Wake Forest University Reynolda Campus, Wake Downtown, Nanotechnology Center

BIOSAFETY PLAN

Department of Environmental Health and Safety

6/22/2017

I. INTRODUCTION

The Department of Environmental, Health and Safety (EHS) has developed the Biosafety Plan to provide guidance and enforce policies and procedures of the Biosafety Committee to microbiological and biomedical practices at Wake Forest University's (WFU) laboratories. These policies and procedures apply to any research involving recombinant or synthetic nucleic acid molecules inserted into cells/organisms and potentially pathogenic microorganisms. In addition, the policies and procedures specify safety practices and the safe handling of biological materials. The recommendations and requirements provided in this manual are based on guidance from the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and Biosafety in Microbiological and Biomedical Laboratories.

When a researcher conducts work involving recombinant or synthetic nucleic acid molecules or pathogenic agents at WFU Reynolda Campus, the safety of WFU personnel, the public and the environment is of paramount importance. The WFU Biosafety Committee establishes and maintains a system for the control of biohazards within the University to deliver a quality Biosafety program. Regulatory compliance and protection of WFU personnel, facilities, and other resources are integral to the committee's work. The policies developed by this committee are submitted to the appropriate administrative offices for approval and implementation.

This Manual should be used with the Wake Forest University (WFU) Chemical Hygiene Plan (CHP), Biohazard Waste Management Plan (Appendix I) and Wake Forest University Bloodborne Pathogen Exposure Control Plan.

An electronic copy of this Biosafety Plan will be kept in each laboratory for your reference.

II. DEFINITIONS

Biological material is a general term referring to all prokaryotic and eukaryotic organisms (and their components), viruses, subviral agents, recombinant deoxyribonucleic acid (DNA), and biologically-derived toxins used in research and instructional laboratories. For biosafety, it is useful to categorize biological material as *biohazardous* or *nonbiohazardous*, and to accurately assess the risks involved in working with each type biological material present in the laboratory.

Biohazardous material includes all infectious agents, vectors known to carry and transmit infectious agents, infected or potentially-infected animals, infectious material, recombinant DNA, and biologically-derived toxins that present either a risk or a potential risk to the health of humans, animals, or plants either directly through infection or indirectly through damage to the environment.

Infectious agents include human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, subviral agents).

Infectious material includes infectious agents and all biological material that contains, or has the potential to contain, infectious agents. Examples of infectious material include all human or nonhuman primate (NHP) material (e.g., blood and other body fluids, organs, tissues, cultured cells), infected animals and materials from infected animals, and environmental samples likely to contain infectious agents.

Nonbiohazardous Material are biological materials that are not normally infectious. This includes nonpathogenic microorganisms, viruses, and subviral agents; plants and NHP animals, biological material not likely to contain infectious agents, recombinant DNA molecules exempt from NIH Guidelines, environmental samples not likely to contain infectious agents, and biologically-derived, nontoxic molecules.

Principal Investigator is defined as a person having ultimate responsibility for all laboratory work, activities being conducted and the oversight of all employees involved in the research at WFU Reynolda Campus. This definition includes clinical laboratory directors, professors of teaching laboratories, and anyone else holding an equivalent position involved in biological work at WFU Reynolda Campus.

Recombinant DNA molecules are considered biohazardous if they are nonexempt from the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA* (NIH Guidelines). The NIH Guidelines are available on the EHS website.

III. AUTHORITY AND RESPONSIBILITIES UNDER THE BIOSAFETY MANUAL

A. Institutional Biosafety Committee (IBC)

1. Develop a comprehensive health and safety program for all areas involved in the use of biohazardous materials.
2. Identify and approve all activities involving biohazardous materials.
3. Assess the principal investigator's qualifications and experience relative to biohazardous materials, the level of containment required, the containment facilities available, and work procedures for storage, handling, and manipulation of biohazardous agents. This assessment may require an inspection of the facility and the preparation of a document outlining specific recommendations for the management of biohazardous materials and the health surveillance of potentially exposed personnel.
4. Provide the WFSM Office of Research and/or WFU Division of Research Sponsored Programs with any certifications required for research grants and contract applications.
5. Review at least every three years the biosafety policies and revise/develop appropriate procedures.
6. Provide oversight and review of the Biosafety program.
7. Review and approve protocols for recombinant DNA research conducted at or sponsored by The University for compliance with the NIH Guidelines as specified in NIH 97-3 Section III, experiments covered by the NIH Guidelines. This review shall include:
   a) Independent assessment of the containment levels required by the NIH Guidelines for the proposed research, and
   b) Assessment of the facilities, procedures, practices, training, and expertise of the personnel involved in recombinant DNA research.
   c) Lowering containment levels for certain experiments as specified in NIH 97-3 Section III-C-2-a, experiments in which DNA from Human or Animal Pathogens (Class 2, Class 3, Class 4, or Class 5 Agents) is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.
   d) Setting containment levels as specified in NIH 97-3 Sections III-C-4-b, Experiments Involving Whole Animals, and III-C-5, Experiments Involving Whole Plants.
   e) Periodically review recombinant DNA research conducted at The University to ensure compliance with NIH Guidelines.
   f) Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate university official and NIH/ORDA within 30 days, unless the Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.
   g) The Biosafety Committee may not authorize initiation of experiments that are not explicitly covered by the NIH Guidelines until NIH (with the advice of the Recombinant DNA Advisory Committee when required) establishes the containment requirement.
   h) Performing such other functions as may be delegated to the Biosafety Committee under NIH 97-3 Section IV-B-2.
8. Review and approve protocols for research conducted at or sponsored by The University for compliance with CDC guidelines as specified in Biosafety in Microbiological and Biomedical Laboratories (CDC 93-8395). This review shall include:

a) Independent assessment of the containment levels required by the CDC Guidelines for the proposed research, and
b) Assessment of the facilities, procedures, practices, training, and expertise of personnel involved in recombinant microbiological and biomedical research.

9. Develop standard protocols for common biohazardous materials.
10. Notify the Principal Investigator of the results of the Biosafety Committee's review and approval process.
11. Develop and adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research, microbiological and biomedical research.
12. Administer the enforcement component of the Biosafety Committee policies and waste disposal procedures.
13. Meet at least quarterly.

The Authority of the committee is to institute policies, procedures, and controls delegated as follows:

For the Reynolda Campus, authority has been delegated by the Vice President of Finance and Administration to the Biosafety Committee, through its Chairman, to the Director of WFU Environmental, Health and Safety Department or their designee. This authority includes (but is not limited to) instituting appropriate control measures when there is a reasonable danger to personnel and/or the environment, and to make decisions concerning biosafety control in the following matters;

I. Develop and review protocols and procedures dealing with aspects of biosafety.
II. Require researchers to conduct and maintain inventories of biohazardous materials.
III. Inspection of laboratories conducting recombinant DNA research, and microbiological and biomedical research.
IV. Assessment of compliance with NIH and CDC guidelines.
V. Collection of chemical and/or biological samples.
VI. The restriction from job duties of faculty, staff, and students who conduct research involving recombinant DNA research, microbiological and biomedical research, and chemical usage without an approved Biosafety Application or in direct contradiction of submitted protocols and/or current regulations.
VII. Recommend disciplinary action to the appropriate university administrator concerning noncompliance or any type of hazard.
VIII. Require corrective action concerning any noncompliance or type of hazard.

B. The Institutional Animal Care and Use Committee (IACUC)

1. Ensure that research animals at WFU are always treated ethically and humanely
2. The Attending Veterinarian retains the ultimate authority about the care and handling of the animals
3. Ensure the numbers of animals are minimal, the procedures meet or exceed current veterinary standards, and that all the appropriate steps are taken to prevent, minimize or eliminate risks to our animals
4. Ensure that research staff are adequately trained and protected from safety risks
5. Consider biosafety requirements and review proposed animal use
6. Provide regulatory guidance to research staff, conducts facility inspections, reviews the program twice each year and delivers extensive reports to federal agencies
7. Ensure a dedicated Laboratory Animal Training Coordinator assembles training programs and provides direct training to laboratory personnel on procedures and how to handle animals.

C. Environmental Health and Safety Department (EHS)

1. Prepare the Biosafety Plan and review annually
2. Ensure availability of the Biosafety Plan to each researcher/personnel that works with biological materials
3. Provide technical assistance in the development of policies and procedures with regards to biosafety
4. Serve as members of the IBC
5. Inspect biological laboratories on a regular basis to monitor for compliance with federal, state, local regulations and enforce the policies and procedures of the Biosafety Committee
6. Investigate laboratory accidents involving biological materials and toxins, pathogenic agents and recombinant or synthetic nucleic acid molecules
7. Maintain current knowledge of laboratory safety regulations and guidelines
8. Ensure overall compliance with the CHP and Biosafety Plan.
9. Review general and lab-specific SOP's.
10. Provide training, as required, to laboratory personnel and Principal Investigator.
11. Collect and dispose of biological waste generated within the laboratory.
12. Provide appropriate signs for identification of laboratory hazards.
13. Provide spill clean-up.

D. Principal Investigator (PI)

1. Ensure that WFU Reynolda Campus safety policies, procedures and good safety practices are followed
2. Assess the risks of the experiments or research
3. Ensure compliance with the Biosafety Plan within the laboratory as well as applicable state and federal regulations and guidelines
4. Develop, review and update Standard Operating Procedures (SOP's) for laboratory specific hazards, as required.
5. Ensure that all personnel under their supervision have completed required and annual training.
6. Provide IBC and IACUC with information on potential hazards associated with the proposed research
7. Notify the Department Chair when any new hazards are introduced into the laboratory.
8. Provide adequate Personal Protective Equipment for all personnel working in the lab.
9. Ensure that all exposures, injuries, accidents and suspected allergic symptoms are reported to the Department Chair.

E. Laboratory Personnel

1. Comply with safety policies and procedures relating to the work being performed
2. Apply good biosafety and chemical hygiene practices as outlined in this Biosafety Plan and the CHP.
3. Complete both Biosafety training and laboratory safety training.
4. Always use the appropriate personal protective equipment provided.
5. Report all accidents, injuries, and illnesses to the Department Chemical Hygiene Officer (DCHO) and PI.

IV. BIOLOGICAL RISK ASSESSMENT, CLASSIFICATION, AND MANAGEMENT

a) Biological Risk Assessment

1. Risk Assessment

Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in an individual's exposure to an agent, the likelihood that such exposure will cause laboratory associated infections (LAIs), and the probable consequences of such an infection. Assessing risks for biological agents is challenging. It is the PI's primary responsibility to assess the risks and apply best management strategies. The information identified by risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs. The Pathogen Safety Data Sheet provide laboratory personnel with information that describes the hazardous properties of a human pathogen and recommendations for work involving these agents in the laboratory.

PI's should assess risks to and select appropriate safeguards based on the types of hazards and the risk of exposure. The recommended approach based on the BMBL is outlined below:

1. Identify agent hazards and perform an initial assessment of risk:
   a) Consider the pathogenicity and viability of any biological agent present.
   b) Probable routes of exposure and transmission.
   c) Type and volume of biological materials.
   d) Availability of preventative measures and effective treatments for the disease.
   e) Make a preliminary determination of the biosafety level that correlates with the initial risk assessment

2. Identify laboratory procedure hazards
   a) Consider probable routes of exposure
   b) Consider specific hazards associated with laboratory procedures
   c) Potential for production of harmful byproducts

3. Make a determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment.
   a) Identify appropriate Personal Protective Equipment for each biosafety level
   b) Take precautions associated with the generation of waste.
   c) Ensure proper storage of materials, waste, and equipment.

4. Evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.
   a) The level of training and technical proficiency of personnel
   b) Use of microbiological practices, availability and condition of safety equipment.
   c) Enforce Appropriate emergency response procedures

5. Review the risk assessment with EHS.
   a) Review the potential laboratory procedure hazards and potential for exposure laboratory
   b) Review high-risk protocols

2. Laboratory Exposure

Laboratory personnel working with infectious material must be aware of probable routes of exposure and transmission of laboratory infections. Awareness of the routes of exposure is helpful in implementing procedures and practices that reduce their risk of exposure in the laboratory.

The predominant probable routes of exposure in the laboratory include direct skin, eye or mucosal membrane exposure, parenteral inoculation by a syringe needle or contaminated sharp, ingestion and inhalation.

• **Direct skin exposure** may result from a needle stick puncture with a contaminated sharp object, bites and scratches from infected animals or arthropod vectors, or through wounds, abrasions, and eczema. To reduce the risk of accidental infection the use of sharps should be avoided when alternate methods are available.

• **Eye or mucosal membrane exposure** can occur by touching mucous membranes with hands that have been in contact with contaminated surfaces (such as bench tops, phones, computers, etc.) or with hands that were not washed after working in a laboratory where the biohazardous material is used.

• **Ingestion** of biohazardous material most often occurs as the result of poor hygiene and poor laboratory practices, such as eating, drinking, or smoking in the laboratory, transfer of material to mouth by contaminated hands, or mouth pipetting.

• **Inhalation:** an agent capable of transmitting disease through respiratory exposure to the aerosolized infectious material is a serious laboratory hazard. This laboratory hazard is serious because infectious aerosols may not be easily detected by laboratory personnel. If inhaled, aerosols are carried to the alveoli creating an exposure hazard for laboratory occupants and for individuals occupying adjacent spaces open to airflow from the laboratory. Aerosols can be produced during procedures such as pipetting, homogenization, sonication, centrifugation, vortexing, electroporation, popping tube caps, flame-sterilizing instruments, flow cytometry, shaking or vigorously stirring cultures, changing animal bedding or handling infected animals. If the generation of an aerosol is likely to occur during the processing of these specimens, the use of a biosafety cabinet is recommended.

b) Classification of Biological risks

The World Health Organization (WHO) has recommended a classification for biological agent's risk groups (RG) based on an agent's capability to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease. The four RG address the risk to both the laboratory worker and the community. In addition, the NIH Guidelines established a comparable classification and assigned human etiological agents into four risk groups based on the hazard (Table 1). Risk Group Classification for specific infectious agents can be found on https://my.absa.org/tiki-index.php?page=Riskgroups. If several RG classifications are listed for an agent, the highest RG number should be used for the risk assessment.

Table 1: Classification of Biological agents by Risk Group

Risk Group Classification	**NIH Guidelines for Research Involving Recombinant DNA Molecules, 2011**	**World Health Organization Laboratory Biosafety Manual, 3rd Edition, 2004**

Risk Group 1	Agents that are not associated with disease in healthy adult humans	(No or individual and community risk) Agents unlikely to cause human or animal disease
Risk Group 2	Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available	(Moderate individual risk; low community risk) Agents that can cause human or animal disease but is unlikely to be a serious hazard to laboratory personnel, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high risk to laboratory personnel but low community risk)	(High individual risk; low community risk) Agents that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)	(High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

c) Risk Management

Risk management involves putting control measures in place to prevent exposure of laboratory personnel and the community. These control measures include engineering, administrative and physical controls which reduce the duration, frequency, and severity of exposure to laboratory hazards. Administrative controls include written safety procedures and practices, training, documentation, access restrictions, and proper signage and labeling. Engineering controls include facility features such as laboratory design, ventilation systems, storage areas, and safety equipment. Physical controls are provided by Personal Protective Equipment (PPE) and good laboratory practices.

1. Administrative Controls

Administrative controls are precautionary measures taken to lessen the risks of accidents in the laboratory. These measures are changes in work procedures such as written standard operation procedures (SOPs)

located in the Chemical Hygiene Plan, training, signage, labeling, record keeping, and medical surveillance to reduce or prevent the duration, frequency and severity of exposure to hazardous materials or hazardous situations.

2. Engineering Controls

Engineering controls are facility features and equipment intended to reduce the likelihood or severity of an exposure. In microbiological and biomedical laboratories, engineering controls are used primarily for containment. Safety equipment is a primary barrier designed to remove or minimize the risk of exposure to hazardous biological materials. Safety equipment includes personal protective equipment such as gloves, lab coats, and protective eyewear. Facility design and construction are secondary barriers designed for protecting the laboratory worker, persons outside of the laboratory, and the public. Facility design features may include specialized ventilation systems, airlocks, or controlled access zones.

a) Biosafety Cabinet

Biosafety cabinets are the primary means of containment developed for working safely with infectious materials. Biological safety cabinets (BSCs) are the primary device used to provide containment of infectious aerosols or splashes during manipulation. A biological safety cabinet (BSC) circulates air so a laminar flow forms that prevents cultures or other materials inside the work area from being contaminated by the outside air. Laminar flow of air also prevents aerosols or microbes inside the hood from escaping. The BSC is not tied into the central ventilation system. It is important to note that the Reynolda Campus of Wake Forest University currently is not equipped for any work requiring BSL-3 or BSL-4. No agents are to be introduced to campus requiring these levels of protection.

BSCs are certified annually in accordance with federal and state regulations. If a cabinet fails to meet certification requirements, discontinue use and contact EHS immediately. For more information refer to the Chemical Hygiene Plan.

3. Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE) provides a physical barrier between a biological, chemical or physical hazard and the wearer. PPE must be provided to and worn by all laboratory personnel, students, and visitors, when entering a laboratory including spaces where research animals are present. The extent and type of PPE selected for a particular activity depends on the risks associated with laboratory operations to be performed. At a minimum, a lab coat, gloves, clothing that covers the legs, and closed–toe shoes must be worn when working with biological materials. Shoe covers, forearm protection, eye protection, or a respirator may be required depending on the type of work being conducted. For areas where research animals are present, shoe covers or the use of sticky mats is required. Laboratory personnel are also required to wear safety glasses, disposable coveralls, hair cover, and an N95 respirator when changing bedding in animal cages. Coveralls and N95 respirators are recommended for all personnel working with or near laboratory or research animals. Anyone using an N95 respirator must first be enrolled in the University Respiratory Protection Program. While PPE is an important component of any biological safety program, it is not a replacement for engineering controls, administrative controls, good work practices, and safety equipment. PPE is most effective when used in conjunction with these controls. OSHA requires the use of PPE to reduce employee exposure to hazards when engineering and administrative controls are not feasible or effective in reducing these exposures to acceptable levels.

a) Proper Clothing

Proper clothing must be considered when working in a laboratory because clothing, accessories, and hair may become entangled in equipment, accidentally spill substances, or pass through flames unintentionally. Always wear clothing that provides adequate coverage for the legs and closed toe footwear that provides adequate support and has suitable traction for laboratory activities. Hair should be confined or tied back. The following may not be worn in the laboratory: loose sleeves, dangling jewelry, clothing that leaves the legs exposed, or shoes with heels greater than one inch. Clothing must adequately cover the torso and legs. Natural fiber clothing is recommended over synthetic fiber, as synthetic fiber will melt to the body in the event it catches fire. Always wear shoes that cover the entire foot, and preferably have a rubber non-slip sole.

b) Eye Protection

Eye protection is always required in the laboratory where hazards to the eye may exist. This includes splashes, sprays, aerosols, dust, powder, fumes and vapor. Eye protection must be worn when working with substances or equipment that present a hazard to the eye such as when changing bedding in animal cages, handling hazardous chemicals or radioactive materials, and when working with biological materials outside of a biological safety cabinet. Eye protection must meet design requirements set forth by ANSI (Z87.1-1998) and must be appropriate for the activity being performed.

Safety glasses should fit securely and be free of smudges or scratches that may obstruct vision. Safety glasses equipped with side shields provide better protection than those without. Safety goggles provide

c) Face Shields

When working outside of a biosafety cabinet, face protection (e.g., goggles, face shield) should be used for anticipated splashes or sprays of biological materials or chemicals. Face shields are designed to be used in combination with safety goggles to provide additional protection to the face and eyes against splashes and particulate matter. Face shields do not provide adequate protection against large projectiles or liquids, unless they are used in combination with safety goggles. Polycarbonate face shields that offer protection against ultraviolet (UV) radiation should be worn when using instruments that produce UV light.

d) Gloves

Gloves should always be worn to prevent direct contact with biological materials and chemicals. Gloves should be comfortable, of sufficient length to prevent exposure of the hand and wrist, and should be appropriate for the type of work to be performed. Gloves should be inspected for visible tears before use, removed aseptically when they become soiled or compromised, and discarded appropriately after use. Gloves should never be worn outside of the laboratory unless required for safety reasons (i.e. transporting autoclaved material). A glove that has potentially come in contact with organisms containing recombinant or synthetic nucleic acid molecules may never be worn outside the lab for any reason. Never touch items with gloves that will be touched with ungloved hands. This includes light switches, elevator buttons, computers, and phones. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Do not wash or reuse disposable gloves and dispose of used gloves with other contaminated laboratory waste.

e) Lab Coats, Gowns, and Coveralls

Lab coats are required for BSL-1 and BSL-2 research laboratories. Lab coats should cover the entire upper body, extend to the knees, and fit comfortably without hanging too loosely from the arms. For research activities, only single use disposable lab coats or lab coats that are routinely laundered by an approved vendor should be used. Lab coats may not be laundered by laboratory personnel. If disposable gowns are worn, they should be secured in the back, cover the entire upper body, extend to the knees, and fit

comfortably without hanging too loosely from the arms. In animal laboratories, disposable gowns should be worn and secured in the back, cover the entire upper body, extend to the knees, and fit comfortably without hanging too loosely from the arms. It is recommended that gowns be changed between each laboratory or animal room entered. Disposable gowns or coveralls are recommended for all personnel working with or near laboratory or research animals. Personnel are required to wear disposable coveralls when changing bedding in animal cages. Lab coats must be removed and hung within the lab prior to leaving. The lab coats used within the lab should not be laundered in any way. If soiled, the lab coat should be discarded with other contaminated laboratory waste.

f) Emergency Showers and Eyewash Stations

An American National Standards Institute (ANSI) approved emergency shower and eyewash station must be available within in a 10-second walk from each area where flammable or corrosive substances are used, be clearly labeled, and easily accessible. Emergency showers and eyewash stations must be installed, maintained, flushed, and tested in accordance with the ANSI Standard for Emergency Eyewash and Emergency Shower Equipment (Z358.1-1990). All laboratory personnel must know the location of the nearest shower and eyewash stations and must be trained in their use. If an emergency shower or eyewash station is not available, contact EHS. Emergency showers are designed to provide immediate response to exposures that cover a significant part of the body. Eyewash stations must be capable of being activated with one hand and maintain appropriate flow without the need for additional control. Eyewash units must be capable of providing 0.4 gallons of water per minute at 30 psi for a minimum of 15 minutes. Both emergency showers and eyewash stations must be flushed every week to verify that they are operating properly and the effluent is clear.

g) First Aid supplies

All laboratories and laboratory support rooms should be equipped with first aid supplies to assist laboratory personnel in responding to minor injuries and spill supplies relevant to the activities of the laboratory. These supplies should be clearly marked, easily accessible, and located near the laboratory exit. All laboratory personnel must know the location of these supplies. Supplies should be routinely inspected and replaced as necessary. EHS will provide and restock spill kits upon request.

h) Hair and Shoe Covers

Personnel working in animal facilities are required to wear disposable hair cover over the head when conducting cage changes. In addition, wearing shoe covers or using sticky mats is required
at all times in animal spaces. Hair and shoe covers are to be removed prior to exiting the facility. Sticky mats must be replaced every three months or when they are no longer tactile, whichever is more frequent.

i) Respiratory Protection

When working with biological material, respiratory protection should only be considered after the appropriate engineering controls have been put in place and additional controls are still needed. The personnel in charge of changing bedding in animal cages are required to wear an N95 respirator. N95 respirators are recommended for all personnel working with or near laboratory or research animals. Prior to wearing a respirator, the lab worker must complete a medical evaluation questionnaire to determine fitness to wear the respirator. Any individual required to wear a respirator must be enrolled in the University Respiratory Protection Program. Wake Forest University's Respiratory Protection Program is administered by EHS.

V. BIOSAFETY LEVELS

The CDC and NIH established biosafety levels to assist in determining risk management strategies at microbiological and biomedical laboratories. These levels indicate the type of laboratory facilities and practices required based on the type of material being used, the laboratory techniques employed, the safety equipment available for use with the material, and the design and construction of the facility in which the material is being manipulated.

A. Laboratory Biosafety Levels

The BMBL outlines criteria for four laboratory biosafety levels and provides safety guidelines for each. A summary of each of the biosafety levels:

1. Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adults, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. More information on BSL-1 standard practices, safety equipment and facility requirements is in Appendix IV
2. Biosafety Level 2 (BSL-2) is assigned to work with infectious agents and materials that cause disease in humans with a varying degree of severity and are a moderate hazard to laboratory personnel and the environment. More information on BSL-2 standard practices, safety equipment and facility requirements is in Appendix V
3. Biosafety Level 3 (BSL-3) is assigned to work with indigenous or exotic agents that may cause serious or potentially lethal disease because of exposure by inhalation. Use of a biosafety cabinet or other physical containment device is required for all procedures involving the manipulation of infectious material in BSL-3 laboratories and special engineering and design features are required. There are no BSL-3 laboratories at Wake Forest University.
4. Biosafety Level 4 (BSL-4**)** is assigned to work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infection and life threatening disease. *Variola spp*. (causative agent of smallpox) and viruses that cause hemorrhagic fever are representative infectious agents assigned to BSL-4. BSL-4 laboratories must be located in a controlled area that is completely isolated from all other areas of the building, preferably in a separate building, and special engineering and design features are required. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. There are no BSL-4 laboratories at Wake Forest University.

B. Animal Biosafety Levels

The BMBL outlines criteria for four animal biosafety levels (ABSL-1 through -4) and provides safety guidelines for each. A summary of each animal biosafety level:

1. Animal Biosafety Level 1 (ABSL-1) is assigned for animal work that does not involve biological agents or involves well-characterized agents that are not known to cause disease in immunocompetent humans, and that are of minimal potential hazard to laboratory personnel and the environment. More information on ABSL-1 standard practices, safety equipment and facility requirements is in Appendix VI.
2. Animal Biosafety Level 2 (ABSL-2) is assigned for animal work with those agents associated with human disease that pose moderate hazards to personnel and the environment. ABSL-2 builds on the practices, procedures, containment equipment, and facility requirements of ABSL-1. More information on ABSL-2 standard practices, safety equipment and facility requirements is in Appendix VII.
3. Animal Biosafety Level 3 (ABSL-3) is assigned to animal work involving indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease.

ABSL-3 builds on the practices, procedures, containment equipment, and facility requirements of ABSL-2. There are no ABSL-3 laboratories at Wake Forest University.

4. Animal Biosafety Level 4 (ABSL-4) is assigned to animal work involving dangerous or exotic agents that pose a high risk of life-threatening disease, aerosol transmission, or related agents with unknown risk of transmission. There are no ABSL-4 laboratories at Wake Forest University.

VI. BIOSECURITY

The term *biosecurity* refers to protection of biological materials from loss, theft, diversion, or intentional misuse. The objective of a biosecurity program is to develop and implement practices and procedures that prevent the loss, theft, or misuse of microorganisms, biohazardous materials, and research related information. Biosecurity includes:

a) Physical security designed to prevent unauthorized removal of materials.
b) Material accountability procedures established to track the inventory, storage, use, transfer, and destruction of biohazardous material.
c) Information security policies for handling sensitive information such as security plans, access codes, inventories, and storage locations.
d) Material transport policies that include accountability measures for the movement of materials within the university.
e) Accident, injury, and incident response plans.
f) Reporting and communication procedures.
g) Training and, in some cases (e.g., BSL-3 laboratories), practice drills.
h) Personnel and visitor identification and screening policies.
i) Routine security updates and evaluations.

A. Laboratory Security and Access

Laboratories contain hazardous substances that can pose a danger to public health if handled by untrained personnel or removed from the laboratory. These laboratories also contain expensive instruments and equipment so it is imperative that appropriate security precautions are implemented to prevent unauthorized access to laboratory materials and equipment.

The following security procedures must be followed in all laboratories:

1. Keep doors closed and locked when to restrict access by unauthorized personnel.
2. Do not leave hazardous substances unattended or unsecured at any time.
3. Restrict access to freezers, refrigerators, storage cabinets, and other equipment where hazardous substances are stored.
4. Limit laboratory access to approved laboratory personnel who are properly trained regarding the hazards present in the laboratory and the type of work they will perform.
5. Restrict off-hours access to individuals authorized by the PI/LS.
6. Escort visitors to and from the laboratory.
7. Challenge or question unfamiliar or suspicious individuals that gain access to restricted areas or to the laboratory. Report these incidents to University Police.
8. Report any missing inventory to University Police.
9. Report all acts of vandalism, theft, or suspicious activities to University Police.

B. Signs and Labels

Signs and labels are used to clearly identify specific laboratory hazards, safety equipment, emergency supplies, critical information, and designated areas within the laboratory.

The entrance to all laboratories and laboratory support rooms must be posted with signs that indicate the hazards present in the laboratory, the National Fire Protection Association rating of the laboratory, appropriate PPE to be worn, access restrictions, and contact information to be used in the event of an emergency. All laboratories and laboratory support rooms classified as BSL-2 or BSL-3 are required to have the universal biohazard symbol posted at all entrances to the laboratory along with the word "biohazard" and the term "BSL-2" or "BSL-3." In animal laboratories, entryway signs must be designated with the appropriate animal biosafety level. Special provisions for entry such as vaccination requirements must be posted as well. Principal investigators should notify EHS when entryway signs to their laboratory need to be updated. The University has a comprehensive space hazard assessment program which is located on the EHS website.

C. Labeling Requirements

All laboratory equipment (e.g., refrigerators, freezers, centrifuges, and incubators), biohazardous waste containers, and shipping or transport containers in which biohazardous material is used, stored, or disposed of must be labeled with the universal biohazard symbol and the word "biohazard." Labels should be affixed to the container or as close as possible to the container using string, wire, adhesive, or any other method that prevents their loss or unintentional removal.

VII. TRAINING

A. Biosafety Training

Biosafety training is required for personnel associated with work in biological laboratories, either for research or teaching purposes. The training ensures that personnel working in certain laboratories have been trained in basic biological safety principals before conducting work in laboratories at Wake Forest University. This training is intended to promote a safe laboratory working environment and to help ensure compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and the Biosafety in Microbiological and Biomedical Laboratories, 5th ed. Biosafety training pertains to all IBC protocols and research that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, all Biosafety Level 2 or higher protocols, and teaching laboratories at Biosafety Level 2.

B. Laboratory Research Checklist

Laboratory Personnel are required to complete the Research Laboratory Training Checklist (Appendix II) prior to beginning work in the lab. The PI is required to review the information on the checklist with everyone under the PI's supervision. As part of initial lab training it is mandatory to read the Biosafety Plan and the WFU Chemical Hygiene Plan. It is required that any time a new hazard is introduced to the lab, the PI will review the hazard with lab personnel and institute all precautionary measures that should be taken.

Individuals working in the laboratory should also read Biosafety in Microbiological and Biomedical Laboratories (BMBL), Edition5, and the Biohazard Waste Management Plan.

C. Lab Compliance Kit

All laboratories have a Lab Compliance Kit. This binder is the central repository for hard copy documentation required in the lab (aside from SDS), as well as a point of reference on laboratory safety.

The kit should always have an updated copy of the Biosafety Plan along with all SOP's appropriate to the lab. The kit should hold copies of all signed training checklists for personnel currently working in the laboratory.
Each kit has a number of quick information sheets on hazards common to many labs. These include sheets on fume hoods and BSC's, fire extinguishers and fire safety, PPE, and other information.
The kit should also contain glove permeation charts for the gloves used in the lab. This allows for quick access to the charts before working with chemicals.
Finally, each kit should contain the contact information (at a minimum name and phone number) of the PI and each individual working in the lab in case of an emergency. A list of emergency numbers including University Police, EHS, and Poison Control should be included on the contact sheet.

All individuals working in or frequenting laboratories where infectious materials are used or stored must receive *Biosafety for BSL-2 Laboratories* training before beginning working within the lab. This training reviews the principles of biosafety including risk assessment and management strategies, risk groups and biosafety levels safe laboratory practices, methods of disinfection and decontamination, waste management, and spill and exposure response.

In accordance with the OSHA Blood Borne Pathogen Standard, training on risks associated with blood borne pathogens, safe laboratory practices, medical waste management, and emergency procedures is provided annually to all individuals at occupational risk for exposure to blood borne pathogens. Individuals working in or frequenting laboratories or clinical settings where blood borne pathogens or other potentially infectious materials are present must receive blood borne pathogens training before beginning work. Training must be renewed annually.

VIII. LABORATORY INSPECTIONS

Laboratory inspections are conducted by an EHS staff monthly to ensure that laboratories performing work with biological materials meet specific requirements and follow certain safety guidelines. These routine inspections are intended to serve as review of the practices, procedures, equipment and to promote a safe working environment. Deficiencies discovered during routine inspections must be corrected as soon as possible and not to exceed two weeks. When correction of safety violations is not possible or practical within two weeks, the principal investigator must provide a corrective action plan to EHS. To ensure that the corrections have been made, the laboratory may be re-inspected. Failure to correct safety violations may be viewed by the Institutional Biosafety Committee as sufficient cause to suspend or cancel authorization to use recombinant DNA or other biohazards.

IX. WORKING WITH BIOHAZARDS

Any organism containing recombinant or synthetic nucleic acid molecules, as well as live biological materials (viruses, bacteria, parasites, etc.) that could infect humans, other animals, or crop plants are labeled as **"**biohazards**"**. Biohazards must be indicated with the following marking:

A. Biohazard Procedures

Each biohazard has its own unique properties, handling requirements, and proper technique for disposal. It is important that you know these requirements, as well as signs and symptoms of exposure. The following rules must be observed:

- Standard Operating Procedures (SOP) will be developed by the principal investigator for the individual laboratories. The SOP must be read and understood prior to performing a procedure within the lab.
- Hand washing must take place after removing gloves within the laboratory, and also prior to leaving the laboratory.
- Federal law prohibits anyone from having their office desk in a lab space where biohazard materials are in use.

B. Biohazard Collection and Disposal

Prior to working with biohazards, lab personnel must read and understand the Wake Forest University Biohazard Waste Management Plan (Appendix I). The Plan covers proper decontamination and disposal techniques for biohazards, blood and bodily fluids, and sharps.

1. Decontamination Procedures

a) It is important to review all disinfecting and decontamination procedures with the PI prior to beginning work in the lab.
b) Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
c) Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using the prescribed method.
d) Materials to be decontaminated outside the laboratory (i.e. autoclaving) must be placed in a durable, leak-proof container and secured for transport. As an added precaution, the secondary container should be sprayed with disinfectant and transported on carts.
e) Materials to be removed from the laboratory for decontamination must be packed in accordance with the applicable local, state and federal regulations. Contact the Biosafety Officer for more information.

2. Broken Glass and Sharps

Broken glass and sharps must both be handled with extreme care in the laboratory to prevent accidental puncture wounds. An annual review of sharps will be performed by the PI to judge feasibility of adopting improved engineering or work practices that reduce risk of sharps injuries (Appendix III).

a. Broken Glass

- Broken glass and empty glass bottles are to be collected in designated glass waste boxes. The box may be purchased prefabricated, although standard heavy duty cardboard boxes may be used as long as all original markings on the box are defaced or removed. The box must be marked with the

words “BROKEN GLASS” on at least opposite sides. The box must be lined with a heavy mil (9mil minimum) plastic bag.

- Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.
- Do not place bottles or glass in the box that are clearly heavily contaminated with chemical residue or potentially biohazard substances. All glassware that may have had contact with biohazard material must be disinfected prior to disposal in broken glass.
- Free liquids or sharps (needles, razors) may not be placed in the box.
- Do not overfill the box. Do not use a large box that will become overly heavy or awkward to lift. It is the responsibility of lab personnel to close and tape shut the broken glass box when it is full. Be sure no glass or sharp edges are protruding from the box. Once taped shut, place the box in the hall outside the lab door for removal by Custodial Services. It is not the responsibility of Custodial Services to tape boxes closed or to remove boxes from laboratories.
- Plasticware should be substituted for glassware whenever possible.

b. Sharps Disposal

Sharps include needles, razors, scalpels, and any other laboratory instruments that may cause punctures or cuts to human skin. The following rules must be followed when disposing of sharps.

- Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed from syringes.
- Immediately or as soon as possible after use, contaminated sharps shall be placed in appropriate Sharps containers.
- Sharps must be disposed of in a container that is rigid, leak-proof when in an upright position and puncture resistant.
- The container must be labeled with the biohazard symbol and the words “Sharps” and "Biohazard."
- Do not overfill the sharps container. Once full, close the container lid and replace with an empty sharps container.
- Contact the Biosafety Officer for information on removal of full sharps containers.

X. EXPOSURE INCIDENT, SPILLS AND ACCIDENT PROCEDURES

A. Exposure incident

Lab personnel incur risk each time they are exposed to blood or other potentially infectious materials. Any exposure incident may result in infection and subsequent illness. Considering the possibility of becoming infected from a single exposure incident, exposure incidents must be prevented whenever possible. In the event of an eye exposure personnel should immediately flush eyes for 5 to 10 mins using an eyewash station. In case of needle stick, the lab worker must clean and wash the area thoroughly with the use of antimicrobial soap or a mild disinfectant for a minimum of 5 minutes while gently massaging the area to make it bleed. In the event of a mucous membrane exposure, the lab worker should immediately flush membranes if

possible and proceed to the Wake Forest University medical provider. Refer to Wake Forest University Bloodborne Pathogen Exposure Control Plan for information on exposure or potential exposure procedures.

B. Biological Spills

In the event of a spill, unplanned release, or potential release of Biohazard waste to the environment, University Police shall be contacted immediately, 24 hours a day, at extension 5911. The dispatcher on duty will contact the Environmental, Health and Safety Department by phone, and Environmental, Health and Safety shall take the necessary actions to mitigate or remediate the situation.

EHS provides general spill procedure guidelines for biological spills below. In addition, the *Chemical Hygiene Plan* provides procedures for handling minor and non-minor spills. Contact EHS for spills involving a combination of biohazardous materials and hazardous chemicals. The area should be cordoned off and signage posted. If a spill poses imminent danger to health and safety and cannot be isolated or contained, evacuate the area and contact University Police by dialing 5911 and provide the following information:

- Name and telephone number of the caller.
- Location of the emergency (building name, room number, and building specific address, if known).
- Nature of the emergency (e.g., agent or material involved, fire, injuries).
- Special considerations (e.g., inhalation hazards present, potential for explosion, people trapped in rooms or buildings, number of people injured and type of injuries, electrical hazards, property damage, and access routes to the emergency).

Biohazard Spill kit materials and written procedures shall be kept in each laboratory where work with microorganisms is conducted.

1. General Spill Clean-Up Guidelines

a) Wear gloves, protective eyewear and a lab coat.
b) Use forceps or other mechanical means to pick up broken glass and discard into sharps container.
c) Wait 30 minutes for aerosol to settle before entering spill area. Assemble clean up materials and personal protective equipment during this time, using Spill Kit if needed
d) Cover spilled material with absorbent material
e) Add diluted disinfectant in sufficient quantity to ensure effective microbial inactivation, let sit 15 minutes.
f) Dispose of absorbent material in red biohazard bag. Work from the outside of the spill and finishing in the center.
g) Wipe spill area with diluted disinfectant. Discard of clean-up materials in waste container.
h) Wash hands with soap and water when finished.
i) Report all spills to EHS by completing a Spill/Incident Report (APPENDIX V)

2. Spill of BSL-1 material

a) Wear gloves and a lab coat, pick up broken glass with forceps and place in sharps container.
b) Absorb the spill with absorbent material.
c) Add diluted disinfectant in sufficient quantity to ensure decontamination, let sit for 15 minutes.
d) Discard these materials into waste container.
e) Wipe the spill area with the appropriate dilution of a disinfectant effective against the organism. Discard all clean-up materials in red biohazard bag
f) Autoclave all gloves and other materials worn to clean up the spill.

g) Wash hands with soap and water.
h) Report all spills to EHS by completing a Spill/Incident Report

3. Spill of Human Blood

a) Wear gloves, face protection and lab coat to clean up spill.
b) If broken glass is present, use forceps to pick up and place in sharps container.
c) Absorb blood with absorbent material and add diluted disinfectant in sufficient quantity to ensure decontamination, let sit for 15 minutes.
d) Using a detergent solution, clean the spill site of all visible blood.
e) Discard all clean-up materials into red biohazard bag
f) Autoclave all gloves and other materials worn to clean up the spill.
g) Wash hands with soap and water.
h) Report all spills to EHS by completing a Spill/Incident Report
i) If an injury has occurred, complete a First Report of Injury form (APPENDIX IV) and seek medical evaluation.

4. Spill of BSL-2 Material

a) Keep other personnel out of the area to prevent spreading of spill material.
b) Post signage if needed.
c) Remove contaminated clothing and put in a biohazard bag for decontamination later.
d) Wash hands and any exposed skin and inform the PI of the spill. Contact EHS for assistance, if needed.
e) Wear gloves, face protection and lab coat to clean up spill.
f) If broken glass is present, use forceps to pick up and place in sharps container.
g) Absorb the spill with absorbent material and add appropriate disinfectant in sufficient quantity to ensure decontamination, let sit for 15 minutes.
h) Discard all materials into red biohazard bag
i) Wipe the spill area with the appropriate disinfectant effective against the organism. Discard of clean-up materials in red biohazard bag
j) Autoclave all gloves and other materials worn to clean up the spill.
k) Wash hands with soap and water.
l) Report all spills to EHS by completing a Spill/Incident Report
j) If an injury has occurred, complete a First Report of Injury form and seek medical evaluation.

5. Spill of Recombinant or Synthetic DNA Material

a) Keep other personnel out of the area to prevent spreading of spill material.
b) Post warning signage if needed.
c) Remove contaminated clothing and put in a biohazard bag for decontamination later.
d) Wash hands and any exposed skin and inform the PI of the spill. Contact EHS Biosafety for your campus for assistance, if needed.
e) Wear gloves, face protection and lab coat to clean up spill.
f) If broken glass is present, use forceps to pick up and place in sharps container.
g) Absorb the spill with absorbent material and add disinfectant in sufficient quantity to ensure decontamination, let sit for 15 minutes.
h) Discard all materials into waste container.

i) Wipe the spill area with the appropriate disinfectant effective against the organism. Discard of clean-up materials in red biohazard bag.
j) Autoclave the gloves and other materials worn to clean up the spill.
k) Wash hands with soap and water.
l) Report all recombinant or synthetic DNA spills to the EHS immediately.
k) If an injury has occurred, complete a First Report of Injury form and seek medical evaluation.

6. Spill in a Biological Safety Cabinet

a) Immediately notify all personnel in the lab and keep other personnel out of the area of the spill. Place contaminated PPE in biohazard bag to be autoclaved
b) Leave the Biosafety Cabinet fan running.
c) Wear gloves and lab coat, spray or wipe cabinet walls, work surfaces, and equipment with an appropriate disinfectant. If necessary, flood work surface, as well as drain pans and catch basins below the work surface, with disinfectant. Allow at least 20-minute contact time.
d) Soak up the disinfectant and spill with absorbent material, and drain catch basin into a container. Lift front exhaust grille and tray, and wipe all surfaces. Ensure that the no absorbent material or solid debris are blown into the area below the grille.
e) Surface disinfect all items that may have been spattered before removing them from the cabinet.
f) Discard all clean-up materials into red biohazard bag. Wash hands and exposed skin areas with soap and water.
g) EHS should be notified if the spill overflows into the interior of the cabinet. It may be necessary to do a more extensive decontamination of the cabinet.
h) For a major spill of BSL-2 material within a cabinet, the cabinet's fan, filters and airflow plenums should be decontaminated by formaldehyde gas procedures. Contact EHS to schedule this procedure.

7. Spill inside a shaking incubator

- Immediately turn off power and unplug power cord from wall socket
- Immediately notify all personnel in the lab and keep other personnel out of the area of the spill.
- If spill volume is large (>2L) close the lid of incubator and call PI or EHS
- If spill can be safely cleaned up by lab personnel:

a) Remove all contaminated clothing and place in red biohazard bag to be autoclaved. If skin is contaminated, treat with non-bleach disinfectant and follow with antimicrobial soap & water rinse.
b) Don appropriate PPE
c) Place absorbent material inside incubator to prevent leakage onto motorized parts below, then close the lid
d) Inform PI of the spill then retrieve Biohazard Spill Kit and appropriate disinfectant
e) Put signage on the incubator that says, **"HAZARDOUS SPILL- DO NOT OPEN"**
f) If the spill liquid is leaking out from the unit, apply disinfectant to the spill as well as the perimeter around the spill. Once the disinfectant takes effect, clean up with absorbent material from Spill Kit. Discard clean up material into red biohazard bag.
g) Spilled liquid cannot be absorbed all at once because of the design of shaking incubators, therefore you must work from top to bottom. Spray disinfectant over the absorbent material you applied earlier. To minimize aerosols and drips, carefully place wet absorbent material in an autoclave bag to be discarded.

h) Immediately apply more absorbent material to the spill if needed. Use pads, socks or pillows from the Spill Kit according to the volume of the spill and the size of the area to cover.
i) Spray interior surface areas of unit with disinfectant, especially any broken vessels associated with the spill. Wait for disinfectant to be effective.
j) Remove the pieces of broken vessels from the incubator interior; use forceps to avoid skin injury. Place broken glass in Sharps container; decontaminate by autoclaving as soon as possible.
k) At this point you may need to remove the incubator's platform to get to lower regions for further spill cleanup.
l) Thoroughly spray platform with disinfectant before removal, and give disinfectant time to work.
m) Before taking platform out of incubator, spray absorbent material with disinfectant and use them to cover an area on lab floor upon which to place the platform. Choose an area of the floor that is out of your way. Place removed platform onto absorbent material and perform a more thorough clean up later. Spray tools with disinfectant.
n) Apply the absorbent material to any spill liquid you see in lower regions of the incubator.
o) After all spilled material has been removed, disinfect every surface of the incubator that is accessible and repeat if necessary. Use cotton-tipped swabs for hard-to-reach areas. Do not use bleach on metal parts. If decontamination of enameled surfaces is performed with a bleach solution, apply a water rinse.
p) Put cleaned, dried platform back into position and leave lid incubator open for additional drying out and autoclave any contaminated PPE.

8. Spill in Centrifuge

a) Immediately notify all personnel in the lab. Leave centrifuge closed for at least 30 minutes for aerosol to settle.
b) Pour adequate amount of disinfectant to spill area and all exposed surfaces
c) Allow contact time of 20 minutes, then absorb spill with absorbent material provided in the spill kit
d) Pour adequate amount of disinfectant on the spill area again and allow 20 minutes contact time, then repeat clean-up process using absorbent material.
e) Finish cleanup with a water rinse and place all clean up materials in red biohazard bag.

9. Spill in water bath or shaker bath

a) Turn power off
b) Pour an adequate amount of disinfectant directly into water/shaker bath to effect decontamination. (CAVICIDE is recommended over bleach to reduce likelihood of damage to metal parts from chloride exposure.)
c) Replace cover and wait for 20 minutes.
d) Discard the water/disinfectant solution by pouring down sink drain, and flush sink drain with water.
e) Disinfect the surfaces of the water/shaker bath, and allow to dry before returning unit to regular use.

10. Spill in incubators or refrigerators

a) In the event of a minor spill which did not generate significant aerosols, the spill may be cleaned up with absorbent material soaked in disinfectant.

b) In the event of a major spill, the door of the incubator or refrigerator should be shut for 30 minutes to allow any aerosol to settle.
c) Use an appropriate disinfectant and allow a contact time of 20 minutes. All exposed surfaces should be disinfected, including equipment, racks, tubes, bottles, etc.
d) Absorb the spill with absorbent material, and pour an adequate amount of the disinfectant to the spill area. After another 20-minute contact time, use absorbent material and finish clean up with a water rinse.
e) All clean up materials should be placed in a red biohazard bag.

C. Emergency Actions

1. Injuries Requiring Medical Attention

For any life-threatening injury, immediately call 911, or x5911 on a campus phone, or 9911 on a Wake Downtown B60 phone. Describe the victim's injury, your location (building, floor, room), and a phone number the 911 operator can call if the line becomes disconnected. Never leave the victim alone. Direct another individual to call 911 if you are not near a phone, and have an individual meet arriving medical personnel and bring them to the victim.

Be sure to protect yourself before administering any assistance. Don gloves, eye protection, and lab coat, if necessary, to avoid potential chemical contact and to avoid blood contact.

For non-life threatening injuries that require medical attention, undergraduate and graduate students should proceed to the Student Health Center in Lot Q. Be sure to inform the PI that an injury has occurred, and at the earliest opportunity complete the First Report of Incident form (above).

Employees injured in the lab should alert their supervisor and proceed to the Wake Forest University medical provider:

Novant Health Urgent Care & Occupational Medicine
7811 North Point Blvd
Winston-Salem, NC 27106
336-759-0700

Be sure to complete the First Report of Injury form with your supervisor as soon as possible, and send a copy to human resources. This will expedite payment of services.

2. Loss of Electrical power when BSL-2 work is in progress

Most biosafety cabinets are not connected to emergency power. In the event of a power outage in the lab when BSL-2 work is in progress, work should be stopped immediately and all open containers of infectious material should be sealed. Post a sign on the cabinet to keep out until power is restored. If a power outage occurs while you are using the biosafety cabinet, immediately STOP procedure, shut sash of the biosafety cabinet and turn blower switch to off position. After power recovery, turn blower switch on and open sash. Let the blower run for 20 minutes before working in biosafety cabinet. Open sash and dispose of items exposed to unfiltered atmosphere while power was off. Place items in red biohazard bag and autoclave immediately if needed.

3. Loss of Electrical power when using the centrifuge

If a power outage occurs while you are using the centrifuge, set the main switch of the centrifuge to the OFF position. The centrifuge lid cannot be opened due to the lid locking safety devise. DO NOT open the lid manually since the rotor could still be rotating. Wait until power is recovers and

set the main switch of the centrifuge to the ON position. Make sure the rotor is stopped and then unlock the lid to recover the sample. If you need to manually unlock the lid to recover the sample, contact the supervisor.

4. Exhaust failures

If the exhaust system stops working or there is a change in air pressure while you are using the biosafety cabinet. Immediately STOP procedure, shut sash of the biosafety cabinet and turn blower switch to off position. All personnel should leave the lab until the situation is resolved. When the exhaust is working normally, turn blower switch on and open sash. Let the blower run for 20 minutes before working in biosafety cabinet.

5. Facilities and Campus Services

Facilities and Campus Service (F&CS) custodial staff will, at times, be required to clean up spills and unplanned releases of potentially biohazardous material. This would include, but is not limited to, blood, urine and feces. These incidents generally occur within residence halls, after normal business hours. The size of bodily fluid at the scene would determine whether the custodial staff would be involved or if an outside contractor is required. Any spill covering more than a 4' x 4' area will be cleaned by an outside contractor. If there is a spill, unplanned release, or potential release of biohazardous material to the environment that does not fall under routine clean up, or is too large a release to be cleaned with normal procedures, University Police shall be contacted immediately, 24 hours a day, at extension 5911. The dispatcher on duty will contact the Environmental, Health and Safety Department by phone or pager, and Environmental, Health and Safety shall take the necessary actions to mitigate or remediate the situation.

The protocol below has been put in place if a bodily fluid spill exceeds the 4'x 4' area:

1. The Resident Adviser (RA) calls the University Operations Center and University Police. The RA must remain at the scene until custodial staff arrive
2. The University Operations Center dispatches custodial staff
3. The University Operations Center must call the Department of Environmental, Health and Safety (EHS) about the spill
4. Upon arrival, the custodial staff must call the University Operations Center and remain until an EHS representative arrives
5. The EHS representative will evaluate the spill and contact the professional vendor and remain at the scene
6. However, if University Police (UP) determines that it is a crime scene, UP will contact University Operations Center to stop the protocol in steps 1 to 5. Once the crime scene can be released, UP would contact FC&S and EHS to contact the professional vendor

WAKE FOREST
UNIVERSITY

BIOHAZARD WASTE MANAGEMENT PLAN

GENERAL INFORMATION

This Plan is intended to provide basic information on the proper handling and disposal of Biohazardous material generated at the Reynolda campus of Wake Forest University. The Solid Waste Section of the North Carolina Department of Environment and Natural Resources (NCDENR) regulates the packaging, labeling, storage, transportation, treatment and disposal of biohazardous waste in North Carolina. Treatment, storage and disposal facilities that accept waste from outside of the facility cannot operate without a permit from the Solid Waste Section.

The Occupational Safety and Health Administration (OSHA) regulate Bloodborne Pathogens and Exposure Control Plans.

Under state regulations a solid waste generator is responsible for the storage, collection and disposal of his or her solid waste. The generator is responsible for ensuring that solid waste is disposed at a site or facility that has all applicable permits required to receive waste.

TYPES OF BIOHAZARDOUS WASTE GENERATED

Wake Forest University (WFU) generates sharps waste; laboratory wastes; waste containing microbiologic specimens; animal parts, tissues, and fluids; waste containing recognizable fluid blood; and other types of biohazardous waste as defined in Section .1200 of the NCDENR Medical Waste Management Rules.

BIOHAZARDOUS WASTE GENERATION SITES

Biohazardous Waste is generated on campus at several locations, including but not limited to:

Wake Downtown Bldg 60
Winston Hall - Biology Department
Salem Hall – Chemistry Department
Olin Hall – Physic Department
Reynolds Gym – Health and Exercise Science, Anatomy Lab, Student Health Center

Due to the nature of their positions, custodial staff and maintenance staff have the potential to come in contact with Biohazard waste in the course of their work at all buildings on Campus.

DEFINITIONS

"Biohazard Bag" means a disposable red bag which is impervious to moisture and has strength sufficient to preclude ripping, tearing, or bursting under normal conditions of handling. A Biohazard bag shall be constructed of material of sufficient single thickness strength to pass the 165-gram dropped dart impact resistant test as prescribed by Standard D 1709-85 of the American Society for Testing and Materials and certified by the bag manufacturer.

"Biohazard Waste" – for purposes of this document, Biohazardous Waste includes:

"Contaminated PPE" meaning any disposable personal protective equipment used during work with Biohazardous material.

"Medical waste" meaning any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.

"Microbiological waste" meaning cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial and industrial laboratories.

"Pathological waste" means human tissues, organs and body parts; and the carcasses and body parts of all animals that were known to have been exposed to pathogens that are potentially dangerous to humans during research, were used in the production of biologicals or in vivo testing of pharmaceuticals or that died of a known or suspected disease transmissible to humans.

"Regulated medical waste" meaning blood and body fluids in individual containers in volumes greater than 20 ml, microbiological waste, and pathological waste that have not been treated pursuant to .1207.

"Sharps" meaning and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.

"Blood and body fluids" means liquid blood, serum, plasma, other blood products, emulsified human tissue, spinal fluids, and pleural and peritoneal fluids. Dialysates are not blood or body fluids under this definition. Please note that the definition of regulated medical waste specifies blood and body fluids that are in a liquid state and in a container, such as a suction canister. This does not refer to blood absorbed by materials such as bandages and dressings.

"Highly communicable disease" means diseases, such as those caused by organisms classified by the federal Centers for Disease Control as Biosafety Level IV organisms, which, in the opinion of the infection control staff, the department, local health officer, attending physician and surgeon, or attending veterinarian merit special precautions to protect staff, patients, and other persons from infection.

"Highly communicable diseases" does not include diseases such as the common cold, influenza, or other diseases not representing a significant danger to non-immunocompromised persons.

"Infectious agent" means a type of microorganism, bacteria, mold, parasite, or virus which normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

"Mixed waste" means mixtures of medical and nonmedical waste. Mixed waste is medical waste, except for the following:

(a) Medical waste and hazardous waste is CONSIDERED TO BE hazardous waste and is subject to regulation as specified in the statutes and regulations applicable to hazardous waste.

(b) Medical waste and radioactive waste is CONSIDERED TO BE radioactive waste and is subject to regulation as specified in the statutes and regulations applicable to radioactive waste.

(c) Medical waste, hazardous waste, and radioactive waste is CONSIDERED TO BE radioactive mixed waste and is subject to regulation as specified in the statutes and regulations applicable to hazardous waste and radioactive waste.

"Sharps container" means a rigid puncture-resistant container which, when sealed, is leak resistant and cannot be reopened without great difficulty.

"Storage" means the holding of medical wastes at a designated accumulation area.

"Tracking document" means the medical waste tracking document

"Treatment" means any method, technique, or process designed to change the biological character or composition of any medical waste so as to eliminate its potential for causing disease.

PROCEDURES

GENERAL WORK PRACTICES

- Prior to working with blood and bodily fluids, employees must have had training on Bloodborne Pathogens and the WFU Exposure Control Plan.
- All WFU faculty and staff will follow the WFU Exposure Control Plan in order to minimize potential exposure to Bloodborne Pathogens.
- Universal precautions will be observed by all University employees to prevent contact with blood and other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, **all body fluids** will be considered potentially infectious. University employees should treat "commercially available" materials derived from human blood, bodily fluids or tissue as potentially infectious, unless it has been tested and proven negative for Human immunodeficiency virus (HIV) and Hepatitis B virus (HBV).
- Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.
- Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.
- Ice Machines used for research may not be used for human consumption, nor may Ice Machines used for human consumption be used for research.
- **Mixed Waste (see definitions) may not be co-mingled with, or shipped as, Biohazardous waste.**

- **Individual Departments and laboratories are responsible for keeping their areas clean and for clean-up and disinfection of any spills or releases occurring in their areas.**

No Highly Communicable Disease or Infectious Agent may be brought on Campus prior to review by the Wake Forest University Bio-Safety Committee.

The Biosafety Committee is charged with evaluating research that is potentially hazardous due to the presence recombinant DNA, or of certain pathogenic organisms. Investigators must submit a complete protocol of their research proposals, outlining the methodology in handling the microorganisms employed, predicting the potential hazards, and recommending methods by which communicability of the microbe to humans or to animals can be reduced.

The committee reviews the proposal and either approves the proposal or sends it back to the investigator with recommendations to increase safety. Prior to the outset of research, the committee must endorse the proposal. The Office of Research Development maintains the rules of safety that serve as guidelines for the committee. These cannot be specifically outlined since they vary according to the organism (or DNA) and the potential for airborne, droplet, direct contact, or fomite communicability.

The committee does not deal with proposals involving human subjects in research.

Contact the Office of Research and Sponsored Programs for more information at the following:

Research & Sponsored Programs
1834 Wake Forest Rd.
117E Reynolda Hall
Winston-Salem, NC 27106

Phone: 336-758-5888

Fax: 336-758-1959

BLOOD AND BODILY FLUIDS

- All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.
- Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
- Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

Requirements for Blood and Bodily Fluids in Individual Containers in Volumes Greater Than 20mL

- Blood and bodily fluids must be stored in a secured area, accessible only to authorized personnel.
- Blood and bodily fluids collected for disposal will be stored in a container that is rigid, leak-proof and puncture resistant.
- The container must be labeled with the biohazard symbol and the word "Biohazard."
- After collection, blood and bodily fluids must be solidified using commercially available blood absorbent. Absorbed blood and bodily fluid will then be collected in a red Biohazard Bag for disposal.

Requirements for Blood and Body Fluids in Individual Containers in Volumes Equal to or Less Than 20 ml

These containers are commonly vacuum tubes used for taking blood samples. If not stored in a secure area accessible only to authorize personnel, these containers must be packaged in a container suitable for sharps.

SHARPS

- Sharps should only be used when alternative engineering methods are not feasible.
- Great care should be used when employing sharps to minimize the chance of accidental skin puncture.
- Wherever possible, engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after implementation of these controls, personal protective equipment shall also be used.
- Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed.
- Immediately or as soon as possible after use, contaminated sharps shall be placed in appropriate Sharps containers.
- An annual review of all sharps will be conducted by the principal investigator (PI) or the owner of the laboratory space to assess current sharp usage and identify engineering controls that would lessen or eliminate the chance of accidental needle sticks.

SHARPS CONTAINER

Disposal of Sharps

- Sharps must be disposed of in a container that is rigid, leak-proof when in an upright position and puncture resistant.
- The container must be labeled with the biohazard symbol and the words “Sharps” and "Biohazard."

Sharps containers must be:

- Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found.
- Maintained upright throughout use.
- Replaced routinely and not be allowed to overfill.
- When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling and placed in a secondary container if leakage is possible.

Compaction of Sharps

Sharps and Sharps containers may not be compacted.

Urine, Feces and Other Bodily Fluids

Collected urine and/or feces will be disposed of as Biohazard Waste. Vomit and other bodily fluids will also be disposed of as Biohazard Waste. Soiled diapers are not regulated medical waste and may be disposed as general solid waste.

ON-SITE BIOHAZARD WASTE TREATMENT

Microbiological specimens generated at WFU are to be treated on-site in one of the autoclaves located in Salem Hall, Winston Hall or Wake Downtown Bldg 60.

Procedures for Microbiological Materials

Potential pathogens and toxic microorganisms such as bacteria, yeast, filamentous fungi, etc., are not required to be disposed of as hazardous waste. Individual laboratories are responsible for destroying all microorganism–related waste they generate. Follow the procedures below developed by the Biology Department for disposal.

- Prior to beginning a procedure, obtain an unlabeled red plastic Bio-Hazard bag, and one of the Bio-Hazard labels. Attach the label to the bag and use it to collect contaminated solids, spent agar plates, etc.
- If you have not filled the red bag with spent agar plates, disposable pipettes and plastic ware, it may be saved and filled at a later date. Fold down the unused portion and tape it shut.
- Also obtain a large beaker or flask from your own laboratory glassware, place a small Bio-Hazard label on it, and add fresh 10% Sodium hypochlorite solution to 1/10th the total volume. Use this container to collect contaminated liquids such as spent media or liquid cultures.
- As you work, place contaminated liquids into the container with fresh 10% Sodium hypochlorite solution. When you are finished working for the day, the liquid waste should be mixed thoroughly. Add the same amount of fresh 10% Sodium hypochlorite solution as you did at the beginning of the procedure. Allow the waste to stand for at least 20 minutes. After 20 minutes, the liquid can then be flushed down the drain, followed with at least 20 volumes of water.

DO NOT COLLECT LIQUID WASTE FOR MORE THAN ONE DAY; DESTROY IT DAILY.

DO NOT HOLD BAGS CONTAINING THESE SOLID WASTES FOR MORE THAN 7 DAYS; STERILIZE THEM.

Sterilization Process:

- To sterilize a red bag, fold down the top portion and tape it loosely with autoclave indicator tape. Place the bag in a shallow tray to catch any leaking media, then autoclave it for at least 20 minutes at 121 degrees C.

- After the bags have cooled, THEY MUST BE RELABELED BEFORE DISPOSAL. Obtain a green Non–Hazardous Waste label and one of the large white ATTENTION HOUSEKEEPING labels. Cover the original Bio-hazardous Waste label with the new label. Place the "Housekeeping" label over the upper end of the bag. Sterilized and relabeled red bags can go into general trash.

- Instruments and any liquid hazardous biological materials that cannot be soaked or mixed with fresh 10% Sodium hypochlorite solution should be decontaminated by boiling them for 20 minutes, or autoclaving them.

Cleaning / Disinfecting of Anatomy Dissection Tables:

- Upon completion of semester when the dissection tables in anatomy have held cadavers the tables will be cleaned and disinfected by an outside contractor.
- General housekeeping, cleaning and disinfecting will be conducted by the Department during the semester while the tables are in use.

Calibration of Autoclaves

On a yearly basis the autoclaves used for decontamination of bio-hazardous materials must be checked for correct autoclave temperatures. This is done using a digital thermometer.

The thermometer will be calibrated by placing the probe in boiling water and adjusting the digital read-out to read 100 degrees Centigrade.

The probe, which consists of a thin insulated wire, is wrapped several times at the point and will be placed between the door gasket and autoclave with tape. This creates a seal at the point the probe enters the autoclave when the door is closed and secured. The sensor end of the probe is place in the center of the autoclave, the door is closed and the autoclave turned to steam. The final temperature is reached when the thermometer read-out does not increase for 10 minutes.

The final temperature and time required to reach equilibrium will be noted in a log kept next to the autoclave.

The Department of Biology is responsible for calibrating the autoclave in Winston Hall and Wake Downtown Bldg 60. The Department of Chemistry is responsible for calibrating the autoclave in Salem Hall.

BIOHAZARD WASTE PACKAGING AND STORAGE

Packaging Biohazard Waste for Off-Site Treatment

- Biohazard Waste must be packaged in a red plastic Biohazard Bag in a rigid fiberboard box or drum in a manner that prevents leakage of the contents.
- The outer surface must be labeled with:
  - Biohazard symbol;
  - the words "INFECTIOUS WASTE" or "MEDICAL WASTE";
  - the name, address and phone number of the generator, transporter, storage facility and treatment facility.

- Use **only** the red plastic Biohazard Bags and fiberboard boxes provided by waste vendor.

Storage of Biohazard Waste Prior to Shipment Off-Site for Treatment

- All Biohazard waste, including regulated medical waste, must be stored in a manner so as not to create a nuisance either by noxious odors or by encouraging the presence of vermin.
- Biohazard waste must be maintained in a non-putrescent state.
- Biohazard waste must be stored in a manner that maintains the integrity of the container, including labels and markings.
- Areas used to store Biohazard waste must be accessible only to authorized personnel.
- Vermin and insects must be controlled.
- All floor drains in the storage area must discharge directly to an approved sanitary sewer (sewer or septic system). Ventilation must be provided.
- A plan must be maintained at the facility to ensure proper management of Biohazard waste.

Generator Responsibilities for Proper Disposal by Commercial Facilities

Generators are responsible for ensuring that waste is disposed of properly.

RECORD RETENTION

All tracking documents, treatment records, and other required documentation will be maintained by the Department that shipped the waste for at least three (3) years.

EMERGENCY ACTIONS – ACADEMIC DEPARTMENTS

In the event of a spill, unplanned release, or potential release of Biohazard waste to the environment, University Police shall be contacted immediately, 24 hours a day, at extension 5911. The dispatcher on duty

will contact the Environmental, Health and Safety Department by phone or pager, and Environmental, Health and Safety shall take the necessary actions to mitigate or remediate the situation.

Spills of biohazardous materials shall be decontaminated using one of the following methods:

- Exposure to hot water of at least 82 degrees Centigrade (180 Fahrenheit) for a minimum of 15 seconds.
- Exposure to chemical sanitizer by rinsing with, or immersion in, one of the following for a minimum of three minutes:
  - Hypochlorite solution (500 ppm available chlorine)
  - Phenolic solution (500 ppm active agent)
  - Iodoform solution (100 ppm available iodine)
  - Quaternary ammonium solution (400 ppm active agent)

Personnel performing disinfection procedures shall be equipped with the appropriate personal protective equipment for the situation, but at a minimum shall wear splash eye protection and latex gloves. Protective clothing, shoes, and a face shield may be required for large quantities of biohazardous materials.

EMERGENCY ACTIONS – FACILITIES AND CAMPUS SERVICES

Facilities and Campus Service (F&CS) custodial staff will, at times, be required to clean up spills and unplanned releases of potentially biohazardous material. This would include, but is not limited to, blood, urine and feces. These incidents generally occur within residence halls, after normal business hours. The size of bodily fluid at the scene would determine whether the custodial staff would be involved or if an outside contractor is required. Any spill covering more than a 4' x 4' area will be cleaned by an outside contractor. If there is a spill, unplanned release, or potential release of biohazardous material to the environment that does not fall under routine clean up, or is too large a release to be cleaned with normal procedures, University Police shall be contacted immediately, 24 hours a day, at extension 5911. The dispatcher on duty will contact the Environmental, Health and Safety Department by phone or pager, and Environmental, Health and Safety shall take the necessary actions to mitigate or remediate the situation.

The protocol below has been put in place if a bodily fluid spill exceeds the 4'x 4' area:

7. The Resident Adviser (RA) calls the University Operations Center and University Police. The RA must remain at the scene until custodial staff arrive
8. The University Operations Center dispatches custodial staff
9. The University Operations Center must call the Department of Environmental, Health and Safety (EHS) about the spill
10. Upon arrival, the custodial staff must call the University Operations Center and remain until an EHS representative arrives
11. The EHS representative will evaluate the spill and contact the professional vendor and remain at the scene
12. However, if University Police (UP) determines that it is a crime scene, UP will contact University Operations Center to stop the protocol in steps 1 to 5. Once the crime scene can be released, UP would contact FC&S and EHS to contact the professional vendor

APPENDIX II: Research Laboratory Training Checklist

WAKE FOREST UNIVERSITY

RESEARCH LABORATORY TRAINING CHECKLIST

Review Signs	Space Hazard Sign ☐ Chemical Storage, Carcinogens, Electrical hazards ☐ Container labels for chemicals not in primary container ☐
Chemical Hygiene Plan **IBC Protocol (if applicable)**	Location of Plan and required to read prior to working in lab ☐ Location of Protocol and required to read prior to working in lab ☐
Safety Showers and Eyewash	Location and proper use ☐ Do not block ☐
Fire Safety	Location and proper use of Fire Extinguisher (PASS) ☐ Do not block Fire Extinguisher or Electrical Panels ☐ Fire Doors remain closed. Do not prop open. ☐ All flames must be attended ☐
Gas Cylinders	Proper use and storage. ☐ Must be capped when not in use. ☐
Vacuum Flask (if applicable)	Proper use. Need to be wrapped. ☐
Fume Hood	Proper use ☐ Flow rate needs to be between 90 and 120 fpm ☐ Do not overcrowd and close sash when not in use ☐
Bio-Safety Cabinet (if applicable)	Proper use ☐ Ensure it has been certified annually prior to use. ☐
Personal Protective Equipment	Identify hazards that may require protection, both chemical and physical ☐ Complete an accurate description of the tasks requiring PPE and review with student ☐ Provide proper PPE and train users on proper use and function of PPE ☐
MSDS	Inform user of the chemical application, health hazards and physical properties prior to using a chemical ☐ Provide location of MSDS to the user and reiterate it is students responsibility to read and understand. ☐ Ensure only approved chemicals are used in the laboratory ☐
Chemical Safety	Identification of hazards ☐ Location of Chemical Incompatibility Chart ☐ Maintain accurate Chemical Inventory ☐ Date peroxide formers when opened. Do not store for more than one year. ☐ Select agent handling protocol and Controlled substance handling protocol (if applicable) ☐
General Housekeeping	Work clean ☐ Do not store glass bottles on the floor ☐ All storage must be 24" below ceiling ☐ No food or drinks in the lab ☐
Waste	Proper labeling for waste containers ☐ Proper segregation of incompatibles ☐ Keep waste containers closed ☐ WFU Biohazard Waste Management Plan (if applicable) ☐ Proper use and disposal of sharps and broken glass ☐
Emergencies and Spills	Emergency contact list ☐ University Police and EHS Office contact information ☐ Proper procedures for spills or emergencies ☐
Lab Specific Hazards	Review all lab specific hazards (if applicable) – including Electrophoresis, Radiation Safety, Laser Safety, etc. ☐
Laboratory Equipment	Review procedures for all standard laboratory equipment ☐
Blood borne Pathogens (if applicable)	Review Exposure Control Plan ☐ Offer Hepatitis B Vaccine ☐

I have presented all above marked information to the individual listed below:

Principle Investigator / Faculty Member	Signature	Date

I have received all above marked information from the Principle Investigator / Faculty Member indicated above:

–

Laboratory Student	Signature	Date

REV. DATE: 09/02/2010

APPENDIX III: Needle/Sharps Annual Review Form

NEEDLE / SHARPS ANNUAL REVIEW FORM

WAKE FOREST UNIVERSITY
Facilities and Campus Services

"Practicing Safe Science"

Safety Needle / Sharps Annual Review Form

All sharps that are being used where there is potential for exposure to bloodborne pathogens must be reviewed on an annual basis. During your annual review of devices, you must inquire about new or prospective, safer options.

Principal Investigator / Supervisor _____

Date _____ Department _____

Extension _____ Lab Room # _____

Please fill out the table below with the appropriate information for documentation of:

1. Annual consideration of new safer sharps devices;
2. To determine which sharp devices are currently in use;
3. To document the criteria used in the selection of the safer sharp device in use.

Sharps Currently in Use

Name of Sharp	Manufacturer	Size(s) in Use	Is it a Safety Sharp?	Are there evaluation forms (or exclusion memos) on file?	Justification for selection of device (enter N/A if no device is currently available)

Principal Investigator / Supervisor Signature

_____

Date_____

****Maintain completed review form in lab compliance kit for auditing purposes****

APPENDIX IV: First Report of Injury form

CONFIDENTIAL
Wake Forest University
First Report of Incident

Employee Information		
Name of Injured Employee:		☐ Male ☐ Female
Job Title:	Department:	
Employee Home Address (street, city, state, zip):		Home Phone #:
SSN:	Date of Birth:	WFU Hire Date:
Wage/Salary Info (HR to complete):		Hrs/Days Worked per Week: /
Incident Information		
☐ Injury ☐ Illness ☐ Vehicle Accident (If vehicle accident, also complete Form ?)		
Date of Incident:	Date Incident Reported:	
Did the incident result in lost workdays? ☐ Yes ☐ No If yes, list dates:		
Was employee interviewed by supervisor? ☐ Yes ☐ No	Supervisor's Name:	
Date of Interview:	Were Witnesses Present? ☐ Yes ☐ No	
Name(s) of Witness(es):		
Were other employees involved in the incident? ☐ Yes ☐ No		
Name(s) of Other Employee(s):		
Was first aid administered at WFU? ☐ Yes ☐ No	Where?	By Whom?
Was EMS dispatched? ☐ Yes ☐ No	Was employee sent to hospital/clinic for treatment? ☐ Yes ☐ No	
Hospital/Clinic where employee was sent:		Authorized By:
Did employee receive Rx for injury/illness?		Treating Physician:
Description of Incident		
What time did employee begin work?	What time did incident occur?	
Where did injury/illness/vehicle accident occur? (include building, room#, area of campus)		
What was employee doing before injury/illness/vehicle accident occurred? (Please be specific)		
How did the injury/illness/vehicle accident occur? (Please be specific)		

APPENDIX V: Spill/Incident Report Form

SPILL / INCIDENT REPORT FORM

Person Reporting:		Phone Number:
Date of Incident	Time of Incident AM PM	Quantity Spilled
Quantity Contained or Recovered	Method of Disposal of Recovered Material	
Location of Spill	Type of Material Spilled	
Source of Spill (Pipe, 55-Gallon drum, Equipment, etc.)		
Cause of Spill or Factors Contributing to Release ☐ Equipment Failure ☐ Operator Error ☐ Faulty Process Design ☐ Training Deficiencies ☐ Weather Conditions ☐ Other _____		
Immediate Actions Taken ☐ Containment ☐ Dilution ☐ Evacuation ☐ Neutralization ☐ System Shut Down ☐ Other _____		
Surface Area Affected (square feet, inside and/or outside)		
Any Release to the Environment? ☐ Yes ☐ No	Area(s) affected (Soil, water, air)	
Notification of Emergency Responders (Fire Department, NC Emergency Management, NCDENR, etc.): Agency: Phone Number: Actions Taken:	Agency: Phone Number: Actions Taken:	
Clean-up Closure Actions (Monitoring, Soil Testing / Remediation, etc.)		
List Any Injuries Related to Spill		
List Names of People Involved in Spill		
Comments:		

WAKE FOREST UNIVERSITY

RETURN TO EHS FOR FILING

APPENDIX VI: Biosafety Level 1 (BSL-1)

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science. The following standard practices, safety equipment, and facility requirements apply to BSL-1:

Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.

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

a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped with 2 hands, removed from disposable syringes, or otherwise manipulated by hand before disposal.

b. Used disposable needles and syringes must be carefully placed in conveniently located puncture- resistant containers used for sharps disposal.

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

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

6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.

b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.

9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. The sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel. Agent information should be posted in accordance with the institutional policy.

10. An effective integrated pest management program is required.

11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self- identify to the institution's healthcare provider for appropriate counseling and guidance.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Special containment devices or equipment, such as BSCs, are not generally required.
2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BSL-1 workers should:

a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.
b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

Laboratory Facilities (Secondary Barriers)

1. Laboratories should have doors for access control.
2. Laboratories must have a sink for hand washing.
3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Laboratories windows that open to the exterior should be fitted with screens.

APPENDIX VII: Biosafety Level 2 (BSL-2)

Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that:

- Laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures;

- Access to the laboratory is restricted when work is being conducted; and

- All procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BSL-2:
Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.

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

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

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

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

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

a) Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
b) Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
c) Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
d) Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.

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

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

8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

    a) Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
    b) Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.

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

10. An effective integrated pest management program is required.

11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

Special Practices

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

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

3. Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.

4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.

5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.

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

7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.

a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation and treatment should be provided and appropriate records maintained.

9. Animals and plants not associated with the work being performed must not be permitted in the laboratory.

10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:

a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.

3. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.

4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:

a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

Laboratory Facilities (Secondary Barriers)

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

2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.

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

4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.

    a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.

6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.

7. Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

8. An eyewash station must be readily available.

9. There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.

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

11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

APPENDIX VIII: Animal Biosafety Level 1 (ABSL-1)

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

A. Standard Practices
    1. The animal facility director establishes policies, procedures, and protocols for emergency situations. Each project is subject to pre-approval by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biohazard Committee (IBC). Any special practices are approved at this time.
    2. Only those persons required for program or support purposes are authorized to enter the facility. Before entering, persons are advised of the potential biohazards and are instructed on the appropriate safeguards.
    3. An appropriate medical surveillance program is in place.
    4. A safety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures.
    5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should only be done in designated areas and are not permitted in animal or procedure rooms.
    6. All procedures are carefully performed to minimize the creation of aerosols or splatters.
    7. Work surfaces are decontaminated after use or after any spill of viable materials.
    8. All wastes from the animal room (including animal tissues, carcasses, and contaminated bedding) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended.
    9. Policies for the safe handling of sharps are instituted.
    10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special requirements for entering the animal room (e.g., the need for immunizations and respirators).
12. An insect and rodent control program is in effect.

B. Special Practices: None.

C. Safety Equipment (Primary Barriers):

1. The wearing of laboratory coats, gowns, and/or uniforms in the facility is recommended. Laboratory coats remain in the animal room. Gowns and uniforms are not worn outside the facility.
2. Persons having contact with non-human primates should assess their risk of mucous membrane exposure and wear appropriate eye and face protection.

D. Facilities (Secondary Barriers)

1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.
2. External facility doors are self-closing and self-locking. Doors to animal rooms open inward, are self-closing, and are kept closed when experimental animals are present. Cubicle room inner doors may open outward or be horizontal or vertical sliding.
3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water resistant.
4. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.
5. Windows are not recommended. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.
6. If floor drains are provided, the traps are always filled with water and/or an appropriate disinfectant.
7. Ventilation should be provided in accordance with the Guide for Care and Use of Laboratory Animals, latest edition. No recirculation of exhaust air should occur. It is recommended that animal rooms maintain negative pressure compared to adjoining hallways.
8. The facility has a hand washing sink.
9. Cages are washed manually or in a cage washer. The mechanical cage washer should have a final rinse temperature of at least 180F.
10. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

APPENDIX IX: Animal Biosafety Level 2 (ABSL-2)

Animal Biosafety Level 2 involves practices for work with those agents associated with human disease. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1.

A. Standard Practices

1. Aside from the standard policies, procedures, and protocols for emergency situations established by the facility director, appropriate special policies and procedures should be developed as needed and approved by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Biohazard Committee (IBC).
2. Access to the animal room is limited to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.
3. An appropriate medical surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented.
4. A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures.
5. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should only be done in designated areas and are not permitted in animal or procedure rooms.
6. All procedures are carefully performed to minimize the creation of aerosols or splatters.
7. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with the infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.
8. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of the agent(s). All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. The outer surface of the containers is disinfected prior to moving the material. Autoclaving of the contents prior to incineration is recommended.
9. Policies for the safe handling of sharps are instituted:

a) Needles and syringes or other sharp instruments are restricted for use in the animal facility only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
b) Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.
c) Plasticware should be substituted for glassware whenever possible.

10. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.
11. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special requirements (e.g., the need for immunizations and respirators) for entering the animal room.
12. An insect and rodent control program is in effect

B. Special Practices

1. Animal care laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes. Records of all training provided are maintained. In

general, persons who may be at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal facility unless special procedures can eliminate the extra risk.
2. Only animals used for the experiment(s) are allowed in the room.
3. All equipment must be appropriately decontaminated prior to removal from the room.
4. Spills and accidents which result in overt exposures to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

C. Safety Equipment
1. Gowns, uniforms, or laboratory coats are worn while in the animal room. The laboratory coat is removed and left in the animal room. Gowns, uniforms, and laboratory coats are removed before leaving the animal facility. Gloves are worn when handling infected animals and when skin contact with infectious materials is unavoidable.
2. Personal protective equipment is used based on risk assessment determinations (see Section V). Appropriate face/eye and respiratory protection is worn by all personnel entering animal rooms that house nonhuman primates.
3. Biological safety cabinets, other physical containment devices, and/or personal protective equipment (e.g., respirators, face shields) are used whenever conducting procedures with a high potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals.
4. When needed, animals are housed in primary biosafety containment equipment appropriate for the animal species. Filter top cages are always handled in properly designed and operating animal biocontainment cabinets recommended for rodents.

D. Facilities (Secondary Barriers)
1. The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.
2. Access to the facility is limited by secure locked doors. External doors are self-closing and self-locking. Doors to animal rooms open inward, are self-closing, and are kept closed when experimental animals are present. Cubicle room inner doors may open outward or be horizontal or vertical sliding.
3. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water resistant.
4. Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.
5. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.
6. If floor drains are provided, the traps are always filled with an appropriate disinfectant.
7. Exhaust air is discharged to the outside without being recirculated to other rooms. Ventilation should be provided in accordance with criteria from Guide for Care and Use of Laboratory Animals, latest edition. The direction of airflow in the animal facility is inward; animal rooms should maintain negative pressure compared to adjoining hallways.
8. Cages are washed manually or in an appropriate cage washer. The mechanical cage washer should have a final rinse temperature of at least 180F.
9. An autoclave is available in the animal facility to decontaminate infectious waste.
10. A hand washing sink is in the animal room where infected animals are housed, as well as elsewhere in the facility.
11. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

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