

ASU Biological Safety Manual

FOREWORD

The Biological Safety Manual (or Biosafety Manual) has been adopted by Arizona State University to be a resource for information, guidelines, policies and procedures that will enable safe research and to help eliminate, or reduce, the potential for exposure to biohazards. The Department of Environmental Health and Safety (EHS) developed this manual to help ensure compliance with the following federal, state and local regulations and guidance materials:

- 7 Code of Federal Regulations § 331
- 9 Code of Federal Regulations § 121
- 18 United States Code § 175b
- 29 Code of Federal Regulations § 1910.1030
- 42 Code of Federal Regulations § 72-73
- 42 Code of Federal Regulations § 1003
- 49 Code of Federal Regulations, § 171-180
- Arizona Administrative Code, Article 14, Biohazardous Medical Waste and Discarded Drugs
- Centers for Disease Control and Prevention/National Institutes of Health, "Biosafety in Microbiological and Biomedical Laboratories"
- National Institutes of Health, "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules"
- Public Act 107-188, HR3448
- United States Department of Agriculture (USDA) Animal Welfare Act

The ASU Biosafety Manual provides a compilation of suggested work practices, protocols and systems to work safely at ASU. The ASU Biosafety Manual should not be considered the only reference for health and safety concerns. It is intended that the principal investigator and supervisory personnel will supplement this information with instruction and guidance regarding specific practices and procedures unique to the work being done in their areas by completing a lab-specific biosafety manual and including all relevant documentation available to laboratory users. In addition, EHS is always available to address health and safety concerns. The ASU Biosafety Manual is reviewed at least annually by EHS and the Institutional Biosafety Committee and was last approved on December 19, 2017.



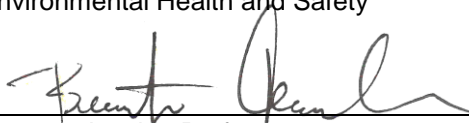
Leon Igras, Chief Safety Officer
Executive Director
Environmental Health and Safety



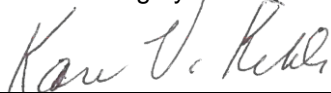
David Gillum, Chief of Staff
CDC Responsible Official/Institutional Biosafety Officer
Environmental Health and Safety



Chantelle Miller, Assistant Director
OKED Research Operations
Research Integrity and Assurance



Bertram Jacobs, Professor
Chair, Institutional Biosafety Committee
Center for Immunotherapy, Vaccines and Virotherapy



Karen Kibler, Assistant Research Professor
Chair, Institutional Animal Care and Use Committee
Center for Immunotherapy, Vaccines and Virotherapy



Dale DeNardo, Associate Professor
Director, Department of Animal Care and
Technologies
School of Life Sciences

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I. Introduction

The Arizona State University (ASU) Biosafety Manual is intended to be a resource for information, guidelines, policies, and procedures that will enable and encourage safe research and to eliminate, or reduce, the potential for exposure to biohazards. The information presented here also reflects the requirements and guidelines of federal and state regulations. The most current version of the Biosafety Manual will be maintained on the [EHS Biosafety and Biosecurity](#) website.

The ASU Biosafety Manual is applicable to all laboratory, research, teaching, and support activities that may involve biohazards. Biohazards are microorganisms, microbial toxins, or other biological agents that can infect and/or cause disease in humans, animals, or plants. Biohazards may include bacteria, bacterial toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically modified organisms, recombinant or synthetic nucleic acid molecules. In addition, biohazards include human blood, body fluid, tissues, and cell lines of human origin. Biohazards are often referred to as infectious agents or etiological agents.

All research protocols must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to beginning work if they involve the use of any of the following:

- Agents that can infect and/or cause disease in humans, animals, or plants.
- Experimentally infected animals and those naturally harboring zoonotic infectious agents.
- Recombinant and synthetic nucleic acid molecules.
- Genetically modified organisms.
- Transgenic plants and animals.
- Human cell lines and other materials of human origin.
- Select agents and toxins.
- Environmental/field samples (e.g., water, soil, and air samples).
- Archaeological samples (e.g., bones, clothing fragments and pottery).
- Biohazardous waste.

Biosafety encompasses the knowledge, techniques, equipment, and facilities necessary to prevent or minimize an exposure to, or release of, a biohazard. The mission of the EHS Biosafety group is to assure a safe and healthy environment for individuals working with biohazards and to protect the community and environment by preventing the release and exposure to biohazards. For information about field work, please refer to ASU's [Safety Guidelines for Field Researchers](#).

The ASU Biosafety Manual also requires that all laboratory animal facilities, operational practices, and quality of animal care meet applicable standards and regulations (e.g., [Guide for the Care and Use of Laboratory Animals and Laboratory Animal Welfare Regulations](#)) and that appropriate species have been selected for animal experiments. ASU is required to have an occupational health and safety program that addresses potential hazards associated with the conduct of animal research. The publication by the Institute for Laboratory Animal Research (ILAR), [Occupational Health and Safety in the Care and Use of Research Animal](#), is most helpful in this regard. Additional safety guidance for working with non-human primates is available in the ILAR publication, [Occupational Health and Safety in the Care and Use of Nonhuman Primates](#).

II. Biosafety Oversight

Guidance documents from the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) form the basis for the biosafety practices included in this manual. There are additional guidance documents and regulations imposed by various funding agencies that individual principal investigators must be aware of and incorporate into a [Laboratory-Specific Biosafety Manual](#). Biosafety requirements must be followed to ensure the continuation of grant funding from federal agencies and for health and safety purposes.

The [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (*NIH Guidelines*) detail procedures and practices for the containment and safe conduct of various forms of recombinant or synthetic nucleic acid research. The *NIH Guidelines*:

- Mandate the establishment of an Institutional Biosafety Committee for the review and oversight of biological research;
- Outline roles and responsibilities for biosafety; and
- Establish the practices, procedures, and conditions under which recombinant and synthetic nucleic acid activities must be conducted.

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

The CDC/NIH manual, [Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL), describes the appropriate measures and facilities for work with all microbial agents, including bacterial, viral, fungal, parasitic, rickettsial, and prion agents as well as toxins of biological origin.

The requirements described in the Occupational Safety and Health Administration's (OSHA) [Bloodborne Pathogens regulation](#) (29 CFR § 1910.1030), available at, apply to work with human blood, tissue, organs, body fluids, and cell cultures. Special training, medical surveillance, procedures, and equipment that must be in place for protection against bloodborne pathogens, needle sticks, and other sharps injuries, are described in the ASU [Exposure Control Plan](#).

Handling and disposal of biohazardous waste is also regulated by OSHA under the OSHA Bloodborne Pathogens regulation and by state and federal statutes. The procedures for biohazardous waste handling are described in the ASU [Biological Waste Handling Procedures](#).

The requirements for packaging and shipment of biohazards are provided in the Department of Transportation's [hazardous materials regulation](#) 49 CFR § 171-180. In addition, permits may be required to ship biological materials. Please refer to the CDC [Etiological Agent Import Permit Program](#) and the Animal and Plant Health Inspection Service (APHIS) [permit program](#). Information on shipping procedures that comply with these regulations is found in the section on "Shipping and Transportation Methods and Requirements" in this manual.

Specific requirements for handling biological toxins are found in the BMBL and OSHA's [Occupational Exposure to Hazardous Chemicals in Laboratories](#), standard 29 CFR § 1910.1450. Information regarding ASU's radiation safety program is found in the ASU Radioactive Materials Manual.

Teaching and research activities involving the use of animals are regulated by the United States Department of Agriculture (USDA) [Animal Welfare Act](#). The Animal Welfare Act was signed into law in 1966. It is one of the laws in the United States that regulates the treatment of USDA-covered species in research, exhibition, transport, and by dealers. The USDA Animal Welfare Act covers all mammals used in research except rats of the genus *Rattus* and mice of the genus *Mus* that are bred for use in research. There are additional exceptions for agricultural research and teaching activities. In addition, the Institutional Animal Care and Use Committee (IACUC) oversees all research and teaching activities involving vertebrate animals.

The Animal Welfare Act has been amended six times (1970, 1976, 1985, 1990, 2002, and 2007) and may be found in United States Code of Federal Regulations (CFR), Title 7, Chapter 54, and Sections 2131 through 2159. The Act is promulgated and enforced by the USDA, Animal and Plant Health Inspection Service (APHIS), Animal Care (AC). Proposed rules are published in the Federal Register and are open for public comment.

The Public Health Service (PHS) [Policy](#) implements the [Health Research Extension Act of 1985](#), which applies to all institutions receiving animal research funds from PHS organizations (such as the National Institutes of Health). This law applies to all vertebrate species. The Health Research Extension Act of 1985 provides the legislative mandate for the PHS Policy. It directs the Secretary of Health and Human Services to establish guidelines for the proper care and treatment of animals used in research and for the organization and operation of animal care committees.

Institutions that receive PHS funds must have an Assurance on file at the Office of Laboratory Animal Welfare (OLAW). The Assurance is the university's statement to OLAW that they will abide by the PHS Policy. Animal care and use facilities must be built and operate in compliance with the recommendations of the Institute for Laboratory Animal Research (ILAR) published in the "Guide for the Care and Use of Laboratory Animals." Yearly reports by the institutions on the status of their animal care program are required.

ASU is accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International](#) (AAALACi). All of the institution's programs and facilities (including satellite facilities) for activities involving animals are evaluated and accredited by AAALACi. The animal care program, including its facilities, is also evaluated by the IACUC at least once every six months.

AAALACi is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary assessment and accreditation programs. AAALACi endorses the use of animals to advance medicine and science when no non-animal alternatives exist and when it is done in an ethical and humane way. When animals are used, AAALACi works with institutions and researchers to serve as a bridge between progress and animal well-being. This is accomplished through AAALACi's voluntary accreditation process in which research programs demonstrate that the institution is effective at setting, achieving, and maintaining high standards for animal care and use in science.

III. Roles and Responsibilities

The biological safety program at ASU developed from the University's commitment to address and comply with regulations and recommendations for biosafety, biosecurity, and the humane treatment of animals in research and teaching activities, as well as the health and safety of the staff, researchers, community, and environment. The Institutional Biosafety Committee and the EHS department provide oversight of ASU's biological safety program.

The Animal Care Program consists of the Institutional Animal Care and Use Committee, the Attending Veterinarian, Clinical Veterinarian, and the Department of Animal Care and Technologies (DACT). Together they assist the university in achieving its academic mission and commitment to public service by providing for the humane care and use of animals. This, in turn, enables research and training programs to achieve their goals, assuring compliance with applicable federal and state guidelines and regulations.

Roles and responsibilities for biosafety and biosecurity are included in this section.

A. Arizona State University

ASU has instituted and maintains a biosafety program for personnel who may be exposed to biological hazards (biohazards) during the performance of their duties. The biosafety program is designed to achieve regulatory compliance and to provide a means for employees to be informed about and protected from biohazards. To maintain regulatory compliance and to protect personnel from biohazards, Arizona State University must:

- Appoint a Biological Safety Officer for the institution.
- Ensure appropriate training is provided to personnel conducting research with biohazards or recombinant or synthetic nucleic acid materials.
- Ensure that research conforms to the provisions of the *NIH Guidelines*.
- Establish an Institutional Biosafety Committee and Institutional Animal Care and Use Committee with adequate expertise and training.
- Establish and maintain a health surveillance program for personnel.
- Implement policies for safe conduct of biological and recombinant or synthetic nucleic acid research.
- Report any significant problems, violations or significant research-related accidents or illnesses to the NIH Office of Biotechnology Activities within 30 days.

B. Institutional Animal Care and Use Committee

ASU's Institutional Animal Care and Use Committee (IACUC) is committed to providing an animal care and use program that provides a humane and compliant environment for animals and supports the research and teaching programs of our researchers, teachers, and students. Research and teaching involving the use of vertebrate animals conducted under the auspices of ASU is reviewed by the IACUC in compliance with federal regulations. Projects involving animal research require that project description and protocol details be submitted to the IACUC for approval prior to initiating any work. Additional duties regarding the IACUC are outlined in the [Policies and Procedures Manual](#). Principal investigators and all personnel involved in the care and use of research animals must obtain certification in the ASU's [Humane Practice of Animal Care and Use Training](#)

Program. In order to use animals at ASU, PIs must have an approved IACUC protocol, completed all requisite training, and received clearance from the ASU Occupational Health and Safety Program. These requirements must be fulfilled prior to the acquisition and use of laboratory animals.

C. Institutional Biosafety Committee

The committee is charged with review, approval and oversight of research involving recombinant or synthetic nucleic acid molecules and biohazards in research and teaching activities. Biohazards are microorganisms, microbial toxins, or other biological agents that can infect and/or cause disease in humans, animals, or plants. Biohazards may include bacteria, bacterial toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically-modified organisms, or r/sNA molecules. In addition, biohazards include human blood, body fluid, tissues, and cell lines of human origin. Biohazards are often referred to as infectious agents or etiological agents.

Responsibilities of the Institutional Biosafety Committee include assessment of facilities in collaboration with EHS, procedures, practices and training of research personnel to assure compliance with *NIH Guidelines* and other pertinent guidelines and regulations.

To successfully carry out these responsibilities, the Institutional Biosafety Committee is appointed to achieve sufficient knowledge and expertise in biomedical research and biosafety. The Institutional Biosafety Committee has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure compliance with applicable regulations and guidelines. For more information about the ASU Institutional Biosafety Committee, please visit <http://researchintegrity.asu.edu/biosafety/forms>.

D. Department of Animal Care and Technologies

Arizona State University and the Department of Animal Care and Technologies (DACT) provide facilities, staff, and established practices that reasonably ensure appropriate levels of environmental quality, safety, and animal care. Laboratory animal facilities are a special type of environment. As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with infectious agents *in vivo* and *in vitro* are comparable.

The DACT is responsible for managing and administering a centralized program of laboratory animal care and use that complies with all applicable standards and regulations for husbandry as set forth in the Animal Welfare Act, National Research Council Guide for the Care and Use of Laboratory Animals, and the Public Health Service policy on the Humane Care and Use of Laboratory Animals. These functions include daily animal husbandry and care, purchase of all live vertebrates, guidance of the University/Attending Veterinarian, provision of research services including surgical assistance and monitoring, and training of research and technical personnel.

However, the animal room can present some unique challenges. In the microbiological laboratory, hazardous conditions are caused by personnel or by the equipment being used. In the animal room, the activities of the animals themselves can present additional

hazards. Animals may generate aerosols, they may bite and scratch, and they may be infected with a zoonotic agent.

Federal rules require laboratory animal facilities, operational practices, and quality of animal care to meet applicable standards and regulations (e.g., [Guide for the Care and Use of Laboratory Animals](#), Animal Welfare Regulations and Standards, and the CDC/NIH document, [Biosafety in Microbiological and Biomedical Laboratories](#) and that appropriate species have been selected for animal experiments. In addition, ASU is required to have an Occupational Health Program. The publication of the Institute of Medicine, "[Occupational Health and Safety in the Care of Research Animals](#)," is a good resource.

Ideally, facilities for laboratory animals used in studies of infectious or noninfectious disease should be physically separate from other activities such as animal production, quarantine, and laboratories. Traffic flow that will minimize the risk of cross contamination should be considered in the plans.

E. Environmental Health and Safety/Biosafety Officer

The responsibilities of Environmental Health and Safety and the Biological Safety Officer include, but are not limited to, the following:

- Advise researchers on proper waste disposal methods based on federal and state regulations.
- Assist researchers in the development of plans for preventing and handling accidental spills and personnel contamination.
- Perform and review the required risk assessment to determine appropriate biosafety level and personal protective equipment (PPE) for handling recombinant and synthetic nucleic acid molecules or biohazards.
- Investigate laboratory accidents involving recombinant and synthetic nucleic acid molecules and biohazards.
- Develop, implement, and maintain the university's biosafety program to address issues of biosafety and biosecurity.
- Develop, implement, and maintain the university's program for select agents and toxins.
- Perform periodic inspections to ensure that laboratory standards are rigorously followed.
- Promote regulatory compliance and a safe laboratory environment.
- Provide advice on laboratory security.
- Provide oversight of the ASU Bloodborne Pathogen Program and conduct training for laboratory personnel with such exposure.
- Provide technical advice to principal investigators and the Institutional Biosafety Committee on research safety procedures.
- Provide training and resources for the safe use and practices for those working with potential biohazards, and laboratory equipment.
- Report to the Institutional Biosafety Committee and the institution any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware. The Biosafety Officer has the authority to immediately halt research that he/she deems to be an immediate threat to safety of personnel, environment, or the community

at large. The Biological Safety Officer must report such action to the Institutional Biosafety Committee immediately.

F. Health Services

The responsibilities of ASU Health Services include, but are not limited to, the following:

- ASU Health Services maintains a medical health surveillance program for individuals who are exposed to animals used for research or teaching purposes, and provides treatment for those with medical problems related to laboratory and/or animal exposures.
- The Medical Health Surveillance of Animal Care and Research Workers umbrella protocol outlines the components of the medical health surveillance program. Where known hazards (biologic or chemical) are introduced into areas where laboratory animals are housed or into the animals themselves, then specific additional personnel health or medical surveillance procedures beyond this basic program may be indicated to address hazards presented by the specific agent. Additional protocols have been developed for all ABSL-2 and ABSL-3 research.

G. Principal Investigator

A scientist, trained and knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazards must be responsible for the conduct of work with any biohazards or materials. This individual should consult with biosafety or other health and safety professionals with regard to risk assessment. Responsibilities of the principal investigator include:

- Accept direct responsibility for the health and safety of those working with animals, biohazardous materials and/or select agents and toxins.
- Adhere to approved emergency plans for handling accidental spills and personnel contamination.
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules, transgenic, or biohazards. This includes permits, material transfer agreements, and other documentation for international, interstate and intrastate transport of genetically modified and biohazardous material.
- Develop specific biosafety standard operating procedures for animals and biohazards used in the laboratory.
- Ensure compliance by laboratory personnel with relevant regulations, guidelines, and policies.
- Ensure all appropriate personal protective equipment is provided and used.
- Ensure proper training, including refresher training, and instruction for laboratory personnel in safe practices and protocols, including, at a minimum, training in aseptic techniques and characteristics of the material(s) used. Please refer to the ASU [Laboratory-Specific Biosafety Training Checklist](#). These signed documents must remain easily accessible in the laboratory at all times.
- Ensure the integrity of the safety equipment (e.g., biological safety cabinets), maintain biological containment (e.g., purity and genotypic and phenotypic characteristics), and ensure correct procedures or conditions are followed to

prevent a release of or exposure to recombinant or synthetic nucleic acid molecules and/or biohazards, select agents or toxins.

- Inform the laboratory staff of the Occupational Health and Safety Program, possible symptoms of illness relating to materials used, and provisions for any precautionary medical practices advised or required, e.g., vaccinations or serum collection.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Provide to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken. Instruct, train and supervise research personnel in:
 - Aseptic technique.
 - Laboratory practices and techniques required to ensure safety.
 - Procedures for dealing with spills or potential exposures to the agents described in the research.
 - Characteristics of the material(s) used.
 - Signs and symptoms biohazards.
 - NIH classification of work (if working with r/sNA molecules).
- Obtain Institutional Biosafety Committee approval prior to initiating or modifying any research involving use of recombinant or synthetic nucleic acid molecules and/or biohazards and maintain that approval through timely submission of annual reviews.
- Immediately report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety and any other university committees (e.g., Institutional Biosafety Committee, Institutional Review Board, Institutional Animal Care and Use Committee) that have reviewed and approved the research activity.
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed. Correct work errors and conditions that may result in accidents, injuries, or the release of biohazards.

Principal investigators are also responsible for full compliance with the *NIH Guidelines* during the conduct of recombinant or synthetic nucleic acid research.

- The PI will consult with the IBC to determine whether the recombinant or synthetic nucleic acid molecule research is subject to the *NIH Guidelines*.
- Develop specific biosafety standard operating procedures for recombinant or synthetic nucleic acid molecules or biohazards used in the laboratory.
- Obtain Institutional Biosafety Committee approval before initiating recombinant or synthetic nucleic acid molecule research subject to the *NIH Guidelines*.
- Make the initial risk assessment and determination of biological containment levels in accordance with the *NIH Guidelines* when registering research with the Institutional Biosafety Committee.
- Immediately report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the Biological Safety Officer, Greenhouse/Animal Facility Director, Institutional Biosafety Committee, NIH Office of Biotechnology Activities, and other authorities, as appropriate.

- Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the disclosure to the Institutional Biosafety Committee for review and approval or disapproval.

H. Laboratory Personnel

The responsibilities of animal care and laboratory personnel include but are not limited to the following:

- Participate in appropriate training and instruction to ensure that they are adequately trained and fully understand the instructions. This includes taking refresher courses as applicable.
- Fully comprehend all biohazards and select agents and toxins being used in the lab and the potential risks associated with exposure, as well as fully understanding the associated emergency response procedures.
- Follow all laboratory practices, protocols, and comply with all applicable policies, procedures, and guidelines.
- Complete any necessary medical surveillance.
- Obtain necessary and recommended vaccinations, or submit declination forms as permitted.
- Report thefts, security incidents, accidents, spills, or contamination incidents to supervisor.

I. Responsible Official

A Responsible Official (RO) is required under the Department of Health and Human Services (HHS) and USDA [Select Agent and Toxin regulations](#). This individual's responsibilities can be found in the applicable regulations. Although this list is not intended to be a complete list, critical responsibilities include:

- Develop and implement safety, security, and emergency response plans.
- Allow only approved individuals to have access to select agents or toxins.
- Provide appropriate training for safety, security and emergency response.
- Transfer select agents or toxins only to registered individuals.
- Provide immediate notice of any theft, loss, or release of a select agent or toxin.
- Provide proper laboratory facilities to contain and dispose of select agents and toxins.
- Maintain complete records relating to select agents as defined in 42 CFR 73.15.
- Report the identification of a select agent or toxin as a result of diagnosis, verification, or proficiency testing.
- Submit changes in the registration information by promptly notifying the CDC or Animal and Plant Health Inspection (APHIS)/USDA in writing. This includes modifications to the list of individuals that have been approved to work or access select agents, changes in work locations, and changes in protocols or objectives of the studies.
- Conduct regular inspections, at least annually, of the laboratory where select agents or toxins are stored or used to ensure compliance with all procedures and protocols of this safety plan. The results of these inspections must be documented and any deficiencies must be corrected and documented.

The RO and primary contacts for the Arizona State University Select Agent Program are listed below:

- David Gillum, Chief of Staff, EHS, RO
- Irene Mendoza, Associate Biosafety Officer, EHS, ARO
- Giorgio Scarpellini, Assistant Biosafety Officer, EHS, ARO
- Catherine Mancini, Biosafety Specialist, EHS, ARO

J. Other Organizations

Other committees, including the Institutional Review Board, Radiation Safety Committee, and the Department of Public Safety must consult and coordinate with the Institutional Biosafety Committee and EHS on any proposals under their purview which involve the use of biohazards.

K. Visitors, Vendors, and Contractors

Contractors must ensure that appropriate personal protective equipment is available for their own workers. All visitors, vendors, and contractors must:

- Comply with all security requirements and procedures.
- Be accompanied by a Department of Justice approved person at all times while in areas with select agents or toxins.
- Use personal protective equipment provided for them by the laboratory or animal handling room.

IV. Incident Reporting

A. Reportable Incidents and Violations

Incidents or problems involving biohazards and/or recombinant or synthetic nucleic acid molecules must be immediately reported to the Biological Safety Officer. Examples of reportable significant incidents include but are not limited to any overt exposure, such as a needle stick, splash, and contamination due to equipment failure, and any potential exposure to biohazards. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals.

It should be noted that waste from recombinant or synthetic nucleic acid molecule research is considered biohazardous and incidents involving improper disposal of recombinant or synthetic nucleic acid molecules must also be reported. Questions regarding reportable incidents should be directed to the Biological Safety Officer.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies. Violations may include but are not limited to conduct of new or ongoing research without appropriate federal or institutional registration, review, approval or oversight.

B. Principal Investigator Responsibilities

The principal investigator and their personnel must report any significant incident, violation of the *NIH Guidelines*, or any significant, research-related accidents and illnesses immediately by contacting the Biological Safety Officer. Examples of incidents and violations include:

- Overt exposures, which are defined as exposures that result in direct personnel exposure to biohazards such as injection, spills, splashes or aerosol inhalation.
- Potential exposures, which are defined as exposures that have a high risk of exposing personnel to biohazards such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Any exposure (overt or potential) in a BSL-3 laboratory.
- Overt or potential exposures in BSL-1 or BSL-2 laboratories.
- Any illness that may be caused by the agents used in the laboratory.
- Any incident involving the improper disposal of recombinant or synthetic nucleic acid molecules.

C. Biosafety Officer Responsibilities

The Biological Safety Officer is required, by the *NIH Guidelines*, to report to the Institutional Biosafety Committee:

- All violations of the *NIH Guidelines* and significant incidents.
- Any significant research-related accidents or illnesses.

D. Institutional Responsibilities

The Institutional Biosafety Committee is required, by the *NIH Guidelines*, to report to the appropriate University official and to the NIH Office of Biotechnology Activities within 30 days any significant incidents, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. The Institutional Biosafety Committee will be responsible to determine what actions, if any, are necessary. For example the Institutional Biosafety Committee may choose to change the frequency of lab inspections, or change the biosafety level of the disclosure, based on results of the incident. Other Institutional Biosafety Committee reporting requirements (to the NIH Office of Biotechnology Activities and other agencies) include but are not limited to:

- Research involving recombinant or synthetic nucleic acid molecules or biohazards without prior Institutional Biosafety Committee approval.
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Significant changes to proposed research risk without prior notification and approval by Institutional Biosafety Committee.

Some incidents must be reported to the NIH Office of Biotechnology Activities on an expedited basis. Spills or accidents in BSL-2 laboratories (involving recombinant or synthetic nucleic acid molecules) resulting in an overt exposure must be immediately reported to the NIH Office of Biotechnology Activities. In addition, spills or accidents involving recombinant or synthetic nucleic acid molecules occurring in high containment (BSL-3 or higher) laboratories resulting in an overt or potential exposure must be immediately reported to the NIH Office of Biotechnology Activities. The Institutional Biosafety Committee will report to the Institutional Official, who, in turn will direct the reporting process to the NIH Office of Biotechnology Activities, any of the above-described incidents.

Institutional violations that will be reported to the appropriate college or department head may include, but are not limited, to:

- Lapses in disclosure approval.
- Failure to comply with institutional and federal regulations, guidelines, and policies.
- Unsafe work practices.

E. Institutional Official Responsibilities

Upon receiving a report from the Institutional Biosafety Committee, the Institutional Official will directly report:

- In writing, any problems with or violations (non-compliance) of the *NIH Guidelines*, or any significant incident, accidents, or illnesses related to recombinant or synthetic nucleic acid molecules, to the NIH Office of Biotechnology Activities within 30 days or immediately for overt exposure to a BSL-2 agent or potential/overt exposure to a BSL-3 agent.
- Any significant research-related illness or accident that may be hazardous to the public health and cooperate with state and local public health departments.

V. Risk Group Classifications

According to the CDC/NIH document, Biosafety in Microbiological and Biomedical Laboratories, also known as the BMBL, the three primary hazardous characteristics associated with biological agents include:

- The capability of an agent to infect and cause disease in a susceptible human or animal host;
- The virulence of an agent as measured by the severity of disease; and
- The availability of preventive measures and effective treatments for the disease.

By taking the route of transmission of the disease into consideration, a standardized methodology was developed to classify biological agents into four different risk groups (see [Table 1](#)). Knowing the risk group of an agent assists researchers and safety professionals in determining the appropriate safety protocols to be followed.

Table 1. Risk Group (RG) Classifications			
RG-1	RG-2	RG-3	RG-4
Agents not associated with disease in healthy adult humans.	Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).

VI. Biological Safety Levels

CDC and NIH have established four levels of biosafety, based on the degree of hazard associated with a microbial agent, to describe the combination of laboratory practices and techniques, safety equipment, and facilities needed to protect against exposure (see [Appendix C](#) for more information). The BMBL outlines four different biological safety levels that are appropriate for the operations performed in a laboratory, the documented or suspected routes of transmission of the biological agent, and the laboratory function or activity. These four biosafety levels (BSL) require successively more stringent practices and facilities as work moves from the least restrictive, BSL-1, to work with the highest hazard level of BSL-4. Exposure to biohazards may be prevented or limited by establishing and following the appropriate biosafety level practices and conditions. The requirements for each laboratory biosafety level can be found in the CDC/NIH BMBL.

The following bullets provide a brief summary of the four biological safety levels:

- **BSL-1** is required 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-2** is required for work involving agents that pose moderate hazards to personnel and the environment.
- **BSL-3** is required for clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.
- **BSL-4** is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission. **Note:** No research with biohazards at BSL-4 is currently permitted in ASU facilities.

Personal protective equipment varies depending upon the biological safety level. Please refer to the table below for specific requirements for each of the four biological safety levels.

Table 2. Biological Safety - Personal Protective Equipment (PPE) Requirements*			
BSL-1	BSL-2	BSL-3	BSL-4
<ul style="list-style-type: none"> • Protective laboratory coats, gowns, or uniforms recommended preventing contamination of personal clothing. • Protective eyewear worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. • Personnel who wear contact lenses in laboratories should also wear eye protection. • Gloves must be worn to protect hands from exposure to hazardous materials. 	<ul style="list-style-type: none"> • Protective laboratory coats, gowns, smocks, or uniforms must be worn while working with hazardous materials. • Eye and face protection (goggles, mask, face shield or other splatter guard) must be used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms are handled outside the Biological Safety Cabinet (BSC) or physical containment device. • Personnel who wear contact lenses in laboratories should also wear eye protection. • Gloves must be worn to protect hands from exposure to hazardous materials. • Eye, face and respiratory protection should be used in rooms containing infected animals. 	<ul style="list-style-type: none"> • Protective laboratory clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls must be worn. • Eye and face protection (goggles, mask, face shield or other splash guard) must be used for anticipated splashes or sprays of infectious or other hazardous materials. [All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices.] • Personnel who wear contact lenses in laboratories must also wear eye protection. • Gloves must be worn to protect hands from exposure to hazardous materials. • Eye, face, and respiratory protection must be used in rooms containing infected animals. 	<ul style="list-style-type: none"> • Not permitted at ASU. • Please refer to the CDC/NIH document, "Biosafety in Microbiological and Biomedical Laboratories" for PPE requirements.

* Safety is improved when PPE is used in combination with physical containment devices or equipment, such as Biological Safety Cabinets (BSCs).

VII. Animal Biosafety Levels

Similar to the BSL, there are four animal biosafety levels (ABSL). These four animal biosafety levels are required for the use of experimentally infected animals housed in indoor research facilities (e.g., vivaria), and also in the maintenance of laboratory animals that may naturally harbor zoonotic infectious agents (see [Appendix D](#) for more information). **As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with infectious agents *in vivo* and *in vitro* are comparable with the animal biosafety level.**

The four animal biosafety levels provide increasing levels of protection to personnel and to the environment, and are recommended as minimal standards for activities involving infected laboratory animals. The four ABSLs describe animal facilities and practices applicable to work with animals infected with agents assigned to Biosafety Levels 1-4, respectively. **Investigators that are inexperienced in conducting these types of experiments should seek help in designing their experiments from individuals who are experienced in this special work.**

The following bullets provide a brief summary of the four biological safety levels:

- **ABSL-1** is required for work in animals involving well-characterized agents that are not known to cause disease in immunocompetent adult humans, and present minimal potential hazard to personnel and the environment.
- **ABSL-2** is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment, and also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.
- **ABSL-3** is required for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission, and agents causing serious or potentially lethal disease.
- **ABSL-4** is required for work with animals infected with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments; or a related agent with unknown risk of transmission. **Note:** No research with biohazards at BSL-4 is currently permitted in ASU facilities.

In addition to animal biosafety consideration, laboratory animal facilities, operational practices, and quality of animal care must meet applicable standards and regulations (e.g., [Guide for the Care and Use of Laboratory Animals and Laboratory Animal Welfare Regulations](#)) and that appropriate species have been selected for animal experiments. The USDA has also developed facility parameters and work practices for handling agents of agriculture significance.

Personal protective equipment varies depending upon the biological safety level. Please refer to the following table for specific requirements for each of the four biological safety levels.

Table 3. Animal Biological Safety - Personal Protective Equipment (PPE) Requirements*

ABSL-1	ABSL-2	ABSL-3	ABSL-4
<ul style="list-style-type: none"> • Protective laboratory coats, gowns, or uniforms recommended to prevent contamination of personal clothing. • Eye, face, and respiratory protection should be used in rooms containing infected animals. • Protective eyewear must be worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. • Personnel who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates. • Gloves must be worn to prevent skin contact with contaminated, infectious, and hazardous materials, and when handling animals. 	<ul style="list-style-type: none"> • Protective laboratory coats, gowns, or uniforms must be worn while in areas where infectious materials and/or animals are housed or manipulated. • Eye and face protection (mask, goggles, face shield or other splatter guard) must be worn when performing manipulations or activities that may result in splashes or sprays from infectious or other hazardous materials and when the animal or microorganisms must be handled outside the BSC or physical containment device. • Personnel who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates. • Gloves must be worn to prevent skin contact with contaminated, infectious and hazardous materials and when handling animals. • Eye, face, and respiratory protection should be used in rooms containing infected animals. 	<ul style="list-style-type: none"> • Disposable personal protective equipment, such as non-woven olefin cover-all suits, wrap-around or solid-front gowns, should be worn (over uniforms or scrub suits) before entering areas where infectious materials and/or animals are housed or manipulated. Front-button laboratory coats are unsuitable. • Eye, face, and respiratory protection must be used in rooms containing infectious materials and in areas where animals are housed or manipulated. [All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices.] • Personnel who wear contact lenses in laboratories must also wear eye protection. • Gloves must be worn to prevent skin contact with contaminated, infectious, and hazardous materials and when handling animals. Double-glove practices should be used. • Boots, shoe covers, or other protective footwear, are used to prevent cross-contamination. 	<ul style="list-style-type: none"> • Not permitted at ASU. • Please refer to the CDC/NIH document, "Biosafety in Microbiological and Biomedical Laboratories" for PPE requirements.

* Safety is improved when PPE is used in combination with physical containment devices or equipment, such as Biological Safety Cabinets (BSCs).

It is the responsibility of institutional management to provide facilities, staff, and established practices that reasonably ensure appropriate levels of environmental quality, safety, security and care for the laboratory animal. There are unique hazards associated with infected animals that must be understood by personnel with animal contact. Animal activity may create aerosols, and bites and scratches can occur.

VIII. Training for Working Safely with Biohazards

The principal investigator and/or laboratory supervisor is responsible for providing or arranging for site-specific training of all personnel. In addition, each employee must attend biosafety training and chemical safety training. Contact EHS or the Biological Safety Officer for more information on scheduling training. All training must be documented. Please refer to the ASU [Laboratory-Specific Training Checklist](#) for more information.

IX. Biohazardous Research Project Registration

Each principal investigator is responsible for the preparation of the Institutional Biosafety Committee disclosure for all research involving potentially biohazards, including the assignment of the required Biological Safety Level (BSL) to the proposed biological research. The Institutional Biosafety Committee, in conjunction with the Biological Safety Officer, will review all submitted registration documents; confirm, where applicable, that exempt status is appropriate for certain recombinant or synthetic nucleic acid work; and consider approval for those registration documents that are complete and that provide for safe handling of potentially biohazards under the appropriate biosafety level. Registration information can be found on the Institutional Biosafety Committee [website](#).

A. Select Agents and Toxins

Select agents are certain microorganisms and toxins specifically identified in federal [regulations](#). Select agents also include nucleic acids that encode for any select agent or toxin. Certain select agent toxins are not regulated as select toxins if the amount under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not exceed, at any time, the amounts indicated in the following table.

Table 4. List of Select Agent Toxins		
Select Agent Toxins	CAS #	Amount
Abrin	1393-62-0	1,000 mg
Botulinum neurotoxins	93384-43-1	1 mg
Diacetoxyscirpenol (DAS)	2270-40-8	10,000 mg
Ricin	96638-28-7	1,000 mg
Saxitoxin	35523-89-8	500 mg
Short, paralytic alpha conotoxins	76862-65-2 / 156467-85-5	100 mg
Staphylococcal enterotoxins (Subtypes A, B, C, D, and E)	11100-45-1	100 mg
T-2 toxin	21259-20-1	10,000 mg
Tetrodotoxin	4368-28-9	500 mg

The ASU Biosafety Manual, when used in combination with the **Laboratory-Specific Biosafety Manual**, is designed to meet the federal requirements of the Department of Health and Human Services (HHS) Standard, 42 CFR § 73, "[Possession, Use, and Transfer of Select Agents and Toxins; Final Rule](#)" and the Department of Agriculture (USDA) Standards, 7 CFR § 331 and 9 CFR § 121, "[Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule](#)."

B. Toxins of Biological Origin

Any biological toxin with a median lethal dose, or LD₅₀, of less than 100 micrograms per kilogram body weight in vertebrates, must be approved by the ASU [Institutional Biosafety Committee](#) prior to beginning research. Research with recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for

vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight requires pre-approval from the National Institutes of Health's Office of Biotechnology Activities. Examples of biological toxins with an LD₅₀ of less than 100 nanograms per kilogram include the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin.

C. Human Blood and Tissue

In any laboratory where work involves the use of and/or exposure to human blood, body fluids, or unfixed human tissue, including human cell cultures, there is the danger of exposure to bloodborne pathogens (disease-causing microorganisms) that may be found in such material. Research with material of human origin (e.g., blood, tissue, organs, cell lines) is regulated by the Occupational Safety and Health Administration. Work with this material must follow the ASU [Bloodborne Pathogens Exposure Control Plan](#). In addition, when human blood or tissue donors are involved, the principal investigator must contact ORIA to determine whether a human subject Institutional Review Board application is required.

D. Recombinant and Synthetic Nucleic Acid Molecules

The use of recombinant and synthetic nucleic acid molecules is regulated by the NIH, as outlined in the *NIH Guidelines*. At ASU this research must be reviewed by the Institutional Biosafety Committee prior to initiation of the work. Guidelines include registration of the recombinant or synthetic nucleic acid molecules, understanding the classification of the use of work, and safe work practices/proper disposal of material (including whole animals) containing recombinant or synthetic nucleic acid molecules. The use of more than 10 liters of organisms containing recombinant or synthetic nucleic acid requires special practices and IBC approval.

E. Environmental Samples

Environmental samples, such as water, air, soil, or plants, may contain pathogens (e.g., bacteria, viruses, spores) that could present a health hazard to people, animals, or the environment. Using appropriate personal protective equipment when collecting environmental samples will reduce exposure to potential pathogens and minimize transfer of pathogens in the environment. Use care when handling environmental samples, especially if the sample will be enhanced in the laboratory by culturing or other growing mechanisms, including greenhouses. Techniques used to enhance and/or culture environmental samples should be conducted at BSL-2 or higher levels in an appropriate containment device, such as a biological safety cabinet or fume hood. If the environmental sample is sterilized prior to experimentation, then the sample may be manipulated in a BSL-1 rated laboratory. All other environmental samples must be registered with the ASU [Institutional Biosafety Committee](#).

X. Controlled Substances

The Controlled Substances Act (Title II of the [Comprehensive Drug Abuse Prevention and Control Act of 1970](#)) places all substances regulated by federal law into one of five schedules or categories based on the medicinal value and the potential for abuse. The Drug Enforcement Administration (DEA), part of the U.S. Department of Justice, has control and enforcement authority for controlled substances. Many drugs used for medical treatment, anesthesia, analgesia, or euthanasia are considered controlled substances. In order to legally purchase, store, use, dispense, and dispose of these drugs a DEA license is required. Table 5 lists the five schedules of controlled substances.

Table 5. DEA Controlled Drug Schedule			
	Potential for Abuse	Medical Use	Examples
Schedule I	High	None	Heroin Hydromorphenol Marijuana Lysergic Acid Diethylamide
Schedule II	High	With restrictions	Fentanyl Methadone Oxymorphone Pentobarbital
Schedule III	Less than I or II	Currently accepted medical use	Euthanasia solutions Nalorphine Buprenorphine Ketamine Hydrochloride
Schedule IV	Low	Currently accepted medical use	Chloral Hydrate Phenobarbital Butorphanol
Schedule V	Lower than IV	Currently accepted medical use	Codeine

Investigators who use controlled substances in their laboratory must obtain a Researcher DEA license. As an ASU employee, the license is free. Information on how to apply for a Researcher DEA license as well as detailed instructions on how to complete the online application can be found within the “Investigator Resources” folder located on the DACT website.

The initial application is submitted on the DEA registration [website](#). Once the online application process has been completed, additional documents that need to be completed will be forwarded to the principal investigator (PI) by the DEA. Once the DEA has completed the application process, the DEA license will be mailed to the PI. The entire process takes approximately 4-6 weeks. The license must be renewed annually.

Once the PI secures a DEA license, they may procure controlled substances independently or through DACT. DACT has a Distributor DEA license and has been granted permission by the DEA to be able to purchase and transfer drugs from the Distributor’s license to the PI’s license. In order to obtain controlled substances through DACT, individuals must have a copy of the PI’s current DEA license on file. DACT will generate a transfer that will document the transfer of the

controlled substance from one DEA license to another. In order to order or obtain Schedule I or Schedule II drugs, a DEA 222 [form](#) is required.

All persons possessing controlled drugs must maintain specific records for a minimum period of 2 years per DEA requirements. Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other records maintained by the registrant. Information that must be on file and available for review includes:

1. **Inventory.** After an initial inventory is taken, a new inventory of all controlled substances on hand should be taken at least once every 2 years. Each inventory must contain the following information:
 - Date the inventory was taken.
 - A list of all unopened bottles by drug name, including the drug name, the number of bottles, the drug concentration or unit size (e.g., 100mg/ml or 50 mg tablets), and the amount of drug in the bottle (e.g., ml or tablets). For example: ketamine, 2 bottles, 100 mg/ml, 10 ml per bottle.
 - A list of all opened bottles and, for each bottle, the drug name, the drug concentration or unit size (e.g., 100 mg/ml or 50 mg tablets), and the amount of drug in the bottle before opening, (e.g., ml/bottle or tablets/bottle) and the remaining units. For example: ketamine, 100 mg/ml, originally 10 ml per bottle, 4.5 ml remaining.
2. **Transfer form or Controlled Drug Inventory form.** If you obtain controlled substances through DACT or transfer drugs from your inventory (e.g., for reverse distribution of expired drugs), you must maintain a copy of the Transfer Form.
3. **Controlled Substance Administration Record (CSAR).** When a controlled substance is administered to an animal, its usage must be documented. DACT can provide CSAR forms to PIs to use or the PI can generate their own tracking form. However, it is essential that all needed information is included. This includes license holder's name and DEA number, name of drug, drug schedule number, concentration, starting amount, and bottle ID, and bottle lot number. For each use from the bottle, the following needs to be recorded: date, name of user, amount used, amount remaining, and the initials of the person entering the information.

As per DEA regulations, expired or unused controlled substances must be disposed of via reverse distribution. DACT will reverse distribute expired or unused controlled substances at no cost to the PI.

XI. Biohazardous Waste

According to the State of Arizona, biohazardous waste is defined as:

- Any solid waste which is generated in the diagnosis, treatment, or immunization of a human being or animal or in any research relating to that diagnosis, treatment, or immunization, or in the production or testing of biological materials.
- Animal carcasses, body parts, and bedding of animals that have been infected with agents that produce, or may produce, human infection.
- Discarded cultures and stocks generated in the diagnosis, treatment, or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biological.
- Discarded products and materials containing blood or blood components.
- Discarded organs and body parts removed during surgery.
- Discarded sharps used in animal or human patient care, medical research, or clinical laboratories. Examples of sharps include hypodermic needles, syringes, pipettes, pipette tips, scalpel blades, blood vials, needles attached to tubing, broken and unbroken glassware, slides, and coverslips.

The National Institutes of Health's "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (NIH Guidelines) requires ASU to manage discarded preparations made from genetically altered living organisms and their products as biohazardous waste. For example, recombinant or synthetic nucleic acid waste materials used in research laboratories is considered biohazardous waste. All waste containing recombinant or synthetic nucleic acid molecules must be inactivated prior to disposal.

XII. Animal Waste

Wastes unique to the animal facility include animal bedding and animal carcasses. These are generated along with the sharps and other biologically contaminated equipment that typically need to be discarded in all laboratories. All animal waste must be treated prior to disposal, unless an alternate disposal method has been pre-approved by EHS.

- **Soiled animal bedding** is placed by the animal care staff in sturdy plastic bags, sealed, and transferred to carts for movement from the facility. Bags of soiled bedding should be limited to 40 pounds to prevent back and shoulder injury during subsequent handling. Animal care staff members are responsible for movement of the bedding carts to the holding area outside the building. Building Services personnel remove the bagged bedding from the holding area in vehicles specially designed and intended for handling bedding waste.
- **Animal carcasses** are bagged, sealed, and stored in freezers located in each animal facility until pick up by the vendor for incineration.
- All **sharps** are disposed of in sharps containers, which, when full, are placed in the red barrels for biological waste when in an animal facility. All other biologically contaminated material is also placed in the red barrels. When the red barrel is full, it is the responsibility of the laboratory staff to contact EHS for pick-up.

XIII. Biohazardous Waste Handling

Wastes associated with biological research materials must be disposed of in special ways. Examples of potentially hazardous items include:

- All sharps (e.g., glass implements, needles, syringes, blades, coming from facilities using infectious materials).
- Agents of any biosafety level containing recombinant or synthetic nucleic acid molecules.
- Animal bedding and animal carcasses.
- Biologically cultured stocks and plates.
- Genetically modified or transgenic plants and animals.
- Human or animal blood, tissues, organs, and cell lines.
- Environmental samples (e.g., soil, water, plants, sewer).
- Archaeological samples (e.g., bones, clothing fragments, containers).
- Any other regulated biohazardous material.

In order for EHS to remove biological waste, the following procedures must be followed:

- Biological wastes derived from human and animal sources (e.g., blood, body fluids, tissues, tumors, human cell lines) are hazardous biological wastes and should be placed in a red or orange biohazard bag. Autoclave the bag under appropriate time and temperature and place it in a red drum for removal by hazardous waste personnel.
- Non-human biological wastes are handled by the same methods as human biological wastes: placed in autoclave bags, autoclaved, and put into red drums for removal by hazardous waste personnel.
- BSL-1 materials containing recombinant or synthetic nucleic acid must be autoclaved or it must be destroyed with bleach (approval must be received from EHS prior to drain disposal).
- Bacteria, viruses, or other microorganisms that are known human pathogens should also be put into a red biohazard bag, autoclaved, and placed in a red drum for removal by hazardous waste personnel.
- Sharps and sharp objects such as glass, syringes, disposable pipettes, and pipette tips that may be contaminated with biohazards (human or non-human) must be placed in a rigid, leak-proof, puncture-resistant container. The container is autoclaved and then placed in a red drum for removal by hazardous waste personnel. **Note:** Needles and other medical sharps must be collected in sharps containers.
- Other wastes, including waste from genetically modified plants and animals, as well as environmental and archaeological samples, are considered biohazardous waste. These wastes should either be chemically inactivated or autoclaved, and placed in a red biohazard bag. Autoclave the bag using appropriate time and temperature and place it in a biohazard drum for removal by hazardous waste personnel.

When a “red-bag,” “yellow drum,” or liquid hazardous waste is ready for removal, call EHS Environmental Affairs to arrange a pick-up, or submit a [hazardous waste pick-up request](#). If you need any other assistance or have questions, please feel free to contact Environmental Health and Safety at 480-965-1823.

XIV. Laboratory Procedures and Equipment

A. Exposure Control

The term “containment” is used in describing safe methods for managing biohazardous and select agents and toxins in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other people, and the outside environment to potentially hazardous agents. The three elements of containment include laboratory practices and techniques, safety equipment, and facility design. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements. Each principal investigator is required to complete a “Health Hazard Assessment” for each biological agent and toxin stored in his or her laboratory. Copies of the Health Hazard Assessments must be included in the principal investigator’s Laboratory-Specific Biosafety Manual.

1. Laboratory Practice and Technique

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or infected materials must be aware of potential hazards and must be trained and proficient in the practices and techniques required for handling such material safely. The principal investigator of each laboratory is responsible for providing or arranging the appropriate training of personnel and for verifying each person’s competence. In addition, each principal investigator must develop a Laboratory-Specific Biosafety Manual to address the use, handling, and disposal of biohazardous material (including select agents and toxins) in the laboratory.

The Laboratory-Specific Biosafety Manual must identify specific hazards that will or may be encountered and consider procedures needed to minimize or eliminate risks. Personnel should be advised of special hazards and are expected to follow the required practices and procedures.

2. Safety Equipment (Primary Barriers)

Safety equipment includes biological safety cabinets, enclosed biohazardous containers, and other engineering controls designed to eliminate or minimize exposures to biohazards and toxins. The biological safety cabinet is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. More information on biological safety cabinet may be found in the “Biological Safety Cabinet” section of this manual.

Primary safety barriers may also include personal protection equipment (PPE) such as gloves, lab coats, safety glasses or goggles, face shields and respirators. Personal protective equipment is often used in combination with biological safety cabinet and other containment devices. In some situations in which it is impractical to work in a biological safety cabinet, personal protective equipment may form the primary barrier between the worker and the infectious materials.

ASU policy requires the use of gloves, lab coat, and eye protection at all times when handling biohazards.

3. Facility Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect those working inside and outside the laboratory and to protect people, plants, or animals in the community from biohazards and toxins which may be accidentally released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agent being manipulated.

The secondary barriers required will depend on the risk of transmission of specific agents. For example, in working with agents at Biosafety Level 2 (BSL-2), the exposure risks involve direct contact with the agents or inadvertent contact through contaminated work environments. Recommended secondary barriers in these laboratories include separation of the laboratory work area from public access, hand washing facilities, and availability of a decontamination facility such as an autoclave.

When the risk of infection by exposure to an infectious aerosol is present, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features include specialized ventilation systems to ensure directional airflow, HEPA filtration to remove agents from exhaust air, controlled access zones, airlocks as laboratory entrances, or separate modules to isolate the laboratory.

B. Biological Safety Cabinets (BSC)

Biological safety cabinets are classified as Class I, Class II, or Class III cabinets. When properly maintained and operated, they effectively contain and capture microbial contaminants and infectious agents using HEPA (High Efficiency Particulate Air) filters (See Figure 1. Source: Biosafety in Microbiological and Biomedical Laboratories 5th Edition, [Appendix A](#)). Biosafety cabinets should not be confused with clean benches which only protect the material being worked with and are not suitable for work with infectious or toxic material. (Although clean benches, like biological safety cabinets, have HEPA-filtered air, in clean benches the air flows over the experimental material toward the user rather than being drawn away.) Biological safety cabinets should also not be confused with conventional fume hoods that do not filter microorganisms.

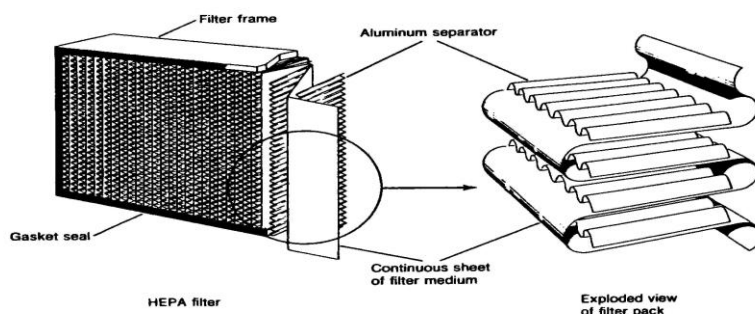
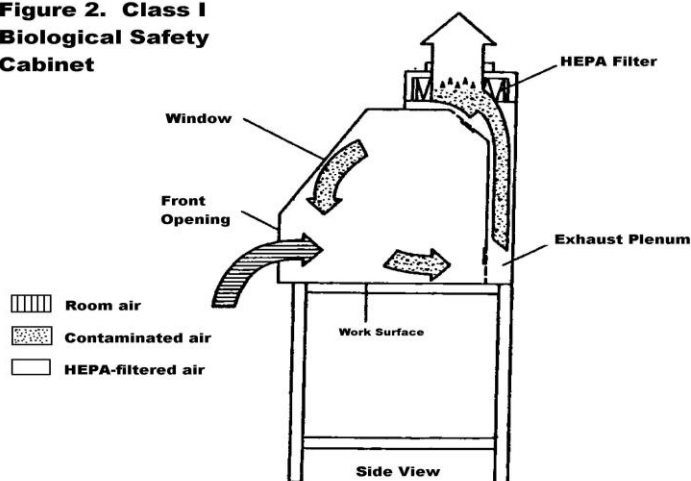


Figure 1. Diagram of HEPA filter. These filters are typically constructed of continuous sheets of paper-thin filter medium, pleated to increase surface area, divided by aluminum separators, and affixed to a frame.

1. Class I Biological Safety Cabinets

Class I biological safety cabinets provide personnel and environmental protection, but not product protection (See Figure 2. Source: Biosafety in Microbiological and Biomedical Laboratories 5th Edition, [Appendix A](#)).

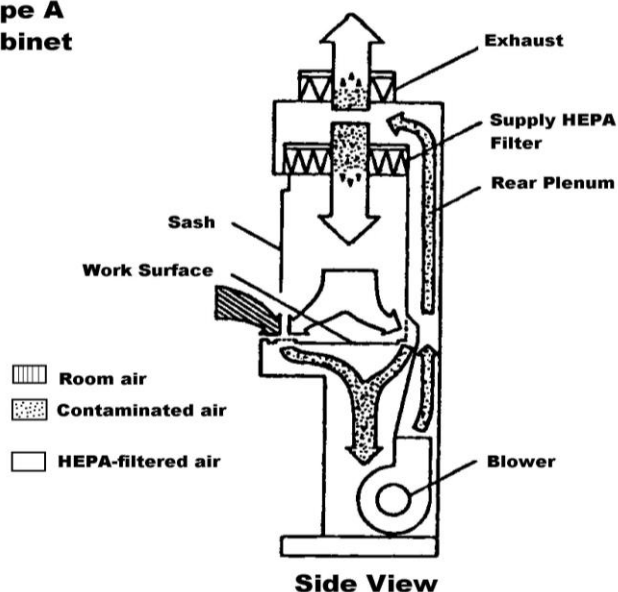
Figure 2. Class I Biological Safety Cabinet



2. Class II Biological Safety Cabinets

Class II biological safety cabinets are the most commonly used biological safety cabinet at ASU for biohazards. These cabinets provide personnel, environmental, and product protection (See Figure 3. Source: Biosafety in Microbiological and Biomedical Laboratories 5th Edition, [Appendix A](#)). Only those which are hard ducted to the outside and provide a face velocity of 80 to 125 feet per minute should be used when working with volatile chemicals. Additionally, cabinets are not designed to prevent ignition of volatile flammable chemicals, such as ethanol and isopropanol.

Figure 3. Class II, Type A Biological Safety Cabinet



C. Guidelines for Working in a Biological Safety Cabinet

1. Turn off the ultraviolet lamp if one is in use. Turn on the fluorescent lamp.
2. Make sure the biological safety cabinet is certified.
3. Inspect the air intake grilles for obstructions and foreign material and remove if necessary.
4. Turn the cabinet on for at least 10 minutes prior to use, if the cabinet is not left running.
5. Don appropriate PPE. Put on a rear-fastening, long-sleeved gown with tight-fitting cuffs. Put on safety glasses and a pair (or two pairs) of high quality nitrile gloves.
6. Disinfect work surface with an appropriate EPA registered disinfectant.
7. Place items into the BSC, at least 6 inches from the front grill and approximately 2-4 inches from the rear grill, without unnecessary disruption of the airflow.
8. Items used for surface decontamination and cleanup of a small spill should be included inside the BSC. Ensure there are biohazard waste containers directly outside of the BSC, but not attached to the unit as it can disrupt airflow.
9. Adjust the working height of the stool so that the worker's face is above the front opening.
10. Employ good microbiological practices; work with materials from the clean to the dirty side.
11. Minimize the movement (e.g., sweeping) of arms and reduce the frequency of placing hands/arms into the BSC and taking them out.
12. Wipe the bottom and side surfaces with disinfectant when work is completed.

NOTE: Be very careful when using small pieces of materials such as paper tissues in the hood. These can be blown into the hood and disrupt the motor operations.

D. Certification of the Biological Safety Cabinet

Biological safety cabinets provide a partial containment system for the safe handling of pathogenic microorganisms, environmental samples, and other biohazardous materials. To ensure safety, biological safety cabinets must be used correctly with good microbiological techniques and be in proper mechanical working order. Cabinets must be certified for performance upon installation using National Sanitation Foundation (NSF) Standard #49. Certification is a series of performance tests on the biological safety cabinet to confirm that it will provide the user and experimental material the protection for which it is designed. The airflow, filters, and cabinet integrity are checked to ensure that the cabinet meets minimum performance standards. A list of vendors who provide certification is maintained by EHS Biosafety.

Biological safety cabinets intended for research with biohazards must be certified:

- After they are received and installed (before use with infectious materials).
- After filter changes.
- After being moved (even a few feet).
- After a mechanical failure.
- **Annually.**

Biological safety cabinet decontamination (using formaldehyde gas, chloride dioxide gas, or other approved method) may be provided (e.g., by an outside vendor) and needs to be done:

- Before any maintenance work requiring disassembly of the air plenum, including filter replacement.
- Prior to cabinet recertification.
- Before moving the cabinet to a new laboratory.
- Before discarding or salvaging.

The production of formaldehyde gas is a health concern. Many biological safety cabinets at ASU are not ducted to the outside; therefore, consideration of a temporary “cease work” order may be implemented and extreme caution must be used when having the procedure performed.

XV. Animal Hazards and Exposures

Good housekeeping practices and sanitation are essential to reducing the risk of physical hazard injuries. It is important to keep work surfaces clean and clear of obstructions, waste, and other materials. All boxes, hoses, or bags of bedding material should be routinely removed from the work area. Mop floors and clean work surfaces with the appropriate cleaning and disinfectant solutions. Keep in mind that poor housekeeping is unprofessional and will increase the risk of accidents and injuries.

A. Bites and Scratches

The risk of animal bites and scratches is associated with handling of animals and is best avoided by proper handling techniques and wearing appropriate personal protective equipment (PPE). Knowledge of animal behavior and how animals respond to their immediate physical environment is important in reducing risk of injury to the individual and the animal.

Animals respond to sights, sounds, and smells as people do, but they also may hear, smell, and react to things that people do not detect. For example, if an animal hears a high-pitched sound, it may become frightened and react defensively. Many animals have a flight zone, and, if approached by another animal or the handler, the affected animal may try to escape. Unsuccessful escape may cause the animal to act aggressively. Of course, inappropriate handling of an animal can cause discomfort, pain, and distress and provoke an animal to bite or scratch.

Animal bites and scratches that cause minor skin damage are sometimes disregarded by animal workers who are unfamiliar with the number of diseases that can be spread by such injuries. Even minor bites and/or scratches can result in infections and illnesses if they are not properly treated. Scrapes and injuries from **contaminated equipment** associated with animal care and housing, such as cages, can be as great a risk as direct animal contact and should be addressed similarly.

Most animals used in research are bred specifically for that purpose and do not have the potential for transmitting the kinds of pathogenic organisms that those in the wild do; however, there are some illnesses and infections that can be passed from animals to people (i.e., zoonoses), and these are discussed in more detail later in this document.

With research animals, biological hazards are of most concern when the animals are naturally infected (e.g., macaques may have Simian Herpes B virus) or if animals are infected with a bacteria, virus or human cells (e.g., tumorigenic cell lines) as part of the experimental work. Under these conditions and when doing field research with wild species, it is of critical importance that appropriate PPE and other appropriate protective measures be used to prevent infection.

The most important step to prevent infection following any bite, scratch (or puncture from sharps exposure) is to immediately and thoroughly wash the injury with soap and water. Inform a supervisor and record the injury in the bite and scratch log located in the animal facility. Contact ASU Health Services for medical consultation or treatment. Incidents and injuries involving non-human primates (NHPs) must follow the

NHP Bite/Scratch standard operating procedures (SOP). In addition, everyone working with NHPs must attend the mandatory annual B-virus training conducted by DACT and ASU Health Services.

B. Physical Hazards

Sharps such as needles, broken glass, syringes, pipettes, and scalpels are all commonly found in animal facilities and laboratories and present a physical hazard. Use extra care to avoid inadvertent contact and injury. **Needlestick injuries** represent substantial risk of becoming infected especially when injecting animals with microbial agents or drawing blood.

The animal facility should have puncture-resistant and leak-proof containers for disposal of sharps. To prevent needle sticks, it is critical to **always place used needles directly into the sharps container without recapping or attempting to bend, shear, break, or remove the needle from the syringe.**

Animal care operations involve a number of activities that can cause physical stress when handling and moving heavy loads. The use of proper lifting techniques can help prevent back and shoulder injuries when moving cages, bags of feed and bedding, pieces of equipment, and supplies. Poor physical fitness, obesity, poor posture, smoking, and medical/physical deficiencies are personal factors that may contribute to back pain. When lifting heavy loads, every attempt should be made to avoid sudden movements and use a two-handed lifting technique. Keep your back straight, feet positioned apart with one slightly ahead of the other, and knees bent as the lift is completed. Reduce loads where possible and get help when lifting awkward loads or those that cannot be handled safely by one person.

C. Chemical Hazards

Personnel involved in the care and use of research animals must be familiar with the **chemical hazards** associated with the animal care and laboratory environment. Chemical properties may include flammability, corrosiveness, reactivity, or the potential to be explosive. Potentially hazardous chemicals used in animal laboratories include **solvents** (e.g., xylene, acetone, dimethyl sulfoxide), **acids** (hydrochloric, sulfuric), **bases** (e.g., sodium hydroxide, quaternary disinfectants), **fixatives** (e.g., formaldehyde, osmium tetroxide), **sterilants** (e.g., peracetic acid, chlorine dioxide, peroxides, glutaraldehyde), and **anesthetics** (e.g., isoflurane, tribromoethanol, methane sulfonate, nitrous oxide, urethane, barbiturates). Each chemical product should be handled carefully using the label directions and recommended PPE in accordance with University guidelines and lab training. Safety Data Sheets (SDS) are also available in each animal facility. These provide additional information on the hazards and precautions related to a chemical's use. Users must be certain that they understand the proper use of the chemical material before they use it.

D. Animal Allergies

Allergic reaction to animals is among the most common conditions that adversely affects worker health. The estimated prevalence of allergic symptoms among workers exposed to animals is from 10% to 40%. Workers who are continually exposed to animal allergens tend to have progressively more frequent and severe symptoms, and an estimated 10% develop **asthma**. Hence, it is critical that all workers seek to minimize their exposure to animal allergens. Additionally, once animal allergy develops, the affected worker should minimize any additional allergen exposure to prevent progression of allergy symptoms.

Allergy is most often manifested by **nasal symptoms** (e.g., allergic rhinitis), **itchy eyes** (e.g., allergic conjunctivitis), and **rashes** (e.g., contact urticaria, atopy). Symptoms usually evolve over a period of 1-2 years and may lead to acute anaphylaxis in a small number of patients. In **rodents**, the allergen protein is of urinary origin and in **rabbits** it is contained in the fur, dander, and, to a lesser degree, the saliva and urine. In **Guinea pigs**, urine is the main allergen with dander, fur, and saliva contributing. Exposure to **birds** can cause rhinitis and asthma symptoms. Multiple bird proteins have been identified as allergens and can be found in serum and fecal droppings that contain serum. **Fish** proteins can be an inhalation allergen for those who are sensitized.

Prudent efforts to prevent allergen exposure and reduce the frequency of sensitization in animal workers require strict work practices and consistent use of PPE. Housing animals in filter-top cages, working in well-ventilated areas, and using ventilated hoods for soiled bedding disposal will minimize exposure to animal allergens.

The work area must be maintained clean to prevent inhalant and contact exposure. Procedures should be adopted that minimize release of airborne materials, including bedding dust and antibiotic aerosols, and the contamination of hands, arms, body, and face. Workers should adopt the use of PPE during each and every animal contact or allergen exposure. Wearing PPE “just some of the time” will not prevent exposure. Of particular importance is wearing a facemask to reduce inhalation and hand-to-face spread of allergens and covering all exposed skin (e.g., gloves, lab coat, sleeve protectors, and hair cover) to prevent allergen contact.

It is also important that once animal procedures are complete, all contaminated PPE and clothing are removed and properly disposed of to prevent repeated exposure while performing subsequent duties. Supervisors or EHS can provide further information and access to approved PPE devices.

E. Latex Gloves and Related Allergies

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

In June 1997, the National Institute of Occupational Safety and Health (NIOSH) issued an alert, "[Preventing Allergic Reactions to Latex in the Workplace](#)" (publication number DHHS (NIOSH) 97-135).

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

NIOSH recommends the following actions to reduce exposure to latex:

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

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

XVI. Zoonoses

Zoonoses are diseases that can be transmitted between species (in some instances, by a vector) from animals to humans or from humans to animals (the latter is sometimes called reverse zoonosis or anthroponosis). They may be a significant exposure hazard in some laboratories where animals are used for research. Fortunately, many laboratory animal species today are bred to be free of zoonoses that were once more common in these animals. However, there remain zoonotic agents associated with laboratory animals, some which can be life-threatening. Field research with wild species also remains a clear source of zoonoses exposure. Prevention of exposure to these animal-related illnesses requires knowledge of the zoonoses related to the animals involved. In the sections that follow, the zoonotic agents listed for each animal species are those that may be present in the animals being used. If someone is exposed through bite, scratch, aerosol droplet, mucosal secretion, feces, or urine, there is the potential for infection, so medical consultation through ASU Health Services is highly recommended.

A. Laboratory Mice

Modern laboratory mice are bred to exclude all zoonotic agents. Also, mice received at ASU from foreign countries have been tested during quarantine for a large number of infectious and zoonotic agents. Therefore, unless the laboratory mice are infected as part of the research procedures or exposed to wild mice (those coming from the natural habitat outside the laboratory), there is limited concern for disease from these research mice. However, there is always concern about secondary infections that can occur with bites and scratches. Common skin, intestinal, and soil bacteria present on a person or an animal can infect the scratch or bite wound and cause these secondary infections. Therefore, users should handle all mice with care and always cleanse any wound immediately with soap and water or antiseptic and seek medical consultation at ASU Health Services for broken skin.

B. Wild Rodents

Wild rodents or laboratory rodents that have been exposed to wild rodents have the potential of carrying a variety of zoonotic bacteria and viruses that can be passed on to workers handling them. Tests should always be completed on wild rodents and those coming from foreign countries when they are received at ASU to screen for these zoonotic agents. Although this provides reasonable assurance that rodents will be free of zoonotic infections, the screening does not guarantee infection-free rodents. Therefore, because of the serious consequences of becoming infected, investigators must always follow good personal hygiene and animal handling procedures and use the provided PPE to protect from exposure. Rodents that have originated from the wild, have had contact with wild rodents, or are from foreign countries could be infected with one or more of the pathogens and should be considered ABSL-2.

1. Hantavirus

Hantavirus is transmitted through inhalation of dried rodent feces and urine when such material is raised into the air from disturbed feces, bedding, or nesting material. Transmission can also occur through rodent bites and contamination of broken skin or mucous membranes. The infection progresses from flu-like

symptoms to respiratory complications and has resulted in death in over 50% of clinical cases, particularly when medical care was not quickly obtained. It is possible to prevent exposure through the use of PPE, good personal hygiene, and properly ventilated handling of waste bedding material.

2. Lymphocytic Choriomeningitis (LCM) Virus

LCM virus is transmitted to humans by inhalation, broken skin, or mucous membrane exposure to blood, urine, feces, and other body secretions from infected mice. The infection results in flu-like symptoms 1 to 3 weeks after exposure. More severe symptoms of meningitis and encephalitis can result. There is a special risk of exposure during pregnancy because the fetus can become infected. Because mice are well screened and provided from virus-free sources, the potential for exposure in ASU animal facilities is very limited. Again, use of proper PPE, such as disposable gloves and lab coat, along with careful hand washing will further reduce the likelihood of exposure. In addition, DACT conducts tests for LCM in laboratory bred mice and rats to ensure these animals remain free of the virus.

C. Laboratory Rats

Modern laboratory rats are bred to exclude all zoonotic agents. Therefore, unless the laboratory rats are experimentally inoculated, cross-contaminated, or exposed to wild rodents (those coming from the natural habitat outside the laboratory), there is limited concern for disease from these research rats. However, there is always concern about secondary infections that can occur with bites and scratches. Common skin, intestinal, and soil bacteria present on you or the animal can infect the scratch or bite wound and cause these secondary infections. Therefore, personnel should handle all rats with care, always cleanse any wound immediately with soap and water or antiseptic, and seek medical consultation for severe wounds.

Historically, rats have been known to carry the bacterium that causes Rat-Bite Fever. However, these bacteria have not been found in laboratory rats for decades due to the special efforts of commercial suppliers to eliminate these bacteria from breeding colonies.

D. Laboratory Rabbits

Modern laboratory rabbits contain few infectious pathogens. Of concern are scratches that can be inflicted with their strong hind legs and sharp claws or from bites. Secondary infection with common skin, intestinal, and soil bacteria present on personnel or the animal can result, so personnel should always cleanse wounds immediately with soap and water or antiseptic and seek medical consultation for severe wounds.

Historically, laboratory rabbits have been known to harbor the bacteria for human Tularemia (Rabbit Fever). Although this zoonotic agent remains present in wild rabbit populations, modern laboratory rabbits are free of this bacterium.

E. Birds

The birds used in research colonies are either caught in the wild or acquired from established flocks. In general, birds are not supplied disease-free and usually contain a number of microbial agents including *Mycobacterium avium*. Of zoonotic concern are the diarrheal bacteria such as *Salmonella* and the bacteria that cause psittacosis, which can cause a more severe type of infection.

1. *Salmonella*

Salmonella bacteria is a common contaminant of fecal droppings and eggs. When ingested by humans, this bacterium has the potential for causing severe intestinal disease. Use of good personal hygiene measures including effective and thorough hand washing along with the proper PPE, such as disposable gloves and lab coat, will greatly reduce the likelihood of infection when handling birds and materials in their environment.

2. Psittacosis

The bacterium *Chlamydia psittaci* is the cause of psittacosis, and it is found most widely in large, imported psittacine birds (e.g., parrots, parakeets, cockatoos, and macaws). Human infection is most often the result of exposure to these imported birds. The risk of exposure from domestic birds is very low.

However, because this bacterium is highly infectious, there is some potential that any bird or mammal may be infected. Acute infection in animals causes such symptoms as reddening of the eyes (conjunctivitis), difficulty breathing (pneumonia), swollen painful joints (arthritis), and reproductive problems. After the acute infection, those animals that survive enter a period without symptoms during which stress can cause the animal to shed the bacterium. Stress can result from such things as the importation process or birds being handled in their new environment. Humans can be infected when coming in contact with the bird's body secretions or feces. In humans, the symptoms include fever, headache, muscle pain, and chills, and may progress to pneumonia as well as liver, heart, and brain inflammation.

USDA regulations require that testing be performed on all psittacine birds imported from foreign countries during an initial 60-day quarantine period. There were no psittacine birds from foreign countries at ASU at the time this document was developed or updated. However, in the event that ASU acquires psittacine birds from a foreign country, they would be quarantined in specially ventilated rooms while testing is done and infected birds would be eliminated from the colony. The use of protective equipment and thorough hand washing would reduce the risk of any potential exposure.

F. Fish and Amphibians

Fish and amphibians used in research colonies are mostly wild-caught or raised on commercial farms. These animals often contain parasites and bacteria. Of zoonotic

concern are gram-negative bacteria that cause secondary infection of contaminated wounds and breaks in the skin. These bacteria include *Aeromonas*, *Pseudomonas*, *Klebsiella*, and *Mycobacteria*. Use of proper PPE, such as disposable gloves, will help prevent contamination of skin surfaces. Likewise, thorough hand washing is very important to further reduce potential for infection.

G. Non-Human Primates (NHP)

A number of potentially serious zoonoses are associated with non-human primates. In addition, the strength and unpredictability of non-human primates pose dangers to those handling them. It is critical that work with non-human primates be done while wearing the appropriate personal protective equipment and following the well-established, safe protocols and procedures.

1. Simian B Virus

Simian (Monkey) B Virus is a herpes virus of Old World macaque monkeys. Common macaque monkeys used at ASU include cynomolgus (*Macaca fascicularis*) and rhesus (*Macaca mulatta*) monkeys. However, all macaques are capable of transmitting the virus. In non-human primates, this virus causes symptoms similar to human cold sore virus, which includes mouth ulcers during acute infection and long periods of inactivity. Viral activity in the monkey commonly occurs with stress or other disease/conditions; otherwise, they appear completely healthy while shedding large amounts of active virus in the saliva.

When humans are infected, the virus produces flu-like symptoms that can lead to death within 3-14 days. Therefore, it is critical to be familiar with and follow all the established practices and procedures before beginning work with non-human primates. The virus will survive on contaminated equipment and a few human cases have been documented after workers were scratched by soiled equipment. Fortunately, the virus is susceptible to killing with bleach solutions and other disinfectants used in the animal facility.

All macaques housed at ASU come from sources that provide animals seronegative for the virus. In addition, Arizona law requires that macaques must have negative serology for Herpes Simian B virus within 30 days of entry into the state. Because Herpes Simian B virus is highly fatal in humans if they become infected, all macaques are treated as being potentially infected with the virus should an exposure occur.

ASU Health Services and DACT have developed a comprehensive program for non-human primate workers at ASU that includes the designation of PPE required for each functional area where non-human primates and potentially-contaminated equipment are handled and detailed procedures for medical response and follow-up for injuries associated with non-human primate care and use.

2. Tuberculosis

Tuberculosis (TB) is caused by bacteria that can be given to and acquired from non-human primates. Tuberculosis is transmitted via water droplets in the air from infected non-human primates and humans. Humans can contract the disease by unprotected exposure to infectious droplets generated by the handling of dirty bedding, the use of high-pressure water sprayers, the coughing of animals with respiratory disease, or contaminated feces of animals with intestinal disease. Likewise, ASU's resident non-human primate colony is susceptible to human tuberculosis that can be transmitted from infected workers.

The prevention and control measures in place involve bi-annual TB testing of each nonhuman primate and the use of PPE that includes respiratory protection. All humans that work with non-human primates are tested by ASU Health Services annually for TB. Required PPE for working with non-human primates is listed on postings located in each of the areas of non-human primate activity. It is very important that employees understand and follow these posted requirements.

3. Measles

Healthy non-human primates are susceptible to measles from exposure to humans who are shedding the measles virus. The infection in non-human primates is severe and produces rash, fever, malaise, and progressive respiratory distress. There is a vaccine available for use in non-human primates. However, all non-human primate populations should be considered susceptible until proven otherwise. At ASU, all personnel who have contact with NHPs are required to have adequate vaccinations (measles, mumps, rubella [MMR]). There are currently no reliable diagnostic tests to indicate measles infection in non-human primates.

XVII. Emergency Response Procedures

ASU has a campus-wide emergency response plan, the ASU Emergency Operations Plan, which is compliant with 29 CFR 1910.120. Protocols for handling biological emergencies are outlined in the plan. A summary of this plan can be found by reviewing the ASU [Emergency Procedures Flipchart](#) or the ASU Police Department [Policies and Procedures Manual](#).

Principal investigators must be aware of the provisions for emergency procedures and preparedness. Emergency procedures and preparedness must be incorporated into the Laboratory-Specific Biosafety Manual and used in the laboratory. Each laboratory should have a written emergency plan specifying the appropriate response to potential emergencies. Accidents and spills of infectious materials will be discussed in Emergency Procedures below. In addition, each principal investigator will submit to EHS the following:

- A completed [Responsible Party Information Sheet](#).
- An annual chemical and biological inventory.
- A Health Hazard Assessment for each biological agent and toxin stored or used in the laboratory.

A. Decontamination

Decontamination is a process or treatment that renders an instrument or environmental surface safe to handle. A decontamination procedure can be as simple as clean-up with detergent and water or as thorough as sterilization. Sterilization and disinfection are two ways to address microbial contamination.

- **Sterilization** is the use of physical or chemical processes to destroy all viable forms of microbial life, such as bacterial spores.
- **Disinfection** is a chemical or physical treatment that destroys the most resistant vegetative microbes or viruses, but not the spores, in or on inanimate surfaces. Effectiveness is influenced by a number of factors, including the type and number of organisms, amount of organic matter, the object being disinfected, the disinfectant being used, concentration, temperature, and exposure time.
- **Antisepsis** is the application of a liquid antimicrobial to skin or other living tissue to inhibit or destroy microorganisms. Examples include hand washing with germicidal solutions or swabbing skin with alcohol before an injection.

Sterilization, disinfection, and antisepsis are all forms of decontamination.

1. When to Decontaminate

In most ASU laboratories, it is recommended that decontamination be accomplished by steam heat sterilization in an autoclave or by surface application of or placement in a chemical disinfectant solution, such as 1:10 bleach solution or an [EPA-registered disinfectant](#) and applied per manufacturer instructions.

All material and equipment contaminated with or containing potentially biohazards should be decontaminated:

- Upon completion of procedures involving the use of biohazardous material;
- In the event of spills of biohazards;
- Before being washed, stored, or discarded; and
- At least daily.

2. Autoclave Use

Autoclaving (saturated steam under pressure of approximately 15 pounds per square inch (psi) to achieve a chamber temperature of at least 250°F for a designated time) is the preferred and most convenient method to rapidly destroy all forms of microbial life. However, to do this, the autoclave process must reach proper temperature, pressure, and time, and also prevent the entrapment of air in the bag or container of treated material.

- Material to be sterilized must come into contact with steam.
- Bags or containers should be left open during autoclaving or water (~200 ml) should be added to sealed bags to generate steam.
- Heat indicator tape should be used outside the bag or container with each autoclave load to indicate that sterilization has been completed.
- Autoclave sterility monitoring should be conducted on a regular basis using biological indicators (such as *B. stearothermophilus* spore strips) placed among treated materials and at locations throughout the autoclave. The spores, which are more resistant to heat than most other biological materials, provide validation of general microbial destruction when they are effectively inactivated by autoclave operation (typically 250°F for 30 minutes).
- Note that the type and frequency of sterility monitoring varies and is based on usage, cycle type, and autoclave type. Contact EHS Biosafety/Biosecurity for more information.

3. Chemical Disinfectant Use

The most practical use of chemical disinfectants is for surface decontamination and, when used in sufficient concentration, as a decontaminant for liquid wastes prior to final disposal. General recommendations are:

Liquid Decontamination

- Add liquid chlorine bleach to provide a final 1:10 (made within one month of use);
- Let stand at least 20 minutes; and
- Discard the solution appropriately. Note: No waste down the drain unless approval has been obtained from EHS.

Surface Decontamination

- Wipe with 1:10 dilution of chlorine bleach; or
- Wipe with iodophor disinfectant (per label concentration); or

- Wipe with another EPA registered disinfectant following manufacturer guidelines.

See [Appendix E](#) for additional information on disinfectants.

B. Decontamination in Animal Facilities

In ASU animal facilities, decontamination is accomplished by use of the provided disinfectants applied to surfaces and equipment; by chemical sterilants; by steam heat sterilization in an autoclave (particularly for surgical equipment and for bedding, animal feed, and other materials used in the barrier animal facility); by gas sterilization; or by use of the cage-washing machine. All animal users should be familiar with the safe and proper use of all chemical decontamination materials and equipment that they need to use as part of their animal lab responsibilities.

C. Exposures to Biohazards

In the event of an exposure to a biohazard, the following guidelines should be used:

Intact Skin

1. Remove contaminated clothing. Clothing should not be pulled over the face as contact with eyes, nose, and mouth may occur.
2. Vigorously wash contaminated skin for 1 minute with soap and water.
3. Call 911 or seek medical attention at the ASU Health Services, if necessary.
4. Inform the laboratory's principal investigator and/or EHS immediately.

Broken, Cut or Damaged Skin or Puncture Wound

1. Remove contaminated clothing. Clothing should not be pulled over the face as contact with eyes, nose, and mouth may occur.
2. Vigorously wash contaminated skin for 5 minutes with soap and water.
3. Call 911 or seek medical attention at the ASU Health Services, if necessary.
4. Inform the laboratory's principal investigator and/or EHS immediately.

Eye

1. Immediately flush eyes for at least 15 minutes with water, using an eyewash. Hold eyelids away from your eyeball and rotate your eyes so that all surfaces may be washed thoroughly.
2. Remove contaminated clothing. Clothing should not be pulled over the face as contact with eyes, nose, and mouth may occur.
3. Call 911 or seek medical attention at the ASU Health Services, if necessary.
4. Inform the laboratory's principal investigator and/or EHS immediately.

Ingestion or Inhalation

1. Move to fresh air immediately.
2. Call 911 or seek medical attention at the ASU Health Services, if necessary.

3. Do not induce vomiting unless advised to do so by a health care provider.
4. Inform the laboratory's principal investigator and/or EHS immediately.

D. Spills of Biohazards

ASU does not have a centralized biological spill response team. Therefore, each laboratory working with potentially hazardous biological material must be prepared and trained to handle its own biological spills. EHS is available for assistance if necessary. Additional information pertaining to spills which involve recombinant or synthetic nucleic acid molecules, blood, microorganisms, or any other bioresearch materials can be found at <http://cfo.asu.edu/emergency>. Performing all work on plastic-backed absorbent liners to absorb spills can minimize the consequences of a spill of a biohazard. The quantities of these materials should be limited so they can be easily contained, cleaned, or destroyed. If respiratory protection is required, the ASU [Respiratory Protection Program](#) must be followed. A simple spill kit with the following supplies should be available and used by trained personnel:

- Bleach or other EPA-registered disinfectant
- Biohazard bag
- Disposable lab coat
- Disposable shoe covers
- Hand sanitizing wipes
- Nitrile gloves (4 pair)
- Mini brush and dustpan (or something to scoop spilled materials)
- Paper towels
- Safety goggles
- Tong or forceps to pick up broken glass
- Spray bottle (to make fresh bleach solution)
- "Biohazard Spill" sign

E. Spills Inside a Biological Safety Cabinet

1. Remain calm and secure research samples.
2. Alert the other laboratory employees of the spill.
3. Leave the cabinet turned on.
4. While wearing gloves, spray or wipe cabinet walls, work surfaces and equipment with disinfectant equivalent to 1:10 bleach solution. If necessary, flood the work surface, as well as drain-pans and catch basins below the work surface, with disinfectant for a contact time of at least 20 minutes.
5. Soak up disinfectant and spill with paper towels.
6. Pick up any pieces of broken glass with forceps or tongs and place in sharps container. Never use hands.
7. Drain catch basin into a container. Lift front exhaust grill and tray and wipe all surfaces. Ensure that no paper towels or solid debris are blown into the area beneath the grill.
8. Dispose cleanup materials in the biohazard waste container.
9. Wash hands and any exposed surfaces thoroughly after the cleanup procedure.
10. Report the spill to the laboratory's principal investigator and the Biological Safety Officer if there was a potential for any material escaping the Biological Safety Cabinet.
11. Resume work if deemed safe by supervisor/manager.

F. Small Spill (<500 mL) Outside a Biological Safety Cabinet

1. Remain calm and make note of whether your person has been contaminated.
2. Alert other laboratory employees in the area and block off the area.
3. Wearing gloves, safety glasses, and a lab coat, cover the spill with paper towels and gently apply disinfectant, proceeding from the outer edge of the spill to its center. Leave in place for 20 minutes.
4. Pick up the towels and discard into a biohazard container.
5. Pick up any pieces of broken glass with forceps or tongs and place in sharps container. Never use hands.
6. Re-wipe the spill area with disinfectant and thoroughly wash hands after glove removal.
7. Report the spill to the laboratory's principal investigator and/or to EHS immediately.
8. Resume work if deemed safe by supervisor/manager.

G. Large Spill (>500 ml) Outside a Biological Safety Cabinet

1. Remain calm and hold your breath and leave the room immediately if no other workers are present. Otherwise:
2. Warn others to stay out of the spill area to prevent spread of contamination.
3. Post a sign stating: "DO NOT ENTER, BIOHAZARD SPILL, contact (name and phone #) for information" and block off area as possible.
4. Remove any contaminated clothing, ensuring that clothing is not pulled over the face, and put into a biohazard bag for later autoclaving.
5. Wash hands, eyes and exposed skin.
6. Notify the principal investigator, supervisor, and EHS immediately.
7. Wait 30 minutes before re-entering the contaminated area to allow for dissipation of aerosols.
8. Meanwhile, put on protective clothing (lab coat, gloves and, if indicated, respirator, eye protection, shoe covers) and assemble clean-up materials.
9. Cover the spill with paper towels and gently apply disinfectant, proceeding from the outer edge of the spill to its center. Leave in place for 20 minutes.
10. Collect all treated material and discard in a biohazard container.
11. Pick up any broken glass with forceps and place them into a sharps container. Never use hands
12. Re-wipe the spill area with disinfectant and wash hands thoroughly at completion of clean-up.

H. Small Spill (<500 ml) of r/sNA Molecules

1. Put on gloves and eye protection if you are not already wearing them.
2. Cover spilled material with an absorbent paper towel or Kimwipe. Once the absorbent material is in place over the spill, wet the material with a 10% solution of bleach or other EPA-registered disinfectant.
3. Let stand 15 minutes, wipe up and wash surface with appropriate disinfectant.
4. Wipe down all equipment and surfaces that may have been splashed.
5. Dispose of contaminated paper towels as infectious waste.

I. Large Spill (>500 ml) of r/sNA Molecules in a Biological Safety Cabinet

1. Biological safety cabinets must run during cleanup to contain aerosols and to filter exhaust air.
2. Don appropriate personal protective gear before initiating cleanup.
3. Initiate clean up as soon as possible using a germicidal disinfectant (phenolic or iodophor). Alcohol is not acceptable.
4. If the spill is contained on a bench pad, remove the contaminated bench pad discard as infectious waste.
5. If the spill is on the work area surface, cover spilled material with disinfectant-soaked towels. Allow 20 minutes contact time then remove the contaminated towels and discard as infectious waste.
6. Wipe down the interior of the cabinet and any splatter on items within the cabinet with a disinfectant-soaked towel.
7. Wipe down non-autoclavable materials with disinfectant. Allow 20 minutes of contact time with disinfectant before any items are removed from cabinet.
8. Place items designated as contaminated used sharps in an appropriate infectious waste sharps container using tongs/forceps. Place other contaminated disposable materials used in the cleanup process in an autoclave bag. Process as infectious waste.
9. Place contaminated re-usable items in biohazard bags, autoclavable pans with lids or wrap them in newspaper. Sterilize, preferably by autoclaving, and then clean for re-use.
10. If the cabinet has a catch basin beneath the work surface and the spill resulted in liquids flowing into this area, more extensive decontamination is required.
 - a. Ensure the drain valve under the cabinet is closed.
 - b. Pour disinfectant onto the work surface and through the front and rear grilles into the drain pan. Allow 20-30 minutes contact time.
 - c. Absorb spilled fluid-disinfectant from work surface with paper towels and discard in biohazard bag.
 - d. Prepare to empty drain pan. Place disinfectant solution in a collection vessel. Attach flexible tubing to the drain valve. The tube should be of sufficient length to allow the open end to be submerged in the collection vessel to minimize aerosol generation.
 - e. Open the drain valve and empty the drain pan into the collection vessel containing disinfectant. Flush the drain pan with water and remove the flexible tubing. Manage contaminated materials as if they are infectious.
 - f. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving. Wash hands when gloves are removed.
 - g. Notify principal investigator, supervisor, and EHS if there was a potential for any material escaping the Biological Safety Cabinet. Consult with EHS to determine whether formaldehyde decontamination of the cabinet and filters is necessary, especially if a high-risk agent or a major spill of a moderate-risk agent occurred.
 - h. Run the biological safety cabinet at least 10 minutes after cleanup, before resuming activity in the cabinet.

J. Large Spill (>500 ml) of r/sNA Molecules Outside a Biological Safety Cabinet

1. If a spill of a biohazard occurs, outside the biological safety cabinet, notify other individuals in the laboratory to evacuate.
2. Exit the laboratory to the hallway, closing the door behind you.
3. Remove any contaminated clothing (turn contaminated portion inward) and place it in an autoclave bag.
4. Wash all exposed skin.
5. Place signs on door(s) to the laboratory warning individuals who may want to enter that a spill occurred and access is denied.
6. Allow aerosols to settle for 30 minutes before re-entering the laboratory.
7. Notify the principal investigator, supervisor, and EHS prior to proceeding with cleanup.
8. Assemble supplies (e.g., disinfectant, sharps containers, towels, tongs, autoclave bags) before entering the laboratory.
9. Don appropriate personal protective equipment (e.g., disposable gown, protective eyewear, gloves, shoe coverings and respiratory protection if needed).
10. Clean up spill with a suitable disinfectant as follows:
 - a. Surround spill area with disinfectant or diking material that is soaked in disinfectant.
 - b. Place paper towels soaked in a disinfectant over the entire spill area.
 - c. Allow 20-minute contact time with the disinfectant to ensure adequate germicidal action.
 - d. Wipe down non-autoclavable materials with germicidal disinfectant.
 - e. Place items designated as contaminated used sharps in an appropriate infectious waste sharps container. Place other disposable materials used in the cleanup process in an autoclave bag. Process as infectious waste.
 - f. Place contaminated re-usable items in biohazard bags or autoclavable pans with lids. Sterilize preferably by autoclaving, and then clean for re-use. Remove protective clothing used during cleanup then place in a biohazard bag for autoclaving.
 - g. Wash hands when gloves are removed.

K. Spill of Biohazards (Including r/sNA Molecules) in a Centrifuge

A single centrifuge spill or release can lead to multiple infections in a laboratory. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge is operating at high speed. Therefore, whenever opening a centrifuge, it must be performed slowly.

Unsealed Buckets

1. If a centrifuge tube breaks while the centrifuge is running, turn off motor. Allow the machine to be at rest for 30 minutes before opening.
2. Unplug centrifuge before initiating clean up.
3. Put on two pairs of nitrile gloves and other PPE before proceeding with clean up.
4. Flood centrifuge bowl with a disinfectant (e.g., 10% bleach solution or other EPA registered disinfectant).
5. Place paper towels soaked in a disinfectant over the entire spill area. Allow 20 minutes contact time.

6. Remove broken tubes and glass fragments using tongs or forceps. Place fragments in a sharps container for autoclaving and disposal as infectious waste.
7. Remove buckets, trunnions, and rotor and place in disinfectant for 20 minutes or autoclave.
8. Unbroken, capped tubes may be placed in disinfectant and recovered after 20 minutes contact time or autoclaved.
9. Remove remaining disinfectant soaked materials from centrifuge bowl and discard as infectious waste.
10. Place paper towels soaked in a disinfectant in the centrifuge bowl and allow it to soak overnight, wipe down again with disinfectant, wash with water and dry. Discard disinfectant soaked materials as infectious waste. NOTE: Household bleach is a corrosive. Use caution when immersing or having metal components in contact with bleach (sodium hypochlorite) for extended periods of time.
11. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving. Wash hands whenever gloves are removed.
12. Notify principal investigator, supervisor, and/or EHS.

Sealed Buckets (Safety Cups)

1. If breakage is suspected, remove the sealed bucket to a biological safety cabinet before opening.
2. If breakage occurred, replace the cap on the safety cup loosely and autoclave.
3. Notify principal investigator, supervisor, and EHS if there was a potential for any material escaping the centrifuge.

L. Reporting Exposures

In the event of an exposure to a biohazard:

1. Report to an Occupational Health Nurse or a primary healthcare provider
2. Complete an Accident/Illness Report Form and submit to EHS within 24 hours of incident.
3. If exposure or incident occurs with s/r NA, work with the principal investigator, supervisor, and Biological Safety Officer to report accident to the NIH Office of Biotechnology Activities as required by the *NIH Guidelines*.

XVIII. Transfers, Packaging, and Shipping of Biological Materials

A. Transfers

The transferring, packing, and shipping of select agents and toxins is HIGHLY regulated. No select agent or toxin shall be transferred, packed, or shipped without the express approval from the RO. Please contact the ASU Biological Safety Officer for more information.

For materials that are not Select Agents, each principal investigator must develop procedures for transferring or shipping from the laboratory. The principal investigator must ensure the following:

- Personnel who package, handle, and ship non-select agents and biohazardous materials (including import and export) are subject to all applicable training. Please refer to [EHS Policy 406](#). The RO must be notified of all select agent transfers; internal or external.
- Standard operating procedures should be in place for all import and export activities.
- Package, label, and transport biohazards in compliance with all applicable local, federal, and international transportation and shipping regulations, including U.S. Department of Transportation (DOT) regulations. Materials that are transported by airline carrier should also comply with packaging and shipping regulations set by the International Air Transport Association (IATA).
- Required permits (e.g., granted by the U.S. Public Health Service, USDA, DOT, U.S. Department of Commerce, and IATA) are obtained before biohazards are prepared for transport.
- Decontaminate contaminated or potentially contaminated materials before they are removed from the laboratory area.
- Avoid hand-carrying biohazards when transferring them to other external facilities. If biohazards are to be hand-carried on common carriers, all applicable packaging, transport, and training regulations should be followed.
- Develop and follow a protocol for intra-facility transfer (between laboratories on ASU campuses) of all biological and biohazards. Contact EHS for assistance.
- Packaging and shipping of biological materials must be completed in a way that ensures the contents will not leak and that the package will arrive in good condition.

B. Packaging

All biological materials including diagnostic specimens and biological products that may contain an etiologic/biohazardous agent must be packaged to withstand leakage of contents, shocks, pressure changes and other conditions possible with ordinary handling and transportation (e.g., passage through cancellation machines, sorters, conveyors). Contents should not leak to the outside of the shipping container even if leakage of the primary container occurs.

Specific packaging requirements apply to materials that are known to contain, or reasonably believed to contain certain etiologic agents. For such materials the following

procedures apply (See Figure 4. Source: Biosafety in Microbiological and Biomedical Laboratories 5th Edition, [Appendix C](#)).

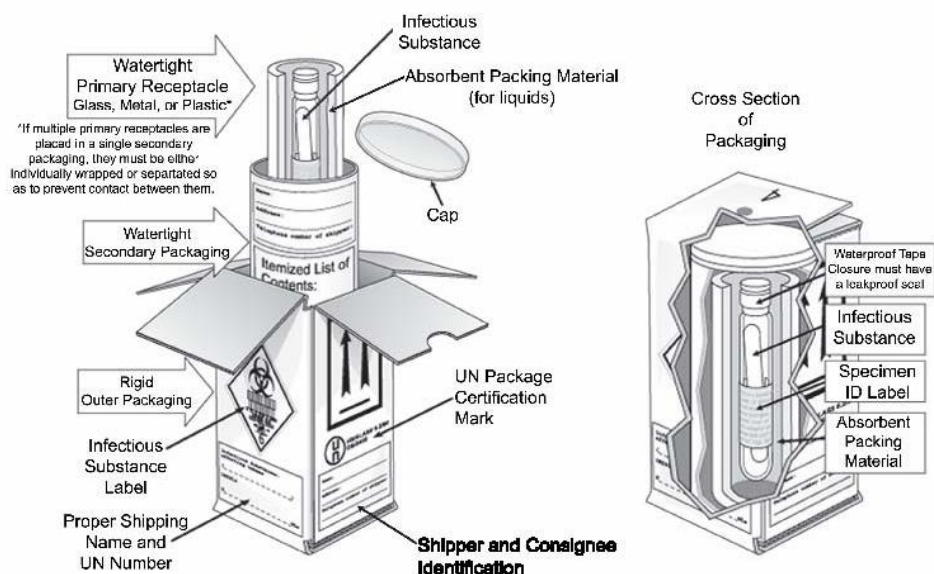


Figure 4. Packaging Diagram for Biohazards

C. Packaging Volumes

Volume not exceeding 50 milliliters (ml)

1. Place material in a securely enclosed, watertight primary container (e.g., test tube, vial). Enclose this primary container in a secondary, durable, watertight container. Several primary containers may be enclosed in a single secondary container as long as the total volume of material in all the primary containers enclosed does not exceed 50 ml.
2. Place absorbent non-particulate material (e.g., paper towels, **not** sawdust or vermiculite) in the spaces at the top, bottom, and sides between the primary and secondary containers. Use enough absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage.
3. Enclose each set of primary and secondary containers in an outer shipping container constructed of corrugated fiberboard, cardboard, wood or other material of equal strength. Do not use bags, envelopes, or similar materials.
4. If you package the material with dry ice, see the Packaging with Dry Ice section in this document.

Volume greater than 50 ml

1. Follow requirements for lesser volumes outlined above.
2. Place shock absorbent material at the top, bottom, and sides between the secondary container and the outer shipping container. (This material should at least equal the amount of absorbent material placed between the primary and secondary containers).
3. Ensure single primary containers contain no more than 1000 ml of material; however, two or more primary containers (combined volumes not exceeding 1000 ml) may be placed in a single secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container must not exceed 4000 ml.

D. Packaging with Dry Ice

1. If used, place dry ice between the secondary and outside containers.
2. Place shock absorbent material so as to prevent the secondary container from becoming loose inside the outer container as the dry ice sublimates.
3. Use the DOT dry ice label. Guidelines for shipping are available by contacting EHS.

E. Labeling

The outer shipping container of all materials containing etiologic/biohazards which are being shipped or transported must bear a special labels. Please contact EHS Biosafety and Biosecurity for more information about shipping labels.

F. Shipping and Transportation Methods and Requirements

1. Registered Mail or the Equivalent

For a list of etiologic agents that use registered mail or an equivalent system which provides the sender with immediate notification of receipt refer to the CDC Select Agent [website](#).

2. Federal Express or UPS

- For Federal Express/UPS shipments, internationally **or** domestically, follow the International Air Transport Association (IATA) Dangerous Goods Regulations. (Receipt of shipment notice is not required since the shipment is traceable through the specific carrier.)
- Apply appropriate labels to the outer shipping container for packages containing dry ice and/or biohazard as shown in **Figures 5** and **6**, respectively.
- Contact the specific carrier's dangerous goods agent prior to shipment for any additional packaging and labeling requirements.

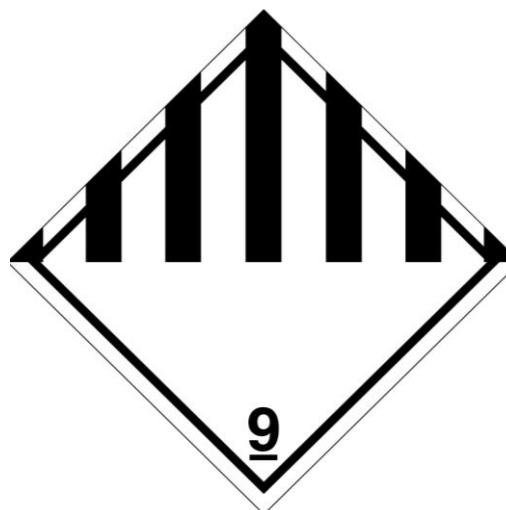


Figure 5.



Figure 6.

3. Damaged Packages

When evidence of leakage or any other damage to packages bearing an Etiological Agents/Biomedical Material label is discovered, the carrier must promptly isolate the package and notify the Director, Centers for Disease Control and Prevention (CDC), 404.633.5313, 1600 Clifton Road NE, Atlanta, Georgia 30333.

4. Notice of Delivery

In the event that a package sent from ASU is not received by the recipient within 5 days following the anticipated delivery of the package, the sender must notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia 30333 or by telephone 404.633.5313.

5. Importation/Exportation of Etiologic Agents

Importation of biohazards, etiologic agents, and vectors that may contain such agents is governed by federal regulation. In general, an importation permit is required for any infectious agent known to cause disease to humans. This includes, but is not limited to, bacteria, viruses, rickettsia, parasites, yeasts, and molds. In some instances, an agent that is suspected of causing human disease also requires a permit.

There are two main import permit types for biologically hazardous agents and vectors: U.S. Public Health Service (USPHS); and Centers for Disease Control and Prevention (CDC).

a) U.S. Public Health Service (USPHS)

Importation permits are issued by the U.S. Public Health Service (USPHS) only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the USPHS Division of Quarantine and release by U.S. Customs.

b) CDC Application for Permit to Import Infectious Biological Agents into the United States

Code of Federal Regulations Title 42 Chapter I Subchapter F Part 71 Subpart F §71.54 requires persons importing etiologic agents to obtain a permit through the CDC.

The permits offered by the CDC include Permit to Import Biological Agents or Vectors of Human Disease (A/BSL 2 and A/BSL 4; and ACL-2 and ACL-3) or Permit to Import or Transport Live Bats. Checklists for compliance with the requirements of the import permit regulations can be found on their [website](#).

Instead of an importation permit, a Letter of Authorization may be issued by the Centers for Disease Control and Prevention after review of an "Application to Import an Etiological Agent." The letter is issued for materials that are judged to be noninfectious, but which U.S. Customs inspection personnel might construe to be infectious. Letters of Authorization may be issued for items such as formalin-fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine, cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent. Letters of Authorization are in effect for two years and do not require a shipping label to be issued by CDC.

Importation permits and Letters of Authorization are issued by the Biosafety Branch, Office of Health and Safety, CDC, 1600 Clifton Road, Atlanta, Georgia 30333, after review of a completed application form. Application forms may be obtained [online](#) or by calling CDC at their FAX Information System. Dial 1-888-CDC-FAXX and enter document number 101000. CDC can also be contacted on their [website](#). Completed forms may be returned to CDC by mail or FAX at 404-639-2294. Application to CDC for the importation permit should be made 15 working days in advance of the shipment date to allow time for processing, issuance, and delivery of the permit and shipping labels to the permittee.

G. Other Permits

Imported shipments may require a United States Department of Agriculture (USDA) permit if your product contains ingredients derived from plants or animals or if there is domestic shipping of infectious agents of livestock, poultry, and other animal diseases, and any materials that might contain these agents. The majority of plant- or animal-derived ingredients do require a permit. It is better to apply for a permit and receive a Letter of No Jurisdiction than to have a shipment delayed or rejected for lack of a proper permit.

There are three main types of import permits offered through the USDA: Veterinary Service Permit and Plant Protection and Quarantine Permit; Animal and Plant Health Inspection Service Permit (APHIS); and U.S. Fish and Wildlife Service (USFWS).

1. USDA Veterinary Service Permit

The Veterinary Service (VS) Permit, issued by the Veterinary Services branch of APHIS, specifies the conditions under which animals, animal products, or products with animal-origin ingredients may be imported into the United States. Often to the surprise of importers, a large number of products – some very unintuitive – require VS Permits. Learning this lesson the hard way, by a Customs Ag hold or Emergency Action Notification, will guarantee increased costs and delay and often USDA-refused products. The importation or domestic transfer of plant pests is also regulated by the USDA. Such a permit is required for plant pests, plant biological agents, or any material that might contain them. Information may be obtained by calling 301-734-3277 or through the web. USDA permits are required for certain live animals and all live bats. Call 800-358-2104 for further information.

3. Plant Protection and Quarantine Permit

The Plant Protection and Quarantine (PPQ) Permit, issued by the Plant Protection and Quarantine branch of APHIS, specifies the conditions under which plants, plant products, or products with plant-origin ingredients may be brought into the United States.

4. USDA Animal and Plant Health Inspection Service (APHIS)

USDA Animal and Plant Health Inspection Service (APHIS) issues permits for the import, transit and release of regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil, and genetically engineered organisms. Tissue culture materials, and suspensions of cell culture-grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are also controlled by the USDA due to the potential risk of introduction of exotic animal disease into the U.S. Applications for USDA/APHIS permits may be obtained by calling the appropriate office at USDA APHIS using the numbers found at their website. However, they also have readily available electronic permit system through the website.

U.S. Fish and Wildlife Service (USFWS) [permits](#) are required for certain live animals, including bats. Please call 800-344-WILD for further information.

Export of infectious materials may require license from the Department of Commerce (DoC). Exporters of a wide variety of etiologic agents of human, plant, and animal diseases, including genetic material and products which might be used for culture of large amounts of agents will require an export license. A key in determining whether an export license is needed from the Department of Commerce is determining whether the item you intend to export has a specific Export Control Classification Number (ECCN). The ECCN is an alphanumeric code, e.g., 3A001 that describes the item and indicates licensing requirements. Information may be obtained by calling the DoC Bureau of Export Administration at 202-482-4811 or through the [web](#).

XIX. Food and Beverages in the Laboratory

In order to reduce potential exposures and to ensure compliance with prudent laboratory operations, regulations, and other best management practices, ASU prohibits the storage and consumption of food and drink in all designated laboratory space. The only exception is for food and beverages used in research and teaching projects. These materials must be labeled, “Not for Human Consumption.”

In order to prevent potential exposure to hazardous materials:

- Do not eat, drink, smoke, chew gum, apply cosmetics, or take medicine in laboratories where hazardous materials are handled or stored.
- Do not store food, beverages, cups, or other drinking and eating utensils in areas where hazardous materials are handled or stored.
- Do not use glassware for laboratory operations to prepare or consume food or beverages.
- Do not use laboratory refrigerators, ice chests, cold rooms, and ovens for food storage or preparation.
- Do not use laboratory water sources or deionized laboratory water for drinking water.

Important: Food and beverages must never be stored in any laboratory refrigerator in which chemicals, biological, and radioactive materials are kept unless they have been labeled, “Not for Human Consumption.”

XX. Nails and Jewelry

Principal Investigators (PIs) at ASU are responsible for ensuring that laboratory personnel maintain appropriate hand and nail hygiene. Hands should be kept clean and washed frequently (e.g., after completing work, after removing gloves, before leaving the laboratory). Jewelry should be kept to a minimum to prevent puncturing or otherwise compromising protective gloves or limiting dexterity. CDC, NIH and WHO recommends nail length should be no longer than 0.25 inch beyond the end of fingertips. Artificial nails (e.g., nail extensions, nail wraps, nail jewelry) are not recommended when working in the laboratory.

XXI. Protective Clothing Beyond the Laboratory

The improper use or lack of protective clothing and equipment in a laboratory can lead to chemical burns, biological exposures, or other potential dangers. To help reduce the risk of exposure, personnel in ASU laboratories are required to wear gloves, safety glasses, lab coats and other personal protective clothing. However, in public areas, such as hallways and lounges, wearing personal protective clothing and equipment is not recommended. This is because contaminated clothing may present a hazard, and the perception of contaminated protective clothing and equipment in a public area may project a careless image to both colleagues and visitors.

Wearing gloves outside the laboratory should be minimized, except to move hazardous materials between laboratories. Chemicals should be transported from place to place on a cart, in a clean secondary container, or in a bottle carrier with secure handles. When this is not an option, personnel should use a clean, ungloved hand to touch common surfaces and a gloved hand to carry the items: the one-glove rule. Alternatively, the material should be packaged so the outer container may be transported without the need for personal protective equipment.

Protective gloves should never come into contact with door handles, elevator buttons, telephones, lavatory faucets, vending machines, bottled water dispensers, ice-making machines, or other surfaces outside the laboratory. Also, please be aware that strict federal and state regulations address the transport of hazardous (e.g., biological, chemical, radiological) materials on public roads.

For the sake of safety, appearances, and courtesy, personnel are asked not to wear contaminated, stained, or potentially contaminated lab coats and other research clothing and equipment in any public area, especially dining areas, lounges, auditoriums, conference rooms, or other non-hazardous areas.

XXII. Laundering Laboratory Clothing

Laboratory coats/gowns and contaminated clothing or clothing suspected to be contaminated with chemicals or biohazards are never be taken home or to a public laundry facility.

A. ASU Laundry Facilities

Laundry facilities exist in a few departments at ASU. Follow departmental procedures for cleaning *mild to moderately* contaminated clothing. Generally, these facilities are for intra-department use only. Laboratory managers may launder mildly contaminated clothing using departmental laundry facilities where available. Contaminated clothing shall be washed, at a minimum in accordance with the manufacturer's directions. However, departments are encouraged to launder contaminated clothing in hot water (160° F or greater). Where departmental facilities are not available, contaminated clothing must be laundered by a professional laundry service.

B. Professional Laundering Services

A professional service company may be used if the department does not have the capability to wash *mild to moderately* contaminated clothing. It is each laboratory's responsibility to determine if the cleaning company is capable and willing to launder the contaminated clothes. Where departmental facilities are not available, contaminated clothing must be laundered by a professional laundry service. Laboratory managers shall ensure that all laundry sent off-site is containerized in leak-proof bags or boxes marked with the biohazard symbol and shall advise the vendor that the laundry is contaminated with blood and/or potentially infectious bodily fluids for textiles that are mildly contaminated.

C. Laundering of Personal Clothing

Clothing contaminated with biohazardous material must be autoclaved prior to laundering at home. Documentation of effective autoclaving must be maintained. **NOTE:** Personal laundering is not acceptable for clothing contaminated with chemicals, blood, blood products, or other bodily fluids.

D. Overtly Contaminated Clothing

Clothing that is overtly contaminated with chemicals must be disposed as hazardous waste. Clothing contaminated with radiological material must be disposed as radiological waste. Clothing that is contaminated with blood, blood products, or other bodily fluids must be removed and containerized in leak-proof bags or boxes at the location where it was used. Containers or bags must be marked with the biohazard symbol.

XXIII. Safety Audits

ASU Environmental Health and Safety (EHS) will conduct regular (e.g., annual) inspections of each laboratory to ensure compliance with the procedures and protocols of this manual. Any significant concerns will be reported to the Institutional Biosafety Committee.

The safety audit typically includes an evaluation of the autoclave, biological safety cabinet, microbiological techniques, emergency and safety equipment, storage of biohazardous material, general housekeeping, and review of the Laboratory-Specific Biosafety Manual. Please refer to the ASU Biosafety and Biosecurity [inspection checklists](#), for more information about the biosafety audit form used by EHS.

EHS will make every attempt to schedule safety audits with faculty members. However, if the principal investigator is unavailable or is unresponsive, EHS will proceed with the safety audit. EHS may also conduct unannounced accident investigations. Please be aware that federal, state, and local inspectors may also conduct unannounced inspections.

Following the biological safety survey, a report listing the safety concerns is sent to the faculty member responsible for the laboratory. The faculty member is responsible for correcting the hazards. If the faculty member fails to correct the hazard, a second notice is sent to the department head with a copy to the faculty member. Follow-up audits may be conducted in laboratories with extremely hazardous conditions and/or numerous concerns.

XXIV. Security

Laboratory security is an integral part of an effective safety program. Follow these steps to ensure a secure working environment in your laboratory:

1. Keep laboratory doors closed and locked when unoccupied.
2. Keep stocks of organisms and hazardous chemicals locked when the laboratory is unoccupied.
3. Keep an accurate record of chemicals, stocks, cultures, project materials, growth media, and those items that support project activities.
4. Notify ASU police if materials are damaged or missing from laboratories.
5. Inspect all packages arriving into the laboratory.
6. When research is completed for the day, ensure that chemicals and biological materials have been stored properly and securely.
7. Decontaminate materials and work surfaces after completing work and at least daily.
8. Turn off equipment, flames, steam supply, and electrical appliances after completing work.
9. Ask strangers (someone you do not recognize as a co-worker or support staff person) to exit the room if they are not authorized to be there.
10. Discuss other security-specific requirements with your supervisor and colleagues.

XXV. Working Alone

All faculty, staff, students, and visitors working[‡] in an area (e.g., laboratory, animal holding room) where hazardous conditions exist should have knowledge of the following:

- Emergency Contacts
- Emergency Response Procedures
- Evacuation Routes
- First Aid Procedures
- Health and Safety Training Requirements
- Personal Protective Equipment Requirements
- Procedures to Report Unhealthy and Unsafe Conditions
- Safety Policies and Procedures
- Spill Response Equipment and Procedures

All personnel working alone[‡] in a laboratory where hazardous conditions exist should:

- Obtain written permission (e.g., e-mail, letter) from the Principal Investigator or Laboratory Supervisor to work alone in the laboratory;
- Ensure that a means to contact emergency response personnel is available when working alone in the laboratory; and
- Require that individuals working alone contact their supervisor before beginning work and upon completion.

[‡]According to the National Safety Council, the term “alone” means that a person is beyond the visual or auditory range of any other individual for more than a few minutes at a time.

XXVI. Recordkeeping

The principal investigator must maintain the following records and be prepared to present these at the annual laboratory inspection:

- An accurate, current list of each biological agent or toxin stored in that room stored in freezers, refrigerators, dehydrated storage, or otherwise.
- A Health Hazard Assessment for each biological agent or toxin stored in that room.
- A current [Responsible Information Party Sheet](#).
- [Training Documentation Forms](#).
- Safety, security, and emergency response plans.
- Safety and security incident reports.

XXVII. Program Evaluation

The review of the elements as noted in the Recordkeeping sections of this document will constitute an evaluation of the ASU Biosafety and Biosecurity Program.

Appendix A. Definitions

Animals: Any member of the animal kingdom except a human including an animal product (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws).

Arthropods: Any living insect including crustaceans, spiders, scorpions, etc. capable of being a host or vector of human disease.

Biohazard: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, protozoa or prions) or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

- Death, disease, or other biological malfunction in a human, animal, plant, or another living organism;
- Deterioration of food, water, equipment, supplies, or material of any kind; or
- Deleterious alteration of the environment.

Biological Product: A biological prepared and manufactured in accordance with regulations that govern the manufacture of vaccines, reagents, etc.

Centers for Disease Control and Prevention (CDC): The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Diagnostic Specimen: Any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids, etc., which is reasonably believed to contain an etiologic agent and is being shipped for purposes of diagnosis.

Etiologic Agent: A viable microorganism or its toxin that causes, or may cause, human disease

Infectious Substance: Any material that is known or reasonably expected to contain a biohazard.

Interstate Shipping: Transporting across state lines within the continental United States.

Intrastate Shipping: Transporting within the State of Arizona.

Recombinant or Synthetic Nucleic Acid (r/s NA) Molecules:

- Molecules that are constructed outside living cells by joining natural or synthetic nucleic acid segments to nucleic acid molecules that can replicate in a living cell, or
- Molecules that result from the replication of those described above, and
- Synthetic nucleic acid segments which are likely to yield a potentially harmful polynucleotide or polypeptide.

Responsible Official: The individual designated by an institution to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations.

Toxin: The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

- Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or
- Any poisonous isomer or biological product, homolog or derivative of such a substance.

Vector: Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.

Appendix B. Acronyms

AAALACi	Association for Assessment and Accreditation of Laboratory Animal Care International
AC	Animal Care
APHIS	Animal and Plant Health Inspection Service
ASU	Arizona State University
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological Safety Cabinet
BSO	Biological Safety Officer
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DACT	Department of Animal Care and Technologies
DEA	Drug Enforcement Administration
EHS	Environmental Health and Safety
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
NHP	Non-Human Primate
NIH	National Institutes of Health
OBA	Office of Biotechnology Activities
OLAW	Office of Laboratory Animal Welfare
ORIA	Office of Research Integrity and Assurance
OSHA	Occupational Safety and Health Administration
PHS	Public Health Service
PI	Principal Investigator
PPE	Personal Protective Equipment
SDS	Safety Data Sheet
USDA	United States Department of Agriculture

Appendix C. Biosafety Guidelines

Guidelines for Good BSL-1 Practices

BSL-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:

1. Standard Microbiological Practices

- a) The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- b) Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- c) 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.
- d) Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- e) 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:

- i. 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.

- ii. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - iii. Non disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - iv. 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.
- f) Perform all procedures to minimize the creation of splashes and/or aerosols.
 - g) Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
 - h) 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:
 - i. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - ii. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
 - i) 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.
 - j) An effective integrated pest management program is required.
 - k) 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.

2. Special Practices

None required.

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

- a) Special containment devices or equipment, such as biological safety cabinets, are not generally required.
- b) Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
- c) 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.
- d) Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment.
- e) Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BSL-1 workers should:
 - i. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.
 - ii. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - iii. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

4. Laboratory Facilities (Secondary Barriers)

- a) Laboratories should have doors for access control.
- b) Laboratories must have a sink for hand washing.

- c) The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
- d) Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - i. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - ii. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
 - iii. Laboratories windows that open to the exterior should be fitted with screens.

Guidelines for Good BSL-2 Practices

BSL-2 builds upon BSL-1 practices. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

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

1. Standard Microbiological Practices

- a) The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- b) Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- c) 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.
- d) Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- e) 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:

- i. 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.
 - ii. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - iii. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - iv. 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.
- f) Perform all procedures to minimize the creation of splashes and/or aerosols.
- g) Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- h) 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:
- i. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - ii. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
- i) 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.

- j) An effective integrated pest management program is required.
- k) 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.

2. Special Practices

- a) All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- b) Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
- c) Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
- d) A Laboratory-Specific Biosafety Manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
- e) The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
- f) Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- g) Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
- i. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.

- ii. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
- h) 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, surveillance, and treatment should be provided and appropriate records maintained.
- i) Animals and plants not associated with the work being performed must not be permitted in the laboratory.
- j) All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a biological safety cabinet or other physical containment devices.

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

- a) Properly maintained biological safety cabinets (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:
 - i. 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.
 - ii. 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.
- b) 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.
- c) 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 biological safety cabinet 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.

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

4. Laboratory Facilities (Secondary Barriers)

- a) Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
- b) 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.]
- c) The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
- d) Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - i. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - ii. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- e) 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.

- f) Biological safety cabinets must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. Biological safety cabinets should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
- g) 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.
- h) An eyewash station must be readily available.
- i) 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.
- j) HEPA filtered exhaust air from a Class II biological safety cabinet 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. Biological safety cabinets 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.
- k) A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

Guidelines for Good BSL-3 Practices

Biological Safety Level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.

All procedures involving the manipulation of infectious materials must be conducted within biological safety cabinets, other physical containment devices, or by personnel wearing appropriate personal protective equipment. A BSL-3 laboratory has special engineering and design features.

The following standard and special safety practices, equipment, and facility requirements apply to BSL-3:

1. Standard Microbiological Practices

- a) The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
- b) Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
- c) 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.
- d) Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- e) 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:

- i. 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.
- ii. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
- iii. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
- iv. 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.
- f) Perform all procedures to minimize the creation of splashes and/or aerosols.
- g) Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.

- h) Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method). Depending on where the decontamination will be performed, the following methods should be used prior to transport:
 - i. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - ii. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
 - i) 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.
 - j) An effective integrated pest management program is required.
 - k) 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.
- for agents handled or potentially present in the laboratory.
 - c) Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
 - d) A Laboratory-Specific Biosafety Manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
 - e) The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.
 - f) Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
 - g) Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
 - i. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - ii. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
 - h) 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, surveillance, and treatment should be provided and appropriate records maintained.
 - i) Animals and plants not associated with the work being performed must not be permitted in the laboratory.
 - j) All procedures involving the manipulation of infectious materials must be conducted within a biological safety cabinet, or other physical containment devices. No work with open vessels is conducted on the bench. When a procedure cannot be performed within a biological safety cabinet, a combination of personal protective equipment and other containment devices, such as a centrifuge safety cup or sealed rotor, must be used.

2. Special Practices

- a) All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- b) Laboratory personnel must be provided medical surveillance and offered appropriate immunizations

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

- a) All procedures involving the manipulation of infectious materials must be conducted within a biological safety cabinet (preferably Class II or Class III), or other physical containment devices.
- b) Protective laboratory clothing with a solid-front such as tie-back or wraparound gowns, scrub suits, or coveralls is worn by workers when in the laboratory. Protective clothing is not worn outside of the laboratory. Reusable clothing is decontaminated with appropriate disinfectant before being laundered. Clothing is changed when contaminated.
- c) 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. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories must also wear eye protection.
- d) 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-3 laboratory workers should:
 - i. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
 - ii. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - iii. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
- e) Eye, face, and respiratory protection must be used in rooms containing infected animals.

4. Laboratory Facilities (Secondary Barriers)

- a) Laboratory doors must be self-closing and have locks in accordance with the institutional policies. The laboratory must be separated from areas that are open to unrestricted traffic flow within the building. Access to the laboratory is restricted to entry by a series of two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
- b) Laboratories must have a sink for hand washing. The sink must be hands-free or automatically operated. It should be located near the exit door. If the laboratory is segregated into different

laboratories, a sink must also be available for hand washing in each zone. Additional sinks may be required as determined by the risk assessment.

- c) The laboratory must be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted. Seams, floors, walls, and ceiling surfaces should be sealed. Spaces around doors and ventilation openings should be capable of being sealed to facilitate space decontamination.
 - i. Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Consideration should be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.
 - ii. Walls should be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
 - iii. Ceilings should be constructed, sealed, and finished in the same general manner as walls.

Decontamination of the entire laboratory should be considered when there has been gross contamination of the space, significant changes in laboratory usage, for major renovations, or maintenance shut downs. Selection of the appropriate materials and methods used to decontaminate the laboratory must be based on the risk assessment of the biological agents in use.

- d) Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment must be accessible for cleaning.
 - i. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - ii. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
- e) All windows in the laboratory must be sealed.
- f) Biological safety cabinets must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. Biological safety cabinets should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.
- g) Vacuum lines must be protected with HEPA filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.

- h) An eyewash station must be readily available in the laboratory.
- i) A ducted air ventilation system is required. This system must provide sustained directional airflow by drawing air into the laboratory from “clean” areas toward “potentially contaminated” areas. The laboratory shall be designed such that under failure conditions the airflow will not be reversed.
 - i. Laboratory personnel must be able to verify directional air flow. A visual monitoring device which confirms directional air flow must be provided at the laboratory entry. Audible alarms should be considered to notify personnel of air flow disruption.
 - ii. The laboratory exhaust air must not re-circulate to any other area of the building.
 - iii. The laboratory building exhaust air should be dispersed away from occupied areas and from building air intake locations or the exhaust air must be HEPA filtered.
- j) HEPA filtered exhaust air from a Class II biological safety cabinet can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer’s recommendations. Biological safety cabinets 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. Biological safety cabinets should be certified at least annually to assure correct performance. Class III biological safety cabinets must be directly (hard) connected up through the second exhaust HEPA filter of the cabinet. Supply air must be provided in such a manner that prevents positive pressurization of the cabinet.
- k) A method for decontaminating all laboratory wastes should be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method)
- l) Equipment that may produce infectious aerosols must be contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.
- m) Facility design consideration should be given to means of decontaminating large pieces of equipment before removal from the laboratory.
- n) Enhanced environmental and personal protection may be required by the agent summary statement, risk assessment, or applicable local, state, or federal regulations. These laboratory enhancements may include, for example, one or more of the following; an anteroom for clean storage of equipment and supplies with dress-in, shower-out capabilities; gas tight dampers to facilitate laboratory isolation; final HEPA filtration of the laboratory exhaust air; laboratory effluent decontamination; and advanced access control devices such as biometrics. HEPA filter housings should have gas-tight isolation dampers; decontamination ports; and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should allow for leak testing of each filter and assembly. The filters and the housing should be certified at least annually.
- o) The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.

Appendix D. Animal Biosafety Guidelines

Guidelines for Good ABSL-1 Practices

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

ABSL-1 facilities should be separated from the general traffic patterns of the building and restricted as appropriate. Special containment equipment or facility design may be required as determined by appropriate risk assessment.

Personnel must have specific training in animal facility procedures and must be supervised by an individual with adequate knowledge of potential hazards and experimental animal procedures.

The following standard practices, safety equipment, and facility requirements apply to ABSL-1.

1. Standard Microbiological Practices

- a) The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergencies.

Each institute must assure that worker safety and health concerns are addressed as part of the animal protocol review.

Prior to beginning a study animal protocols must also be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC) and the IBC.

- b) A safety manual specific to the animal facility is prepared or adopted in consultation with the animal facility director and appropriate safety professionals. The safety manual must be available and accessible. Personnel are advised of potential hazards and are required to read and follow instructions on practices and procedures.
- c) The animal facility supervisor must ensure that animal care, laboratory, and support personnel receive appropriate training regarding their duties, animal husbandry procedures, potential hazards, manipulations of infectious agents, necessary precautions to prevent exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.). Personnel must receive annual updates and additional training when procedures or policies change. Records are

maintained for all hazard evaluations, employee training sessions and staff attendance.

- d) An appropriate medical surveillance program is in place as determined by risk assessment. The need for an animal allergy prevention program should be considered.

Facility supervisors should ensure that medical staff is informed of potential occupational hazards within the animal facility, to include those associated with research, animal husbandry duties, and animal care and manipulations. This is accomplished at ASU by having the Occupational Health and Safety Program physician and/or nurse regularly attend IACUC meetings.

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

Personnel using respirators must be enrolled in the ASU Health Services respiratory protection program.

- e) A sign incorporating safety information must be posted at the entrance to the areas where infectious materials and/or animals are housed or manipulated. The sign must include the animal biosafety level, general occupational health requirements, personal protective equipment requirements, the animal facility supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the animal areas. Identification of specific infectious agents is recommended when more than one agent is being used within an animal room. However, at ASU all research with biohazard agents are conducted at ABSL-2 or higher.

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

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

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

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

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

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

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

Persons must wash their hands after removing gloves and before leaving the areas where infectious materials and/or animals are housed or are manipulated.
Eye, face, and respiratory protection should be used in rooms containing infected animals as dictated by the risk assessment.

- h) Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption is not permitted in laboratory areas. Food must be stored outside of the laboratory in cabinets or refrigerators designed and used for this purpose.
- i) All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.
- j) Mouth pipetting is prohibited. Mechanical pipetting devices must be used.
- k) Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.

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

- i. Use of needles and syringes or other sharp instruments in the animal facility is limited to situations where there is no alternative for such procedures as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

- ii. Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible.

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

- iv. 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.

- v. Equipment containing sharp edges and corners should be avoided.

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

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

- n) An effective integrated pest management program is required.

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

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

2. Special Practices

None required.

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

- a) A risk assessment should determine the appropriate type of personal protective equipment to be utilized.
- b) Special containment devices or equipment may not be required as determined by appropriate risk assessment.

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

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

- d) Protective eyewear is worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates.

Persons having contact with non-human primates must assess risk of mucous membrane exposure and wear protective equipment (e.g., masks, goggles, face shields, etc.) as appropriate for the task to be performed.

- e) Gloves are worn to protect hands from exposure to hazardous materials.

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

Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

Gloves must not be worn outside the animal rooms.

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

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

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

4. Laboratory Facilities (Secondary Barriers)

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

Access to the animal facility is restricted.

Doors to areas where infectious materials and/or animals are housed, open inward, are self-closing, are kept closed when experimental animals are present, and should never be propped open. Doors

to cubicles inside an animal room may open outward or slide horizontally or vertically.

- b) The animal facility must have a sink for hand washing.

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

- c) The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors and ceilings) are water resistant. Floors must be slip resistant, impervious to liquids, and resistant to chemicals.

It is recommended that penetrations in floors, walls and ceiling surfaces, including openings around ducts, doors, and doorframes, be sealed to facilitate pest control and proper cleaning.

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

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

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

- f) Ventilation should be provided in accordance with the Guide for Care and Use of Laboratory Animals. No recirculation of exhaust air may occur.

It is recommended that animal rooms have inward directional airflow.

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

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

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

- i) Cages are washed manually or preferably in a mechanical cage washer. The mechanical cage washer should have a final rinse temperature of at least 180°F (82°C). If manual cage washing is utilized, ensure that appropriate disinfectants are selected.
- j) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
- k) Emergency eyewash and shower are readily available; location is determined by risk assessment.

Guidelines for Good ABSL-2 Practices

Animal Biosafety Level 2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-1. ABSL-2 is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.

ABSL-2 requires that: 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals, and the manipulation of pathogenic agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations, and husbandry procedures; and 4) a biological safety cabinet (BSC) or other physical containment equipment is used when procedures involve the manipulation of infectious materials or where aerosols or splashes may be created.

Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Implementation of employee occupational health programs is required.

The following standard and special practices, safety equipment, and facility requirements apply to ABSL-2:

1. Standard Microbiological Practices

- a) The animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergencies.

Each organization must assure that worker safety and health concerns are addressed as part of the animal protocol review.

Prior to beginning a study, animal protocols must also be reviewed and approved by the IACUC and the IBC.

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

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

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

- c) The animal facility supervisor must ensure that animal care, laboratory, and support personnel receive appropriate training regarding their duties, animal husbandry procedure, potential hazards, manipulations of infectious agents, necessary precautions to prevent hazard or exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.). Personnel must receive annual updates or additional training when procedures or policies change. Records are maintained for all hazard evaluations, employee training sessions, and staff attendance.
- d) An appropriate medical surveillance program is in place, as determined by risk assessment. The need for an animal allergy prevention program should be considered.

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

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

Personnel using respirators must be enrolled in the ASU Health Services respiratory protection program.

- e) A sign incorporating the universal biohazard symbol must be posted at the entrance to areas where infectious materials and/ or animals are housed or are manipulated when infectious agents are present. The sign must include the animal biosafety level, general occupational health requirements, personal protective equipment requirements, the animal facility supervisor's name (or names of other responsible personnel), telephone number, and

required procedures for entering and exiting the animal areas. Identification of all infectious agents is necessary when more than one agent is being used within an animal room.

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

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

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

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

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

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

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

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

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

- h) Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption is not permitted in laboratory areas. Food must be stored outside of the laboratory in cabinets or refrigerators designated and used for this purpose.
- i) All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.

- j) Mouth pipetting is prohibited. Mechanical pipetting devices must be used.

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

- i. The use of needles and syringes or other sharp instruments in the animal facility is limited to situations where there is no alternative such as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
- ii. Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible.
- iii. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- iv. Broken glassware must not be handled directly; it should be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- v. Use of equipment with sharp edges and corners should be avoided.

- l) Equipment and work surfaces are routinely decontaminated with an appropriate disinfectant after work with an infectious agent and after any spills, splashes, or other overt contamination.
- m) Animals and plants not associated with the work being performed are not permitted in the areas where infectious materials and/or animals are housed or manipulated.
- n) An effective integrated pest management program is required.
- o) All wastes from the animal room (including animal tissues, carcasses, and bedding) are transported from the animal room in leak-proof containers for appropriate disposal in compliance with applicable institutional, local, and state requirements.

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

2. Special Practices

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

When appropriate, a baseline serum sample is stored.

- b) Procedures involving a high potential for generating aerosols should be conducted within a biosafety cabinet or other physical containment device. When a procedure cannot be performed within a biosafety cabinet, a combination of personal protective equipment and other containment devices must be used.

Restraint devices and practices that reduce the risk of exposure during animal manipulations (e.g., physical restraint devices, chemical restraint medications) should be used whenever possible.

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

A method for decontaminating routine husbandry equipment as well as sensitive electronic and medical equipment should be identified and implemented.

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

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

- d) Equipment, cages, and racks should be handled in a manner that minimizes contamination of other areas.

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

- e) Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
- f) Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the safety manual. All such incidents must be reported to the animal facility supervisor or personnel designated by the institution. Contact ASU Health Services for more information. Medical evaluation, surveillance, and treatment should be provided as appropriate and records maintained.

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

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

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

- b) A risk assessment should determine the appropriate type of personal protective equipment to be utilized. Scrub suits and uniforms are removed before leaving the animal facility. Reusable clothing is appropriately contained and decontaminated before being laundered. Laboratory and protective clothing should never be taken home.

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

- c) Eye and face protection (mask, goggles, and face shield or other splatter guard) are used for manipulations or activities that may result in

splashes or sprays from infectious or other hazardous materials and when the animal or microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates.

Persons having contact with non-human primates should assess risk of mucous membrane exposure and wear protective equipment (e.g., masks, goggles, face shields) appropriate for the task to be performed. Respiratory protection is worn based upon risk assessment.

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

Gloves are changed when contaminated, glove integrity is compromised, or when otherwise necessary.

Gloves must not be worn outside the animal rooms.

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

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

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

4. Laboratory Facilities (Secondary Barriers)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- h) Floor drains must be maintained and filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases.
- i) Cages should be autoclaved or otherwise decontaminated prior to washing. Mechanical cage washer should have a final rinse temperature of at least 180°F (82°C). The cage wash area should be designed to accommodate the use of high-pressure spray systems, humidity, strong chemical disinfectants, and 180°F water temperatures during the cage/equipment cleaning process.
- j) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.
- k) If BSCs are present, they must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.

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

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

- l) If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.
- m) An autoclave should be present in the animal facility to facilitate decontamination of infectious materials and waste.
- n) Emergency eyewash and shower are readily available; location is determined by risk assessment.

Guidelines for Good ABSL-3 Practices

Animal Biosafety Level 3 involves practices suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol

transmission, and agents causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2.

The ABSL-3 laboratory has special engineering and design features. ABSL-3 requires that: 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals, and the manipulation of potentially lethal agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations, and husbandry procedures; and 4) procedures involving the manipulation of infectious materials, or where aerosols or splashes may be created, must be conducted in BSCs or by use of other physical containment equipment.

Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Employee occupational health programs must be implemented.

The following standard and special safety practices, safety equipment, and facility requirements apply to ABSL-3.

1. Standard Microbiological Practices

- a) The animal facility animal facility director establishes and enforces policies, procedures, and protocols for institutional policies and emergencies.

ASU must assure that worker safety and health concerns are addressed as part of the animal protocol review.

Prior to beginning a study, animal protocols must be reviewed and approved by the IACUC and the IBC.

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

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

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

- c) The facility supervisor must ensure that animal care, laboratory and support personnel receive appropriate training regarding their duties, animal husbandry procedures, potential hazards, manipulations of infectious agents, necessary precautions to prevent hazard or exposures, and hazard/exposure evaluation procedures (physical hazards, splashes, aerosolization, etc.). Personnel must receive annual updates or additional training when procedures or policies change. Records are

maintained for all hazard evaluations, employee training sessions, and staff attendance.

- d) An appropriate medical surveillance program is in place as determined by risk assessment. The need for an animal allergy prevention program should be considered.

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

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

Personnel using respirators must be enrolled in the ASU Health Services respiratory protection program.

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

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

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

- f) Access to the animal room is limited to the fewest number of individuals possible. Only those persons required for program or support purposes are authorized to enter the animal facility and the areas where infectious materials and/or animals are housed or manipulated.

All persons, including facility personnel, service workers, and visitors, are advised of the potential hazards (natural or research pathogens, allergens,

etc.) and are instructed on the appropriate safeguards.

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

Gloves are worn to prevent skin contact with contaminated, infectious/hazardous materials and when handling animals. Double-glove practices should be used when dictated by risk assessment.

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

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

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

- h) 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.
- i) All procedures are carefully performed to minimize the creation of aerosols or splatters of infectious materials and waste.
- j) Mouth pipetting is prohibited. Mechanical pipetting devices must be used.
- k) Policies for the safe handling of sharps such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.

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

- i. Use of needles and syringes or other sharp instruments in the animal facility is limited to situations where there is no alternative such as parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.
- ii. Disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand

before disposal. Used disposable needles must be carefully placed in puncture-resistant containers used for sharps disposal. Sharps containers should be located as close to the work site as possible.

- iii. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
- iv. Broken glassware must not be handled directly; it should be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
- v. Use of equipment with sharp edges and corners should be avoided.
- l) Equipment and work surfaces are routinely decontaminated with an appropriate disinfectant after work with an infectious agent and after any spills, splashes, or other overt contamination.
- m) Animals and plants not associated with the work being performed must not be permitted in the areas where infectious materials and/ or animals are housed or manipulated.
- n) An effective integrated pest management program is required.
- o) All wastes from the animal room (including animal tissues, carcasses, and bedding) are transported from the animal room in leak-proof containers for appropriate disposal in compliance with applicable institutional, local, and state requirements. Decontaminate all potentially infectious materials before disposal using an effective method.

2. Special Practices

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

When appropriate, a baseline serum sample should be stored.

- b) All procedures involving the manipulation of infectious materials, handling of infected animals, or the generation of aerosols must be conducted within BSCs or other physical containment devices when practical.

When a procedure cannot be performed within a biosafety cabinet, a combination of personal

protective equipment and other containment devices must be used.

Restraint devices and practices are used to reduce the risk of exposure during animal manipulations (e.g., physical restraint devices, chemical restraint medications).

- c) The risk of infectious aerosols from infected animals or their bedding also can be reduced if animals are housed in containment caging systems such as solid wall and bottom cages covered with filter bonnets, open cages placed in inward flow ventilated enclosures, HEPA-filter isolators and caging systems, or other equivalent primary containment systems.
- d) Actively ventilated caging systems must be designed to prevent the escape of microorganisms from the cage. Exhaust plenums for these systems should be sealed to prevent escape of microorganisms if the ventilation system becomes static, and the exhaust must be HEPA filtered. Safety mechanisms should be in place that prevent the cages and exhaust plenums from becoming positive to the surrounding area should the exhaust fan fail. The system should also be alarmed to indicate operational malfunctions.
- e) A method for decontaminating all infectious materials must be available within the facility, preferably within the areas where infectious materials and/or animals are housed or manipulated (e.g., autoclave, chemical disinfection, or other approved decontamination methods).

Consideration must be given to means for decontaminating routine husbandry equipment as well as sensitive electronic and medical equipment.

Decontaminate all potential infectious materials (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse) by an appropriate method before removal from the areas where infectious materials and/or animals are housed or manipulated.

It is recommended that animal bedding and waste be decontaminated prior to manipulation and before removal from the areas where infectious materials and/or animals are housed or manipulated, preferably within the caging system.

Develop and implement an appropriate waste disposal program in compliance with applicable institutional, local, and state requirements.

- f) Equipment, cages, and racks should be handled in a manner that minimizes contamination of other areas.

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

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

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

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

- a) Properly maintained BSCs and other physical containment devices or equipment should be used for all manipulations for infectious materials and, when possible, animals. These manipulations include necropsy, harvesting of tissues or fluids from infected animals or eggs, and intranasal inoculation of animals.

The risk of infectious aerosols from infected animals or bedding can be reduced by primary barrier systems. These systems may include solid wall and bottom cages covered with filter bonnets, ventilated cage rack systems, or, for larger species, cages placed in inward flow ventilated enclosures or other equivalent systems or devices.

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

Personnel within the animal facility wear protective clothing such as uniforms or scrub suits. Reusable clothing is appropriately contained and decontaminated before being laundered. Laboratory and protective clothing should never be taken home. Disposable personal protective equipment such as non-woven olefin cover-all suits or wrap-around or solid-front gowns should be worn over this clothing before entering the areas where infectious materials and/or animals are housed or manipulated. Front-button laboratory coats are unsuitable.

Disposable personal protective equipment must be removed when leaving the areas where infectious materials and/or animals are housed or manipulated. Scrub suits and uniforms are removed before leaving the animal facility.

Disposable personal protective equipment and other contaminated waste are appropriately contained and decontaminated prior to disposal.

- c) All personnel entering areas where infectious materials and/or animals are housed or manipulated wear appropriate eye, face, and respiratory protection. To prevent cross contamination, boots, shoe covers, or other protective footwear are used where indicated.

Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses should also wear eye protection when entering areas with potentially high concentrations or airborne particulates.

- d) Gloves are worn to protect hands from exposure to hazardous materials.

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

Procedures may require the use of wearing two pairs of gloves (double-glove).

Gloves are changed when contaminated, glove integrity is compromised, or when otherwise necessary.

Gloves must not be worn outside the animal rooms.

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

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

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

4. Laboratory Facilities (Secondary Barriers)

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

Access to the animal facility is restricted.

Doors to areas where infectious materials and/or animals are housed open inward, are self-closing, are kept closed when experimental animals are present, and should never be propped open.

Entry into the containment area is via a double-door entry, which constitutes an anteroom/airlock and a change room. Showers may be considered based on risk assessment. An additional double-door access anteroom or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility.

- b) A hand-washing sink is located at the exit of the areas where infectious materials and/or animals are housed or manipulated. Additional sinks for hand washing should be located in other appropriate locations within the facility. The sink should be hands-free or automatically operated.

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

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

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

Penetrations in floors, walls, and ceiling surfaces, including openings around ducts and doorframes, are sealed to facilitate pest control, proper cleaning, and decontamination. Walls, floors, and ceilings should form a sealed and sanitizable surface.

Floors must be slip resistant, impervious to liquids, and resistant to chemicals. Flooring is seamless, sealed resilient or poured floors, with integral cove bases.

Decontamination of an entire animal room should be considered when there has been gross contamination of the space, significant changes in usage, for major renovations, or maintenance shut downs. Selection of the appropriate materials and methods used to decontaminate the animal room must be based on the risk assessment.

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

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

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

- f) Ventilation of the facility should be provided in accordance with the Guide for Care and Use of Laboratory Animals. The direction of airflow into the animal facility is inward; animal rooms maintain inward directional airflow compared to adjoining hallways. A ducted exhaust air ventilation system is provided. Exhaust air is discharged to the outside without being recirculated to other rooms. This system creates directional airflow, which draws air into the animal room from "clean" areas and toward "contaminated" areas.

Ventilation system design should consider the heat and high moisture load produced during the cleaning of animal rooms and the cage wash process. HEPA filtration and other treatments of the exhaust air may not be required, but should be considered based on site requirements, specific agent manipulations, and use conditions. The exhaust must be dispersed away from occupied areas and air intakes.

Personnel must verify that the direction of the airflow (into the animal areas) is proper. It is recommended that a visual monitoring device that indicates directional inward airflow be provided at the animal room entry. The ABSL-3 animal facility shall be designed such that under failure conditions the airflow will not be reversed. Alarms should be considered to notify personnel of ventilation and HVAC system failure.

- g) Internal facility appurtenances such as light fixtures, air ducts, and utility pipes are arranged to minimize horizontal surface areas to facilitate cleaning and minimize the accumulation of debris or fomites.
- h) Floor drains must be maintained and filled with water and/or appropriate disinfectant to prevent the migration of vermin and gases.
- i) Cages are washed in a mechanical cage washer. The mechanical cage washer has a final rinse temperature of at least 180°F (82°C). Cages should be autoclaved or otherwise decontaminated prior to removal from ABSL-3 space. The cage wash facility should be designed and constructed to accommodate high-pressure spray systems, humidity, strong chemical disinfectants, and 180°F water temperatures during the cage cleaning process.
- j) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

- k) BSCs (Class II, Class III) must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. Class II BSCs should be located away from doors, heavily traveled laboratory areas, and other possible airflow disruptions.

HEPA filtered exhaust air from a Class II BSC can be safely re-circulated 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 exhausted directly to the outside through a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified. BSCs should be certified at least annually to assure correct performance.

Class III BSCs must supply air in such a manner that prevents positive pressurization of the cabinet or the laboratory room.

All BSCs should be used according to manufacturers' specifications.

When applicable, equipment that may produce infectious aerosols must be contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into

the animal facility. These HEPA filters should be tested and/or replaced at least annually.

- l) An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious materials and waste before moving it to the other areas of the facility. If not convenient to areas where infectious materials and/or animals are housed or are manipulated, special practices should be developed for transport of infectious materials to designated alternate location/s within the facility.
- m) Emergency eyewash and shower are readily available; location is determined by risk assessment.
- n) The ABSL-3 facility design and operational procedures must be documented. The facility must be tested to verify that the design and operational parameters have been met prior to use. Facilities should be re-verified at least annually against these procedures as modified by operational experience.
- o) Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions or other applicable federal, state, or local regulations.

Appendix E. Disinfection Tables

DISINFECTANT ACTIVITY											
Disinfectants		Practical Requirements					Inactivates				
Type	Category	Use Dilution	Contact Time (min) Lipovirus	Contact Time (min) Broad Spectrum	Temperature (C°)	Relative Humidity (%)	Vegetative Bacteria	Lipoviruses	Nonlipid Viruses	Mycobacteria	Bacterial Spores
Liquid	Quaternary Ammonia Compounds	0.1%-2.0%	10	NE			+	+			
	Phenolic Compounds	1.0%-5.0%	10	NE			+	+	B		
	Chlorine Compounds	500 ppm*	10	30			+	+	+	+	+
	Iodophor	25-1600 ppm*	10	30			+	+	+		
	Alcohol, Ethyl	70%-85%	10	30			+	+	B		
	Alcohol, Isopropyl	70%-85%	10	30			+	+	B		
	Formaldehyde	0.2%-8.0%	10	30			+	+	+	+	+
	Glutaraldehyde	2%	10	30			+	+	+	+	+
Gas	Ethylene Oxide	8-23g/ft ³	60	60	37	30	+	+	+	+	+
	Paraformaldehyde	0.3 g/ft ³	60	60	>23	60	+	+	+	+	+

NE=not effective

B=Variable results dependent on virus

*=Available halogen (1:100)

DISINFECTANT CHARACTERISTICS												
Disinfectants		Important Characteristics										
Type	Category	Effective Shelf Life >1 week (A)	Corrosive	Flammable	Explosion Potential	Residue	Inactivated by Organic Matter	Compatible for Optics (D)	Skin Irritant	Eye Irritant	Respiratory Irritant	Toxic (E)
Liquid	Quaternary Ammonia Compounds	+					+	+	+	+		+
	Phenolic Compounds	+	+			+			+	+		+
	Chlorine Compounds		+			+	+		+	+	+	+
	Iodophor	+	+			+	+		+	+		+
	Alcohol, Ethyl	+		+						+		+
	Alcohol, Isopropyl	+		+						+		+
	Formaldehyde	+				+			+	+	+	+
	Glutaraldehyde	+				+		+	+	+	+	+
Gas	Ethylene Oxide	N/A		+(B)	+(B)			+	+	+	+	+
	Paraformaldehyde	N/A		+(C)	+(C)			+	+	+	+	+

N/A=not applicable (A)=Protected from light and air (B)=Neither flammable nor explosive in 90% CO₂ or fluorinated hydrocarbon, the usual form (C)=At concentrations of 7%-73% by volume in air, solid exposure to open flame (D)=Usually compatible, but consider interferences from residues and effects on associated materials such as mounting (E)=By skin or mouth, or both. Refer to manufacturer's literature and the MSDS.

DISINFECTANT APPLICATIONS												
Disinfectants		Important Characteristics										
Type	Category	Work Surface	Dirty Glassware	Large Area	Air Handling	Portable Equip. Surface Decon	Portable Equip. Penetrating Decon	Fixed Equip. Surface Decon	Fixed Equip. Penetrating Decon	Optical and Electronic Inst.	Liquid and Discard	Book, Paper
Liquid	Quaternary Ammonia Compounds	+	+			+		+				
	Phenolic Compounds	+	+			+		+				
	Chlorine Compounds	+	+			+		+			+	
	Iodophor	+	+			+		+				
	Alcohol, Ethyl	+	+			+		+				
	Alcohol, Isopropyl	+	+			+		+				
	Formaldehyde	+	+			+		+				
	Glutaraldehyde	+	+			+		+				
Gas	Ethylene Oxide					+	+			+		+
	Paraformaldehyde			+	+	+	+		+	+		

Appendix F. Serum Storage Procedures

All personnel participating in the Serum Storage Program will be asked to sign the “Consent for Drawing Baseline Serum Specimen” (available at ASU Health Services) and provide a serum baseline donation as a recommended condition of participation in research, if the work involves any of the following:

- Human Immunodeficiency Virus (HIV);
- *Mycobacterium tuberculosis*;
- Select agents or toxins;
- Microorganisms classified as Biosafety Level (BSL)-3/Animal Biosafety Level (ABSL)-3; and
- As recommended by the ASU Biosafety Officer, and/or the ASU Health Services, and/or the IBC.

Principal Investigators or supervisors may also request for serum samples to be collected when research involves pathogenic, drug-resistant microorganisms, or microorganisms classified as BSL-2/ABSL-2.

Individuals choosing to decline to have a baseline serum sample drawn must sign the “Serum Storage Program Declination Form” (available at ASU Health Services).

A. Collection

A serum sample may be collected following an exposure (e.g., percutaneous or mucous membrane exposure to a body fluid, animal bite) to an infectious agent or other biohazardous material or at the conclusion of the work with the particular agent. Additional serum samples in addition to the baseline sample may be collected if requested by the individual or the supervisor based on a risk assessment or documented occupational exposure. These samples will not be processed through a clinical laboratory for the purposes of diagnostic reporting unless there is an occupational exposure. A new consent form must be obtained if additional serum is drawn.

B. Laboratory Process

One 8.5 ml vial of blood will be obtained via venipuncture by an ASU Health Services phlebotomist. Becton-Dickinson tiger-top serum separator tubes should be used for this process. Once drawn, the specimen should be left to sit for 30 minutes. Subsequently, the clotted specimen should be centrifuged so that serum is separated from the cellular elements.

1. One milliliter (1 ml.) of serum is then pipetted into each of two cryo vial tubes with an O ring on top. These tubes should be labeled with a unique identification number rather than the worker's personal information. This identifier will be linked with a log kept by the Occupational Health Nurse that states the worker's name and work location.
2. The two (2) labeled specimens will be divided into two freezers. DACT personnel will place one sample in a -80°C freezer in ISTB-1 and another will be placed in a -80°C freezer in The Biodesign Institute.
3. The Serum Sample Log ([Attachment 1](#)) will be completed when entering and removing samples from the -80°C freezer.
4. The sera will be retained by ASU for purposes of this program for 30 years or for 10 years after the individual leaves the university.

- a. The Occupational Health Nurse will be responsible for compliance with all regulations related to the collection, storage, and release of medical information. Any information gained from testing a baseline serum sample will not be used for discrimination purposes or for any reason not addressed in the consent.
- b. Specimens will be stored in accordance with recommendations of the American College of Clinical Pathologists by ASU Health Service under the supervision of the Occupational Health Nurse. The specimens will be stored at -80°C or lower, in a secure and confidential freezer, maintained by DACT. The freezer is stored in a location with a back-up emergency generator. Storage of employee serum samples in laboratory freezers is not appropriate.

C. Storage and Retrieval Procedures

The Department of Animal Care and Technologies (DACT) will 1) provide the space for the two freezers to include having them both on back-up power, 2) receive samples from ASU Health Services, and place one sample in each freezer, 3) complete the Serum Banking Log ([Attachment 1](#)), and 4) respond to any freezer failures by consolidating the samples into the remaining functional freezer until the failed freezer is functioning normal again.

The Occupational Health Nurse will be permitted to release stored specimens in the following instances and only if appropriate consent has been obtained:

1. In the event of an exposure to an infectious or other biohazardous agent

Note: As stated above, the worker will be asked to sign a consent form allowing an aliquot of his or her serum to be released for testing.

2. During a public health emergency potentially associated with the laboratory

Note: The county or state health department may request information from ASU under such circumstances. For the purposes of public health emergencies, obtaining consent is not legally required.

and

3. If the worker requests that an aliquot of his/her sera be released to assist in providing medical care.

Note: A written request by the worker must be made in such situations.

4. Specimens obtained for the purposes of this program will become the property of ASU. Once the individual has provided the specimen, the individual will have no access to it unless there is a written request from a medical provider and the worker's signed consent.

D. Verification

1. Biosafety/Biosecurity staff will meet with the Occupational Health Nurse and a representative from DACT to physically verify the serum sample inventory once a year.
2. Biosafety/Biosecurity staff will provide a report on the status of annual verification to the Director of Environmental Health and Safety, Director of ASU Health Services, and Director of DACT.

Attachment 1: ASU Serum Banking Log

[illegible]