Kennesaw State University

Biological Safety Manual

Working with Biologically Hazardous Materials in the Lab
Common Acronyms Used

A. KSU – Kennesaw State University
B. USG – University System of Georgia
C. IBC – Institutional Biosafety Committee
D. IACUC – Institutional Animal Care and Use Committee
E. EHS – Department of Environmental Health and Safety
F. BSO – Biosafety Officer
G. PI – Principal Investigator
H. NIH – National Institutes of Health
I. OBA – NIH Office of Biotechnology Activities
J. ABSA – American Biological Safety Association
K. NASBB – National Advisory Board on Biosecurity
L. DURC – Dual Use Research of Concern
M. OSHA – Occupational Safety and Health Administration
N. OCGA – Official Code of Georgia
O. GAEPD – Georgia Environmental Protection Division
P. EPA – Environmental Protection Agency
Q. USDA – United States Department of Agriculture
R. APHIS – Animal and Plant Health Inspection Service
S. CFR – Code of Federal Regulations
T. CDC – Centers for Disease Control
U. BMBL – Biosafety in Medical and Biomedical Laboratories
V. RG – Risk Group
W. BSL – Biosafety Level
X. ABL – Animal Biosafety Level
Y. BBP – Bloodborne Pathogens
Z. OPIM – Other Potentially Infectious Materials
AA. LAI – Laboratory Acquired Illness
BB. BSC – Biosafety Cabinet
CC. SOP – Standard Operating Procedure
DD. IPM – Integrated Pest Management
Kennesaw State University (KSU) is committed to providing and maintaining a safe teaching, learning, living, and working environment for all members of its community. Laboratories are unique work environments that entail a variety of operations and activities, involving working with hazardous materials. Laboratory personnel, therefore, are at risk of exposure to various types of hazards, including chemical, biological, physical and radiological. However, with prudent laboratory practices, appropriate equipment, proper facilities and awareness, all laboratory operations can be handled safely, without undue risk to KSU's employees, students, properties or the environment.

The responsibility of ensuring a safe laboratory environment at KSU is a shared responsibility between laboratory personnel, administrators and Environmental Health and Safety (EHS) personnel. Nevertheless, laboratory supervisors, principal investigators (PIs) and managers have the primary responsibility for safety in laboratories under their supervision, and for ensuring compliance with the applicable health, safety and environmental regulations and policies with their labs.

The KSU Biosafety Manual is intended to provide guidance to all faculty, laboratory personnel and students on how to minimize or eliminate the potential for exposure to biological hazards while working in the laboratory. The information presented here also reflects the requirements and guidelines prescribed by the federal government and the state. It is intended that the PI and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done in their laboratories. This manual will be reviewed, and revised as necessary and at least annually.
## Contact Information

| **Environmental Health & Safety (EHS)** | Tel: (470) 578-3321  
Fax: (470) 578-9041  
Email: ehs.kennesaw.edu  
Web: www.kennesaw.edu/ehs |
|---|---|
| **Biosafety Officer (BSO)** | Rodrick Esaw, MPH, ASP  
(470) 578-4803  
Email: resaw@kennesaw.edu |
| **Institutional Biosafety Committee (IBC)** | Dr. Charles Amlaner  
VP of Research  
Tel: (470) 578-6738  
Fax: (470) 578-3620  
Email: camlaner@kennesaw.edu  
Web: www.kennesaw.edu/research/ |
| **Biohazard information; Laboratory spills or accidents involving biological agents; Biological safety cabinets; Recombinant DNA guidelines; laboratory spills or accidents involving chemicals; Chemical hygiene plan; Permits** | Rodrick Esaw, MPH, ASP  
Laboratory Safety Manager and Biosafety Officer  
(470) 578-4803 |
| **Hazardous waste disposal (chemical, toxic, animal); Shipping Requirements;** | Vanessa Biggers  
Chemical Safety Manager  
Tel: (470) 578-2415  
Email: vbigger1@kennesaw.edu |
| **Ventilation (HVAC) problems; Fume hood operation; Laboratory safety design** | Plant Operations/HVAC Shop  
Tel: (470) 578-6224  
Web: web.kennesaw.edu/plantops/ |
| **Research animal use** | Dr. Jared Tagliatela, Chair, IACUC  
(470) 578-3678  
Web: www.kennesaw.edu/research/compliance/index.html#section-4 |
| **Bloodborne pathogens training and information** | Rodrick Esaw, MPH, ASP  
Laboratory Safety Manager and Biosafety Officer  
(470) 578-4803 |
| **Public Safety, Security and Emergency Management (KSU Police)** | Public Safety Department  
Emergency: (470) 578-6666  
Non-Emergency: (470) 578-6206 |

*For the most current contact information, access the EHS website at [www.kennesaw.edu/ehs/](http://www.kennesaw.edu/ehs/).*
# Table of Contents

1. **Purpose and Scope** .................................................................................................................. 9
   
   A. Purpose ...................................................................................................................................... 9
   
   B. Scope ........................................................................................................................................ 9

2. **Responsibilities** .................................................................................................................. 9
   
   A. The University .......................................................................................................................... 9
   
   B. Deans ........................................................................................................................................ 10
   
   C. Department/School Chairpersons ......................................................................................... 10
   
   D. Institutional Biosafety Committee (IBC) .............................................................................. 11
   
   E. Environmental Health & Safety (EHS)/Biosafety Officer (BSO) ........................................... 13
   
   F. Principal Investigators (PIs) .................................................................................................... 14
   
   G. Laboratory Managers/Laboratory Supervisors ...................................................................... 14
   
   H. Employees Working in the Lab ............................................................................................... 15

3. **Regulatory Requirements** .................................................................................................. 16
   
   Dual Use Research ...................................................................................................................... 18

4. **Risk Management** .............................................................................................................. 18
   
   A. Risk Management Steps .......................................................................................................... 18
   
   B. Risk Groups ............................................................................................................................ 19
      
      Risk Group 1 ............................................................................................................................ 19
      
      Risk Group 2 ............................................................................................................................ 19
      
      Risk Group 3 ............................................................................................................................ 20
      
      Risk Group 4 ............................................................................................................................ 20

5. **Routes of Infection and Exposure Sources** ........................................................................ 20
A. **Clinical and Pathological Specimens** ................................................................. 20
B. **Cultures** .............................................................................................................. 21
C. **Animals** ............................................................................................................... 22
D. **Latex Gloves and Related Allergies** ................................................................. 22

6. **Laboratory Exposure Potential** ........................................................................... 23
A. **Teaching Laboratories** ........................................................................................ 23
B. **Research Laboratories** ....................................................................................... 23
C. **Clinical Laboratories** .......................................................................................... 23

7. **Biosafety Levels and Laboratory Practices** ...................................................... 23
A. **Biosafety Levels** .................................................................................................. 23
   Procedure for Laundering Laboratory Protective Clothing ..................................... 28
B. **Biosafety Cabinets** .............................................................................................. 29
C. **Centrifuge Operation** .......................................................................................... 33
D. **Working with Sharps** .......................................................................................... 34
   Sharps Safety ........................................................................................................ 34

8. **Waste Handling and Disposal Procedures** ...................................................... 37
   E. **Collection of Biological/Biohazard Waste** ..................................................... 37
   F. **Decontamination and Disposal of Biohazard Waste** ...................................... 37
   G. **Autoclave Use** .................................................................................................. 38
   General Autoclave Operation Rules ................................................................. 39
   H. **Autoclave Validation** ....................................................................................... 42
   Odor Control .......................................................................................................... 43
   Training .................................................................................................................. 43
9. INFORMATION AND TRAINING .............................................................................. 43
   A. EHS Required Training ..................................................................................... 44
   B. Additional Training Requirements .................................................................... 45

10. Incident/Emergency Response ........................................................................... 45
    A. Emergency Procedures ....................................................................................... 45
    B. Reporting of Incidents/Emergencies ................................................................. 47
    C. Post-Exposure Evaluation and Follow-Up ......................................................... 48

11. Decontamination of Biological Spills .................................................................. 48
    A. Spills in the Biosafety Cabinet ......................................................................... 49
    B. Spills in Incubators ............................................................................................ 49
    C. Spills in Centrifuges .......................................................................................... 50
    D. Spills Outside of the BSC .................................................................................. 51

12. Medical Surveillance Program ............................................................................. 52
    A. Health Status ...................................................................................................... 52
    B. Medical Surveillance ......................................................................................... 52
    C. Immunizations .................................................................................................... 53
    D. Medical Restrictions .......................................................................................... 53
       Pregnancy ........................................................................................................... 53
       Other Restrictions ............................................................................................... 53

13. Laboratory Design ............................................................................................... 54

14. Equipment Repairs/Service ................................................................................ 55

15. Animal Biosafety ................................................................................................... 55
16. Plant Biosafety ............................................................................................................. 56
17. Pest Control .............................................................................................................. 56
18. Appendices ............................................................................................................... 59
1. **PURPOSE AND SCOPE**

   A. **Purpose**

   This document will focus on the regulatory requirements and best practices for the safe handling and manipulation of biological hazards encountered when working in research laboratories in KSU facilities. The information provided is based upon the National Institutes of Health (NIH) Guidelines for Research with Recombinant DNA Molecules, the Occupational Health and Safety Administration (OSHA) Bloodborne Pathogen Standard (BBP) (29 CFR 1910.1030), and the best practices found in the Centers for Disease Control’s Biosafety in Medical and Biomedical Laboratories, 5th Edition (BMBL).

   B. **Scope**

   The KSU Biosafety Manual is applicable to activities in all facilities owned, leased or operated by KSU, where KSU employees and students work with biological or biohazardous agents and/or their derivatives. These agents include, but are not limited to:
   - Bacterial, fungal, and/or parasitic agents
   - Viral agents/viral vectors
   - Recombinant DNA (rDNA)
   - Materials of human origin (including blood, blood components, cells, cell lines, DNA, bodily fluids, and tissues)
   - Biological toxins

   The manual applies to all faculty, staff, students, contractors and other personnel at KSU or under the management or control of KSU.

2. **RESPONSIBILITIES**

   A. **The University**

   KSU has an obligation to provide a workplace for its employees that is reasonably safe from all recognized hazards, including biological hazards that could cause illness in exposed individuals. Therefore, KSU has instituted a biosafety program for all personnel who may be exposed to biological hazards (biohazards) during the performance of their duties. Under the biosafety program, the University assumes the following responsibilities:

   - Appointing a Biological Safety Officer (BSO) for the institution.
   - Ensuring appropriate training is provided to personnel conducting research with biological/biohazardous agents (e.g. – bloodborne pathogens, bacteria, viruses/viral vectors, rDNA).
   - Ensuring that research is conducted in accordance with the NIH Guidelines, Center for Disease the BMBL, the OSHA BBP Standard, and all Georgia State laws.
• Establishing an Institutional Biosafety Committee (IBC) and an Institutional Animal Care and Use Committee (IACUC) with appropriate expertise and training.

• Establishing and implementing policies for safe conduct during research activities involving biohazards and recombinant DNA.

• Providing adequately designed facilities and containment devices for work with biological agents.

• Providing appropriate personal protective equipment (PPE) for employees.

• Making the necessary vaccinations available (those which protect the employee from work related illness) at no cost to all employees.

• Establishing and maintaining a health surveillance program for personnel.

• Reporting any significant problems, violations, or significant research-related accidents or illnesses to the NIH Office of Biotechnology Activities (OBA) within 30 days.

B. Deans

• Creating vision, enforcing policy, setting performance expectations, and ensuring timely availability of resources that support biosafety at KSU.

• Providing leadership to ensure effective implementation of the biosafety program and ensuring the College’s compliance with governing laws, regulations, and policies. To this end, Deans may designate a safety officer(s) within the College/School.

• Reviewing laboratory and safety-related assessment reports as a mean to assess and direct actions necessary to continually improve biosafety at the College/School.

*Note: This applies only to Deans that oversee colleges and departments where biohazards are used in teaching and research.

C. Department/School Chairpersons

• Setting performance expectations, managing biosafety risks, and ensuring the Department’s compliance with this program and other Environmental and Occupational Safety (EOS) governing laws, regulation and policies.

• Effectively implementing KSU’s biosafety program and its requirements within their respective units and laboratories.

• As appropriate, incorporating the biosafety program requirements and responsibilities into employee job descriptions and address performance related to the same.

• Ensuring that individuals under their supervision, including but not limited to supervisors, regular and temporary employees, contractors, and other affected personnel, obtain required biosafety training.

• Developing a process to maintain incident/illness prevention and environmental protection programs within the department.
• Ensuring prompt reporting and appropriate investigations of incidents/accidents within the unit, in accordance with the University’s Incident Reporting and Investigation requirements (EOSMS-108).

• Ensuring development and implementation of a process for conducting hazard/risk assessments within their respective unit or laboratory inclusive of periodic safety inspections of work areas and/or facilities and ensuring non-compliance items are corrected with follow-up and closure.

• Ensuring assessment of the environmental and occupational safety impact of biological agents and/or biohazards, processes and equipment, and incorporate appropriate controls.

D. Institutional Biosafety Committee (IBC)

In accordance with NIH Guidelines, The IBC shall be established as follows:

• It shall be constituted of a minimum of five (5) voting members;

• Collectively, the membership shall have experience and expertise in biohazardous materials and recombinant DNA technology; and

• The membership shall have the capability to assess the safety of biohazardous and recombinant DNA research and identify any potential risks to public health or the environment.

• The IBC shall include at least one individual with expertise in microbial pathogens and rDNA containment principles. The IBC shall have at least two members unaffiliated with the institution (apart from their membership on the committee) and they shall represent the interest of the surrounding community with respect to public health and protection of the environment.

• All appointments to the committee shall be for three-year terms. Members shall be appointed, or reappointed, by the Vice President of Research or designee. The committee’s current membership may be obtained by contacting the Office of Research at (470) 578-6738. Additional duties regarding the IBC are outlined in the IBC Charter and Procedures Manual.

Under the KSU Biosafety Program, the IBC is responsible for:

• Local oversight and review of activities that use the following potentially biohazardous materials or procedures:
  o Recombinant or synthetic nucleic acid molecules (rDNA/RNA)
  o Select agents and toxins, as determined by the Federal Select Agent Program (approval of research involving these activities is contingent upon their approval and registration with the Federal select agent program – see “Other Regulatory Requirements”)
  o Biological agents that require Biosafety Level 2 containment or higher, including agents in Risk Group 2, 3, and 4
- Blood borne pathogens (from human and non-human primates)
- All other biological agents that can cause disease in humans

- Stem cell research
- Biological Nanotechnology (e.g., drug delivery via nanoparticles, etc.)
- Importing/Exporting of etiologic agents (which require BSL-2 and or BSL-3 containment) into/out of the campus
- Xenotransplantation
- Recommending or prescribing, and publishing for the KSU community, the appropriate requirements, conditions, and restrictions necessary (e.g. – training, vaccinations, work practices, control measures, PPE, etc.) according to NIH guidelines; federal, state, and local laws and regulations; and University System of Georgia (USG) Policies.
- Certifying and assigning investigators/teachers/workers, their laboratories or other workspaces, and/or their practices for work, at appropriate biological safety levels prescribed in the latest edition of the BMBL. Activities identified as Biosafety Level 2 (BSL-2) and greater may not proceed without the written consent of the IBC prior to initiation of work.
- Reviewing and approving protocols/proposals for research involving biologically hazardous agents.
- Notifying each applicant of the IBC’s decision regarding his/her protocol(s)/proposal(s)
- Conducting annual reviews of protocols/proposals and recertification every three years for activities listed in section IIB to ensure compliance with NIH guidelines and all federal, state, and local regulations and USG policies.
- Keeping the KSU community aware of any changes/updates in the NIH guidelines, laws, policies, and regulations associated with biosafety.
- Reviewing reports from the Biosafety Officer concerning instances of urgent issues, including personnel exposure, loss/theft of biological agents, breaches in biosafety containment, and accidental spills involving rDNA, synthetic nucleic acids, and other biohazards; reporting such instances to the NIH and regulatory agencies as necessary.

*Reportable incidents must be reported to NIH/Office of Biotechnology Activities within 30 days*

- Overseeing the monitoring follow-up of those persons testing positive for identified pathogens resulting from confirmed laboratory acquired infections.
- Implementing corrective actions when KSU policies, NIH Guidelines, federal, state, and/or local regulations are not followed. These actions may include (not limited to):
  - Terminating of authorizations
  - Restricting the receipt of biological agents
  - Ordering the removal of biological agents from laboratories
  - Terminating of access to laboratories and/or other facilities
The IBC may choose to reverse these penalties after a thorough review finds that all operations are in compliance with NIH Guidelines, and all applicable policies and regulations.

- Maintaining records of all IBC meeting minutes, protocol reviews, and any other documents associated with the IBC or the use of biological agents at KSU.
- Periodically reviewing IBC policies and procedures.

E. Environmental Health & Safety (EHS)/Biosafety Officer (BSO)

The responsibilities of EHS and the BSO include, but are not limited to, the following:

- Developing, implementing, and maintaining the University’s Biosafety Program.
- Developing protocols and procedures to address biosafety issues.
- Developing, implementing, and maintaining the University’s program for select agents and toxins.
- Developing and maintaining the KSU Bloodborne Pathogens Exposure Control Program (ECP)
- Providing training in the safe use and practices for those working with potentially biohazardous materials (e.g. - bloodborne pathogens, viruses/viral vectors, recombinant DNA, etc.).
- Providing technical advice to PIs, the IACUC, and the IBC on research safety procedures.
- Consulting with researchers on issues of animal care, biosafety, and the safe use of biological materials in the laboratory.
- Performing periodic inspections to ensure that standard operating procedures (SOPs) are being followed and regulatory requirements are being met.
- Providing guidance to researchers on laboratory security.
- Providing guidance to researchers on proper waste disposal methods in accordance with federal and state regulations.
- Assisting in the development of emergency plans for handling accidental spills and personnel contamination.
- Investigating laboratory accidents involving biohazardous materials and rDNA research.
- Providing guidance with regard to laboratory design in accordance with USG laboratory design guidelines.
- Reporting to the IBC and the institution any significant problems, violations of the NIH Guidelines, and/or any significant research-related accidents or illnesses of which the BSO becomes aware unless the BSO determines that a report has already been filed by the PI.
- Serving as a member of the IBC and IACUC.
- Working in conjunction with the IBC to review all registration forms for research proposals submitted by PIs.
F. Principal Investigators (PIs)
PIs are responsible for conducting diagnostic and/or research activities in a manner which minimizes the risk in the laboratory environment. These responsibilities include, but are not limited to:

- Obtaining the required approval from the IBC for new research proposals as well as amended existing proposals (i.e., addition of new agents, animals, etc.) prior to the commencement of such work laboratory environment.
- Completing and documenting risk assessments conducted for the purpose of determining level of risk and/or lowering the level of risk.
- Ensuring that lab employees and support personnel who will work with biohazards are: (prior to working in the laboratory):
  - Properly trained and show proficiency in standard microbiological practices at the appropriate biosafety level(s).
  - Aware of biohazards and precautions to be taken in conducting research activities.
  - Advised of the nature recognized and potential hazards.
  - Informed of the indicators of accidental infections.
- Completing (PI) all required training for working with biohazards.
- In collaboration with the BSO, ensuring that the appropriate immunizations, serologic monitoring, post exposure prophylaxis, and other medical monitoring are provided to personnel should the handling of the infectious agents require such precautions.
- In collaboration with EHS and the BSO, developing procedures for dealing with accidental spills and accidental exposures among personnel.
- Reporting to the BSO and/or EHS issues pertaining to:
  - All accidents/incidents within the lab that may pose a risk.
  - Exposure of personnel to biological/biohazardous agents.
  - Compromise of biological or physical barriers.
  - Major equipment failure which could compromise safe operations in the laboratory.
- In conjunction with the BSO, correcting procedures, which may result in hazardous incidents or employee exposures.

G. Laboratory Managers/Laboratory Supervisors
Laboratory Managers/Supervisors are responsible for supervising the day-to-day operations lab environment. Their responsibilities include but are not limited to:

- Overseeing the activities of laboratory employees and students engaged in research involving biological/biohazardous agents.
- In collaboration with the PI and BSO, ensuring that new staff and/or visiting scientists (e.g., volunteer workers, high school students, etc.) are properly trained for their assigned tasks.
- Ensuring that lab personnel demonstrate proficiency in standard and special microbiological practices before working with biohazardous agents.
• In conjunction with the BSO, ensuring that physical containment systems, support equipment, waste disposal and operation of lab are in accordance with the design and safety guidelines of the BSL-2 facility.

• Performing regular checks/assessments of containment devices, equipment, and PPE.

• Notifying the BSO and/or EHS of any incident or problem that compromises the safety of the staff or the integrity of the lab.

H. Employees Working in the Lab

All laboratory personnel who engage in research activities have a shared responsibility for ensuring their own safety while working in the lab. Responsibilities for all laboratory personnel include, but are not limited to:

• Completing all assigned EHS and lab specific training to work proficiently and independently in the laboratory.

• Conducting all research activities in accordance with University's policies, procedures and guidelines, including the standards in this Biological Safety Manual.

• Being familiar with the standard operating procedures for laboratory activities, the potential hazards of the infectious agents in use, and emergency procedures.

• Employing good housekeeping practices to help maintain the laboratory in good working condition.

• Completing all medical surveillance requirements.

• Reporting any medical restrictions, reportable illnesses, and any event that may be the result of an exposure to the PI and Lab Manager/Supervisor.

• Reporting irregular laboratory conditions or accidents to the PI and EHS immediately.

• Performing all duties as assigned in a prudent manner.

I. Students in the Laboratory

Students who are participating in laboratory activities for undergraduate academic credit or volunteer credit must be supervised by a PI, lab manager, or teaching assistant while in the lab, especially when working with biohazards. Student activities involving hazardous materials, equipment, and/or processes should be limited at the discretion of the PI/Lab Manager. Students have a shared responsibility for ensuring their own safety while participating in lab activities. These responsibilities include, but are not limited to:

• Completing and submitting the Kennesaw State University Volunteer Program form prior to beginning laboratory activities (See Appendix A).
Note: Minors must have a parent complete and sign the Waiver and Release Agreement regarding the use of Kennesaw State University Science labs (See Appendix B).

• Completing all assigned EHS, departmental, and lab specific training.
• Conducting all laboratory activities (under the supervision of a PI or Lab Manager) in accordance with University's policies, procedures and guidelines, including the standards in this Biological Safety Manual.
• Being familiar with the SOPs for laboratory activities, the potential hazards of the materials in use, and emergency procedures.
• Employing good housekeeping practices to help maintain the laboratory in good working condition.
• Reporting any injuries, reportable illnesses, and any event that may be the result of an exposure to the PI and Lab Manager/Supervisor.
• Reporting irregular laboratory conditions or accidents to the PI and EHS immediately.
• Performing all duties as assigned in a prudent manner.

3. REGULATORY REQUIREMENTS

The biosafety practices outlined in this manual are based on the NIH Guidelines and the best practices found in the BMBL. There are additional guidance documents and regulations imposed by various funding agencies that individual PIs must be aware of and incorporate into their lab-specific Biosafety Manuals. Biosafety requirements must be followed to ensure the continuation of grant funding from federal agencies and for health and safety purposes.

NIH Guidelines

The NIH Guidelines detail procedures and practices for the containment and safe conduct of various forms of recombinant DNA research, including research involving genetically modified plants and animals, as well as human gene transfer. The NIH Guidelines require:

• The establishment of an IBC for the review and oversight of biological research.
• The appointment of a Biological Safety Officer.
• The establishment of practices, procedures, and conditions under which recombinant DNA activities must be conducted.

All institutions, including KSU, receiving NIH funding for recombinant DNA activities must comply with the NIH Guidelines. Researchers at institutions that are subject to the NIH Guidelines must comply with the requirements even if NIH does not fund their individual projects. Non-compliance
with the NIH Guidelines may result in suspension, limitation, or termination of financial assistance for the research project and of NIH funds for other recombinant DNA activities at KSU or the requirement for prior NIH approval of any and/or all recombinant DNA projects at KSU.

**Center for Disease Control Best Practices**

The BMBL, describes the appropriate measures and facilities for work with all microbial agents, including bacterial, viral, fungal, parasitic, rickettsial, and prion agents as well as toxins of biological origin. The BMBL also addresses the appropriate measures and facilities for work with vertebrate animals and sets forth biosafety level criteria that are detailed in this document.

**OSHA Bloodborne Pathogens Standard**

The requirements described in the OSHA BBP Standard ([29 CFR § 1910.1030](https://www.osha.gov/SLTC/bbp)) and the O.C.G.A. (Official Code of Georgia_ 31-12) apply to work with materials of human origin, including human blood, tissue, organs, body fluids, cells, and DNA. The BBP Standard is a program outlines requirements includes training, medical surveillance, procedures, and equipment that must be in place for protection against bloodborne pathogens. Although bloodborne pathogens are included in biosafety, the more specific requirements for working with BBPs are explained in detail in the KSU BBP Exposure Control Plan.

**Other Regulatory Requirements**

Currently, select agents and biological toxins are not used in research laboratories at KSU. However, in the event that any select agent or biological toxin is approved for use in research, they are subject to federal regulations and must be registered with the Federal Select Agent Program. The Select Agent and Toxin rules, which implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 may be found in Department of Health and Human Services (HHS) Standard, “Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule” ([42 CFR § 73](https://www.cfr.gov/cfr/text.asp?n=20180101_42)) and the Department of Agriculture (USDA) Standard, “Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule” ([7 CFR § 331](https://www.cfr.gov/cfr/text.asp?n=20180101_7) and [9 CFR § 121](https://www.cfr.gov/cfr/text.asp?n=20180101_9)). A list of Select Agents and Toxins can be found at the Federal Select Agent Program website.

Handling and disposal of biohazardous waste is regulated by OSHA under the BBP Standard and by Georgia State Rule 391-3-4: Solid Waste Management, specifically, 391-3-4.15: Biomedical Waste. The procedures for biohazardous waste handling are highlighted in the waste disposal section of this document.

The requirements for packaging and shipment of biohazardous materials are provided in the Department of Transportation’s hazardous materials regulation 49 CFR, Parts 171 – 180. For more information on shipping procedures at KSU that comply with these regulations, refer to the Shipping and Transportation Guidelines on the EHS website.
In addition, permits may be required to ship biological materials. Please refer to the CDC Etiological Agent Import Permit Program and the Animal and Plant Health Inspection Service (APHIS) permit program.

**Dual Use Research**

“Dual use” (as broadly defined), refers to the malevolent misapplication of technology or information initially developed for benevolent purposes. In life sciences, “dual use” refers to the potential misuse of microorganisms, toxins, recombinant/synthetic nucleic acid technology, or research results to threaten public health or national security. “Dual Use Research of Concern,” referred to as DURC, is research that has a potential to be DIRECTLY misapplied.

The National Science Advisory Board on Biosecurity (NSABB) is an advisory board to the U.S. Government on issues of biosecurity. The NSABB is administered through the NIH Office of Biotechnology Activities (NIH-OBA), which publishes the most recent NSABB discussions and NSABB reports on issues involving Dual Use Research. A video prepared by the NSABB is available on the NIH-OBA website, which can be accessed here: http://oba.od.nih.gov/biosecurity/biosecurity.html.

If you think someone may be misusing biological agents or data in a manner that may be harmful to public health or national security or wish to learn more about DURC, please contact the Biosafety Officer by phone 470-578-4803, or visit the KSU Environmental Health and Safety main office at 1200 Chastain Rd NW, Suite 201. Your identity will be kept confidential.

**4. RISK MANAGEMENT**

**A. Risk Management Steps**

Risk management encompasses three main concepts, which include risk characterization, assessment/evaluation of the risk, and management of the risk. An effective risk management process includes the following steps:

- Identifying the hazard – What hazardous materials are we dealing with?
- Assessing the hazard – What could potentially go wrong from working with these hazardous materials?
- Determining the risks – What risks are acceptable, if any?
- Determining appropriate controls measures - What can be used/done to minimize or remove this hazard?
- Implementing the appropriate control measures – Put developed control measures into practice.
- Evaluating – After an evaluation period, review the control(s) implemented to determine their effectiveness, or if additional control(s) are warranted.

Risk characterization is a process used to identify the hazardous characteristics of a known infectious/potentially infectious agent or biohazardous material, the activities that can result in an
individual’s exposure to an agent, the likelihood that such exposure will cause a Laboratory-
Acquired Illness (LAI), and the probable consequences of such an infection.

Risk assessment is an important responsibility for individuals who manage microbiological and
biomedical laboratories (e.g. principal investigators, laboratory supervisors, etc.). This
responsibility must be shared by various groups (and individuals) throughout the University.
However, there are specific University personnel that have responsibilities for ensuring
appropriate risk assessments are conducted. At KSU, the responsibility of conducting risk
assessments rests primarily on the BSO/EHS and PIs, in consultation with IBC.

The information identified by a risk characterization, risk assessment, and other important factors
will help guide the management of risk through the selection of appropriate containment levels,
microbiological practices, safety equipment, and facility safeguards that can prevent LAIs or other
impacts. Other important factors include the nature and risk group of the biological agent, host
susceptibility, potential routes of exposure, and methods to inactivate the agent.

B. Risk Groups

Biological agents have been classified into risk groups (RG) based on the transmissibility,
invasiveness, virulence or disease causing capability, lethality of the specific pathogen, and the
availability of vaccines or therapeutic interventions. The list of pathogenic microorganisms includes
bacteria, viruses, fungi, parasites, and other infectious agents. The scheme ascends in order of
increasing hazard from Risk Group 1 (RG1) agents, which do not cause disease in healthy human
adults, to Risk Group 4 (RG4) agents, which cause lethal disease in healthy human adults, and for
which preventative or therapeutic measures are not available.

The American Biological Safety Association also provides a comprehensive risk group listing, which
references global agencies. This list is accessible at https://my.absa.org/tiki-

Another reliable source of information about human pathogens is the Pathogen Safety Data Sheets

The descriptions of the four risk groups are as follows:

**Risk Group 1**

Agents are not associated with disease in healthy adult humans. Examples: *E. coli* K-12,
*Saccharomyces cerevisiae.*

**Risk Group 2**

Agents are associated with human disease that is rarely serious, and for which preventive
or therapeutic interventions are often available. Examples: *E. coli* O157:H7, *Salmonella
typhimurium*, and *Cryptosporidium parvum.*
Risk Group 3
Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). Examples: Yersinia pestis, Brucella abortus, Mycobacterium tuberculosis.

Risk Group 4
Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). Examples: Ebola virus, Macacine herpesvirus (formerly Cercopithecine herpesvirus 1, also called Herpes B or Monkey B virus).

Microorganisms that are RG1 require standard laboratory facilities and microbiological practices, whereas those in RG4 require maximum containment facilities. Many of the agents likely to be handled experimentally at KSU are RG1, RG2 or RG3 pathogens (low, moderate and high hazard, respectively). RG3 agents typically require more sophisticated engineering controls than standard laboratories, as well as special handling and decontamination procedures.

Microorganisms classified as RG2 or higher have been reported to cause infection and disease in otherwise healthy adults. Many have been associated with laboratory-acquired infections. The progression from exposure, to infection, to disease following contact with an infectious agent depends upon the route of transmission, inoculum, characteristics of the agent, and resistance of the person exposed, whether innate or acquired. Not all exposures result in infection, and even fewer develop into clinical disease. However, it is prudent to handle such agents at the prescribed biosafety level.

5. ROUTES OF INFECTION AND EXPOSURE SOURCES
Depending on the organism in question, pathogens can be transmitted via four potential routes of exposure. The most common routes of exposure are:

- Inhalation – breathing in airborne materials such as infectious aerosols or dusts
- Absorption (exposure of mucous membranes to infectious droplets)
- Ingestion (from contaminated hands or utensils)
- Percutaneous inoculation (injection, incision, or animal bite).

Appropriate precautions can be implemented to reduce the risk of such exposures.

A. Clinical and Pathological Specimens
Specimens from human patients or animals may contain infectious agents. Specimens most likely to harbor such microorganisms include blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, and tissues. There are other
potentially infectious materials (OPIM) that are not usually considered infectious unless they contain blood. These materials include sputum, nasal secretions, urine, vomit, and feces. When blood is visible in these materials, they should be treated as infectious. Personnel in laboratories and clinical areas handling human blood, body fluids, non-human primate material, human cell lines, or other potentially infectious materials should practice general universal precautions – an approach to infection control wherein all human blood and certain human body fluids are treated as if known to be infectious for Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C (HCV) and other bloodborne pathogens. Such personnel are required by law (OSHA 29 CFR 1910.1030) to undergo BBP training. At KSU, this training requirement can be satisfied either online or by attending a classroom training session. For information on obtaining this training, access the EHS Website.

Some animals, or animal tissues, may harbor endogenous pathogens that cause disease in humans. It is prudent for personnel handling these animals or their tissues/body fluids to treat their blood and body fluids as if they are infectious.

B. Cultures

Accidental spilling of liquid infectious cultures is an obvious hazard due to the generation of aerosols and/or small droplets. The following routine manipulations of cultures may release microorganisms via aerosol formation:

- Popping stoppers from culture vessels
- Opening closed vessels after vigorous shaking
- Spattering from flame-sterilized utensils
- Expelling the final drop from a pipette
- Spinning microfuge tubes in a standard microfuge
- Aerosols generated immediately following vortexing

When preparing aliquots of infectious material for long-term storage, consider that lyophilization of viable cultures may release high concentrations of dispersed particles if ampules are not properly sealed. Breakage of ampules in liquid nitrogen freezers may also present hazards because of survival of pathogens in the liquid phase.

Equipment used for manipulations of infectious materials, such as cell sorters and automated harvesting equipment, must be evaluated to determine the need for secondary containment and to consider decontamination issues. Costly equipment of this type is often operated at multi-user or core facilities; the inherent variability in risk from one project to another makes it imperative that operators and users of these facilities understand risks and methods for risk mitigation.

Use of human or animal cell cultures in laboratories requires special consideration. Cell or tissue cultures in general present few biohazards, as evidenced by their extensive use and lack of infection transmitted to laboratory personnel. Clearly, when a cell culture is inoculated with (or known to contain) an etiologic agent, it should be classified and handled at the same biosafety level as the agent.
C. Animals
Exercise care and thoughtfulness when using animals to isolate and propagate microorganisms, study pathology, or produce antibodies. Laboratory animals may harbor microorganisms that can produce human diseases following bites, scratches, or exposure to excreted material. In the process of inoculating animals, an investigator can be exposed to infectious material by accidental self-inoculation or inhalation of infectious aerosols.

During surgical procedures, necropsies, and processing of tissues, aerosols can be produced unintentionally, or the operator can inflict self-injury with contaminated instruments. Since animal excreta can also be a source of infectious microorganisms, investigators should take precautions to minimize aerosols and dust when changing bedding and cleaning cages.

Online training is available through the Collaborative Institutional Training Initiative (CITI) web-based training program. Please consult with the IACUC administrator for more information on the appropriate training modules for a specific research or teaching program. Information on how to register for the training is available here. The certification must be renewed every three years.

D. Latex Gloves and Related Allergies
Allergic reactions to natural rubber latex have been increasing since 1987, when the Centers for Disease Control recommended the use of universal precautions to protect against potentially infectious materials, bloodborne pathogens, and HIV. Increased glove demand also resulted in higher levels of allergens due to changes in the manufacturing process. In addition to skin contact with the latex allergens, inhalation is another potential route of exposure. Latex proteins may be released into the air along with the powders used to lubricate the interior of the glove.

NIOSH studies indicate that 8-12% of healthcare workers regularly exposed to latex are sensitized, compared to 1-6% of the general population. Latex exposure symptoms include skin rash and inflammation, respiratory irritation, asthma, and shock. The amount of exposure needed to sensitize an individual to natural rubber latex is not known, but when exposures are reduced, sensitization decreases.

NIOSH recommends the following actions to reduce exposure to latex:

a) If latex gloves must be used, choose reduced-protein, powder-free latex gloves.
b) Whenever possible, substitute another glove material.
c) Wash hands with mild soap and water after removing latex gloves.

When using antibiotic materials, procedures should be adopted that minimize release of airborne materials and skin contamination. Of particular concern are releases of penicillin-type (or other) antibiotics during syringe-loading from multi-dose vials. Persons who have had previous exposures and have developed sensitivity can quickly go into anaphylactic shock after inhaling a mist of antibiotic material. Be sure to handle these materials with caution and according to use directions. Use and caution inserts for each antibiotic are provided in the product packaging and should be read and understood prior to use. Investigators inexperienced in conducting these types of
experiments should seek help in designing their experiments from individuals who are experienced in this special work.

6. LABORATORY EXPOSURE POTENTIAL

A. Teaching Laboratories
Whenever possible, we recommend the use of avirulent strains of infectious microorganisms in teaching laboratories. However, even attenuated microbes should be handled with care. Students should be cautioned against and trained to prevent unnecessary exposure, as exposure to "avirulent" strains may be problematic in immunocompromised individuals. Establishment of safety consciousness is integral to the conduct of good science.

B. Research Laboratories
The risk of exposure increases with experiments in research laboratories using high concentrations or large quantities of pathogens. The use of animals in research on infectious diseases also presents greater opportunities for exposure.

C. Clinical Laboratories
Personnel in laboratories performing diagnostic work-up of clinical specimens from human or animal patients are often at risk of exposure to infectious agents. The absence of an infectious disease diagnosis does not preclude the presence of pathogens. This is especially true of materials from patients who have received immunosuppressive therapy since such treatment may activate latent infections or make hosts more likely to harbor infectious agents.

7. BIOSAFETY LEVELS AND LABORATORY PRACTICES

A. Biosafety Levels
Biosafety Levels consist of combinations of laboratory practices and procedures, safety equipment, and laboratory facility design features appropriate for the operations to be performed within the lab, and are based on the potential hazards imposed by the agents used and for the specific lab activity. It is the combination of practice, equipment, and facility that form the basis for physical containment strategies for infectious agents.

There are four biosafety levels, with Biosafety Level 1 (BSL1) being the least stringent and Biosafety Level 4 (BSL4) being the most stringent. Laboratory work with biological materials at KSU generally falls under the requirements of BSL1 or BSL2. The requirements for these two biocontainment levels are explained further in the following paragraphs.

Biosafety Level 1 (BSL-1)
When working with biological agents that are not known to consistently cause illness or disease in healthy adult humans, BSL-1 is the appropriate level of containment, unless otherwise indicated
through a thorough risk assessment. BSL-1 work areas are not required to be separated from normal laboratory work areas or activities. Special practices or special equipment (e.g. – biosafety cabinets) is not usually required. Experiments being conducted at BSL-1 are usually conducted on open bench tops; however, standard microbiological practices and prudent practices must be employed. Lab personnel who conduct laboratory work at BSL-1 must be trained in standard microbiological practices.

All KSU lab personnel working at BSL-1 must adhere to the following requirements:

**Standard Microbiological Practices**

- Wash hands using soap and water immediately after working with biological materials, after removing PPE, and prior to leaving the laboratory.
- Do not eat, drink, smoke, instill contact lenses, or apply cosmetics in the laboratory area. Keep all of these materials and their containers outside of laboratory work areas.
- Never pipette materials by mouth; use mechanical pipetting devices.
- Conduct all procedures in a way that minimizes the creation of splashes and/or aerosols.
- Decontaminate all work surfaces after completion of work, and especially after spilling or splashing of potentially infectious materials.
- Use an appropriate disinfectant to decontaminate surfaces (e.g. – 10% bleach solution, 70% ethanol, etc.)
- Decontaminate all cultures, solutions, and waste materials prior to disposal using an appropriate method (e.g. – autoclaving, chemical deactivation, etc.)
- Handle all contaminated sharps appropriately to prevent accidental percutaneous exposures
- Ensure that all areas where biological/bio-hazardous agents are used have appropriate signage, marked with the universal biohazard symbol and the correct Biosafety Level. The sign may also include other information, including the agent(s) in use and contact information for responsible personnel.
- Ensure the work area is free of pests.

**General Safety Practices**

- Wear appropriate attire, such as long pants, dresses, or skirts that are ankle length. Avoid wearing shorts, dresses or skirts that leave skin exposed.
- Always wear footwear that completely covers the foot. Avoid sandals, open toed, open heeled, or high-heeled shoes.
- Appropriate gloves are recommended to be used when handling biological materials. Inspect all gloves for holes and defects before using.
- Change gloves when they become contaminated, torn, or otherwise compromised.

- Avoid washing and/or reusing disposable gloves. Once gloves are removed from hands, a new pair should be donned.

- Dispose of used gloves as biohazard waste. Gloves are not to be disposed of in the general waste stream.

- Wearing of an appropriate laboratory coat or apron while working in the laboratory is recommended. Replace it immediately if it becomes contaminated or soiled.

- Wearing of appropriate eye protection is recommended. Minimally, safety glasses with side shields should be worn; however, in the event that aerosols and/or splashes are possible, splash proof goggles should be worn for better protection.

*Note: While wearing eye protection, gloves, and lab coat are recommended for working at BSL-1, they are required for working with chemical hazards in the laboratory.*

- Do not wear lab coats, gloves, or other PPE outside of the laboratory area (laboratory plus adjacent hallways/stairways/elevators between laboratories, cold rooms, animal facilities, etc.). Remove all PPE prior to leaving the lab area to prevent contamination of public areas (e.g. break rooms, rest rooms, etc.). When wearing gloves between laboratories, observe the “one glove” rule. Gloved hands must not touch door knobs, light switches, or elevator buttons.

**BSL-1 Facility Requirements**

A BSL-1 facility must have the following safeguards in place:

- Doors to control access

- Sink(s) for hand washing

- Surfaces that are easy to decontaminate using an appropriate disinfectant
  - No carpet or Rugs
  - Bench tops must be impervious to water and resistant to heat and chemical hazards (e.g. – solvents, acids, bases, etc.)
  - Chairs/stools must be impervious to water and easy to decontaminate using an appropriate disinfectant

- Furniture must be capable of supporting anticipated loads and uses.

- Spaces between benches, cabinets, and equipment should be accessible for cleaning.
**Biosafety Level 2 (BSL-2)**

When working with biological agents that pose moderate hazards, and have the potential to cause illness or disease in healthy adult humans, BSL-2 is the appropriate level of containment, unless otherwise indicated through a thorough risk assessment. KSU Personnel working at BSL-2 containment must adhere to the requirements of BSL-1 containment (see previous section), and the following requirements (as prescribed by the BMBL):

- Lab personnel must have specific training for handling of pathogenic agents and must be supervised by scientists who are competent in handling infectious agents and associated procedures.
- Access to the laboratory must be restricted when vacant and when work is being conducted.
- All procedures in which aerosols and/or splashes may be created (e.g. – mixing, pipetting, vortexing, etc.) must be conducted in a biosafety cabinet (BSC) or other physical containment device.

**Training**

- Laboratory personnel must receive the appropriate training regarding their duties, exposure prevention, and exposure evaluation procedures.
- Personnel must receive annual updates or additional training when there are changes in policies or procedures.
- All laboratory personnel, particularly women of childbearing age must be educated on immune competence and conditions that may predispose them to infection.
- Women of childbearing age or expectant mothers should consult their healthcare provider to receive counseling and/or guidance.

**Special Practices**

- All personnel who work in the lab must be advised of the potential hazards and must adhere to specific entry/exit requirements.
- All personnel seeking to work with BSL-2 agents must demonstrate proficiency in standard and special microbiological practices prior to beginning work with those agents.
- All personnel must be provided with medical surveillance as needed.
- The collection and storage of serum samples from at-risk personnel should be considered.
- All personnel must be offered (at no cost) the available immunizations for agents that are handled or are potentially present in the work environment.
• The KSU biosafety manual must be available and accessible to all laboratory employees.

• A lab specific biosafety manual, or at minimum, biosafety SOPs should be prepared and available to all employees.

• Potentially infectious materials must be placed in durable, leak-proof containers when collecting, handling, processing, storing, or transporting them within a facility.

• Lab equipment must be decontaminated by properly trained personnel using an appropriate disinfectant both regularly and after all potential contamination.

• All equipment used with infectious materials must be decontaminated prior to repair, maintenance, or removal from the laboratory.

**Safety Equipment and PPE**

• Biosafety cabinets, PPE, or other physical containment devices must be used as follows:
  
  o Anytime procedures are conducted that have the potential for creating infectious aerosols or splashes (e.g. – pipetting, centrifuging, grinding, blending, mixing, shaking, or sonicating open containers of infectious materials)
  
  o When inoculating certain animals intranasally
  
  o When harvesting infected tissues from animals or eggs
  
  o When high concentrations or large volumes of infectious agents are used. These materials can also be centrifuged in the open laboratory as long as sealed rotors or centrifuged safety cups are used.

• Lab coats, gowns, or other laboratory uniforms must be worn when working with bio-hazardous materials.

• When infectious/bio-hazardous materials are handled outside of the BSC, eye and face protection must be used. Minimally, safety glasses with side shields must be worn; however, in the event that aerosols and/or splashes are possible, splash proof goggles must be worn for better protection.

*Note:* To transport potentially infectious material in the laboratory area between laboratory rooms, first load the material into durable, leak proof secondary containment (e.g., trays, Styrofoam coolers with ice, plastic beakers with ice), then remove gloves and wash hands thoroughly prior to leaving the laboratory. Continue to wear eye protection and laboratory coat while transporting. As always, if the laboratory coat becomes contaminated, remove the coat and replace with a clean one. After arrival to the destination, wear new gloves. When transporting potentially infectious materials between laboratory rooms, the use of a wheeled
*cart is the best practice. Using the “one-glove” method is not appropriate. As always, PPE should not be worn in non-laboratory areas (break rooms, bathrooms, etc.)*

- When working with infected animals, eye, face, and respiratory protection should be used.
- Contaminated protective clothing must be either disposed of as biohazard waste, or laundered by an institutional laundry service (i.e. laboratory protective clothing must not be taken home for laundering).
- When contaminated, eye and face protection must either be discarded as contaminated waste or decontaminated prior to reuse.

**Procedure for Laundering Laboratory Protective Clothing**

Disposable protective clothing, which is placed in biomedical waste after use, is preferred. Reusable laboratory protective clothing must be decontaminated by autoclaving before disposal or laundering. Reusable laboratory protective clothing must be bagged, autoclaved and then washed before being returned to the laboratories for reuse.

**BSL-2 Facility Requirements**

A BSL-2 facility must have the following safeguards in place:

- Laboratory doors should be self-closing and equipped with a locking mechanism.
- In addition to having hand washing sinks, the sinks should be hands free (e.g. foot petal operated) or motion operated to avoid touching. There should also be sinks located near exit doors.
- All laboratory windows that open to the outside must be fitted with screens.
- Biosafety cabinets must be installed in a way that airflow fluctuations do not interfere with operations. This includes installing BSCs away from high traffic areas, doors, and windows that can be opened.
- Biosafety cabinets must be certified annually to ensure proper operation. This will ensure that any recirculated air exhausted back into the laboratory or to the outside by way of a thimble or canopy is properly filtered before release.
- All vacuum lines should be protected with liquid disinfectant traps.
- Emergency eyewash stations must be readily available in the event that there is an eye exposure.
- Directional airflow must be negative with respect to the hallways/corridors of the building, although there are no specific requirements for ventilation systems.
- All laboratory wastes should have a way to be decontaminated within the facility (e.g. chemical disinfection, incineration, autoclaving, or other validated method).

**Biosafety Levels 3 and 4 (BSL-3, BSL-4)**

BSL-3 and BSL-4 containment levels must be used when working with exotic agents that pose high risk for life-threatening disease. There is currently no research being conducted that requires BSL-3 or BSL-4 containment. For a more comprehensive description of BSL-3 and BSL-4, consult the BMBL.

**Recombinant DNA (rDNA) Experiments**

Experiments involving rDNA also require adequate biosafety containment where highly specific biological barriers are considered in the risk assessment process. Specifically, biosafety containment considers natural barriers that limit either (1) the infectivity of a vector or vehicle (plasmid or virus) for specific hosts, or (2) its dissemination and survival in the environment. The NIH outlines the biosafety containment requirements for experiments based these considerations. For additional information on biosafety containment in rDNA experiments, refer to the NIH Guidelines.

**B. Biosafety Cabinets**

**BSC Use Protocol**

A properly certified and operated BSC in combination with appropriate contamination control procedures and aseptic techniques will do an excellent job of controlling airborne contaminants. They are equipped with High Efficiency Particulate Air (HEPA) filters that remove contaminants from the air. BSCs are designed to provide 3 levels of protection:

- Personnel or operator protection
- Product or sample protection
- Environmental Protection

For example, in a Class II AII BSC, approximately 70 percent of the intake air is recirculated inside the cabinet, while 30 percent is exhausted through the exhaust port in the top of the cabinet back into the laboratory. All filtered air is considered free of contaminants as long as the BSC and its components are working properly. Additional information on biosafety cabinets, the different types of BSCs, and how they function can be found at http://www.nuaire.com/products/biological-safety-cabinets/how-class-two-bsc-work.html.

BSCs are to be used only with biological materials, unless otherwise approved by EHS, and are not to be confused with Chemical Fume Hoods, which provide only personnel or operator protection. The following general considerations must be observed when using a BSC:

- All BSCs shall be professionally certified at the time of installation and annually thereafter.
- If a BSC is to be moved, it shall be professionally decontaminated before moving and recertified before work commences. Contact the BSO for assistance with certification, decontamination and other services.
• The front, rear, or side intake grills must not be obstructed with equipment or supplies.
• Do not work in a BSC while the warning light is illuminated or the alarm is signaling.
• Avoid cluttering the BSC with unnecessary equipment or supplies.
• BSCs are equipped with ultraviolet (UV) lights for the purpose of decontaminating surfaces. However, if good microbiological practices are followed, UV lights are not needed.
  • UV lights destroy the plastic equipment and supplies in the BSL-2.
  • All UV lights shall be turned off whenever the laboratory is occupied.
  • UV lights will not be used unless the BSC is completely empty.
  • UV lights must not be changed by lab personnel or staff.
• Avoid using toxic, explosive, or radioactive substances in the BSC unless the procedure has been reviewed and approved by EHS.
• Understand how your BSC works. The effectiveness of the BSC is a function of directional airflow, inward and downward, through a HEPA filter. Anything that disrupts the airflow pattern reduces cabinet effectiveness, such as; rapidly moving your arms in and out of the BSC, people walking rapidly behind you, down-drafts from ventilation systems, drafts from open laboratory doors, and excess supplies and equipment in the cabinet.
• Never store boxes and supplies on top of a BSC. Storage on top of the BSC can interfere with the airflow.
• Wash your hands thoroughly before and after working in your BSC. Wearing a clean laboratory coat and gloves while working in a BSC increases your safety and helps reduce contamination of research materials.
• On a monthly basis decontaminate under the work grills and work surfaces if these parts are removable.
• Plan your work ahead. Protect yourself, your research, and your coworkers.

**How to Work in a BSC**

When working in a biosafety cabinet, the following steps should be followed:

• Turn off the ultraviolet (UV) germicidal lamp and turn on the fluorescent light.
• Inspect the air intake grilles for obstructions and foreign materials. Remove any obstructions.
• Make sure the view screen window (sash) is adjusted (if adjustable) to the proper height.
• Turn on the blower motor and allow it to operate for at least five minutes. This purges the air from the internal BSC cabinetry.
• Wash your hands thoroughly with soap and water.
• Don a long-sleeved laboratory coat and ensure that it is buttoned completely.
• Put on a pair (or two pairs, depending on procedure and agent being used) of high quality latex or nitrile gloves. Additional protection from contamination may be provided by wearing disposable sleeve protectors and a second or third pair of latex or nitrile gloves.
- Disinfect the interior surfaces of the BSC by wiping with appropriate disinfectant (e.g. – 10% Wescodyne, 10% dilution of household bleach, or 70% Ethanol; Remember ethanol is highly flammable—DO NOT USE in the presence of flame or spark).

- Place a plastic-backed pad or bench liner on the dry, disinfected work surface of the BSC. DO NOT cover the air intake and exhaust grilles.

- Assemble all necessary items for your experiment in the BSC. Be sure to keep clean items segregated from dirty items. Avoid overloading the work surface with equipment and supplies, which may compromise the effectiveness of your BSC.

- Work from “clean” to “dirty” areas. Organize your material so that dirty “contaminated” items are not passed over (cross contaminate) clean items.

*Note: A good work layout of materials would be to position clean items (e.g. - pipettes, cultures, flasks, etc.) toward the front or either side of the work surface, while placing your waste container and contaminated pipette trays to the rear.*

- You should work at least six inches back from the front of the air intake grille.

- Protect the house vacuum system or pump from contamination by installing a trap and filter system. Use a primary collection flask containing disinfectant, followed by an overflow flask, which leads through a HEPA or hydrophobic filter.

- After all equipment and supplies are added to your BSC, allow it to operate for an additional five minutes. This will allow the BSC to purge itself of airborne contaminants.

- Assume a comfortable sitting position in front of the BSC. Your chair should be adjusted to a comfortable height that promotes ergonomic posture.

- When inserting your arms into the BSC, remember that they are penetrating a delicate “curtain” of air that can only provide protection from contamination as long as it is not disrupted. Allow the air curtain to stabilize around your arms before starting work.

- Avoid making rapid, jerking arm motions. Use smooth motions that do not disrupt the air curtain.

- If you need to introduce new items or remove items from the BSC, move your arms in and out slowly to minimize airflow disruption.

- If you use equipment that creates air turbulence, i.e., centrifuge, blender, or sonicator, place the equipment as far back in the BSC as possible (usually 1/3 of the way back from the front intake grill is acceptable). Stop other work while the equipment is operating.

- Follow good microbiological techniques (e.g. - holding open tubes and bottles as horizontal as possible.

- Never pipette materials by mouth. Use mechanical pipetting aids.

- Keep your hands away from your face (face protection helps to minimize the potential for this route of exposure).

- Do not use vertical pipette discard canisters or baskets on the floor next to the BSC. Use horizontal pipette discard pans inside the BSC.

- Avoid using Bunsen burners inside Biosafety cabinets.
The flame creates turbulence in the airflow and will compromise sterility. If the lip of a tube or flask is wet, an aerosol may be created when the lip is flamed.

Heat buildup can also damage expensive HEPA filters. Unattended burner pilot lights have created extensive fire damage to BSC’s and sometimes entire laboratories.

In the event that the pilot is extinguished, the recirculation of oxygen and natural gas creates a potential explosion hazard should a spark be created by the fan motor or other electrical components.

- Clean up all spills inside the BSC immediately. Wait 3-5 minutes before resuming work, if your laboratory operating procedures allow.
- Avoid the use of sharps, where possible (e.g. - glass Pasteur pipettes, needles and syringes). Substitute plastic for glass whenever feasible (e.g. - plastic pipettes, plastic pipette tips and pipette tip extenders, aspirators, etc.).
- If the use of sharps cannot be avoided, maintain a sharps container at the point of use.
- Discard intact needles and syringes immediately after use. Never recap, bend, break or otherwise manipulate sharps by hand. If you must remove the needle from the syringe, use the small opening on the top of the needle box for this purpose. Forceps, tweezers, or small pliers may also be utilized.
- Collect all waste within the BSC. Waste containers should be placed inside the BSC to avoid breaking the air barrier and bringing contaminated items out into the room. Smaller biohazard waste bags may be utilized along with beakers or shallow trays containing disinfectant for the collection and disinfecting of pipettes and other contaminated items. Waste can also be collected within the BSC in the following manner.
  - **Horizontal collection:** Horizontal trays containing disinfectant allow total immersion of pipettes.
  - **Vertical collection:** Beakers containing disinfectant can be used if disinfectant is drawn up inside the pipette and allowed to run down the interior wall upon disposal into the beaker.
  - **Bags:** Bags have the potential for creating aerosols when moved. Seal autoclave bags within the cabinet and place within a second bag. Carefully add water to the primary bag before sealing (25 ml for smaller bags, 200 ml for larger bags). The addition of water will help to generate steam within the bag during the autoclave cycle.
- An externally mounted drain valve is located under the drain pan of many BSC’s. In the event of an accidental spill, you can remove large volumes of disinfected, spilled materials from under the work surface. The drain valve is not to be connected to a sink or similar drain. A bucket can be used to collect any spilled liquid for decontamination and disposal.

**Cleaning the BSC**

- After completion of work, enclose or cover all equipment and materials.
- Wipe items down with an appropriate disinfectant prior to removal from the BSC.
- Allow the BSC to run for five minutes to purge airborne contaminants from the work area.
• Decontaminate interior surfaces (work surface, grilles, sides, back and inside front view screen) with an appropriate disinfectant after removal of all materials, cultures and apparatus.
• If using 10% bleach solution on work surfaces, allow it to air dry then follow up with 70% ethanol wipe to prevent rusting of stainless steel surface.
• Periodically decontaminate under work grills and work surfaces if these parts are removable.
• Remove and decontaminate all waste materials from the BSC
  o Decontaminate liquid waste with household bleach (diluted 10% against the volume of the waste. Allow at least a 30 minute contact time for full decontamination. Autoclaving liquid waste is also an option.
  o Transport waste to autoclave in a leak-proof container.

C. Centrifuge Operation

Centrifuges are commonly used in laboratories as a means of separating materials according to size and density. They operate at high speeds to accomplish this task, and if used inappropriately, can cause injury or exposure to hazardous materials. Consider the following general procedures when operating centrifuges:

• Prior to operation, read all instructions for care and use of the centrifuge.
• Follow the appropriate SOPs for centrifuge use.
• Ensure that all tubes for use in the centrifuge are compatible.
• Examine tubes and bottles for cracks or stress marks before using them.
• Do not attempt to operate the centrifuge while the door/lid is open.
• Before removing samples (particularly those that are infectious or potentially infectious) from super speed or ultracentrifuges, wait 10 minutes before opening the centrifuge to allow any aerosols produced to settle.
• Always wear appropriate PPE when loading and removing samples from the centrifuge.
• Keep all centrifuge equipment cleaned.
• Avoid the use of caustic chemicals that may weaken centrifuge components (e.g. – bleach; concentrated or diluted).
• Use centrifuge logbooks to keep track of usage.

When centrifuging materials that are known or anticipated to be infectious, adhere to the procedures below:

• Fill and decant all centrifuge tubes and bottles within the biological safety cabinet
• Never overfill centrifuge tubes, as leakage may occur when tubes are filled to capacity. The maximum for centrifuge tubes is 3/4 full.
• Wipe outside of tubes with disinfectant before placing in safety cups or rotors.
• Place all sealed tubes in safety buckets or sealed rotors.
Inspect the "O" ring seal of the safety bucket, the inside of safety buckets or rotors and correct rough walls caused by erosion or adhering of matter and remove debris from the rubber cushions.

- Seal rotor or bucket and wipe down with disinfectant, remove outer gloves, and transport to the centrifuge.

- Ensure that the correct rotor is used and that the allowable speed is not exceeded.
- Before removing samples from super speed or ultracentrifuges, wait 10 minutes before opening the centrifuge to avoid potential exposure to infectious aerosols.
- Decontaminate the rotor or safety bucket by spraying with an appropriate disinfectant and allowing to air dry. Wipe the throw line within the centrifuge with disinfectant. In the event of a spill during centrifugation, follow the spill response procedures outlined in the Biosafety Spill Response section of this manual.

Avoid using microfuges, which are difficult to contain. If this is not feasible, use a model that has built in secondary containment (a sealed rotor) along with microfuge tubes equipped with an O-ring seal. Please contact your PI for assistance in identifying containment features for purchasing new microfuge or to evaluate upgrading your existing model.

### D. Working with Sharps

#### Sharps Safety

Sharp objects are hazards that are commonly used in research labs for a variety of purposes. Sharps can become contaminated when used with chemical or biohazardous agents, and if due care is not taken by lab personnel while in use, injuries and exposures to hazardous substances can occur. Sharps that may be identified in the laboratory environment include but are not limited to:

- Syringes/Needles
- Cutting tools (e.g. – razor blades, scalpels, etc.)
- Broken glass items (e.g. - microscope slides, capillary tubes, Pasteur pipettes, glassware, etc.)

When using sharps in the lab, the following practices should be avoided:

- Manipulating needles by hand prior to disposal (bending, breaking, shearing, removing from the syringe)
- Recapping of needles (this increases the incidence of needlestick injuries)
- Leaving sharps on work surfaces with the sharp edge exposed (reaching for these objects can result in punctures or cuts)
- Cleaning up broken glass by hand (always use forceps, tongs, or a dustpan and broom)
- Disposing of sharps in containers other than an appropriate sharps disposal container or broken glass box
• Reaching into sharps disposal containers to retrieve a sharp object

**Sharps Disposal**

After sharps have been used and/or contaminated, they must be disposed of properly. When disposing of sharps, the following best practices should be followed:

• Discard sharps immediately after use into an approved sharps disposal container.

• When working with sharps, ensure that sharps disposal containers are:
  o Positioned at the point of generation or use
  o Positioned upright throughout use
  o Replaced as necessary to avoid overfilling (sharps containers should only be filled ¾ of the way before the container is replaced).
  o Made of rigid and puncture resistant material (i.e. – no soda bottles, milk jugs, or other plastic containers)
  o Leak-proof on the sides and bottom
  o Closed (not locked) unless adding sharps
  o Portable, if portability is necessary, to ensure easy access by the user
  o Labeled in accordance with local regulations.

When any filled sharps container needs to be disposed of, the following conditions must be met prior to disposal:

• The container must be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

• The container must be placed in a secondary container if leakage is possible.

The second container must be:
  o Closeable
  o Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
  o Labeled according to local regulations.

**NOTE:** Ideally the use of any sharps in the laboratory should be minimized or eliminated. If elimination is not feasible, safer devices, such as retractable needles or plastic materials, or other substitutes are recommended.
Needleless Systems, Needle Devices and non-Needle Sharps

Other types of withdrawal/administration systems can be used as alternatives to sharps. These systems are engineered by design to be safer than conventional devices.

- Needleless systems shall be used for:
  - Withdrawal of body fluids after initial venous or arterial access is established;
  - Administration of medications or fluids; and
  - Any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices.

- If needleless systems are not used, needles with engineered sharps injury protection shall be used for:
  - Withdrawal of body fluids;
  - Accessing a vein or artery;
  - Administration of medications or fluids; and
  - Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.

- If sharps other than needle devices are used, these items shall include engineered sharps injury protection.

Exceptions

- The following exceptions apply to the engineering controls:
  - The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.
  - Availability of Safety Performance Information. The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer’s procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer’s workplace.

**NOTE:** Exceptions can only be applied following a thorough risk assessment, objective demonstration of ineffectiveness or lack of reliable information on the engineering control method in question and upon approval of IBC and BSO.
8. WASTE HANDLING AND DISPOSAL PROCEDURES

E. Collection of Biological/Biohazard Waste

Research activities involving the use of biological/bio-hazardous materials will produce waste materials that contain these potentially infectious materials. This waste must be collected properly in an effort to prevent the spread of contamination and/or accidental exposure to laboratory personnel, staff, and the general public. The following best practices must be followed regarding the collection of biohazard waste:

- Ensure that all biohazard waste containers are labeled with the universal biohazard symbol and when appropriate, the contents of the container (e.g. – cell culture media).
- Collect all waste in sturdy, leak proof containers.
- Discard all contaminated materials (e.g. – disposable pipettes, pipette tips, gloves, paper towels, etc.) into biohazard waste containers; do not dispose of contaminated waste in the general waste stream.
- Always position biohazard waste containers upright.
- Ensure that all containers are closed unless adding waste.
- Do not overfill biohazard waste containers; only fill containers ¾ full to ensure proper closure.
- Never compress waste by hand to make room in the container for additional waste.
- Never mix biohazard waste with other hazardous waste (e.g. – chemical, radioactive, etc.)
- Ensure that vacuum lines are protected with liquid disinfectant traps (i.e. – for liquid biohazard waste).

F. Decontamination and Disposal of Biohazard Waste

Laboratory waste from the use of biological/biohazard materials must be treated as biomedical waste in accordance with Georgia Environmental Protection Division’s (EPD) Rules for managing Biomedical Waste found in chapter 391-3-4-.15 of Georgia’s Rules and Regulations. Therefore, all waste from the use of biological/bio-hazardous materials must be considered potentially infectious and must be decontaminated prior to disposal.

Liquid Biological/Biohazard Waste

Liquid biological/biohazard waste (e.g. – liquid samples, cell culture media, etc.) can be decontaminated using a liquid disinfectant, but can also be sterilized using a validated autoclave.

For decontamination using a liquid disinfectant, these steps should be followed:

- Decontaminate with sodium hypochlorite (5000 ppm). This final concentration can often be achieved by making a dilution of 10% bleach against the volume of waste to be deactivated.
- Allow a minimum contact time of 30 minutes to ensure complete deactivation.
• Dispose of the mixture down the sink using large amounts of water followed by an appropriate disinfectant.

**Solid Biological/Biohazard Waste**

Solid biological/biohazard waste (e.g. – disposable pipettes, pipette tips, used gloves, etc.) must be decontaminated using a validated autoclave prior to disposal, or by incineration through an appropriate vendor.

**Autoclave Method**

- Contaminated solid waste must be collected within the BSC in biohazard autoclave bags or other appropriate biohazard containers.
- Solid wastes are then sterilized by autoclaving. Autoclaves are operated at 121- 132°C (250-270°F) and 15-27 pounds per square inch pressure for 60 minutes.
- The biohazard autoclave bags should not be taped closed.
- In accordance with GAEPD Rule 391-3-4-.15, once the waste has been autoclaved, it can be considered no longer infectious, and can be discarded via the regular waste stream
  - The waste should not be discarded in bags marked with the universal biohazard symbol.
  - The disposal bag should be tied securely prior to discarding in the regular waste stream.

**Incineration Method**

- Contaminated solid waste must be collected in containers that are impervious to moisture, and are strong enough not to tear or burst during normal use.
- Common containers include a large cardboard box clearly labeled with the universal biohazard symbol and lined with a plastic orange or red bag with the same markings.
- The container should be filled only ¾ full.
- When closing, the plastic bag should be tied using the “gooseneck” method and taped ensure that all contents remain inside the bag (i.e. – even if inverted for 5 minutes).
- Once the bag has been tied, the box should be taped shut, and the appropriate vendor’s label should be placed on the outside of the box in preparation for pick-up.

**G. Autoclave Use**

Steam sterilization is the most reliable means for complete destruction of all microbial life, including bacterial spores. Autoclaves accomplish this by generating moist, high temperature, pressurized steam within a sealed chamber.

There are two types of steam sterilizers referred to as autoclaves:
• **Gravity flow sterilizers** must reach a temperature of 250°F (121°C) at 15 pounds per square inch of pressure for 60 minutes.

• **Vacuum type sterilizers** must reach a temperature of 270°F (132°C) at 27 pounds per square inch of pressure for 45 minutes.

Autoclave units must be maintained on a quality control program as outlined below. Effective quality assurance includes the following:

- Using chemical and biological indicators to check autoclave operation.
- Selecting appropriate containers to hold waste while being decontaminated.
- Using effective decontamination processing times for each cycle.
- Maintaining proper autoclave use records.
- Providing odor control when necessary.
- Providing personnel training for the operation of an autoclave.

**General Autoclave Operation Rules**

*Note: Only personnel with adequate training on autoclave use should be permitted to operate an autoclave. Personnel must wear proper PPE (i.e., heat resistant gloves, eye protection, face protection, arm protection, etc., particularly when unloading the autoclave).*

- Regularly inspect your autoclave components for proper operation.
- Autoclave door clamps and seals should be inspected for wear and damage.
- Ensure all debris has been removed from the autoclave chamber floor drain and rubber door seal.
- If a problem is found, promptly notify your area safety coordinator or supervisor who will call an authorized service representative.

*Note: DO NOT OPERATE THE AUTOCLAVE UNTIL IT HAS BEEN REPAIRED PROPERLY.*

- Each appropriately packaged item in a load must be placed so that steam penetrates into and among all materials to be decontaminated.

- Never leave materials tightly sealed or stoppered as they may not be effectively decontaminated, and may become dangerously pressurized causing injury when removed from the autoclave.

- At the end of a decontamination cycle make sure that the pressure in the autoclave chamber is at zero before opening the door.
• Slowly crack the autoclave door open after the end of the cycle and allow the steam to gradually escape from within the autoclave.

**CAUTION:** Opening the autoclave door too quickly may result in glassware breakage and/or steam burns on your skin. The decontaminated materials should be allowed to cool for 10 minutes before they are taken out of the autoclave.

**Things to Avoid:**

- Dead air pockets where steam cannot penetrate (i.e., closed screw cap tubes) because temperature within the air pocket is much lower than the saturated steam.

- Avoid dry packages; add some water to the load. To avoid creation of infectious aerosols while adding water, trickle water down the sides of the container instead of pouring water directly onto the material in the container.

**Autoclave Processing Times**

The US Environmental Protection Agency (EPA) has reported that “Infectious wastes from departments of health care facilities may be rendered noninfectious by subjecting the waste to autoclave temperatures of 121°C (250°F) and 15 minutes of pre-vacuum of 15 psi for the following dwell times when proper containers are used:”

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DWELL TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRASH</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>GLASSWARE</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>LIQUIDS</td>
<td>60 Minutes / Gallon</td>
</tr>
<tr>
<td>ANIMAL CARCASSES</td>
<td>Evaluate</td>
</tr>
<tr>
<td>ANIMAL BEDDING</td>
<td>120 Minutes</td>
</tr>
</tbody>
</table>

After loading and starting the autoclave, processing time starts after the autoclave reaches normal operating temperature (121°C/ 250°F; Pressure = 15 psi).

Decontamination cycle times vary based on several factors:

- Type of load (solid or liquid material)
- Load volume (loosely-packed or tightly-packed)
- Container type (polypropylene, glass, stainless steel)
- Type of material to be decontaminated
Therefore, processing times will vary according to the conditions of each decontamination cycle. In
general, the larger the load, the longer it will take to decontaminate.

The processing time to decontaminate laboratory and medical waste is at least 60 minutes (unless a
shorter interval has proven effective when tested with biological indicators). Add additional time as
necessary if polypropylene containers are used.

A minimum of at least 90 minutes is recommended for decontaminating waste in low-sided
polypropylene containers with bags half-filled and loosely-gathered. If bags are tightly-closed, a
processing time of 120 minutes is recommended. If your autoclave is equipped to operate at 132º C
(270 degrees F), you may be able to reduce processing time.

**Autoclave Containers**

Materials that are to be decontaminated should be transported to the autoclave in closed, leak-
proof containers. Containers used to hold material while being autoclaved are outlined in the
following sections.

**Primary Containers**

Biohazard waste to be autoclaved should be collected in plastic autoclave bags. These
polypropylene bags are made to withstand the high temperatures inside a functional autoclave.
Also known as "biohazard bags", they come in a wide variety of sizes, shapes and colors. However,
if the decontaminated waste will be discarded in the regular waste stream, the bags should be clear
and void of biohazard symbols. Autoclave bags are usually placed in polypropylene or stainless
steel pans during decontamination cycles to catch liquids that may drain out of the bag. Autoclave
bags must be left open or loosely closed during decontamination procedures to allow steam to
penetrate into the bag.

**Secondary Containers**

**Polypropylene Containers**

Pans/bins are containers with 6-12 inch sides. This material is favored over polyethylene and
polystyrene because as previously stated, polypropylene can withstand autoclaving without
melting.

*Note: When using polypropylene containers, add extra processing time to the autoclave
decontamination cycle because polypropylene does not conduct heat well.*

**Stainless Steel Containers**

Stainless steel containers are durable and come in a variety of sizes and shapes. Stainless steel is a
good conductor of heat. Where waste containment is mandatory, stainless steel containers may be
the container of choice because it is durable. Restaurant supply companies are a good source for
these pans.
H. Autoclave Validation

Biological Indicator Tests
Biological indicator systems are designed to demonstrate that an autoclave is capable of killing microorganisms. *Geobacillus stearothermophilus* spores must be used to monitor the effectiveness of steam autoclaves. This process should be completed at least once a month.

Typical biological indicator systems consist of a vial with spore strips or a small glass ampule of growth medium with spores and indicator dye. The biological indicator is removed from a load after it has been autoclaved. Then, the biological indicator is incubated at 56°C for three days. Your control vial, that was not autoclaved, should be turbid after incubation; the successfully decontaminated test vial should remain clear without evidence of turbidity (no growth) and the pH should not change. If the autoclaved biological indicator is turbid (cloudy, indicating growth) the autoclave did not function properly. Notify your area supervisor when this happens.

Chemical Color Change Indicators
Chemical indicators for steam autoclaves change color after being exposed to normal autoclave operating temperatures of 121°C (250°F) at 15 psi. Hence, chemical indicators can give you a quick visual reference for heat penetration inside the load. Chemical indicators should be positioned near the center of each load, and toward the bottom front of the autoclave.

*CAUTION: Most chemical indicators can only be used to verify that your autoclave reaches normal operating temperature for decontamination, 121°C (250°F). Chemical indicators alone are not designed nor intended to prove that organisms are actually killed during a decontamination cycle.*

Tape Indicators
Tape indicators are adhesive backed paper tape with heat sensitive, chemical indicator markings. Commonly used heat sensitive markings include diagonal stripes (autoclave tape), and/or the word “sterile”. These markings only appear when the tape has been exposed for a few minutes to normal autoclave decontamination temperatures. Tape indicators should be used on all material decontaminated by autoclaving to show that the material has been processed. A three to four inch strip of autoclave tape placed on the outside of the autoclave pan, bag, or individual container is sufficient. If the temperature sensitive tape does not indicate a temperature of at least 250°F (121°C) was reached during the sterilization process, the biomedical waste is not considered decontaminated.

*CAUTION: Tape indicators can only be used to verify that the autoclave is reaching normal operating temperatures for decontamination, 121°C (250°F). Tape indicators alone are not designed nor intended to prove that organisms have actually been killed.*
Odor Control
Some waste materials, such as anaerobic bacteria, feces or decaying organic materials have an extremely noxious odor. When decontaminating these materials, it may become necessary to add an odor control additive to the load. A scoop full of unused animal bedding (cedar shavings) works quite well. These additives may produce chemical exposure symptoms for some people.

Training
It is imperative that supervisors provide training to qualify their staff for both the basic use of autoclaves, as well as to decontaminate materials. Qualified autoclave users should understand the time, temperature, and pressure relationships required for proper decontamination of infectious materials. Additional training on handling materials to be decontaminated should also be provided. Supervisors should maintain permanent records of training provided to their staff. EHS should also receive copies of the training records. Additional training support on the effective use of autoclaves is available from the Biosafety Officer.

Record Keeping
An autoclave logbook should be kept as a permanent record of autoclave use. The logbook should be located in an easily accessed location near the autoclave, and should include the following information:

- Autoclave User,
- Date Used,
- Materials Decontaminated,
- Process Type,
- Run Duration (Cycle Time),
- Chemical/Biological Indicator Used,
- Chemical/Biological Indicator Results,
- Envelope for “Wheel Graphs” or “Data Strips”.

Additional information provided on the log sheet should include the following:

- Autoclave Manufacturer
- Autoclave Serial Number
- Department Room Location
- Date Log Book Started
- Maintenance Work Done
- Materials Processing

9. INFORMATION AND TRAINING
All employees who conduct research or participate in laboratory activities that include the manipulation of microorganisms (bacteria, viruses, cells, etc.), some of which are natural, genetically modified, and/or infectious, and can cause illness and disease in healthy humans are
required to be trained prior to working in the lab. Employees must complete all EHS required training, as well as any department level and lab specific training.

A. EHS Required Training

Biosafety Training

Employees who have the potential to be exposed to potentially infectious agents through working with recombinant or synthetic nucleic acid molecules, or with agents that require BSL1 or BSL2 (or higher) containment, must complete Biosafety training in accordance with BMBL and the NIH Guidelines. Training shall be provided as follows:

- Training will be provided at the time of initial assignment of job duties that have the potential for exposure to potentially infectious agents.
- Refresher training is required every 3 years.
- Additional training shall be provided as a result of modifications to work practices and/or addition of new work practices that may affect employees’ exposure potential.
- Individuals who administer Biosafety training must be knowledgeable in all content presented in the training program as well as how it relates to the workplace environment.
- Training administrators must allow all personnel attending the training course to ask interactive questions on the subject matter.

Bloodborne Pathogens Training

Employees who have the potential for occupational exposure to bloodborne pathogens (BBPs) or other potentially infectious materials (OPIM) must complete BBP training in accordance with OSHA 29 CFR 1910.1030. Training shall be provided for each qualifying employee as follows:

- Training will be provided at the time of initial assignment of job duties that have the potential for exposure to human blood and OPIM.
- Refresher training is required at least annually, and must be provided within one year after initial training.
- Additional training shall be provided as a result of modifications to work practices and/or addition of new work practices that may affect employees’ exposure potential.
- Individuals who administer training on BBPs must be knowledgeable in all content presented in the training program as well as how it relates to the workplace environment.
- Training administrators must allow all personnel attending the training course to ask interactive questions on the subject matter.

Training Methods

- Training may be provided using the following methods:
  - Computer based training (OwlTrain)
  - Personal instruction (classroom model)
B. Additional Training Requirements

For most work with biological hazards, additional laboratory specific training is required. This additional training could be at the department level, laboratory specific, or a combination of both.

- The PI or Laboratory Supervisor must ensure that all personnel who have occupational exposure potential have prior experience working with biological hazards.
- Personnel must be trained on lab specific SOPs, and must demonstrate proficiency in standard microbiological practices before beginning work.
- The employee must not participate in work involving biological hazards until proficiency is demonstrated.
- A training program must be provided to employees who have no prior experience in working with biological hazards. A progression of work activities must be assigned as techniques are learned and proficiency is developed. The employer must assure that employees participate in work activities involving biological hazards only after proficiency has been demonstrated.

10. INCIDENT/EMERGENCY RESPONSE

A. Emergency Procedures

In the event of an incident, injury, emergency event, or near-miss, everyone working in the laboratory should be trained and prepared to respond appropriately. These events may involve fire, explosion, hazardous chemicals, and more specifically for biological/biomedical research labs, biologically hazardous materials (e.g. – human blood, pathogenic bacteria, viruses, etc.). While all incidents must be reported, some may require immediate first aid. In these circumstances, always administer the appropriate immediate first aid, then seek medical attention. The following steps should be followed when an emergency event occurs:

- Call, or have someone call the KSU emergency number (KSU Police) and clearly state the nature of the incident and where it has occurred.
  - Kennesaw Campus - 470-578-6666, extension 6666, or 911
  - Marietta Campus - 678-915-5555, extension 5555, or 911
- Assess the safety of the situation. Do not enter or reenter the area if it is unsafe.
- Warn personnel in adjacent areas of any potential risks to their safety.
- Render assistance to the people involved and remove them from exposure to further injury if it is safe to do so.
- Render immediate first aid, if required. Appropriate measures include washing under a safety shower, activating emergency eyewash stations, or washing the affected area(s) in a sink. CPR and special first aid measures can only be administered by trained personnel.
• Provide emergency personnel with as much information as possible about the nature of the hazard.

• In case of medical emergency, remain calm and do only what is necessary to protect life.
  o Summon medical help immediately by calling KSU Police
  o 6666 (Kennesaw Campus) or 5555 (Marietta Campus).
  o Do not move an injured person unless he or she is in danger of further harm.
  o Remain in the area in a safe place until help arrives. You may be needed to answer additional questions about the incident.

Fire Incident

• Extinguish small fires by using a portable extinguisher, but only if you have been trained on the use of fire extinguishers and are comfortable doing so. Turn off nearby equipment and remove combustible materials from the area. For larger fires, you must call 6666 (Kennesaw Campus) or 5555 (Marietta Campus) immediately.

• If clothing is on fire and a safety shower is immediately available, douse the person with water.

• If a safety shower is not immediately available, move the person to the floor and roll him/her around, or use a fire blanket to smother the flames. Once the flames are extinguished, escort the victim to the nearest emergency shower, activate, and drench with water.

Chemical Exposure

• If harmful chemicals have been spilled on the body, flood the exposed area with sufficient running water from the safety shower, and immediately remove any contaminated clothing.

• If a chemical has splashed into the eye, immediately wash the eyeball and the inner surface of the eyelid with plenty of water for 15 minutes. All eye exposures require a medical evaluation.

• If possible, determine the identity of the chemical involved and inform the emergency response team/medical personnel attending the injured person. It may be helpful to provide the SDS if it is accessible.

Exposure to Infectious Materials

• If exposure to pathogenic/infectious materials has occurred due to a puncture wound with a contaminated needle wash the affected area with soap and warm water for a minimum of 15 minutes.

  Note: Be sure to complete the sharps injury log following a needle stick exposure.

• If exposure to pathogenic/infectious materials has occurred due to absorption due to contact with broken skin, wash the affected area with soap and warm water for a minimum of 15 minutes.

• If a pathogenic material has splashed into the eye or other mucous membranes, activate the emergency eyewash station or sink immediately and the affected area with plenty of water for 15 minutes.
B. Reporting of Incidents/Emergencies

All incidents/emergencies must be reported immediately to the laboratory PI/supervisor, Safety Coordinator and the BSO. Such incidents include but are not limited to inadvertent fires, explosions, chemical or biohazard exposures, injuries, and near-misses. The PI/supervisor must assist EHS personnel with investigations and reports as required. All external reports, other than those of an immediate nature such as summoning the fire department in case of a fire, are to be made by or through the Director of EHS or BSO, depending on the incident.

- All incidents and accidents shall be reported in accordance with the University process for Incident Reporting and Investigating (EOSM-108). The incidents should be reported using the appropriate incident reporting form from the EHS website.

- All KSU employees and contractors should report, as soon as possible, any of the following that occurs on campus, at a University controlled workplace, or while engaged in any University sanctioned activity:
  - Incidents resulting in injury or illness
  - Incidents resulting in exposures to chemical or biological hazards
  - Incidents or near misses with no injuries
  - Incidents resulting in environmental damage (e.g. – chemical released into storm drain, contamination of soil, etc.)
  - Incidents resulting in property damage
  - Each situation or condition observed on the job which has the potential for injuring or endangering the health of people and/or causing damage to property or environment.

- Serious incidents or incidents requiring immediate medical attention should be reported immediately by calling the campus emergency number 470-578-6666 (Ext.6666) or 911. Serious accidents for this purpose are those which result in:
  - Fatality.
  - Hospitalization or medical treatment (beyond first-aid) for both KSU’s and non-KSU personnel.
  - Fire
  - Property damage exceeding $1,000.00.
All other incidents must be reported in writing **within 24 hours of becoming aware of the incident, injury or illness.**

C. **Post-Exposure Evaluation and Follow-Up**

Post-exposure evaluation and follow-up will be provided at no cost to employees following exposure incidents. The post-exposure monitoring periods are dependent on the type of exposure and the variety of incubation periods characteristic of the infectious agents.

All employees who have an exposure incident will be offered a confidential post-exposure medical evaluation and follow-up appointment. The post-exposure medical evaluation and follow-up include the following:

- A review/evaluation of the route of exposure and the circumstances under which the incident occurred.
- The employee will be offered post exposure prophylaxis at the recommendation of the attending medical professional.
- The employee will be given appropriate treatment and counseling concerning precautions to take during the period after the exposure incident. The employee will also be advised on what symptoms to be aware of, and to report any unusual signs or symptoms to appropriate personnel.

All other findings or diagnoses will remain confidential and will be recorded in the employee’s medical record. All laboratory tests are conducted at no cost to the employee.

11. **DECONTAMINATION OF BIOLOGICAL SPILLS**

Spills of biologically hazardous materials must be decontaminated in a manner that considers both protects lab personnel and prevents the spread of these agents within the facility. Only individuals who are trained to decontaminate biological spills can perform these procedures. In most cases, lab personnel will clean up their own spills without assistance from the BSO.

Laboratories should have a biohazard spill kit (or the materials to create one) inside the lab. The kit must be readily accessible and labeled for easy identification. The spill kit should include at least the following items:

- Safety Goggles
- Nitrile gloves
- Housekeeping gloves (vinyl heavy-duty)
- Heavy duty shoe covers
- 1:10 dilution of household bleach (should be dated and replaced at least monthly) or other EPA approved disinfectant
- Plastic dust pan and squeegee
- Paper towels
- Sponges
- Red/Orange Biohazard bags (large)

Other potential items to include in the kit are as follows:

- Disposable Tyvek suit
- Sponges
- Autoclave bags
- Kevlar gloves and sleeve protectors
- N-95 respirator

The following methods should be implemented when spills of biohazardous/infectious agents occur in laboratories:

**A. Spills in the Biosafety Cabinet**

- Allow the BSC to continue running.
- Stop all work and secure containers and samples.
- Don personal protective equipment (i.e. – goggles, double gloves, lab coat/apron) if not already wearing it.
- For a small spill,
  - Cover the spill with absorbent paper towels, carefully pouring an appropriate disinfectant onto the towel-covered spill
  - Wait an appropriate amount of time to the disinfectant to work (approximately 10 minutes).
  - Remove the contaminated absorbent paper towels and placing them into the biohazard bag.
  - Any splatter onto items within the cabinet, as well as the cabinet interior, should be immediately wiped with a towel dampened with decontaminating solution.
- For larger spills (large enough to result in liquids flowing through the front or rear grilles), a more extensive decontamination is required.
  - Remove all items within the cabinet and set aside (on absorbents) for decontamination.
  - After ensuring that the drain valve is closed, pour decontamination solution onto the work surface and through the grille(s) into the drain pan.
  - Allow a deactivation time of approximately twenty to thirty minutes
  - Empty the contents of the drain pan into a collection vessel containing disinfectant.
- Dispose of cleanup materials appropriately (including all contaminated PPE) in biohazard bags and dispose of as biomedical waste.

**B. Spills in Incubators**

- Don personal protective equipment (i.e. – goggles, double gloves, lab coat/apron) if not already wearing it.
- Decontaminate the surfaces of all laboratory items (flasks, plates, bottles, etc.) that were in the incubator before placing them in another incubator.
• If the incubator has a decontamination cycle, follow the provided instructions and perform the procedure. If the incubator does not have a decontamination cycle continue with the instructions below.
• Put absorbent towels on the puddles and soak with an appropriate disinfectant as described for a spill in the BSC.
• Remove the shelves from the incubator, put them in an autoclave bag, and autoclave.
• Decontaminate the water in the floor of the incubator with any quaternary ammonium based disinfectant.
• Remove this water using the aid of a vacuum collection flask located within a BSC. If this is not possible, ensure there is a vacuum trap flask and a HEPA filter on the vacuum pump.
• Disinfect the interior surfaces of the incubator with a surface wipe of an appropriate disinfectant.
• Remove all absorbents and contaminated PPE, and discard as biohazard waste.

C. Spills in Centrifuges

• Turn the centrifuge off.
• If it is already assumed that a spill has occurred, allow the centrifuge to sit for at least 30 minutes before opening to allow any aerosols generated to settle.
• Inform other personnel of the spill and advise the discontinued use of the centrifuge until decontamination is complete.

Note: If the centrifuge is opened immediately after the cycle is complete and the spill is discovered, it is safe to assume aerosols have been generated. The incident should be treated as a potential exposure, and appropriately reported. Inform others in the work area of the possibility of generated aerosols, and ensure that everyone leaves the work area for at least 30 minutes. Post a (time-stamped) notice on the closed door advising against entering for at least 30 minutes.

• Don the appropriate PPE for decontaminating the spill (e.g. – double gloves, lab coat/apron, goggles)
• To decontaminate the centrifuge:
  o Place the spill control pad over any liquid puddle to absorb and control the spread of liquid.
  o Add 1:10 dilution of household bleach, or another EPA approved disinfectant to soak the spill control pad
  o Allow a deactivation time of at least 10 minutes.
  o Carefully remove pad, discard into a doubled biohazard bag.
  o Decontaminate all exposed centrifuge and environmental surfaces with an appropriate disinfectant.
• After the spill is decontaminated, the area must be thoroughly cleaned with mild detergent (window cleaner) and dried, and decontaminated again with an appropriate disinfectant.
• Remove rotor and place in a BSC. To decontaminate rotor, soak it in an appropriate disinfectant, followed by mild detergent (window cleaner), then water rinse and dry.
• Discard all contaminated PPE and contaminated absorbents as biohazard waste.

D. Spills Outside of the BSC

Small Volumes

• Don the appropriate PPE for decontaminating the spill (e.g. – double gloves, lab coat/apron, goggles, shoe covers/booties)
• Cover the spill area with paper towels or absorbent pads to control the spread of liquid.
• Apply a 1:10 dilution of household bleach, or another EPA approved disinfectant to the absorbent and allow a deactivation time of at least 10 minutes.

*Note: When applying disinfectant, pour from the outside of the absorbent inward. Add no more than necessary to completely soak the absorbent pads.*

• Gather all absorbents (you can use the dust pan and squeegee from the spill kit), and discard as biohazard waste.
• If broken glass or other sharps are present, use forceps to discard these items into a sharps container.
• The dustpan, forceps, and squeegee should be placed in an autoclave bag and autoclaved according to standard procedures.

Note: Do not place reusable items to be autoclaved into standard red/orange biohazard bags. Removal of these items from non-autoclavable plastic should be avoided as separation of the plastic after autoclaving can be very difficult.

• After discarding all spill decontamination materials, apply disinfectant to the spill area a second time. Allow a contact time of at least 10 minutes, and then wipe dry with paper towels or absorbents.
• Remove and discard PPE as biohazard waste.

Large Volumes

• If a large volume of biohazard material was spilled, or you believe aerosols may have been generated, the incident should be treated as a potential exposure.
• Leave room immediately and close the door. If possible, do not inhale until clear of contaminated area.
• Inform all others in the work area that infectious aerosols may have been generated.
• Ensure that everyone evacuates the room immediately. Warn others not to enter the contaminated area.
• Post a (time-stamped) notice on the closed door advising against entering for at least 30 minutes.
• If splashed, remove contaminated garments by turning exposed areas inward. Place garments in autoclave bags and autoclave if possible. Wash exposed areas thoroughly with soap and water.
• Wait at least 30-60 minutes to allow dissipation of aerosols by the room ventilation changes.
• Notify the Laboratory Supervisor, Principal Investigator, and BSO. Spills in the laboratory, outside a BSC or other physical containment device, must be reported immediately. Complete the appropriate incident reporting form from the EHS website.
• The BSO will determine how the work area will be decontaminated.

12. **MEDICAL SURVEILLANCE PROGRAM**

**A. Health Status**

It is a prudent practice to inform your personal physician about your occupational risks, especially work with biohazardous or potentially biohazardous agents, so the information can be on record. Certain medical conditions increase your risk of potential health problems when working with pathogenic microorganisms and/or animals. These conditions can include, but are not limited to: diabetes, pregnancy, certain autoimmune diseases, immunodeficiency or immunosuppression, animal-related allergies, chronic skin conditions or respiratory disorders, and steroid therapy, even if only temporary.

**B. Medical Surveillance**

A medical surveillance program of KSU personnel engaged in biological research should be conducted by a University-contracted physician. The program may include precautionary measures including, but not limited to, immunizations, periodic physical examinations, and collection of serum samples.

The purpose of the medical surveillance program is to:

a) Ensure individual employees are physically fit for the nature and extent of the work to be undertaken.

b) Recommend appropriate medical precautions.

c) Perform periodic reassessment of employees to determine if medical conditions associated with employment are prevalent and, if so, to undertake definitive measures to alleviate them.

The extent of medical surveillance for a given employee will vary greatly and be dependent upon:

a) Nature of the research project in which involved

b) Biological agents to which directly or potentially exposed

c) Factors relating to the current or previous health status of the individual.

The EHS is to provide the University-contracted physician with guidelines and descriptions of conditions that may have significance for personnel assigned to laboratories. It is the ultimate
responsibility of the PI or lab supervisor to inform the EHS about current or new laboratory employees. The survey frequency of an employee working with high consequence agents is determined by the type of research performed and the recommendation of the employee's supervisor or PI.

Medical surveillance is provided at no cost to any University employee working in biological research laboratories.

C. Immunizations

Employees who have the potential to come in contact with human blood, human bodily fluids, or other potentially infectious materials must be offered the Hepatitis B vaccine due to an increased risk of exposure to bloodborne pathogens. If an employee declines the vaccine, he or she is required to sign a waiver by completing the Hepatitis B Vaccine Declination form (Appendix D) indicating that they were offered vaccine protection but declined.

D. Medical Restrictions

Pregnancy

It is recognized that exposure to certain infectious agents may adversely affect a fetus during pregnancy if the mother is infected with the agent. Women that are pregnant or become pregnant are encouraged to inform their supervisors or PIs and their physician. Employees are urged to discuss exposure issues with their supervisors or PIs regarding associated risks of research being conducted and pregnancy. Your personal or University-contracted physician should be consulted to give advice on necessary precautions.

Other Restrictions

Restrictions or recommendations will be made on an individual basis after discussion with the employee's personal physician. Examples of conditions that may warrant special precautions are HIV infection, immunosuppressive conditions or drug therapy that suppresses the immune system. Therefore, if you have any of the above conditions, you must inform your physician.
13. LABORATORY DESIGN

The more virulent an organism, the greater the degree of physical containment required. Proper safety equipment provides primary containment; laboratory design provides secondary containment. Laboratory design features for BSL-1 and BSL-2 facilities can be found in Appendix A and in the table below.

<table>
<thead>
<tr>
<th>SUMMARY OF BIOSAFETY LEVEL REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosafety Level</td>
</tr>
<tr>
<td>Isolation of laboratory</td>
</tr>
<tr>
<td>Room sealable for decontamination</td>
</tr>
<tr>
<td>Inward air flow ventilation</td>
</tr>
<tr>
<td>Mechanical ventilation via building system</td>
</tr>
<tr>
<td>Mechanical, independent ventilation</td>
</tr>
<tr>
<td>Filtered air exhaust</td>
</tr>
<tr>
<td>Double-door entry</td>
</tr>
<tr>
<td>Airlock</td>
</tr>
<tr>
<td>Airlock with shower</td>
</tr>
<tr>
<td>Effluent treatment system</td>
</tr>
<tr>
<td>Autoclave on site</td>
</tr>
<tr>
<td>Autoclave in laboratory/suite</td>
</tr>
<tr>
<td>Double-ended autoclave</td>
</tr>
<tr>
<td>Class II BSC</td>
</tr>
</tbody>
</table>
14. **EQUIPMENT REPAIRS/SERVICE**

Contaminated equipment that has to be sent out for repair/service or to be discarded must be decontaminated as thoroughly as possible. Therefore, prior to relocating equipment for service, repair, or surplus, it must be decontaminated in accordance with the [KSU SOP for Surface Decontamination of Infectious Agents](#). In addition to decontamination, the appropriate documentation must accompany the equipment. The [KSU Equipment Decommissioning and Relocation Form](#) must be completed, which will indicate when the equipment was decontaminated, what disinfectant was used, and the name of the person who performed the decontamination.

Copies of the form must be sent to EHS and to the next owner of the equipment. EHS must also inspect each piece of equipment, and will certify that decontamination has been completed by affixing a signed Equipment Decontamination Notice to the equipment.

Notify the BSO if all contaminated portions of the equipment could not be sufficiently decontaminated. Note: Insufficiently decontaminated equipment cannot be discarded. Contact the BSO to identify an adequate decontamination procedure.

Thorough decontamination of some equipment, including highly technical or sensitive equipment or equipment with limited access to contaminated areas, may not be feasible. In these instances, decontaminate the equipment to the degree possible (flushing lines or wiping down the exterior) and complete the Equipment Decommissioning and Relocation form indicating what portions of the equipment remain contaminated. Notify the BSO, who will arrange for a vendor to complete the decontamination prior to relocating the equipment.

15. **ANIMAL BIOSAFETY**

The use of animals in research experiments presents a unique set of challenges in the laboratory environment. Animals can be carriers of diseases that can be transmitted to humans, animals, or both. They may generate aerosols or dusts from disturbing the bedding in their enclosures. They can cause injuries to handlers by biting, scratching, or pecking. Lastly, their fur or dander may cause allergic responses in susceptible individuals. For this unique set of hazards, risk assessments must be conducted to determine the best method(s) of containment. [BMBL, Section V](#) prescribes four Animal Biosafety Levels (ABSLs), which are combinations of work practices, equipment, and facility design. ABSL 1-4 provides increasing levels of protection to employees and the environment, with ABSL1 being the least stringent, and ABSL4 being the most stringent. These four animal biosafety levels (1-4) outline facility designs and practices that are suitable to work with animals infected with agents that that require BSL 1-4, respectively.

Research using animals at Kennesaw State University primarily involves fish, reptiles, and amphibians, which are housed in the aquatics facilities. Since there are currently no infectious agents, or agents that require containment higher than BSL1, most of the research involving animals is done at ABSL1. The work practices, training, and facility requirements for ABSL1 are prescribed in the [BMBL Section V](#). All activities involving animals at KSU are also done in accordance with several other regulations and standards, including the USDA's [Animal Welfare Act](#).

### 16. PLANT BIOSAFETY

Plants are used in a number of research and teaching labs at KSU. Research with plants does not usually pose hazards to human health; however, if care is not taken to prevent the spread of certain plant pathogens, there could be harm caused to the natural and/or agricultural environment. Therefore, biosafety principles must be geared toward the containment of plants, plant material, and plant pathogens. The primary goal(s) of plant containment are to prevent:

- Unintentional transfer of recombinant or synthetic nucleic acid molecule-containing plant material to other plants
- Unintentional spread of plant pathogens or noxious plants to native plants or crops
- The cause of harmful effects to the environment outside of the experimental facility
- Introduction of non-native or exotic organisms into a new habitat

As with all other aspects of biosafety, a through risk assessment must be conducted to determine the required level of containment, which takes several factors into consideration, including the nature of the materials being used, employee work practices, and facility design. Containment for plants can be accomplished by two means: physical and biological. Physical containment includes isolating plants in greenhouses, or using secondary containment to prevent the contamination if soil. Biological containment measures prevent pollination by removing or deactivating the reproductive parts of plants or eliminating microorganisms or vectors that could spread plant pathogens.

There are four biosafety levels for plant containment; BL1-P – BL4-P (P=Plants), with BL1-P being the least stringent and BL4-P being the most stringent. These four plant biosafety levels are explained in detail in Appendix P of the NIH Guidelines.

Research that uses plants, plant products, plant pests, and the importation, exportation and release of genetically engineered plants and arthropods, are regulated under the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). A list of laws, regulations, and guidelines governing plant use and protection can be found on the USDA APHIS website.

### 17. PEST CONTROL

The management of pests is an important aspect of Biosafety, and in the management of research facilities. Pests such as nuisance insects (e.g. - flies, roaches, etc.) and rodents (e.g. – rats, mice, etc.) often carry communicable diseases which could potentially contaminate the work environment and also transmit diseases to laboratory employees. In addition to the potentially compromising of the
work environment, pests also give an unsightly appearance, even with the absence of contamination. For these reasons, their presence must be eliminated from the work environment.

**Integrated Pest Management**

When considering pest management, usually the first thought is to apply pesticides to the affected area(s). While this may appear to solve the issue, it is only a temporary solution. Pesticides wear off and need to be reapplied, and in some cases, this continuous application can result in contaminating the area with pesticide residue. Therefore, as recommended by the BMBL, an integrated pest management program (IPM) should be adopted to eliminate the presence of pests from the work environment. IPMs consist of three main elements:

- Housekeeping
- Maintenance, and
- Pest Control Services

While IPM also uses the application of pesticides to eliminate pests, the primary focus is on making the area less attractive to pests through housekeeping and maintenance efforts, while limiting pesticide use.

IPM should be specific to the type of work area where it is applied. For example, the efforts that must be applied to a laboratory may differ from the efforts needed for an animal facility. Therefore, prior to developing an IPM program, a thorough assessment needs to be conducted of each type of work area to determine the most effective strategy.

**Housekeeping and Maintenance**

Housekeeping plays an important role in IPM strategy. Reducing clutter, emptying waste receptacles regularly, sanitizing surfaces, and limiting food items to only breakroom and/or kitchen areas will foster an environment less conducive to pest infestation. In addition to housekeeping, other efforts should be made to ensure that all structural deficiencies, including holes in exterior walls, cracks around and under doors, breaches in the walls and ceilings, and any other issues that could permit pests to enter the facility are sealed and/or repaired with appropriate materials.

**Pesticide Use**

Primary pest control tactics used should be non-chemical in nature (i.e., traps, exclusion, removal/disposal, etc.). Pesticides may be applied as a secondary measure. While the use of pesticides is not encouraged, they should be used for treatment only, not as a form of prevention. When used, only baits and solid formulations of pesticides should be used. This will eliminate the potential for drift and volatilization of petroleum distillate and solvents associated with the use of some liquid and aerosol formulation of pesticides. Pesticides must be restricted only to the areas
where there is known pest activity. Also, the pesticides applied must be the least toxic products available, and applied in the lowest quantity that will eliminate the pests from the area.

**Record Keeping**

An IPM logbook will be compiled to track all pest management products that have been used in the work environment. In addition, the logbook will contain protocols and procedures for performing routine and emergency pest management services and reporting pest activity.
Appendix A

Kennesaw State University Volunteer Program

Kennesaw State University is self-insured through the Department of Administrative Services against state tort claims. This coverage is extended to KSU volunteers who are part of a structured program organized, controlled and directed by a Kennesaw State University Department for the purpose of carrying out the functions of the University. The liability coverage is for injuries and/or property damage volunteers may cause others while acting in the course of their official volunteer duties. Liability coverage does not apply when volunteers deviate from the course of their volunteer duties.

Kennesaw State University does not provide volunteers with any accident or medical insurance. Volunteers are not eligible or entitled to any employee benefits. Volunteers are not covered by worker’s compensation laws in connection with their officially approved volunteer activities. If the volunteer activities involve the use of the volunteer’s personal vehicle, no comprehensive or collision coverage would be provided to their personal vehicles.

Departments that wish to utilize volunteers for the purpose of carrying out the functions of their department must briefly describe what benefit the University derives from their volunteer program and complete the Volunteer Agreement Form. The Volunteer Agreement Form is to include signatures as required and acceptance of the responsibilities associated with this agreement. The volunteer agreement form will establish the guidelines and description of duties for the structured volunteer program.

The following forms are needed to be in compliance with the structured volunteer program:

1. The Kennesaw State University Volunteer Agreement form
2. The Kennesaw State University Volunteer Services Description form

Submit the volunteer agreement and description of duties forms via email to: jhull@kennesaw.edu or to Janet Nash at Mail Drop 1402. The approval will be sent to the Dean or Director.

If there are any questions regarding the structured volunteer agreement or additional information is needed, please call or email Janet Nash at 470-578-6985 or jhull@kennesaw.edu
Volunteer Services Description

Department/Unit: ________________________________

Full Name of Volunteer: ________________________________

Volunteer’s Responsible Supervisor: ________________________________

Volunteer Services: From: ___________ To: ___________  

Purpose for Volunteer Services:

__________________________________________________________________________________________________________
__________________________________________________________________________________________________________
__________________________________________________________________________________________________________

Scope of Volunteer’s Work and Duties (per responsible supervisor):

__________________________________________________________________________________________________________
__________________________________________________________________________________________________________
__________________________________________________________________________________________________________

Department/Director Approval: ________________________________

Date Approved: ___________ Email & Phone: ________________________________

Responsible Supervisor Signature: ________________________________

Volunteer Signature: ________________________________

Parent’s Signature (if under 18): ________________________________

Please maintain copies of the Agreement for Volunteer Service and Volunteer Services Description forms on file with your Department/Unit for at least 2 yrs. Forward original copies to the Risk Manager, Janet Nash at jhull@kennesaw.edu or Mail Drop 1402.
AGREEMENT FOR VOLUNTEER SERVICES

I, ________________________________, agree to work as a volunteer in  
______________________________ at Kennesaw State University from ______ until _______.

_____ I agree that services are offered strictly on a volunteer basis. I understand that I will not be paid  
or compensated in any way for my services by KSU, nor will I be considered an employee of KSU for any  
purpose. I understand that I am not entitled to any worker’s compensation.

_____ I agree that my participation in the activities outlined in the attached Description of Volunteer  
Duties (which is part of this agreement) is not in exchange for any consideration (i.e. payment,  
employment or the promise of either in the future).

_____ I understand that KSU is self-insured through the Department of Administrative Services  
against state tort claims. This coverage is provided for volunteers in programs organized, controlled  
and directed by KSU for the purposes of carrying out the functions of KSU. **I UNDERSTAND THAT  
COVERAGE DOES NOT APPLY WHEN I DEVIATE FROM THE COURSE OF MY VOLUNTEER DUTIES.**

_____ I release and hold harmless the Board of Regents of the University Systems of Georgia,  
Kennesaw State University, their members, employees, agents and authorized representatives from all  
losses, damages, costs, and expenses, claims, demands, rights and causes of action resulting from any  
personal injury, death, or damage to property arising out of my volunteer activities.


Volunteer’s Signature __________________________ Date __________

______________________________

Parent’s Signature (If volunteer is a minor) __________________________ Date __________
Appendix B

Waiver and Release Agreement regarding the Use of Kennesaw State University Science Labs

PLEASE READ THE FOLLOWING CAREFULLY BEFORE SIGNING:

LIABILITY RELEASE, INDEMNITY AND PROMISE NOT TO SUE:

I, the undersigned below, in consideration of Kennesaw State University allowing my and/or my child’s or ward’s to use the KSU laboratories in relation to my and/or my child’s or ward’s high school projects, I understand that the use of such labs and any related activities thereto including training, preparation, and travel (separately and collectively, the “Activities”) involves an inherent risk of serious injury and I freely assume on my own and/or my child’s or ward’s behalf all risks incidental to such participation. I further agree to follow all rules and directions from university personnel regarding use of the facilities and equipment. Further, in my own and/or my child’s or ward’s behalf, and on behalf of my and/or my child’s or ward’s heirs, executors, administrators and next of kin, I hereby release, covenant not to sue, and forever discharge the Released Parties (as defined below) of and from all liabilities, claims, actions, damages, costs and expenses of any nature arising out of, related to, or in any way connected with my or my child’s or ward’s participation in the Activities and/or any such related and associated activities, and further agree to indemnify and hold each of the Released Parties harmless from and against any and all such liabilities, claims, actions, damages, costs and expenses including by way of example, but not limited to, all attorneys’ fees, costs of court, and the costs and expenses of other professionals and disbursements up through and including any appeal. I, for myself and my child and/or ward, understand that this Release and indemnity includes any claims based on the negligence, action or inaction of any of the Released Parties and covers bodily injury (including, without limitation, death), property damage, and loss by theft or otherwise, whether suffered by me or my child or ward either before, during or after such participation. I declare that I or (if participating) my child or ward are physically fit and have the skill level required to participate in the Activities and/or any such related and associated activities. I further authorize medical treatment for me and/or my child or ward, at my cost, if the need arises. For the purposes hereof, the “Released Parties” are: Kennesaw State University, the Board of Regents of the University System of Georgia, and the officers, directors, employees, agents, representatives, successors, assigns and volunteers of each of the foregoing entities.

This Waiver and Release Form shall be governed by the laws of the State of Georgia, and any legal action related to or arising out of this Waiver and Release Form shall be commenced exclusively in the Superior Court in and for Cobb County, Georgia.

If I am executing this Waiver and Release Agreement on behalf of my child or ward, I certify that the information set forth above pertaining to my child or ward is true and complete. If I am
executing this Waiver and Release Agreement on my own behalf, I certify that I am eighteen (18) years of age or older.

I HAVE READ, UNDERSTOOD AND ACCEPT THE CONDITIONS OF THIS LIABILITY RELEASE, INDEMNITY, AND PROMISE NOT TO SU.

Participant Information: *(Please PRINT)*

Name: __________________________________________

Emergency Contact and Phone Number: ________________________________

Signature of Participant: ___________________________ Date: ____________

Name of Parent/Guardian: ____________________________

Signature of Parent/Guardian: ________________________ Date: ____________
Biological Safety Manual

EOSMS-203 Rev 1.0 effective date 2/1/17

By signing below, I hereby certify that the above document has been reviewed and approved by the Institutional Biosafety Committee.

Dr. Charles Amlaner
Vice President for Research

1/17/17

Date