and/or *CDC Manual* for proposed research.

D. Assessing the facilities, procedures, practices, and training and expertise of personnel involved in covered research activities for compliance with federal and state guidelines and law.

E. Ensuring that all aspects of Section-III of the NIH Guidelines have been appropriately addressed by the Principal Investigator.

F. Ensuring no research participant is enrolled in a human gene transfer experiment until the NExTRAC review process has been completed (See Section IV-B-1-f & Section III of the NIH Guidelines for review requirements), IBC approval from the clinical site has been obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained.

G. For human gene transfer protocols selected for public NExTRAC review and discussion, considering the issues raised and recommendations made as a result of this review and considering the PI's response to the NExTRAC recommendations.

H. Ensuring final IBC approval is not granted until after the NExTRAC review process has been completed.

I. Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines and this University policy.

J. The University's Chief Executive Officer has authorized the IBC to disapprove of or suspend research in noncompliance with policies and procedures described in the Biosafety Manual, NIH Guidelines and/or University policy, and the IBC has the responsibility to do so. Likewise, if a lab inspection

results in a determination that lab procedures are not being followed, research may be halted until actions are taken to correct deficiencies.

I. Notifying the PI of the results of the IBCs review and approval or disapproval. In the case of disapproval, notifying the PI of the reason for the disapproval and giving the PI an opportunity to respond.

J. Lowering containment levels for certain experiments as specified in Section III-D-2-a of the NIH Guidelines

K. Setting containment levels as specified in Sections III-D-4-b and III-D-5 of the NIH Guidelines when applicable.

L. Reviewing covered research conducted at or sponsored by the University to ensure compliance with the NIH Guidelines.

M. Adopting emergency plans covering accidental spills (See Appendix B of this Policy, NIH Lab Safety Monograph for reference) and personnel contamination resulting from recombinant DNA research.

N. Reporting significant problems or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the Institutional Official, who shall file a report to NIH and the OSP within 30 days. Unless the IBC determines a report has already been filed to the NIH and the OSP by the PI.

O. For recombinant DNA work not explicitly covered by the NIH Guidelines, not approving initiation of such experiments until NIH establishes the containment requirement.

P. Ensuring compliance with the University's OSHA Exposure Control Plan (Appendix C of this Policy), when applicable.

Q. The IBC is responsible for reporting incidents to the Institutional Official.

*Refer to Section 13 of this policy for IBC procedure.

1.4.5 Biological Safety Officer

A. The Biological Safety Officer is a faculty/ or staff member knowledgeable of biosafety issues who is appointed by the Chief Executive Officer. The Biological Safety Officer shall always be a member of the IBC. The University shall have a Biological Safety Officer with the following responsibilities include but are not limited to:

1. Periodically inspecting lab facilities to ensure that laboratory standards are rigorously followed.

2. Investigating every accident with possibility of escape and/or exposure to materials that are potentially infectious or toxic.

3. Reporting to the IBC and the University any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator.

4. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research.

5. Ensuring that following of decontamination procedures after spills and/or breakage involving biohazardous materials and keeping record of such accidents and incidents, ensuring that materials and equipment are being appropriately decontaminated and monitoring infectious waste disposal after treatment for safety.

6. Providing advice on laboratory security.

7. Providing technical advice to Principal Investigators and the IBC on research safety procedures.

Note: See the *Laboratory Safety Monograph* (Appendix B of this Policy) for additional information on the duties of the Biological Safety Officer.

8. Complying with all IBC procedures, Section 13 of this Policy (including 13.10(A)).

9. Serving as a member on the University's IBC.

1.4.6 Office of Research Compliance

The ORC has the responsibility for all official communication between the University and federal and state agencies such as NIH, NSF, the USDA, HHS, etc. The ORC maintains the IBC website, oversees, and administers training modules and examinations required of PIs and other research personnel. The Office of Research Compliance is also responsible for maintaining documentation of research personnel training.

1.4.7 Executive Vice President for Research

The responsibility for assuring comprehensive programs on campus for safe handling of infectious agents, recombinant DNA molecules, and all other biohazardous materials at the University rests with the Executive VPR. The EVPR is responsible for administration of the University's Biosafety policies. This includes appointing members to the IBC in coordination with the Chief Executive Officer, appointing the Biological Safety Officer, and approving all IBC-recommended policies and procedures. As IO, the EVPR is responsible for all IO duties, including providing final incident reports to the NIH OSP.

2. Biological Risk Assessment

Before submitting a protocol for review by the IBC, all PIs are required to conduct a risk assessment of the proposed research and materials to be used (see Pg. 41 of the *Biosafety Manual*). The CDC and NIH require such risk assessments to protect the health of lab personnel and the public. The PI's goal during risk assessment is to identify potential hazards and risks involved with the planned research or teaching activities, then to develop and implement standard operating procedures and practices to minimize those risks to the lowest possible level. The PI must conduct a risk assessment of each of his or her research and/or teaching labs. After the risk assessment, the PI must assign the appropriate Biosafety Level (BSL) to the agents that will be used. Additionally, through risk assessment the PI must assess several factors that contribute to potential risk, including, but not limited to, the hazardous characteristics of the lab procedures to be used; the training, experience and habits of lab personnel; and the adequacy of the lab facility and equipment. The following policy outlines these elements. If the *Biosafety Manual*, *NIH Guidelines* and any other mentioned reference materials do not account for the type of agents or nature of the lab procedures that are contemplated for the research, the PI is responsible for using the best information available. In all risk assessments, the PI should consult available scientific references along with, and not in place of, his or her professional judgment.

Note: Biological Safety Level 4 and Animal Biological Safety Level 4 Research is Currently Prohibited at the University.

Note: For any activity involving a select agent or toxin, in addition to risk assessment, developing lab safety procedures, and getting approval from the IBC, all federally mandated applications to applicable federal agencies must be approved before beginning the activity. These select biological agents and toxins are listed in 7 CFR 331 at https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1 , 9 CFR 121 at https://www.ecfr.gov/current/title-9/chapter-I/subchapter-E/part-121?toc=1 , 42 CFR 73 at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1 , and on the HHS and USDA select agents and toxins list online. Select Agents are also discussed in Section Six and listed in Appendix F of the *Biosafety Manual*. Also, see the U.S. Government's Select Agent list for reference. A list of Select Agents can be found in Appendix F of this Policy.

2.1 Risk Assessment Procedure

The risk assessment process consists of the following five steps. Principle investigators should refer to Section 2 of the *Biosafety Manual* for detailed guidance on conducting these steps.

A. Identify agent hazards and perform an initial assessment of risk.

B. Identify Laboratory Procedure Hazards

C. Determine Appropriate Biosafety Level and Select Additional Precautions as indicated by the Risk Assessment.

D. Evaluate the Proficiencies of Staff Regarding Safe Practices and Integrity of Safety Equipment.

E. Review the Risk Assessment with IBC and a biological safety expert and/or consultant when determined necessary by the PI, IBC, or University.

2.2 Risk Assessment Guidance

A. Guidance for the Procedural Steps Outlined Above in Section 2.1 of this Policy.

1. Identify agent hazards and perform initial Assessment of risk

For this initial phase of the risk assessment, PIs should begin by consulting the *Biosafety Manua*l, Section 2 (beginning pg. 9).The process of the risk assessment for hazardous characteristics of an agent is explained in pages 9-20. PIs should also consult Section 4 (pg. 32), **unless lab work is to be conducted with animals**, in which case consult Section 5 (page 70) instead; Table 1, *Summary of Laboratory Biosafety Levels* (pg. 68); and the *Agent Summary Statements*, Section 8, Page 147. Additionally, for research involving recombinant DNA, see Section 2.3 of this policy. For research involving HIV, Hep B or other Bloodborne pathogens, additionally see Section 2.4 of this policy. Page 12 of the *Biosafety Manual* offers additional detail for risk assessment for cell cultures and furthermore, Appendix I provides guidance for work with human, non- human primate, and other mammalian cells and tissues.

2. Identify Lab Procedure Hazards

Pages 12 and 14 of the *Biosafety Manual* explain the process of identifying laboratory procedure hazards.

3. Determine Appropriate Biosafety Level and Select Additional Precautions as indicated in Risk Assessment

Page 16 -17 of the *Biosafety Manual* explain the process of determining the appropriate biosafety level and additional precautions.

4. Evaluate Proficiencies of Staff Regarding Safe Practices and Integrity of Safety Equipment. Page 18 of the Biosafety Manual provides an overview of evaluating staff and safety equipment.

5. Review the Risk Assessment with a Biosafety Professional, Subject Matter Expert, and the IBC. Page 18 of the *Biosafety Manual* provides more information about reviewing the risk assessment with other parties.

2.3 Additional Risk Assessment Guidance for Research Involving Recombinant DNA (for both Animal and Non-Animal Lab Work)

In addition to the resources contained in Section 2.2 of this policy, when beginning a risk assessment for recombinant research, Principal Investigators should also consult the *NIH Guidelines*, Section II-A, *Risk Assessment*, and *NIH Guidelines*, Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard*.

After this initial assessment of agents, to determine and document proper containment measures, the PI shall consult the following guidance in the *NIH Guidelines*: Section II-B, *Containment*; Section V, *Footnotes and References of Sections I-IV*), Appendix G, *Physical Containment*, Appendix I, *Biological Containment*.

For research involving plants, PIs shall additionally reference Appendix L of the *NIH Guidelines.* For research involving animals, PIs shall additionally reference Appendix M of the *NIH Guidelines*.

2.4 Additional Risk Assessment Guidance for Research Involving Bloodborne Pathogens

For research or teaching activities involving Bloodborne pathogens, PIs shall additionally consult the University's OSHA Exposure Control Plan when assessing risk and developing lab safety procedures.

3. Development of Lab-Specific Safety/Standard Operating Procedures

After completing an appropriate risk assessment as described in Section 2 of this policy and Section 2 of the *Biosafety Manual*, investigators must develop lab safety/standard operating procedures that minimize or eliminate the risks determined in the risk assessment. For most BSL-1 labs, standard operating procedures need only include the standard microbiological practices contained on page 32, of the *Biosafety Manual*, or for work with animals, page 71 of the *Biosafety Manual*, unless the PI, after conducting a risk assessment, determines additional safety measures should be integrated in the lab safety procedures. The standard microbiological practices, or when applicable, animal microbiological practices, apply to all research, but additional practices are recommended for each ascending biological or animal biological safety level.

A. Guidance for Developing Lab Safety/Standard Operating Procedures as Required in Section 3 of this Policy Above.

In addition to consulting his or her own risk assessment of the contemplated research, PIs should consult the *Biosafety Manual* for recommended microbiological practices, safety equipment (both primary barriers and personal protective equipment), and laboratory facilities (secondary barriers) to integrate in their lab's standard operating procedures. The *Biosafety Manual* is not meant to be an exhaustive source for developing lab procedures. PIs should consult the best information available for their research as well as their professional judgment. **For recombinant research, PIs must consult Appendix G of the *NIH Guidelines* for developing procedures**, when applicable based on the type of recombinant research**.** When developing lab procedures for an animal lab, PIs must consult both the *Biological Safety Manual* **and** the PHS *Guide for the Care and Use of Laboratory Animals, 8th Edition*. Be sure to include any other necessary content such as decontamination, Exposure Control Plan, Occupational health, chemical hygiene procedures, biological spill response plan, etc.

The *Biosafety Manual* offers the following sections for guidance:

1. Procedures for Research Not Involving Animals

   For microbiological research not involving animals, PIs should consult pages 32-36 of the *Biosafety Manual*, for BSL-1 research, pages 37- 42 for BSL-2 research, pages 43-48 for BSL-3 research. BSL-4 research is not currently allowed at the University.

2. Procedures for Research Involving Animals

   For microbiological research involving animals, PIs should consult pages 71-77 of the *Biosafety Manual for* Animal BSL-1 (ABSL-1), pages 78-86 for ABSL-2, and pages 87-97 for ABSL-3. ABSL 4 is not currently allowed at the University. Additionally, PIs must develop lab procedures that comply with the PHS *Guide for the Care and Use of Laboratory Animals, 8th Edition.*

3. Biological Safety Cabinets

When applicable, to assist in selecting proper biological safety cabinets and developing proper procedures, PIs should consult Appendix A of the *Biosafety Manual* beginning on page 367 and Table 1, *Selection of BSC through Risk Assessment*, page 388.

4. Safety Equipment: Proper Use, Maintenance

4.1 PIs are responsible for being familiar with, and instructing all lab personnel on the proper use of all laboratory equipment including Incubators, centrifuges, autoclaves, emergency, biological safety cabinets, and all other equipment, including what to do in the event of a spill involving the equipment.

4.2 Biological Safety Cabinets (BSC)

A. Overview

Biological Safety Cabinets are a form of primary containment aimed at protecting personnel, the environment, and the product, depending on the type of BSC. BSCs are classified into three types, Class I-III. Class III BSCs are further sub-classified as Type A or B. A BSC contains a High Efficiency Particulate Air Filter (HEPA) to remove particles from the air stream. A HEPA filter does not remove vapors or gases.

National Sanitation Foundation Standard # 49 – 2007 governs all models of Class II cabinets (A1, A2, B1, B2). On-site field-testing as per NSF/ANSI Standard 49-2007 Annex F plus Addendum #1 must be performed by qualified personnel. The Standard provides information to assist with the frequency of, qualifications for and procedures for testing. Each of the three classes of BSCs require **annual testing and recertification.**

B. Selection, Installation, and Use of Biosafety Cabinets (BSC)

PIs are responsible for being familiar with and practicing proper selection, installation, and use of BSCs. Appendix A, beginning on page 367 of the *Biosafety Manual*, provides guidance of which PIs must be knowledgeable. A description of the different classes of BSCs begins on page 370. Issues relating to lab hazards and risk assessment are addressed on page 376. Guidance for working with chemicals, as well as possible radiological hazards, within BSCs begins on page 376. Proper work practices and procedures begin on page 300. Possible hazards are addressed on page 378. BSC decontamination information is summarized on page 383. PIs, BSOs, and the University are responsible for working together to ensure the facility and engineering requirements beginning on page 384 are properly met and maintained. The University is responsible for obtaining annual certification from the appropriate manufacturers and/or certifying bodies. Table 1, Selection *of BSC through Risk Assessment*, page 388 of the

Biosafety Manual is a helpful reference during the risk assessment phase described in Section 2 of this Policy.

5. Spills

5.1 Reporting

5.1.1 Time Frames for Reporting

Any significant problems with or violations of the *NIH* Guidelines for work with recombinant DNA molecules or any significant research-related accident and illness must be reported to the appropriate institutional official and the NIH/OSP within 30 days (*NIH Guidelines,* Sec. IV, B(2)(b)(7). Spills and accidents that result in an exposures or loss of containment involving materials in BSL-2 require immediate reporting to the DOR and Biosafety Officer. Spills, overt or potential exposures and loss of containment involving materials in BSL-3 also require immediate reporting to the DOR and Biosafety Officer. Any spills, accidents, or breach of containment involving recombinant DNA materials must be reported immediately to the IO, ORC and Biosafety Officer. The PI is responsible for reporting the above incidents to the ORC and Biosafety Officer. The ORC and BO will help in determining if an event requires reporting to the NIH/OSP. The designated official for the University will report any incidents to NIH OSP. The IBC will direct a follow up investigation if warranted.

5.2 Biological spill kit

A biological spill kit must be located in every lab handling biological agents. The spill kit should easily accessible in a central location. Spill kits must be checked monthly to ensure contents are complete. A sample list of items to include in a spill kit includes the following. Note this list is not exhaustive for all laboratories, procedures and organisms, and must be modified when the PI deems necessary to enhance protections.

- Plastic container with closable lid to contain the contents of the spill kit
- Absorbent towels
- Forceps to pick up sharps or glass
- Biohazard bags
- Household bleach or appropriate disinfectant for the organism being manipulated
- Container to mix dilute disinfectant solution, one-gallon jug
- Appropriate PPE (gloves, goggles, jump suit, booties, specific PPE to protocols)
- Comet®, Ajax® or the like can be used to contain small spills. The chlorine in these products can be corrosive.
- Plastic scoop, plastic scraper and or autoclave-able/disposable broom and dust pan

5.3 Biological Spill Response Plan

It is the responsibility of the PI to develop a biological spill plan for each of his or her labs. The plan must be appropriately customized for the agents and research in the lab for which it is developed. The spill response plan should be available to both personnel working in the laboratory and visitors. Also, the spill response plan must be posted visibly in the lab. PI's risk assessment(s) should be included in the plan. The following elements should be included in a biological spill response plan:

- Principal investigator's/lab director's name and current contact information. Lab staff and current contact information.
- The Biosafety Officer contact information.
- Office of Research and Sponsored Programs contact / The Office of Research Compliance contact information.
- Microbiological agents being manipulated in the lab. If necessary, can be exceptions due to select agent requirements (Consult CDC, USDA - 7 CFR 331, 9 CFR 121, 42 CFR 73 for guidance on select agents as well as, Section 2.2(A) (6) of this policy).
- Location/inventory of spill kit(s).
- Location of closest spill kit outside the lab.
- Decontamination plans.
- Data sheets for the microbiological agents and procedures to follow if potential for exposure exists.

5.4 Elements of a Biological Spill Risk Assessment

5.4.1 When developing a biological spill plan for a lab, the PI must first conduct a risk assessment of the factors that will affect the outcome of a spill. After identifying the risks, the investigator must evaluate whether equipment, procedures, the agent, etc. be changed in a way to reduce risk without eliminating the ability to carry out the research.
If so, the PI must implement those measures. Identified risks must be communicated to all lab personnel. Consider the following factors when conducting a biological spill risk assessment:

1. The microbiological organism.

2. The risk group classification of the organism. See Section 2.2(A)(1) of this policy and Section 2 of the *Biosafety Manual*.

3. Route of infection (mucous membrane exposure, aerosol, ingestion, etc.).

4. The volume manipulated.

5. Determine appropriate disinfectant for the agent, contact time for the disinfectant, and equipment considerations with the disinfectant (e.g., if bleach, be aware that can corrode equipment and requires wiping down with water after use).

6. Whether the spill would be contained or not (would it occur in a BSC, open lab, or open common spaces?

7. Would there be potential for environmental contamination.

8. Are any glass or sharp objects used in the research activity?

9. What procedures will be used in the lab? Could they be modified in a way to reduce risk of spills/risks identified with spills?

10. Where would the work be performed?

11. Would biological material be transported outside the lab?

6. Exposure to Infectious Agent or Material/Emergency Procedures:

Before beginning research, the PI must integrate emergency procedures into the laboratory safety procedures. For Bloodborne pathogens, the University's Exposure Control Plan shall be followed (Appendix C of this Policy). For exposure involving other infectious agents/materials, the PI must delineate procedures in cases of exposures involving intact skin; broken, cut, damaged skin, puncture wounds, eye exposure, and ingestion/inhalation. The lab procedures shall indicate an emergency contact number. Lab procedures must also instruct exposed personnel, when appropriate, to call 911 or seek medical advice from the occupational health care provider PIs wishing to have assistance in developing exposure/emergency procedures should contact the Biosafety Officer & Office of Research Compliance at 816-654-7602 or irb@kansascity.edu.

7. Medical Surveillance (Available Vaccines/Treatments for Lab's Infectious Agent, Procedures To Follow, Symptoms To Monitor).

When applicable, PIs should consult the University's Occupational Health Program when developing their protocol and integrate the OCP into their lab procedures when appropriate. The IBC and IACUC will withhold approval when the appropriate lab personnel are not enrolled in the University's Occupational Health Program.

8. Decontamination and Disinfection

A. General

PIs are responsible for integrating effective decontamination and disinfection procedures into their standard operating procedures, as well as ensuring such procedures are taught to lab personnel and implemented in practice. Physical and chemical means of decontamination fall into five main categories: heat, liquid, chemical vapors, gases, and radiation. To select the proper method and tools, it is important to consider, for example, the following aspects:

1. Type of biohazardous agents, concentration and potential for exposure.

2. Physical and chemical hazards to products, materials, environment and personnel.

The Biosafety *Manual offers* guidance on decontamination and disinfection, and PIs are responsible for being in compliance with the *Biosafety Manual*. Guidance can be found in Appendix B, *Decontamination and Disinfection*, page 400 of the *Biosafety Manual*. PIs should be familiar with Figure 1: *Descending Order of Relative Resistance to Disinfectant Chemicals*, page 404 of the *Biosafety* Manual and Table 1, *Activity Levels of Selected Liquid Chemical Disinfectants*, page 407-408. Decontamination of large spaces can be found on page 405 of the *Biosafety Manual* and decontamination of surfaces on page 406. Page 408 of the *Biosafety Manual* covers special infectious agent issues.

B. Recombinant Materials

PIs working with recombinant materials shall additionally refer to any decontamination and disinfection guidance offered in the *NIH Guidelines*. The *NIH Guidelines* require that all recombinant DNA materials be appropriately decontaminated before disposal. Any and all recombinant DNA materials, including transgenic animal carcasses, must be decontaminated by autoclave treatment, chemical treatment, incineration or by any other acceptable means specific to those materials. The IBC must be notified in the event that the decontamination of rDNA materials cannot be met. See Appendix G-II-B-2-I and G-II-C-2-n of the *NIH Guidelines.*

C. Assistance

PIs wishing to have assistance with developing decontamination and disinfection procedures should contact the Biosafety Officer & Research Compliance Coordinator at 816-654-7602 or irb@kansascity.edu.

9. Infectious Waste Disposal and Disinfection

9.1 Authority

Infectious waste disposal is governed by the state of Missouri. Missouri has issued regulations governing infectious waste disposal, and those standards apply to the University, which resides in Missouri. For the purposes of this policy, biohazardous waste and infectious waste are considered the same. The standards for infectious waste disposal are in the Missouri Code of State Regulations, Title 10 – Department of Natural Resources, Division 80 – Solid Waste Management, Chapter 7 – Infectious Waste Management.

9.2 Responsibility:

Any person who generates infectious waste as defined in the Missouri Code of State Regulations is responsible for the safe disposal of that waste (see Section 9.3 of this policy for infectious waste definition). Infectious waste at the University is also considered biohazardous. Waste generated in any lab at the University that could be reasonably included in the below definitions (Section 9.3) of infectious waste must be considered waste that infectious/biohazardous waste.

9.3 Definition of Infectious Waste

In Missouri, a "small quantity generator" of infectious waste produces 100 kg or less per month (10 CSR 80-7.010(1)(A)(2). Under this definition, the University is a small quantity generator. According to 10 CSR 80-7010(1)(A)(2), infectious waste for small generators is defined under 19 CSR 20-20.010(21). Infectious waste is defined as:

> …waste capable of producing an infectious disease. For a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease. Infectious waste generated by small quantity generators shall include the following categories:
>
> (A) Sharps-all discarded sharps including hypodermic needles, syringes and scalpel blades. Broken glass or other sharp items that have come in contact with material defined as infectious are included;
>
> (B) Cultures and stocks of infectious agents and associated biological-included in this category are all cultures and stocks of infectious organisms as well as culture dishes and devices used to transfer, inoculate and mix cultures; and

(C) Other wastes-those wastes designated by the medical authority responsible (physician, podiatrist, dentist, veterinarian) for the care of the patient which may be capable of producing an infectious disease.

*The University is exempted from requiring an infectious waste processing permit under 10 CSR 80.7(C)(4).

10 Disposal of Infectious Waste Procedural Guidance

10.1 General

Infectious waste disposal at the University can be accomplished in two ways to meet the Missouri regulations. First, the waste may be inactivated and then disposed of in regular solid waste disposal. See Section 10.5 of this policy for information on inactivation. Secondly, the waste may be disposed of by an outside company contracted to dispose of infectious waste. Red-colored biohazard tubs from the contracted company are stored in designated areas on campus. These tubs are picked up by the contracted company on a specified schedule. The Executive Vice President of Research, the Biosafety Officer and / or and Research Compliance Office in the ORSP can assist in the establishment of an account. The cost associated with the account will be the responsibility of waste generator.

Inactivation of infectious/biohazardous waste at the University can be accomplished with a variety of methods. The accumulation, storage and transportation of any infectious waste must be in a secondary container. The container must be rigid and be puncture resistant. The use of a biohazard waste barrel, tub or other suitable container should be used while transporting waste for decontamination. The container should be labeled with the biohazard symbol. For solid and liquid waste, the materials can be autoclaved. The length of the autoclave cycle is determined by the type of autoclave, the volume of materials, type of materials etc. The autoclave run must be recorded with the minimum of the following information; User Name, Date, Start Time and End Time. Error codes and Action Taken (if applicable). This information should be retained by the individual or laboratory that generated the waste for documentation of inactivation of that waste. After sterilization the solid waste may be disposed of in the solid waste stream. The biohazard bags MUST be placed into a black bag or opaque bag or container prior to final disposal. Liquid waste may be disposed of into the sanitary sewer unless chemical or radiological hazards are present. Contact the Biosafety Officer and / or Research Compliance Office in the ORSP for guidance on final disposal if other hazards are present.

Sharps containers **MUST NOT** be disposed of in the solid waste stream. Sharps and sharps containers must be disposed of by the appropriate disposal company with whom the University has contracted. The sharps containers may be autoclaved prior to being deposited into the final disposal bins that are

disposed of by the contracted company. As a best practice. The sharps containers must be securely sealed shut before disposal. Laboratory tape works well.

Many liquid infectious/biohazardous wastes may be inactivated by chemical decontamination/disinfection. The user of a liquid disinfectant must follow the directions of the disinfectant. The products information sheet will provide information on amount of disinfectant to use, contact time and final disposal will be outlined. The use of some disinfectants may produce a hazardous chemical waste that may need to be disposed of in the hazardous waste stream. Inactivated liquid waste can be then disposed of in the sanitary sewer system.

Any person or lab that generates infectious waste at the University has a responsibility to dispose of the waste in a way that is safe to anyone that will come in contact with the waste downstream. The waste must be disposed of in accordance with any and all state of Missouri requirements. Contact the EVPR, The Biosafety officer and / or the Research Compliance Office in the ORSP with any questions concerning waste disposal.

10.2 Procedure

Any infectious waste generated must be disposed of in a manner outlined in the Missouri regulations. The generator of the waste is responsible for knowing and following the University's disposal of infectious waste policy. This section describes disposal of infectious waste as mandated by the Missouri Code of State Regulations, 10 CSR 80-7.010 (1).

(A) All sharps shall be packaged in rigid, leak-resistant and puncture-resistant containers and sealed prior to disposal.

(B) Infectious waste treated to render it innocuous may be disposed as a solid waste provided the treater certifies to the transporter, if other than the generator, and certifies to the sanitary landfill operator or processing facility operator that the waste has been rendered innocuous as required by Section 260.203, RSMo. (Note: Treated infectious waste is not required to be transported in accordance with the requirements of section (4) of this rule.)"

(C) Certification of treated infectious waste, at a minimum, shall contain the following information: the name, mailing address, location (when different from the mailing address) and phone number of the office/facility treating the infectious waste; the printed name and the signature of the facility/office manager or person responsible for the treatment process; a brief description of the treated waste (sharps in metal containers, sharps in heavy gauge plastic containers, incinerator ash, laboratory wastes in autoclave bags); and a brief description of the method(s) of treatment (for example, steam sterilization, incineration, disinfection with bleach solution). In addition to these minimum requirements, the generator need only include a statement that the waste has been managed in accordance with the Missouri Solid Waste Management Law and rules and may legally be placed in a sanitary landfill. The certification shall be revised when changes in the operation of the office/facility result in a change to the information required by this paragraph. The University qualifies for an exemption from a processing facility permit under 10 CSR 80-7.010(c)(4).

11 Packaging of Infectious Waste: 10 CSR 80-7.010

(A) Prior to transport, all infectious waste shall be placed in rigid or semi- rigid, leak-resistant containers clearly marked with the universal biohazard symbol prominently displayed and labeled Infectious Waste or Biohazard Waste and sealed. All containers shall be closed in such a manner as to completely contain all waste and the outside of the container shall be kept free of contamination. For the purpose of this rule, leak-resistant containers are defined as containers that are closable with a tight-fitting lid and are leak-proof on the bottom and sides. Containers meeting the requirements of 29 CFR 1910.1030 are acceptable.

(B) Plastic bags. Plastic bags shall be tear resistant and leak resistant. Plastic bags shall not be used as primary containers for transportation of infectious waste. Infectious waste contained in plastic bags shall be placed within rigid or semi-rigid containers prior to transport.

(C) Sharps Containers. Sharps shall be packaged in rigid, leak-resistant and puncture-resistant containers and sealed.

(D) Glass Containers. Glass containers shall not be used as primary containers for transportation of infectious waste. Glass containers must be placed into a rigid or semi-rigid leak-resistant container and protected from breakage.

(E) Reusable containers. Reusable containers shall be constructed of either heavy wall plastic or noncorrosive metal. Each container shall be cleaned and sanitized before it is reused

.

11.1 Tracking Documents, 10 CSR 80-7.010(3):

(A) Generators. The generator of infectious waste that is to be transported to a permitted infectious waste processing facility shall-

1. Prepare tracking documents which shall include, at a minimum, the following information:

a. The printed or typed name, mailing address, location (when different from the mailing address) and telephone number of the generator;

b. The printed or typed name and address of the designated facility which is permitted to process waste. The name and address of an alternate facility may also be designated to which the waste may be transported in the event an emergency prevents delivery of the waste to the primary designated facility;

c. The printed or typed name, address and Missouri Transporter identification number of the transporter's company, if other than the generator;

d. The quantity, in volume or weight, of waste to be transported;

e. A name and signature block for the transporter, if other than the generator; and

f. A name and signature block for the receiving facility;

2. Sign the tracking document by hand. The name of the generator signing the document shall also be printed or typed on the tracking document;

3. Obtain the handwritten signature of the transporter. If other than the generator, and date of acceptance on the tracking document. The name of the transporter signing the document shall also be printed or typed on the tracking document;

4. Retain one (1) copy of the tracking document with the signatures required in this subsection; and

4. Give the transporter the remaining copies of the tracking document.

11.2 Recordkeeping:

The appropriate University personnel shall ensure infectious waste disposal records are kept in accordance with 10 CSR 80-7.010(6) below:

> All tracking documents, operating logs, quarterly fees report, records, test results and process monitoring records shall be kept for a period of at least three (3) years. The period of record retention extends upon the written request of the [Missouri] department [of Natural Resources] or automatically during the course of any unresolved enforcement action regarding the regulated activity. These records shall be made available for inspection by the [Missouri] department [of Natural Resources] upon request.

12. Shipping Infectious Materials

12.1 Federal Regulation

All biohazardous materials that are regulated must be packaged and shipped in a manner compliant with current federal guidelines and codes. Appendix C, *Transportation of Infectious Substances*, page 415 of the *Biosafety Manual* offers guidance. Such shipping is governed by the United State Department of Transportation and international agencies and associations. In the United States, the United States Postal Service, the Department of Transportation, Department of Agriculture, Federal Aviation Administration, Centers for Disease Control and Prevention and various other agencies have some regulatory administration over the transport of infectious materials. Internationally the International Air Transport Association (IATA) and the International Civil Aviation Organization (ICAO) as well as the World Health Organization and the United Nations have input on the transportation of infectious substances and biological specimens. Because of the numerous and varied organizations involved a person who ships infectious materials should stay aware of the annual updates and changes made in the requirements to avoid shipping delays and fines.

The codified regulations in the United States falls under 49 CFR parts 171, 172, 173 and 175. 49 CFR is the codified federal regulation that regulated the transportation of any hazardous material in the United States. These regulations cover all forms of transportation. Fines can be leveled against an individual or organization that violates any part. Fines can range up to $500,000 and imprisonment up to five years. Many federal agencies can level fines against a violator. Universities and their employees are not immune.

The shipper should consult with the relevant guidelines for updates and additions to the applicable regulation to ensure full compliance. International shipments entering and leaving the United States will require import export documentation and further approvals. The approval process may be lengthy. Agents that have been included in the select agents list may require approval from CDC/APHIS and multiple other agencies **BEFORE** shipment. Plan ahead, the approval process can be lengthy.

12.2 Training requirements for Shipping

Anyone involved in shipping must be adequately trained. The training renewal frequency is every three years for the DOT and every two years for the IATA. For more information contact the Biosafety Officer at 816-654-7621 & Research Compliance Office at 816-654-7602 or irb@kansascity.edu.

13. IBC Procedures

Generally, the IBC ensures research activities conducted at the University comply with the *NIH Guidelines* and The Select Agent Rule (list of Select Agents located in Appendix F of this Policy), reviewing protocols for biosafety concerns, and overseeing implementation of University biosafety procedures, updating the OSHA Occupational Exposure Plan, submitting reports as required to the regulatory agencies, documenting exposures. Detailed explanations of the IBC's responsibilities and conducting of meetings/reviews our outlined below.

13.1 Applicability

The IBC reviews all research protocols involving 1) recombinant DNA (Defined in Section 1.1(G) of this Policy) and 2) biological materials that are BSL-1 or higher (infectious agents, biological toxins, and other biohazardous materials) (Defined in Section 1.1(A) of this Policy), regardless of whether recombinant DNA is involved. The IBC also reviews 1) Exposures to biological agents or recombinant DNA, 2) theft or loss of biohazardous material, and 3) all incidents that warranted emergency response and make a determination as to whether the protocol must be modified or the research halted. The IBC ensures research activities conducted at the University comply with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines) and *The Select Agent Rule*, reviewing protocols for biosafety concerns, and overseeing implementation of University biosafety procedures. Those materials falling within the scope of this policy must be registered with the IBC before the PI commences research. Funding source does not affect the applicability of this policy. Only University faculty members are allowed to submit protocols to the IBC.

13.2 Responsibilities

A. Principal Investigators

PIs wishing to conduct biohazardous research outlined in 1.1(A) of this policy must conduct a risk assessment as described in Section 2 of this policy and submit to the IBC an application (Appendix G of this Policy and available on IRBNet) to have any recombinant materials registered with the committee prior to beginning the research activity. PIs must also submit to the IBC renewal applications (Appendix J of this Policy available on IRBNet) for ongoing research as described by this policy. PIs are responsible for submitting any changes in the protocol to the IBC as well as 1) exposures to biological agents or recombinant DNA, 2) theft or loss of biohazardous material, and 3) all incidents that warranted emergency response.

B. The IBC

The IBC is responsible for reviewing all research and teaching activities involving recombinant DNA conducted at or sponsored by the University for adherence with *NIH Guidelines*, regardless of funding source for the research. The committee is responsible for reviewing all research and teaching activities involving other biohazardous material conducted at or sponsored by the University for adherence to the *Biosafety Manual*, regardless of funding source for the research. The committee must approve those research and teaching activities involving recombinant DNA if they conform to the *NIH Guidelines* and other biohazardous materials if they conform to the *Biosafety Manual*. The committee must review research and teaching activities involving select agents and toxins conducted at or sponsored by the University, regardless of funding source, for adherence to the Select Agent Final Rule (a list of Select Agents is available in Appendix F of this Policy) and approving those activities if they comply. The committee must notify the PI in writing of the determinations made after review in regard to applications/protocols.

The IBC must also conduct risk assessments to determine appropriate levels of containment as defined in applicable regulations and assess lab facilities, procedures, practices, training, and expertise of involved personnel. The IBC is also charged with conducting periodic reviews to ensure compliance with federal, state and university laws, regulations, and guidelines. The committee must receive and review incident reports involving 1) exposures to biological agents or recombinant DNA, 2) theft or loss of biohazardous material, and 3) all incidents that warranted emergency response (See Sections 13.6(c)(4) and 13.11(a)-(c) for more on incident reports).

The IBC must report any noncompliance with IBC mandates/determinations, pertinent regulations, laws, guidelines, and University to the EVPR. The committee must perform periodic reviews of this policy and suggest changes when needed to the EVPR. This policy should be updated approximately every year or when applicable. Annually, the IBC shall review the University's OSHA Exposure Control Plan.

13.3 Committee Composition

A. Appointment of Members

Voting members shall be appointed by the Chief Executive Officer in Consultation with the EVPR. If authority to appoint is delegated, such delegation must be specific and in writing.

B Number of Members

The IBC shall consist of at least five members

C. Required Member Qualifications

The committee must collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health and/or the environment. The following are specific IBC membership requirements:

1. The University's Biosafety Officer shall be a member of the IBC (See Section 1.4.5 of this Policy for other Biosafety Officer responsibilities).

2. At least two members not affiliated with the University, besides membership on the IBC, must sit on the IBC to represent the community's health and environmental interests.

3. When submitted protocols involve research contained in Appendix L, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, a plant expert must sit on the committee to assist in conducting review.

4. When submitted protocols involve research contained in Appendix M, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, an animal expert must sit on the committee to assist in conducting the review.

5. Whenever the University participates in or sponsors recombinant DNA research involving human subjects, the University shall ensure there is an IBC member who has sufficient experience and training in the field of human gene transfer. Institutional Biosafety Committee approval must be obtained from the clinical trial site.

6. When submitted protocols involve research outside the IBC's range of expertise, an Ad Hoc consultant shall be utilized.

7. It is recommended that at least one lab technical staff member sit on the IBC.

a. Ex-Officio Members:

There shall be at least one member from the ORSP whose major role is research compliance appointed as an Ex Officio Member of the IBC.

E. OSP Contact Person

The Research Compliance Coordinator and / or Chair of the IBC shall serve as the contact person whom the OSP may contact with questions and important information regarding the University's IBC.

F. Rosters

Under Section IV-B-2-a-(3) of the *NIH Guidelines*, IBCs are required to submit committee rosters and bio-sketches of its members to the NIH. The NIH must disclose that information if requested to through the Federal Freedom of Information Act. See Section 12.4 (F)(2) below for redaction information.

13.4 Valid Method of IBC Review of Protocol Applications

Official business can only be validly conducted by a convened quorum of the IBC and members with sufficient expertise present except for addition of personnel, which could be reviewed, administratively by the Chair and Vice Chair or any other IBC member if there is a conflict of interest. No process of expedited review in which one or more members reviews or approves protocols on behalf of the entire IBC is allowed expect as stated in Section 10.5. All members of the IBC shall have the opportunity to review all documents relating to a protocol at minimum seven days prior to the convened meeting. IBC Chair may assign one or more IBC members to conduct a specialized pre-review of a protocol prior to the meeting and present their findings at the convened meeting.

13.5 Meetings

A. Frequency

Meetings shall be held once a month unless there is no official business to conduct. At minimum, a meeting shall be held every six months.

B. Format

Meetings shall be in person or by tele/videoconference. E-mail is *not* an acceptable manner in which to conduct official business under any circumstances because e-mail does not allow for adequately preparing meeting minutes, nor accommodating public attendance.

C. Open to the Public

When possible and consistent with the protection of privacy and proprietary interests, the University will open its IBC meetings to the public. When meetings are open to the public, their time and place will be listed on the University's website. Any comments or questions received by the public regarding the committee's actions shall be responded to by the committee within 30 days. Any public comments regarding any action made by the IBC must be responded to and both the comments and IBC's response sent to the Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20817 or by email at NIHGuidelines@od.nih.gov. Phone: 301-496-9838, 301-496-9839 (fax).9839 (fax).

D. Voting

1. Quorum Requirement for Conducting Official Business

A quorum is defined as greater than half of the voting members (at least 50% of the members plus 1). Official business shall only be conducted by a convened quorum. Actions (such as approval of a protocol) can only take place with a majority vote from a convened quorum.

2. Conflict of Interest

No member shall take place in the review or approval of a research protocol for which he or she has been or expects to be engaged in or have a direct financial interest. However, members with a conflict of interest may still provide information about the protocol to the IBC if necessary.

E. Attendance

Chronic nonattendance by members implies a lack of participation in oversight responsibilities of the IBC and often makes reviews of protocols impossible for lack of appropriate expertise. Chronic nonattendance will be addressed appropriately with such measures as adding additional members.

F. Minutes

1. Content/Detail

Minutes shall be taken every meeting and contain at minimum: the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, all major motions, major points of order, and whether motions were approved, and the time of meeting adjournment. Minutes shall offer sufficient detail to serve as a record of major points of discussion and the IBC's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities as outlined under Section IV- B-2-b of the *NIH Guidelines.* Minutes do not need to be transcripts or kept at a level of detail that attributes each remark to a specific individual.

2. Availability to the Public

Upon request, the University shall make meeting minutes available to the public. Requested minutes shall be distributed via mail or e- mail within 5 days of ORSP's receipt of the request. Pursuant to Section IV-B-2-a-(7) of the *NIH Guidelines*, the University may choose to redact information from meeting minutes and other documents that might become publicly available to protect private or proprietary information. Information that might be redacted, upon request from interested members, is trade secret information/other confidential commercial information, home telephone numbers and home addresses of IBC members, and specific information whose disclosure would directly compromise institutional or national security.

G. Principal Investigator Participation

PIs may attend the meetings per a formal invitation for which their protocols are being discussed. PIs shall leave the voting room or tele/videoconference before a vote is taken regarding their protocol.

13.6 IBC Review of Research Protocols

A. General

Before beginning research involving recombinant DNA or materials that are biosafety level 1 or higher, such protocols must be reviewed and approved by the IBC and the materials registered. Likewise, modifications and amendments to previously approved protocols must be reviewed. All protocols must be reviewed and re-approved annually to continue research. The IBC does not conduct expedited reviews. All official business must be conducted with a convened quorum to be in keeping with the *NIH Guidelines*.

B. Protocols Covered

All research and teaching protocols involving work with recombinant DNA and any materials that are Biosafety Level 1 or higher must be reviewed and approved before the study is commenced, and the materials registered with the IBC.

C. When/What Form(s) PIs Must Submit

1. Initial Application/Registration Document

To have the IBC review a protocol, the PI must submit an application form located in the IRBNet at www.irbnet.org and Appendix J. If recombinant DNA is planned for use, the Principal Investigator shall also submit a rDNA Registration Form located in the IRBNet at www.irbnet.org and Appendix I specifying which section of the *NIH Guidelines* to which their research is subject, the source of the DNA, the host and vector to be used and containment conditions. Proof of completing training requirements (See Sections 1.4.1(J) and 13.8(1) of this Policy) and, when applicable, registration in the Occupational Health Program must be submitted with the application. Protocols will not be reviewed until such required proof is submitted.

a. Exemption.

Sections IV-B-2-b-(1) and7-c-(3) of the *NIH Guidelines* cover recombinant work that is exempt from being registered. On the registration form, the Principal Investigator is asked to determine whether research is exempt under the *NIH* Guidelines,

however, the University requires all recombinant work to be registered with the IBC. The IBC Office and
BSO in consultation with the IBC Chair verify whether such recombinant work determined exempt by the PI is in fact exempt for *NIH Purposes*. Even if such work is exempt for NIH purposes, the protocol will still be reviewed and subject to this policy if the material is biosafety level 1 or higher.

2. Annual Renewal of Protocol Approval and Registration

As part of the IBC's written approval of a PI's initial protocol and registration of materials, the IBC shall give notice to the PI of when he or she must submit an application for annual Re-Approval (Appendix J of this Policy and available on IRBNet. The PI will receive notice of upcoming approval expiration 90, 60, and 30 days prior to the expiration date. The PI is responsible for submitting a continuing review application to the IBC minimum 30 days prior to the project's expiration. When submitting the renewal application, keep in mind the 15-day rule described in Section 13.7(A) of this Policy. The IBC shall conduct de novo review of annual renewal applications.

3. Changes to Protocol

The Principal Investigator must submit a Protocol Amendment Form located in the IRBNet at www.irbnet.org if contemplating a change to a protocol. Such changes must be approved by the IBC *prior* to the changes being implemented.

4. Noncompliance Complaints/Adverse Events

Individuals aware of noncompliance with this policy or any of the policies, rules, regulations, and/or laws regarding research or teaching projects involving work with recombinant and/or other biohazardous materials should contact the Research Compliance Coordinator and / or Executive Vice President for Research. Knowledge of the following events shall be submitted to the IBC for full committee review: 1) exposures to biological agents or recombinant DNA, 2) theft or loss of biohazardous material, and 3) all incidents that warranted emergency response. At that point, the IBC shall conduct an investigation to determine whether the protocol must be modified or the research halted (See Section 14 of this Policy). Any of the above adverse events or those listed in Section 14 of this Policy must be reported to the Research Compliance Coordinator.

Both noncompliance complaints and adverse events must be submitted to the IBC with the appropriate information (See Sections 13.6(c)(4) and 13.11(a)-(c) of this Policy for guidance). In the event of an adverse event, see Section 11 of this policy and follow the instructions.

13.7 Timelines/Deadlines

A. Form Deadlines Prior to Review

Because all IBC members must have at least seven days to review protocol documents before they are reviewed, Principal Investigators must have all forms properly submitted, training completed, and be enrolled, when applicable, in the Occupational Health Program at least 15 days prior to the meeting in which they wish to have their protocol reviewed. Meeting dates and times are posted on the University's website and the IRBNet once determined.

B. Protocol Approval Period Expiration

IBC approvals for protocols are valid for one year from the date specified as the approval date in the IBC's written approval document. There are absolutely no extensions or grace periods.

All IBC protocols are approved for a one-year time period and expire at the end of that expiration month regardless of approved date. If a protocol submission for renewal has not been submitted by the PI or by designated person with full access on IRBNet to the IBC prior to IBC submission deadline date for the expiration month that protocol will expire at the end of the month. The IBC will classify the study as "inactive." All activities involving recombinant/synthetic nucleic acid (r/sDNA) molecules, infectious agents, and biological toxins must cease if protocol has a lapse in IBC approval. No research described in this protocol may be conducted until the submission for renewal is approved by the IBC. If a lapse in IBC approval occurs, notification to the IO will be sent. If an IBC decision is still being determined and a protocol expires, the protocol will be placed on Administrative Hold (see below). If renewal has been resubmitted and is not approved by the IBC prior to expiration, the study is required to cease until resubmission and subsequent full committee approval.

C. Consequences for Continuing Covered Research Activities After IBC Approval has Lapsed and Other Noncompliance

The Chief Executive Officer of the University has authorized the IBC to disapprove of or suspend research in noncompliance with policies and procedures described in the Biosafety Manual, NIH Guidelines and/or University policy, and the IBC has the responsibility to do so.

Likewise, if a lab inspection results in a determination that basic lab procedures are not being followed, research may be halted until actions are taken to correct the deficiencies.

Administrative Hold:
If the annual continuing review materials or required revisions are not approved by the expiration date determined by the IBC, the protocol will be placed on administrative hold. The protocol is considered to be on administrative hold effective immediately on the expiration date. Therefore, the Principal Investigator must discontinue research involving r/sDNA molecules, infectious agents, and biological toxins. However, in the interest of continuity of research BSL1/low risk prior approved procedures may continue with approval of the IBC chair and/or BSO until they determine otherwise. The IBC Chair will issue a notice to the PI with regard to the administrative hold status of an IBC protocol.

13.8 Review Criteria

A. the IBC shall review the following elements of covered protocols.

This list is not necessarily meant to be exhaustive:

1. Completion of training requirements.

As mandated in the *NIH Guidelines* Section IV-B-7-d-(2)-(3), the Principal Investigator is responsible for ensuring lab staff and others involved with research are sufficiently trained.
The University requires compliance with its Training Program (Appendix A below). The PI is responsible for additional laboratory-specific training. The University shall inform the Principal Investigator of the training expectations and requirements under the *NIH Guidelines* by making available the OSP's instructional brochure (Appendix K of this Document). Proof that the appropriate personnel have satisfied training requirements outlined in Appendix A of this Policy is mandatory before a protocol is submitted to the IBC for review. Subsequently, the IBC can withhold approval if it deems additional training is necessary and has not been accounted for in the protocol. If the PI has administered lab- specific training, he or she must document that training as Specified in Section 1.4.1(J) of this Policy and submit a copy to the IBC and ORSP in the IRBNet. See Section 1.4.1(J) for more on training and recordkeeping requirements related to training.

2. Compliance with University's Exposure Control Plan (Appendix C of this Policy), Occupational Health Program, and necessary vaccinations when applicable.

3. When work with animals is involved, verification that personnel are enrolled in Occupational Health Program as required by the University. IBC review shall be withheld at the administrative level until proof of enrollment in the OHP has been provided.

13.9 Outcomes of Protocol Review

A. There are three possible outcomes of review of an initial protocol application, annual renewal or modification:

1. Approval

Once the IBC renders approval, the IBC Office will send out an approval letter. After PI receipt of the letter, the approved study may be initiated. IBC approval is valid for one year.

2. Modifications Required to Secure Approval

The IBC may require modifications to the protocol before granting approval. In such cases, the Principal Investigator must modify the protocol and submit the modified protocol to the IBC for full committee review.

The IBC shall only grant approval after a convened quorum is satisfied that the required modifications have been made satisfactorily, unless the modifications are minor and the committee stated that the modifications should be re-reviewed by the assigned reviewers or the IBC Office then the modifications will be acknowledged and the approval will be issued. The Principal Investigator shall not conduct research until all required modifications have been made and subsequently approved by the IBC. PIs must submit original protocol documents with the required modifications highlighted. Protocol Amendment Forms are inappropriate as they are only to be used for changes to previously approved protocols.

3. Approval Withheld

The IBC may withhold approval until the PI has made outlined modifications to the protocol. PI's are not to begin research until they have received an approval letter from the IBC Office.

B. The above actions require a formal vote of a convened IBC quorum.

C. Notification of Outcome

The IBC shall notify Principal Investigators and the University in writing of its decisions regarding protocols. If the IBC withholds approval of an activity, it shall include in the written notification a statement of the reasons for its decision and give the Principal Investigator and opportunity to respond in person or in writing. A document indicating approval shall contain the date by which approval must be renewed.

C. Administrative Review

The IBC Chair, The Vice Chair, or an assigned IBC voting member, if there is a conflict of Interest, shall administratively review and approve only change to protocol personnel.

13.10 Semi-Annual Review of Laboratories and Biosafety Program

A. At minimum every six months, the Biosafety Officer is responsible for conducting laboratory inspections to ensure that lab standards are being followed in accordance with federal/state/and local laws and guidelines. The Biosafety Officer shall report the results of all inspections to the IBC. If the Biosafety Officer or the IBC has reason to believe inspections should be carried out more frequently, the Biosafety Officer shall do so.

B. Every year or as needed, the IBC shall review the University's blood-borne Pathogen Hazard Control Plan and general biosafety and IBC policies and procedures for compliance with current federal and state laws and regulations.

The IBC shall also conduct review of the biosafety program after significant adverse events in order to determine whether the event is a result of programmatic flaw.

13.11 Reporting

A. Internal Reporting

Annually the IBC shall submit a report to the Institutional Official (the EVPR) to allow for assessment of the IBC's performance and compliance with the *NIH Guidelines*. The report shall include results of facility evaluations, an overview of the effectiveness of the biosafety program and Bloodborne pathogens program and compliance with current federal regulations. Incidents listed in Section13.11 B(3)(a) and 4 below shall be reported internally to the IBC and responsible official when they occur.

B. External Reporting

1. General/Reporting Responsibilities

When the University has an assurance with the OSP, the IBC is responsible for fulfilling reporting requirements to its office for covered research sponsored by or conducted by the University. The following outline specifics for reporting to the NIH OSP.

2. Annual Report

Annually the Institutional Official shall file an annual report with OSP in compliance with NIH-OSP requirements and procedures, which includes a roster of all IBC members and indicating the IBC chair.

3. Reports of Incidents, Accidents, or Violations to NIH and OSP

The *NIH Guidelines* require reporting of "any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the NIH and OSP within 30 days (*NIH Guidelines*, Section IV-B-2-b-(7)). Principal Investigators are responsible for reporting the following incidents to the Biosafety Officer and/or IBC. The Biosafety Officer is responsible for reporting any incidents reported to him or her to the IBC. The IBC is responsible for reporting incidents to the Institutional Official. The Institutional Official is responsible for preparing and submitting the final incident report to the NIH OSP.

a. Events that must be reported to OSP include:

1. Any spill or accident involving recombinant DNA research as described in Section IV-B-2-b-(7) of the *NIH Guidelines*.

2. Any incident that leads to personal injury. An example includes skin punctures with needles containing recombinant DNA.

3. Any incident that leads to a breach of containment. Examples include the escape or improper disposition of a transgenic animal or spills of high- risk recombinant materials occurring outside of a biosafety cabinet.

   Note: Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need reported to the OSP. The OSP staff should be contacted when there is uncertainty surrounding whether or not to report and incident to their office.

4. Failure of a PI to adhere to the containment and biosafety practices articulated in the *NIH Guidelines.*

5. Events described in Appendix G of the *NIH Guidelines*. See Section 13.11(B)(3)(b) below.

b. Immediate Reporting

Certain events must be immediately reported to the NIH OSP:

1. Accidents as described in Appendix G of the *NIH Guidelines*. Examples include spills or accidents in BSL-2 laboratories resulting in overt exposure (*NIH Guideline* Appendix G-II-C-2-k. Spills or accidents occurring in high containment (BSL-3 or BSL-4) resulting in an overt or potential exposure must be immediately reported to the IBC, BSO, and OSP (NIH Guideline Appendices G-II-C-2-q and G-II-D-2-k).

c. Contents of Incident Reports

Incident reports must contain sufficient information to allow for an understanding of the nature, causes, and consequences of the incident. The report must also include the measures the University took to mitigate the problem and preclude its reoccurrence.

4. Adverse Events Involving Human Gene Transfer Trials

Adverse events in human gene transfer trials are subject to a separate set of reporting requirements outlined in the *NIH Guidelines*, Appendices M-1-C-3 and M-1-C-4. Serious and unexpected adverse events that are possibly associated with a gene transfer product must be reported to OBA within 15 calendar days of sponsor notification, unless they are fatal or life threatening, in which case they should be reported within 7 calendar days. Other serious adverse events should be reported to the OBA as part of the PI's annual report to the OBA

5. OSP Contact for Incident Reports

Incident Reports should be sent by mail to:

Dr. Kathryn Harris
National Institutes of Health
Office of Science Policy
MSC 7985
6705 Rockledge Dr., Suite 750
Bethesda, MD 20892-7985

Fax: ATTN: Dr. Kathryn Harris
(301)496-9839

E-mail: HGTprotocols@mail.nih.gov
NIHGuidelines@od.nih.gov

13.12 Recordkeeping

A. The University shall maintain records of the following IBC documents:

1. IBC minutes
2. Protocols reviewed and any attachments/amendments of protocol.
3. IBC member roster.

B. Length of Time Records Shall be Maintained:

1. All records shall be maintained for a period of at least three years. In the case of protocols and attachments/amendments, the three years begins three years after termination of the protocol.

C. Accessibility of Records

All records regarding covered projects shall be accessible for inspection and copying by authorized government representatives at reasonable times and in a reasonable manner.

14. Non-Compliance Complaints

14.1 Individuals concerned that there is non-compliance with this policy or any applicable policies, rules, regulations, and laws regarding biological safety in research and teaching, should contact the EVPR or the Research Compliance Coordinator.

14.2 Whistleblower Protection

Complaints are confidential and will remain anonymous to the largest extent possible. Law protects such "whistleblowers" protected from being retaliated/discriminated against. University policy further protects whistleblowers from retaliation.

14.3 Complaint/Investigation Procedure

An individual reporting a complaint will remain anonymous to the extent reasonably possible if so requested by the individual. After receiving a complaint, the EVPR will conduct an initial investigation to determine whether there is any credible evidence substantiating the claim. This initial investigation and an accompanying report shall be completed within 10 days from receipt of the complaint. Within that time period, if it is determined there is any credible evidence substantiating the claim, EVPR shall draft his or her decision to conduct a further investigation in the aforementioned written report that includes what evidence has been found so far. Once a decision has been made to begin further investigation, the IBC, as well as any party who has been accused of culpability for the animal welfare violation, shall be notified if they have not already been so informed. Within 7 days from the determination that there is evidence of a violation, the IBC Chair shall appoint a subcommittee to further investigate the complaint. The subcommittee shall conduct a thorough investigation to be completed within 30 days of its appointment to gather information about the complaint. At the end of these 30 days, the full IBC shall be convened to hear the evidence surrounding the

complaint, as well as witnesses and anyone, against whom a complaint has been lodged, If such accused persons desire to be heard.

The IBC shall decide:

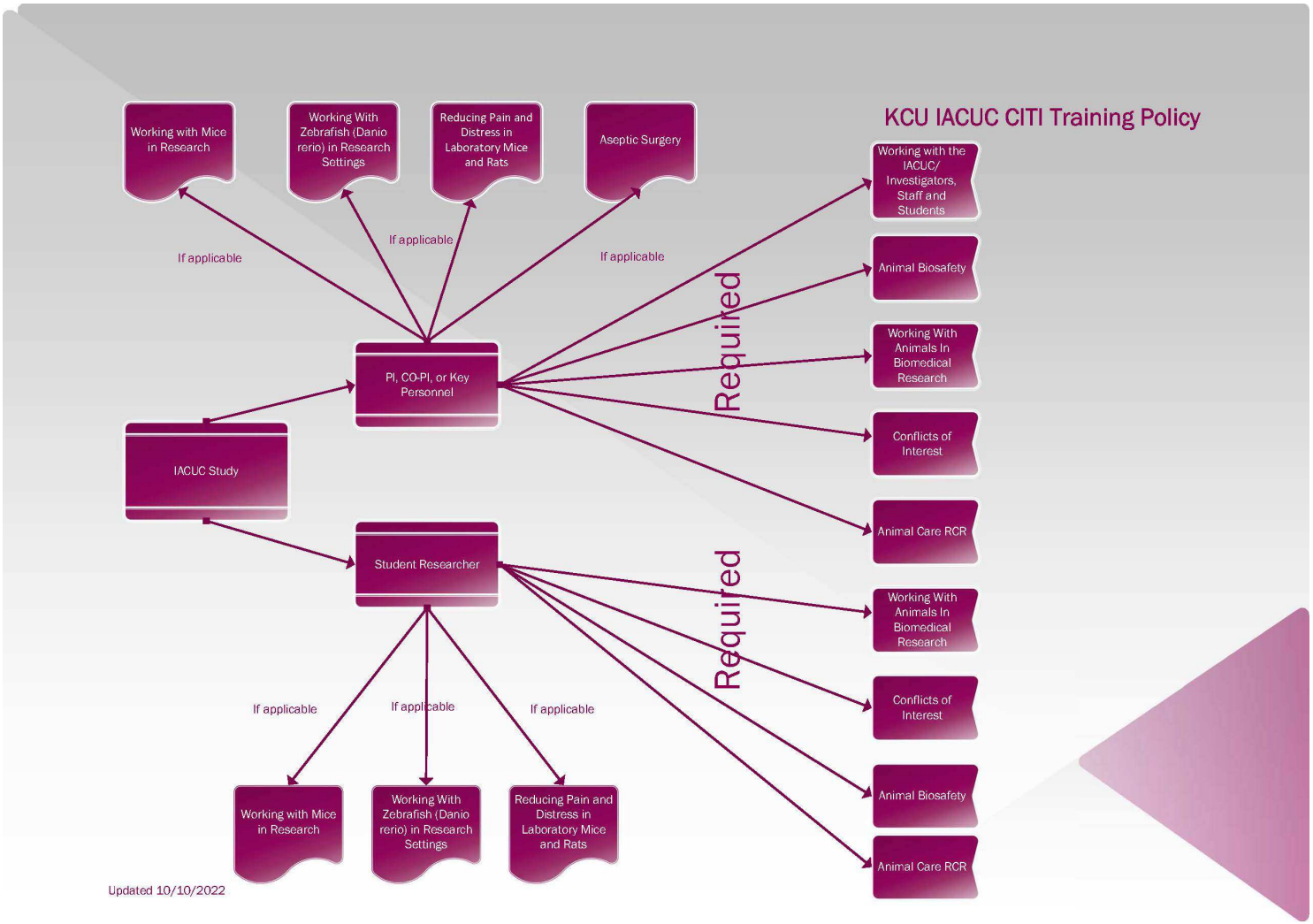
- The investigation did not reveal an issue of non-compliance,
- The investigation revealed non-compliance,
- The related aspects of the program require further review
- Other related institutional programs may require review.
- If there has been animal welfare violation, and if so, what actions must be taken as well as a timeframe in which such actions should be completed. If there has been an animal welfare violation involving research funded by PHS, then as soon as possible, and no later than 10 days from the IBC's meeting surrounding the complaint, the committee must write a report as described in Section 14.3 of this policy, submit the report to the institutional official, and the institutional official shall submit the report to the appropriate PHS Official/Office as determined by usual methods of inquiry.

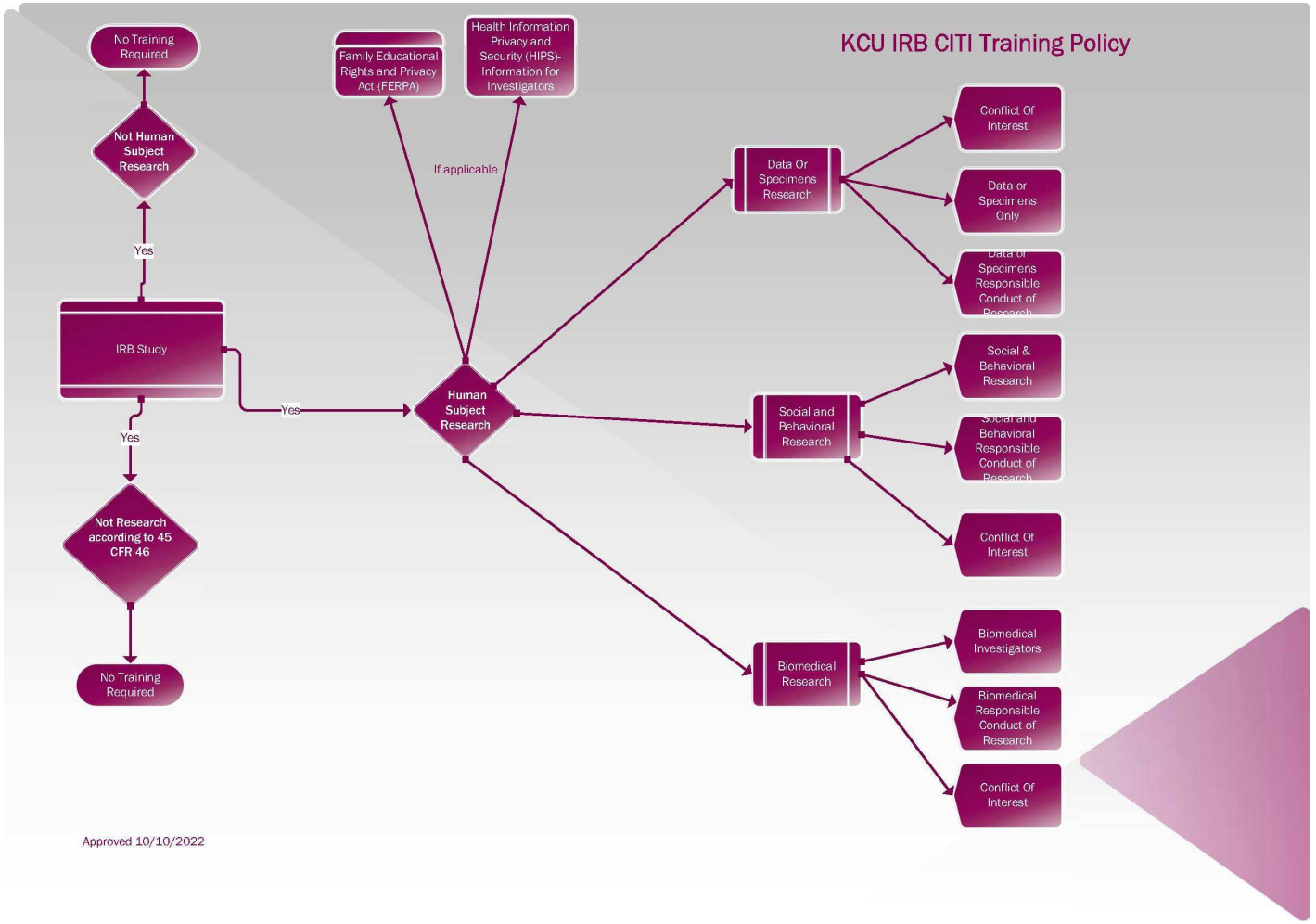
For any noncompliance, the IBC must prescribe corrective and preventive action plan along with appropriate deadlines and reporting requirements. Such plan should also include root cause analysis and monitoring plan. The IBC must also determine whether the noncompliance meets the criteria "serious or continuing noncompliance" or "serious deviation" so as to require reporting to NIH.

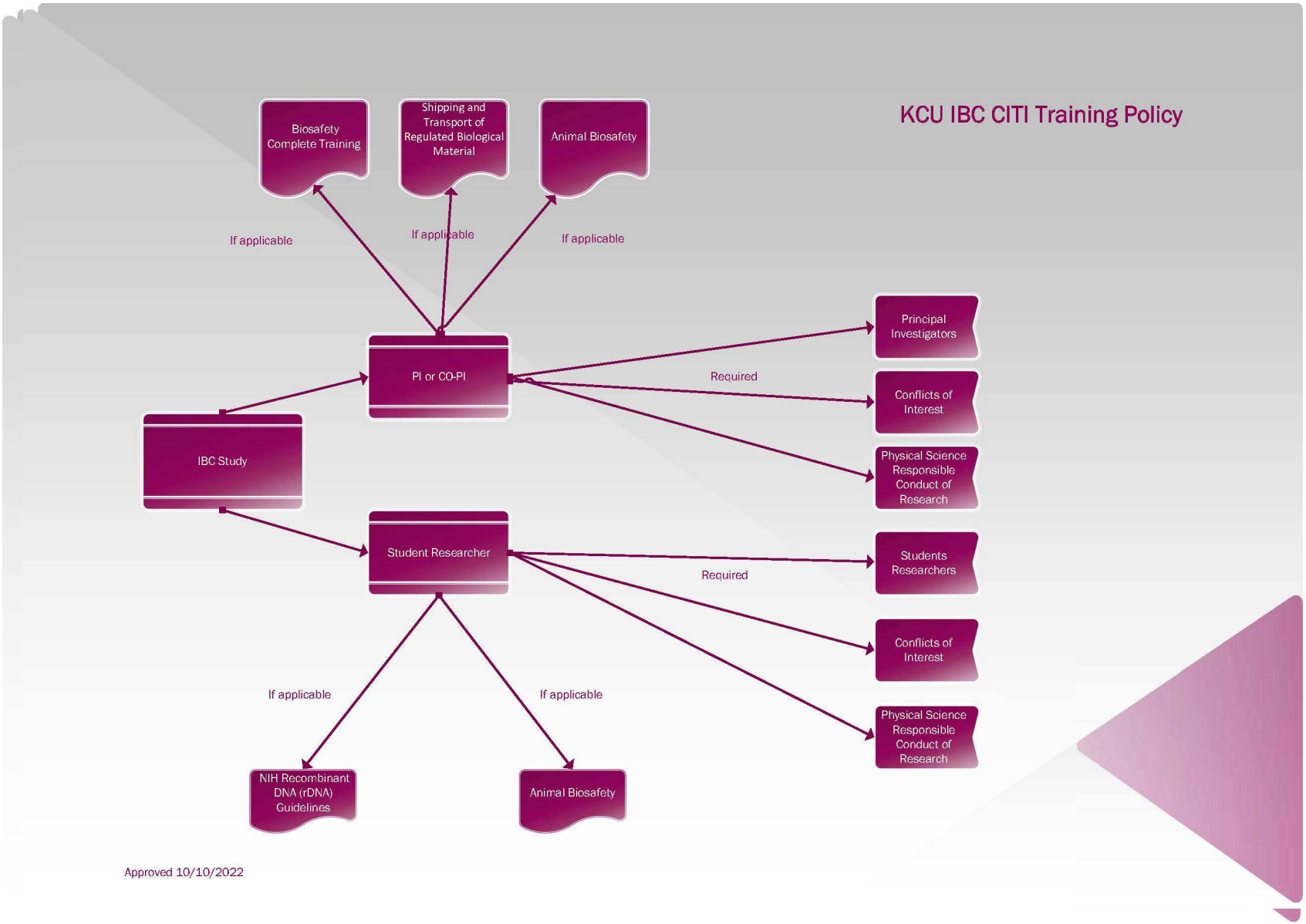
Notification in Writing:
IBC Chair will communicate, in writing, the results of the IBC evaluation of a reported concern to the person(s) responsible for the situation reported, the Institutional Official, and the person reporting the concern if they wish to be notified of the outcome. The communication will contain a summary of the concern, the findings of the investigation, determinations of the IBC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) responsible for the situation reported of his/her option to appeal the decision by writing the IBC Chair, within 10 days of receipt of the letter detailing the basis of the appeal and requesting a meeting with the IBC.

Appeals:
Disputes regarding interpretation of this policy or decisions made by the IBC are referred to the Institutional Official for adjudication.

Appendix A


KCU IACUC CITI Training Policy
Working with Mice in Research
Working With Zebrafish (Danio rerio) in Research Settings
Reducing Pain and Distress in Laboratory Mice and Rats
Aseptic Surgery
If applicable
If applicable
If applicable
PI, CO-PI, or Key Personnel
IACUC Study
Student Researcher
Required
Required
Working with the IACUC/ Investigators, Staff and Students
Animal Biosafety
Working With Animals In Biomedical Research
Conflicts of Interest
Animal Care RCR
Working With Animals In Biomedical Research
Conflicts of Interest
Animal Biosafety
Animal Care RCR
If applicable
If applicable
If applicable
Working with Mice in Research
Working With Zebrafish (Danio rerio) in Research Settings
Reducing Pain and Distress in Laboratory Mice and Rats
Updated 10/10/2022


KCU IRB CITI Training Policy
No Training Required
Not Human Subject Research
Yes
IRB Study
Yes
Not Research according to 45 CFR 46
No Training Required
Yes
Human Subject Research
If applicable
Family Educational Rights and Privacy Act (FERPA)
Health Information Privacy and Security (HIPS)- Information for Investigators
Data Or Specimens Research
Conflict Of Interest
Data or Specimens Only
Data or Specimens Responsible Conduct of Research
Social and Behavioral Research
Social & Behavioral Research
Social and Behavioral Responsible Conduct of Research
Conflict Of Interest
Biomedical Research
Biomedical Investigators
Biomedical Responsible Conduct of Research
Conflict Of Interest
Approved 10/10/2022


KCU IBC CITI Training Policy
Biosafety Complete Training
Shipping and Transport of Regulated Biological Material
Animal Biosafety
If applicable
If applicable
If applicable
PI or CO-PI
Principal Investigators
Required
Conflicts of Interest
Physical Science Responsible Conduct of Research
IBC Study
Student Researcher
Students Researchers
Required
Conflicts of Interest
Physical Science Responsible Conduct of Research
If applicable
If applicable
NIH Recombinant DNA (rDNA) Guidelines
Animal Biosafety
Approved 10/10/2022

Appendix B

NIH Lab Safety Monograph

https://www.cambridgepublichealth.org/services/regulatory-activities/biosafety/NIH-Monograph-1979.pdf

Appendix C

KANSAS CITY UNIVERSITY

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

TABLE OF CONTENTS

SECTION I

PURPOSE OF THE PLAN

PURPOSE OF THE PLAN

The purpose of the Bloodborne Pathogen Exposure Control Plan (hereafter Exposure Control Plan) for Kansas City University (KCU) is to promote safe work practices in an effort to minimize the incidence of illness and injury experienced by employees. Employees of KCU Occupational Healthcare provider should refer to that location's Exposure Control Plan.

The Occupational Safety and Health Administration (OSHA) has enacted the Bloodborne Pathogen Standard with the purpose of "reducing occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other Bloodborne pathogens" that employees may encounter in their workplace.

KCU believes that there are a number of "good general principles" that should be followed when working with blood -borne pathogens, including:

- It is prudent to minimize all exposures to blood-borne pathogens.
- All blood and body fluids should be treated as potentially infectious.
- Our facility should institute as many engineering and work practice controls as possible to eliminate or minimize employee exposure to blood-borne pathogens.

We have implemented this Exposure Control Plan to meet the letter and intent of the OSHA Blood borne Pathogens Standard. The object of this plan is:

- To protect our employees from the health hazards associated with blood-borne pathogens.
- To provide appropriate treatment and counseling should an employee be exposed to blood-borne pathogens.

SECTION II

GENERAL PROGRAM MANAGEMENT

GENERAL PROGRAM MANAGEMENT

A. PROGRAM MANAGERS

Biological Safety Officer

B. RESPONSIBLEPERSONS

There are three major "Categories of Responsibility" that are central to the effective implementation of our Exposure Control Plan. These are:

- The "Biosafety Officer" working with the Research Compliance Administrator.
- Department Chairs, Directors and Supervisors
- Our Employees

The following sections define the roles played by each of these groups in carrying out our plan.

BIOSAFETY OFFICER

The "Biosafety Officer" will be responsible for overall management and support of our facility's Blood-borne Pathogens Compliance Program. Activities which are delegated to the Biosafety Officer include, but are not limited to:

- Overall responsibility for implementing the Exposure Control Plan for the entire facility.
- Working with physicians and other employees to develop and administer any additional blood-borne pathogens policies and practices needed to support the effective implementation of this plan.
- Looking for ways to improve the Exposure Control Plan, as well as to revise and update the plan as necessary.
- Knowing current legal requirements concerning blood-borne pathogens.
- Acting as facility liaison during OSHA inspections.

- Coordinate training to all employees who have the potential for exposure to blood-borne pathogens.

- Assist facility management in keeping an ongoing updated record of personnel requiring training.

- Maintains appropriate training documentation such as "sign-in sheets".

- Annually reviews the training program with department chairs and directors to include appropriate new information.

DEPARTMENT CHAIRS AND DIRECTORS

Department Chairs and Directors are responsible for exposure control in their respective areas. They work directly with the Biosafety Officer and our employees to ensure that proper exposure control procedures are followed. For instance, Department Chairs and Directors are responsible for the collection, handling of and disposal of biohazardous waste generated in their areas, as well as receiving reports of exposure incidents of employees within their department.

EMPLOYEES

Our employees have the most important role in our Blood-borne Pathogens Compliance Program, for the ultimate execution of much of our Exposure Control Plan rests in their hands. In this role, they must:

- Know what tasks they perform that have occupational exposure.

- Attend the blood borne pathogen training sessions.

- Plan and conduct all operations in accordance with our work practice controls.

- Develop good personal hygiene habits.

C. AVAILABILITYOFEXPOSURECONTROLPLANTOEMPLOYEES

To help them with their efforts, our facility Exposure Control Plan is available to our employees at any time. Employees are advised of this availability during their education/training sessions. Copies of the Exposure Control Plan are kept in the office of the Chair of the Safety Committee and in research laboratories.

D. REVIEWANDUPDATEOFTHEPLAN

- To ensure that our Exposure Control Plan is up-to-date, the plan will be reviewed and updated under the following circumstances:
- Annually, on the beginning of the academic year.
- Whenever new or modified tasks and procedures are implemented which affect occupational exposure of our employees.
- Whenever our employees' jobs are revised such that the new instances of occupational exposure may occur.
- Whenever we establish new functional positions within our facility that may involve exposure to blood-borne pathogens.

SECTION III

EXPOSURE DETERMINATION

EXPOSURE DETERMINATION

One of the keys to implementing a successful Exposure Control Plan is to identify those employees who may be at risk for exposure to blood borne pathogens, including HIV and HBV, hazardous materials and waste, infectious waste.

The attached list contains job classifications of those personnel who may have occupational exposure to human blood and/or other potentially infectious materials, possibly resulting in an exposure to blood-borne pathogens. The Biosafety Officer will work with department chairs and directors to revise and update this list as classifications change.

Blood-borne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Hazardous materials and waste - materials, of which the handling, use, and storage are guided by local, state, or federal regulation (for example, OSHA's Regulations for Blood-borne Pathogens regarding the disposal of blood and blood-soaked items; Nuclear Regulatory Commission's regulations for the handling and disposal of radioactive waste) and hazardous energy sources (for example, ionizing or non-ionizing radiation, lasers, microwave, or ultrasound).

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Reference: Federal Register – See Appendix

JOB CATEGORIES	TYPE	CATEGORY
Executive Administrative Managerial	HAZ,HIV & HBV,INF	III, III, III
Clinical Research Coordinator	HAZ,HIV & HBV,INF	I, I, I
Other Professionals	HAZ,HIV & HBV,INF	III, III, III
Academic Assistant	HAZ,HIV & HBV,INF	II, II, II
Clinical Research Super	HAZ,HIV & HBV,INF	I, I, I
Dir of Clinical Research	HAZ,HIV & HBV,INF	I, I, I
Research Assistant	HAZ,HIV & HBV,INF	I, I, I
Score 1 Coordinator	HAZ,HIV & HBV,INF	II, II, II
Score 1 RN	HAZ,HIV & HBV,INF	II, II, II
Technical & Paraprofessionals	HAZ,HIV & HBV,INF	III, III, III
Clerical & Secretarial	HAZ,HIV & HBV,INF	III, III, III
Asst. Coordinator Score 1	HAZ,HIV & HBV,INF	II, II, II
Clinical Res Cood. II	HAZ,HIV & HBV,INF	II, II, II
OPP Fellowship	HAZ,HIV & HBV,INF	I, I, I
Research Asst. I	HAZ,HIV & HBV,INF	I, I, I
Student Asst. I and II	HAZ,HIV & HBV,INF	II, II, II
Student Asst. IV	HAZ,HIV & HBV,INF	I, I, I
Skilled Crafts	HAZ,HIV & HBV,INF	III, III, III
Service/ Maintenance	HAZ,HIV & HBV,INF	III, III, III
Custodian I and II	HAZ,HIV & HBV,INF	I, I, I
Security Officer	HAZ,HIV & HBV,INF	II, II, II
Faculty	HAZ,HIV & HBV,INF	II, II, II
Assoc. Prof Clinical Science	HAZ,HIV & HBV,INF	I, I, I
Assoc. Prof OB GYN	HAZ,HIV & HBV,INF	I, I, I
Assoc. Prof Surgery	HAZ,HIV & HBV,INF	I, I, I
Asst. Dean Clinical Science	HAZ,HIV & HBV,INF	I, I, I
Asst. Prof Clinical Science	HAZ,HIV & HBV,INF	I, I, I
Asst. Prof OB GYN	HAZ,HIV & HBV,INF	I, I, I
Asst. Prof Surgery	HAZ,HIV & HBV,INF	I, I, I
Prof Surgery	HAZ,HIV & HBV,INF	I, I, I
Prof BS Research	HAZ,HIV & HBV,INF	II, II, II
Prof Clinical Science	HAZ,HIV & HBV,INF	I, I, I
Prof OB GYN	HAZ,HIV & HBV,INF	I, I, I
Research Epidemiologist	HAZ,HIV & HBV,INF	III, III, III
Teaching Assistant	HAZ,HIV & HBV,INF	I, I, I
Instruction/Research Assistants	HAZ,HIV & HBV,INF	I, I, I

Type: HAZ = Hazardous Materials; HIV&HBV = Human Immunodeficiency Virus & Hepatitis B Virus; INF = Infectious Waste

Legend: Category I = High exposure to hazardous materials and infectious waste
Category II = Potential exposure to hazardous materials and infectious waste
Category III = Little or no exposure to hazardous materials and infectious waste

SECTION IV

METHODS OF COMPLIANCE

METHODS OF COMPLIANCE

We understand that there are a number of areas that must be addressed in order to effectively eliminate or minimize exposure to blood-borne pathogens in our facility. The first five areas we deal with in our plan are:

- The use of Standard Precautions - (formerly known as Universal Precautions),
- Establishing appropriate Engineering Controls,
- Implementing appropriate Work Practice Controls,
- Using necessary Personal Protective Equipment, and
- Implementing appropriate Housekeeping Procedures.

Each of these areas is reviewed with our employees during their blood borne pathogens related training (see the "Information and Training" section of this plan for additional information). By following the requirements of OSHA's Blood borne Pathogens Standard in these five areas, we feel that we will eliminate or minimize our employee's occupational exposure to blood borne pathogens as much as possible.

A. STANDARDPRECAUTIONS(formerlyknownasUniversalPrecautions)

In our facility we have observed the practice of "Standard Precautions" to prevent contact with blood and other potentially infectious materials. As a result, we treat all human blood and the following body fluids as if they are known to be infectious for HBV, HIV, and other blood borne pathogens:

- Semen
- Vaginal secretions
- Cerebrospinal fluid
- Synovial fluid
- Pleural fluid
- Pericardial fluid
- Peritoneal fluid
- Amniotic fluid
- Saliva
- Sputum

In circumstances where it is difficult or impossible to differentiate between body fluid types, we assume all body fluids to be potentially infectious.

DepartmentChairsandDirectors are responsible to oversee our Standard Precautions Program.

B. ENGINEERINGCONTROLS

One of the aspects of our Exposure Control Plan is the use of Engineering Controls to eliminate or minimize employee exposures to blood-borne pathogens. As a result, our facility employs equipment such as sharps disposal containers, self-sheathed IV piggyback needles and syringes, and ventilating laboratory hoods as appropriate.

Department Chairs and Directors periodically work with employees to review tasks and procedures performed in our facility where engineering controls can be implemented or updated.

In addition, the following engineering controls are used throughout our facility:

- Handwashing facilities (or antiseptic hand cleaners and towels), which are readily accessible to all employees who have the potential for exposure.
- Containers for contaminated sharps having the following characteristics:
    - Puncture-resistant
    - Labeled with a biohazard warning label
    - Leak-proof
- Specimen containers which are:
    - Leak-proof
    - Labeled with a biohazard warning label
    - Puncture resistant, if necessary
- Secondary containers which are:
    - Leak-proof
    - Labeled with a biohazard warning label
    - Puncture resistant
- Eye wash stations
- B-D Safety-Lock Syringes

C. WORKPRACTICECONTROLS

In addition to engineering controls, our facility uses a number of Work Practice Controls to help eliminate or minimize employee exposure to blood-borne pathogens.

Many of these Work Practice Controls have been in effect for some time.

The individuals in our facility who are responsible for overseeing the implementation of these Work Practice Controls are Department Chairs and Directors. They will work with supervisors and employees to implement Standard Precautions.

Our facility has adopted the following Work Practice Controls as part of our Blood-borne Pathogens Compliance Program:

- Employees wash their hands immediately, or as soon as feasible, after removal of gloves or other personal protective equipment.
- Following any contact of body areas with blood or any other infectious materials, employees wash their hands and any other exposed skin with soap and water as soon as possible. They also flush exposed mucous membranes with water. See Section V of this policy.
- Contaminated needles and other contaminated sharps are not bent, recapped, or removed unless:
    - It can be demonstrated that there is no feasible alternative.
    - The action is required by specific medical procedure.
    - In the two situations above, the recapping or needle removal is accomplished through the use of a medical device or a one-handed technique.
- Contaminated reusable sharps are placed in appropriate containers immediately, or as soon as possible, after use.
- Eating, drinking, applying cosmetics or lip balm, and handling contact lenses is prohibited in work areas where there is potential for exposure to blood-borne pathogens.
- Food and drink are not kept in refrigerators, freezers, on countertops or in other storage areas where blood or other potentially infectious materials are present.
- Mouth pipetting/suctioning of blood or other infectious materials is prohibited.

- All procedures involving blood or other infectious materials minimize splashing, spraying, or other actions generating droplets of these materials.

- Specimens of blood or other materials are placed in designated leak-proof containers appropriately labeled for handling and storage.

- If outside contamination of a primary specimen container occurs, that container is placed within a second leak-proof container and appropriately labeled, for handling and storage. (If the specimen can puncture the primary container, the secondary container must be puncture-resistant as well.)

- Equipment, which becomes contaminated, is examined prior to servicing or shipping, and decontaminated as necessary (unless it can be demonstrated that decontamination is not feasible.)

    - An appropriate biohazard-warning label is attached to any contaminated equipment, identifying the contaminated portion.

    - Information regarding the remaining contamination is conveyed to all affected employees, the equipment manufacturer and the equipment service representative prior to handling, servicing, or shipping.

- When a new employee comes to our facility, or an employee changes jobs within our facility, the following process takes place to ensure that they are trained in the appropriate work practice controls:

    - The employees' job classification, tasks and procedures that he/she will perform are checked against the Job Classification list which we have identified in our Exposure Control Plan as those in which occupational exposure occurs.

    - If the employee is transferring from one job to another within the facility, the job classification, tasks, and procedures pertaining to their previous position are also checked against this list.

    - Based on this "cross-checking" the new job classification and/or tasks and procedures which will bring the employee into occupational exposure situations are identified.

    - The employee is then trained by their supervisor regarding any work practice controls that the employee is not experienced with.

D. PERSONALPROTECTIVEEQUIPMENT

Personal Protective Equipment is our employee's last line of defense against blood borne pathogens. Because of this, our facility provides (at no cost to our employees) the Personal Protective Equipment that they need to protect themselves against such exposure. This equipment includes, but is not limited to:

- Gloves (NOTE: Hypoallergenic gloves are available to employees who are allergic to the gloves our facility normally uses).
- Gowns
- Laboratory coats (knee-high)
- Face shields/masks
- Safety glasses/goggles
- Resuscitation bags
- Shoe covers
- Hoods/caps

The Department Chair or Director working with employees is responsible for ensuring that all departments and work areas have appropriate personal protective equipment available to employees.

Our employees are trained regarding the use of the appropriate personal protective equipment for their job classifications. Additional training is provided, when necessary, if an employee takes a new position or new job functions are added to their current position.

To determine whether additional training is needed, the employee's previous job classification and tasks are compared to those for any new job of function that they undertake. Any needed training is provided by their department manager or supervisor.

To ensure that personal protective equipment is not contaminated and is in the appropriate condition to protect employees from potential exposure, our facility adheres to the following practices:

- All personal protective equipment is inspected periodically and repaired or replaced as needed to maintain effectiveness.
- Reusable personal protective equipment is cleaned, laundered, and decontaminated as needed.

- Single-use personal protective equipment (or equipment that cannot, for whatever reason, be decontaminated) is disposed of in the infectious waste receptacle and forwarded to our facility's Environmental Services Department for proper disposal.

To make sure that this equipment is used as effectively as possible, our employees adhere to the following practices when using their personal protection equipment:

- Any garments penetrated by blood or other infectious materials are removed immediately, or as soon as feasible.
- All personal protective equipment is removed prior to leaving a work area.
- Gloves are worn in the following circumstances:
  - Whenever employees anticipate hand contact with potentially infectious materials.
  - When performing vascular access procedures.
  - When handling or touching contaminated items or surfaces.
- Disposable gloves are replaced as soon as practical after contamination or if they are torn, punctured, or otherwise lose their ability to function as an "exposure barrier".
- Utility gloves are decontaminated for reuse unless they are cracked, peeling, tone or exhibit other signs of deterioration, at which time they are disposed of.
- Masks and eye protection (such as goggles, face shields, etc.) are used whenever splashes or sprays may generate droplets of infectious materials.
- Protective clothing (such as a gown) is worn whenever potential exposure to the body is anticipated.
- Surgical caps and shoe covers are used in any instance where "gross contamination" is anticipated (such as autopsies and orthopedic surgery).

E.COMPLIANCE TOUSEOF PERSONAL PROTECTIVE EQUIPMENT

To ensure employee compliance with the use of personal protective equipment, compliance will be monitored by supervisors and managers. Personnel who violate these regulations will be subject to disciplinary action.

F.HOUSEKEEPING

Maintaining our facility in a clean and sanitary condition is an important part of our Blood-borne Pathogens Compliance Program. To facilitate this, there are schedules for cleaning and decontamination of various areas of the facility. A schedule for cleaning and appropriate decontamination is based on the following:

- The area to be cleaned / decontaminated
- Time of scheduled work.
- Cleaners and disinfectants to be used
- Any special instructions that are appropriate.

Using this schedule, building services and/or laboratory personnel will employ the following practices:

- All equipment and surfaces are cleaned and decontaminated after contact with blood or other potentially infectious materials.
- Surfaces are to be cleaned and decontaminated when they are overtly contaminated.
- Protective coverings, such as imperviously backed absorbent paper, will be removed and replaced when overtly contaminated
- All pails, bins, cans and other receptacles intended for use routinely are inspected, cleaned, and decontaminated as soon as possible if visibly contaminated.
- Potentially contaminated broken glassware is picked up using mechanical means (such as dust pan and brush, tongs, forceps, etc.)

Director and Supervisors of building services are responsible for setting up a routine cleaning and decontamination schedule and making sure it is carried out within our facility.

Directors and Supervisors are responsible for the cleaning and decontamination of accidental spills in their areas.

Regulated waste (including contaminated sharps, laundry, used bandages, and other potentially infectious materials) must be handled with care. They will be discarded and/or "bagged" in containers that are:

- Closable
- Puncture-resistant for sharps
- Leak-proof if the potential for fluid spill or leakage exists
- Red in color and labeled with the appropriate biohazard warning label (if infectious waste).
- Located throughout our facility within easy access of our employees and as close as possible to the sources of the waste.
- Maintained upright, routinely replaced and not allowed to overfill.
- Whenever our employees move containers of regulated waste from one area to another, the containers are immediately closed and placed inside an appropriate secondary container (marked in the same manner as the primary container) if leakage is possible from the first container.

Contaminated laundry is handled as little as possible and is not sorted or rinsed where it is used. If laundry is sent offsite to a facility that does not utilize Standard Precautions, the laundry must be bagged and labeled as set forth above.

Directors and Supervisors are responsible for the collection, handling and disposal of our facility's biohazardous waste generated in their areas.

SECTION V

HEPATITIS B VACCINATION, POST EXPOSURE EVALUATION AND FOLLOW-UP

HEPATITIS B VACCINATION, POST-EXPOSURE

EVALUATION AND FOLLOW-UP

A. HEPATITISBVACCINATION

Hepatitis B vaccine and all medical evaluations, procedures and lab tests associated with such vaccination are available, free of charge, to all employees who have occupational exposure to blood or other potentially infectious materials. A list of job classifications of persons likely to have such occupational exposure is outlined in the section of this plan entitled "Exposure Determination."

This vaccine is made available at the time of initial hiring and if the employee chooses not to take the vaccine at that point in time, it is available on request.

It is the option of the employee whether or not to receive the Hepatitis B vaccine. However, the employee must understand that his/her possible occupational exposure to blood or other potential infectious materials could result in acquiring of Hepatitis B virus (HBV) infection.

The vaccination program consists of a series of three inoculations over a six-month period. As part of their blood-borne pathogens training, our employees have received information regarding Hepatitis vaccination, including its safety and effectiveness.

The Biosafety Officer is responsible for setting up and operating our vaccination program.

Vaccinations are performed under the supervision of a licensed physician or other healthcare professional. Employees who have declined to take part in the program have signed a declination form to that effect. Employees wishing to be vaccinated can call the Biosafety Officer to make an appointment.

Booster doses are not currently recommended. However, if routine boosters are recommended at a later date, such booster doses will be made available.

B. POST-EXPOSUREEVALUATIONANDFOLLOW-UP

It is KCU's purpose to confidentially evaluate, prophylaxis/treat and immediately follow-up on all occupational exposures to blood and body fluids via needle sticks, other sharps injury, mucous membrane or parenteral contact with blood or other potentially infectious materials.

Personnel who have exposure to blood or body fluids of another person (patient or staff) via "sharps' injury, mucous membrane or percutaneous route, must follow these steps:

- Thoroughly wash wound or exposed area with soap and water. If splashed in the eyes, flush with copious amounts of water or saline.

  This process will help to physically remove contaminates

- Go to their Doctor or the Emergency Room within 24 hours for evaluation and to obtain baseline blood draws.

- Notify Department Chair, Director or supervisor and Occupational Health Officer.

  - Supervisor can investigate the incident in a timely manner and evaluate immediate steps to prevent further incidents, where possible.

- Fill out "Employee Incident" form.

  - Absolutely necessary for Workers' Compensation coverage.

  - This information will be used to determine effective strategies for preventing future exposures.

- Contact the Department Chair, Director or supervisor for processing.

- Identify source patient when possible. Provide this information to the Department Chair, director or supervisor.

  - This will help the staff and physician perform an accurate risk assessment.

  - The Safety Committee along with Department Chair or Director will be responsible for reviewing any employee exposure that results in a need for a modification of tasks or procedures performed by that employee.

- Post-exposure evaluation will consist of:

- Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred.

- Identification and documentation of the source individual (when known).

- Serological status will be determined by the following:

    - The source individual's blood will be tested as soon as possible and after consent is obtained in order to determine HBV and HIV infectivity.

    - When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV and HIV status is not repeated.

    - Results of the source individual's testing will be made available to the exposed employee and the employee will be informed of applicable laws and regulations concerning disclosures of the identity and infectious status of the source individual.

    - The exposed employee's blood will be collected as soon as possible and tested after consent is obtained.

    - If the employee consents to baseline blood collection, but does not give consent at that time for HIV serological testing, the sample will be preserved for at least 90 days.

        - If, within 90 days of the exposure, the employee elects to have the baseline sample tested, such testing will be conducted.

    - Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service will consist of
    -

        - Counseling

        - Evaluation of reported illnesses

        - Treatment, if indicated should be started within 24 hours.

C. COUNSELING

Counseling will be provided prior to testing for HIV and/or HBV after obtaining consent from the employee and the source patient. Results of the source patient's testing will be made available to the exposed employee and appropriate treatment will be provided. The employee will be informed of applicable laws and regulations concerning disclosure of the identity and infectious nature of the source individual.

D. INFORMATION PROVIDED TO THE HEALTHCARE PROFESSIONAL

We will ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of the federal regulations related to the Bloodborne pathogens standards located at 29 C.F.R. §1910.1030.

We will also ensure that the healthcare professional evaluating an employee after an exposure event is provided with:

- A copy of the federal regulations related to the Bloodborne pathogens standards located at 29 C.F.R. §1910.1030;
- A description of the exposed employee's duties as they relate to the exposure incident;
- Documentation of the route(s) of exposure and circumstances under which exposure occurred;
- Results of the source individual's blood testing, if available; and
- All medical records relevant to the appropriate treatment of the employee that we are required to maintain, including vaccination status.

E. HEALTHCARE PROFESSIONALS WRITTEN OPINION

A written opinion from the healthcare professional evaluating the exposure will be provided to the exposed employee. The written opinion will contain the following information:

- Whether Hepatitis B vaccination and Hepatitis B Immune Globulin (Recombivax) is indicated for the employee.
- Whether the employee has received the Hepatitis B vaccination.
- Confirmation by the employee's signature that he/she has been informed of the results of the evaluation.

- Whether anti-viral agents for HIV are indicated.

- Confirmation that the employee has been told about any medical conditions resulting from the exposure incident which requires further evaluation or treatment.

F. MEDICAL RECORDKEEPING

To make sure that we have medical information available to the healthcare professional evaluating the exposure, our facility maintains comprehensive medical records on our employees. TheOccupationalHealthOfficer is responsible for setting up and maintaining these records, which includes, but are not limited to, the following information:

- Name, department, position of employee

- Copy of the employee's Hepatitis B. Vaccination status with dates of any vaccinations and place the vaccination received

- Copies of the results of the examination, medical testing and follow-up procedures which took place as a result of an employee's exposure to blood borne pathogens.

As with all information in these areas, we recognize that it is important to keep the information in these medical records confidential. We will not disclose or report this information to anyone without our employee's written consent (except as required by law). These medical records will be retained for the duration of employment plus 30 years.

SECTION VI

LABELS AND SIGNS

LABELS AND SIGNS

For our employees the most obvious warning of possible exposure to blood-borne pathogens are biohazard labels. Because of this, we have implemented a comprehensive biohazard warning labeling program in our facility using labels of the type shown below. Department Chairs and directors are responsible for assuring the appropriate placement of labels and signs.

The following items in our facility were labeled:

- Containers of regulated waste
- Refrigerators/freezers containing blood or other potentially infectious materials
- Sharps disposal containers
- Other containers used to store, transport, or ship blood and other infectious materials
- Laundry bags/containers
- Contaminated equipment

On labels affixed to contaminated equipment, we have also indicated which portion of the equipment is contaminated.

We recognize that biohazard signs must be posted at entrances to HIV and HBV research laboratories and production facilities. However, the laboratory in our facility performs only waived clinical diagnostic work, which is not covered by these special signage requirements.

BIOHAZARD LABEL

SECTION VII

INFORMATION AND TRAINING

INFORMATION AND TRAINING

Having well informed and educated employees is extremely important when attempting to eliminate or minimize our employees' exposure to blood-borne pathogens. Because of this, all employees who have the potential for exposure to blood-borne pathogens are put through a comprehensive training program and furnished with as much information as possible on this issue.

Employees will be retrained at least annually to keep their knowledge current. Additionally, all new employees, as well as employees changing jobs or job functions, will be given any additional training their new position requires at the time of their new job assignment. Training will be offered at no cost to the employee with the employee being compensated for their time.

The Biosafety Officer in coordination with the Research Compliance Administrator are responsible for seeing that employees who have the potential for exposure to blood borne pathogens receive this training through CITI Training program or other methods implemented by the Biosafety Officer.

A. TRAININGTOPICS

The topics covered in our training program include, but are not limited to:

- The Blood-borne Pathogens Standard itself
- The epidemiology and symptoms of blood-borne diseases
- The modes of transmission of blood-borne pathogens
- Our facility's Exposure Control Plan (and where employees can obtain a COPY)
- A review of the use and limitations of methods that will prevent or reduce exposure, including:
    - Engineering Controls
    - Work Practice Controls
    - Personal Protective Equipment

- Selection and use of personal protective equipment including:
    - Types available
    - Proper use
    - Location within facility
    - Handling
    - Disposal
    - Removal
- Visual warnings of biohazard within our facility including labels and signs
- Information on the Hepatitis B Vaccine, including its:
    - Efficacy
    - Safety
    - Method of administration
    - Benefits of vaccination
    - Our facility's free vaccination program
- Actions to take and persons to contact in an emergency involving blood or other potentially infectious materials
- The procedure to follow if an exposure incident occurs, including incident reporting
- Information on the post-exposure evaluation and follow-up, including medical consultation that our facility will provide.

B. TRAININGMETHODS

The training is completed through CITI Training program at https://www.citiprogram.org/index.cfm?pageID=14&region=1

C. RECORDKEEPING

To facilitate the training of our employees, as well as to document the training process, we maintain training records containing the following information:

- Dates of all training sessions
- Contents of the training sessions
- Names and job titles of employees attending the training sessions

These training records are available for examination and copying to our employees and their representatives in https://www.citiprogram.org/index.cfm?pageID=14&region=1 , as well as OSHA and its representatives

SECTION VIII

DEFINITIONS

DEFINITIONS

Blood - Human blood, human blood components, and products made from human blood

Blood-borne Pathogens - pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Contaminated - presence or the reasonable anticipated presence of blood or other potentially infectious materials on an item or surface

Contaminated Laundry - laundry which has been soiled with blood or other potentially infectious materials or may contain sharps

Contaminated Shares - any contaminated objective that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires

Decontamination - use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal

Engineering Controls - controls (i.e., sharps disposal containers, self-sheathing needles) that isolate or remove the blood-borne pathogens hazard from the work place

Exposure Incident - specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties

HBV - Hepatitis B virus

HIV - human immunodeficiency virus

Licensed Healthcare Professional - person whose legally permitted scope of practice allows him/her to independently perform the activities required by the Hepatitis B vaccination and post-exposure evaluation and follow-up

Occupational Exposure - reasonable anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties

Parenteral - piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions

PersonalProtectiveEquipment - specialized clothing or equipment worn by an employee for protection against a hazard (NOTE: General work clothes not intended to function as protection against a hazard are not considered to be personal protective equipment).

Regulated Waste - liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials

SourceIndividual - any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components

Sterilize - use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores

StandardPrecautions - an approach to infection control. According to this concept, all human blood and certain body fluids are treated as if known to be infectious for HBV, HIV, and other blood-borne pathogens

WorkPracticeControls - controls that reduce the likelihood of exposure to altering the manner in which a task is performed (i.e., prohibiting recapping of needles by a two-handed technique)

SECTION IX

STANDARD PRECAUTIONS

SPECIFIC GUIDELINES FOR

KANSAS CITY UNIVERSITY

STANDARD PRECAUTIONS

General Information:

- Standard precautions are designed to protect employees from exposure to potentially infectious agents through the use of barriers such as gloves, gowns, masks, and protective eyewear.

- All patients have organisms present in their body substances such as respiratory secretions, feces, oral secretions, emesis, and sometimes urine and wounds that are causing "colonization" if not "infection".

- Colonized body substances can be a major reservoir for Multiple-drug-resistant organisms that can be transmitted from patient to patient on the hands of personnel.

- Standard precautions reduce the risks of such transmission by the consistent use of barriers whenever the employee is likely to contact anybody substance.

- Contact not involving blood/body substances, or contact with items not contaminated with such, does not require the use of protective barriers.

- If unanticipated exposure occurs, wash hands immediately, follow KCU policy for exposure.

- If injury (puncture wound, needle stick, or mucous membrane exposure) occurs, report and follow KCU policy for exposure.

- These guidelines are the minimum requirements recommended during controlled situations, to protect the employee from potentially infectious agents. Judgment is required on the part of the employee to assess the need for additional barrier protection in less controlled situations.

- Other barriers may be required to protect the patient during certain procedures.

- If an employee has an open cut or abrasion on their hands, they are responsible for protecting it through the use of gloves.

- Sterile technique is to be used during sterile procedures.

- Handwashing remains the number one factor in preventing the spread of infection.

Precautionary measures in addition to handwashing after contact

- No additional precautions are necessary unless there is contact with patient's blood or body substances, at which time gloves should be worn.

- Other departments, not listed, that do not have contact with patient's blood or body substances do not require any special precautions.

APPENDIX

FEDERAL REGISTER Department of Labor Occupational Safety and Health Administration 29 CFR 1910.1030

Occupational Exposure to Bloodborne Pathogens Final Rule
- https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

Appendix D

Office of Biosafety, Biosecurity, and Emerging Biotechnology

https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/

Appendix E

TEMPLATE FOR LAB-SPECIFIC SOP'S

Laboratories using biohazardous agents must have a biosafety manual available for immediate reference. Those labs using chemicals must also provide a chemical hygiene plan. The information in this template must be located in every lab and constitutes that lab's safety manual. Listed below are some suggestions for information that could be included in this manual. Regardless of format used, all information contained in this template must be included in the lab's manual.

Date _____

Principal Investigator _____

IBC Protocol No. _____

Containment Level: BSL1 ABSL2
BSL2 ABSL3
BSL3

Biohazardous Agent(s) Used:
(List all RG-2 and/or RG-3 agents)

Personal Protective Equipment Required:

Immunizations and/or Clinical Baseline Testing Required:

List of Trained Personnel:

Specific Procedure(s):
(Describe briefly any specialized procedures utilized in this laboratory that are not otherwise contained in the *NIH/CDC Biosafety Manual*. Additional sheets may be attached if necessary)

Emergency information:
(As applicable, provide information regarding emergency procedures and equipment specific to the lab(s) under your control. Include, evacuation procedures (e.g., close fire doors, secure certain equipment, etc.); first-aid kit (location contents, maintenance responsibility, etc.); spill cleanup materials (e.g., location, contents, maintenance, procedures, etc.); (Lab monitors or alarms (e.g., operation, response, maintenance, etc.).

Material Safety Data Sheets (MSDS):
Per OSHA, all lab chemical users must know: a) what and MSDS is, B) MSDS relevance to their health and safety, (c) where they are located and how to readily access them. Labs are encouraged to maintain their own MSDS for the hazardous chemicals they routinely use.

Appendix F

Select Agent List

https://www.selectagents.gov/sat/list.htm

Appendix G

Biosafety Manual
(BMBL Version 6)

https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

Appendix H

NIH Guidelines

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Appendix I

Recombinant DNA Registration Form

https://www.irbnet.org/release/libraries/manage.do?orgId=823645&libId=774

Appendix J

IBC Initial-Renewal-Modification Application

https://www.irbnet.org/release/libraries/manage.do?orgId=823645&libId=774

Appendix K

Investigator Responsibilities under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

https://osp.od.nih.gov/wp-content/uploads/Investigator_Brochure_Recombinant_DNA_2021.pdf