ARKANSAS STATE UNIVERSITY
BIOLOGICAL SAFETY
GOVERNING PRINCIPLES

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1.0 INTRODUCTION

Arkansas State University (ASU) is committed to maintenance of a safe campus and has developed policies and procedures that govern the safe use of biohazardous materials in the workplace.

2.0 PURPOSE

This document is intended to satisfy all regulatory and containment requirements concerning biological safety, including compliance with *National Institutes of Health Guidelines*, and have the express purpose of protecting students, faculty, staff, and the public from potential adverse exposure to biological material used in research and teaching activities at ASU.

3.0 DEFINITIONS

Agent Stability or Viability. Stability and viability refer to the ability of a biohazardous material to retain its biohazardous characteristics such as aerosol infectivity and survival time in environment. Factors such as temperature, humidity, pH, oxygen, sunlight or ultraviolet light, chemical disinfectants, growth factors (food reservoir or media), and competition with endemic organisms must be considered.

Biosafety Level (BL). A description of the degree of physical containment being employed to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment, as defined by the NIH. In Appendix G of the NIH Guidelines, these are graded from BL-1 (the least stringent) to BL-4 (the most stringent). BL-N refers specifically to the animal biosafety level and BL-P refers to the plant biosafety.

Biohazardous Materials. Biohazardous materials are any microorganism, or infectious substance, or any naturally occurring, bio-engineered, or synthesized component of any such microorganism or infectious substance, capable of causing: 1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; 2) deterioration of food, water, equipment, supplies, or material of any kind; or 3) harmful alteration of the environment. These include, but are not limited to:

- Certain bacteria, fungi, viruses, rickettsiae, protozoa, parasites;
- Recombinant organisms;

- Select agents and toxins of biological origin, as classified by the Centers for Disease Control (CDC) at http://www.cdc.gov/od/sap/docs/salist.pdf;
- Allergens;
- Cultured human or animal cells and the potentially infectious agents these cells may contain ;
- Viroids and prions;
- Any material requiring a CDC import license or a USDA permit; and
- Other infectious agents as outlined in laws, regulations, or guidelines.

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

Biohazard Workers. Biohazard Workers include any persons who work with biohazardous materials, regardless of frequency, who are under the supervision of a Principal Investigator or Supervisor (Registered User).

Bloodborne Pathogens. Pathogenic microorganisms that are present in human blood and can cause disease in humans. Examples of these pathogens include Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), Hepatitis C Virus, Malaria, Syphilis, Babesiosis, Brucellosis, Leptospirosis, Arboviral Infections, Creutzfeld-Jakob Vector, Human T-Lymphotrophic Virus Type I, and Viral Hemorrhagic Fever.

Concentration (Amount of Agent). Concentration is the number of infectious organisms per unit volume. As the viable agent concentration and volume increases, the risk potential gets higher. The media/reservoir, laboratory activity, volume (especially >10 liters) need to be considered in risk determination.

Direct (Skin/Eye) Contact Hazards. Direct contact to biohazardous materials occurs through cross-contamination and mucous membrane exposure including the skin, eyes, inside of the mouth, nose, and the genitals. The main avenues by which biohazardous materials enter the body through the skin are hair follicles, sebaceous glands, sweat glands, and cuts or abrasions. Examples of how exposure occurs include:

- Splash or spray of biohazardous material onto skin, eye, mouth, or nose;
- Handling contaminated equipment with unprotected non-intact skin;
- Transfer or rubbing by contaminated fingers or gloved hand; or
- Applying cosmetics or contact lens in laboratory

Infectious Dose. The infectious dose is the number of microorganisms required to initiate an infection. This dose can range from one to hundreds of thousands of units depending on agent, exposure route, virulence, and host immune status or susceptibility for the disease.

Ingestion Hazards. Ingestion of biohazardous materials occurs frequently as the result of poor personal hygiene and poor laboratory practice. Proper hand washing minimizes the opportunity for mouth and eye exposures. Examples of how ingestion occurs include:

- Eating, drinking, and smoking in laboratory;
- Mouth pipetting and suction techniques; or
- Transfer of microbes to mouth by contaminated fingers or articles.

Inhalation Hazards. Inhalation of aerosolized biohazardous materials is the most common route of entry into the body. Inhalation of aerosols involves microscopic solid or liquid particles small enough to remain dispersed and suspended in air for long periods. Sources of aerosols include:

- Aerosolized solid material (spores, dust, particulate, etc.).
- Liquid material (mists and sprays, coughing, spittle, sputum, etc.).
- Technical process (blending, grinding, sonicating, lyophilizing, sawing, centrifuging, etc).

Injection or Inoculation Hazards. Inoculation or injection occurs when biohazardous material is accidentally introduced into the body with contaminated objects through the intact skin barrier. Inadequate control of sharp instruments and infected animals or arthropod vectors usually results in accidental inoculation or injection. Examples of injection and inoculation hazards include:

- Inoculation with hypodermic needles, broken glassware, scalpels, or other sharp instruments;
- Sharps injuries (needle sticks, glass pipettes, syringes, etc.); or
- Animal bites, scratches, kicks, abrasions, punctures.

Immune Status: Immune status is the current condition of a living organism to resist and overcome infection or disease. The primary function of the immune system is to protect the body from foreign substances by an acquired ability to distinguish self from non-self. Host susceptibility or immune status helps determine the level of risk of acquiring a disease upon exposure. CDC and NIH guidelines presume a population of immunocompetent individuals.

Institutional Biosafety Committee (IBC). An institutional committee created under the *NIH Guidelines* to review research involving recombinant DNA. The role of IBCs has evolved over time, and many committees also review other forms of research that entail biohazardous risks as part of their institutionally assigned responsibilities.

National Institutes of Health (NIH). Federally-funded medical research institutions and the pre-eminent federal funder of medical research in the U.S. The NIH, comprised of 27 separate Institutes and Centers, is one of eight health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services.

NIH Guidelines for Research Involving Recombinant DNA Molecules (***NIH Guidelines***). A document created in 1976 that outlines principles for the safe conduct of research employing recombinant DNA technology. The NIH Guidelines detail practices and procedures for the containment of various forms of recombinant DNA research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. As a living document, it is periodically revised to keep pace with the changing state of science.

Office of Biotechnology Activities (OBA). The NIH office responsible for developing, implementing, and monitoring NIH policies and procedures for the safe conduct of recombinant DNA activities, including human gene transfer.

Pathogenicity or Virulence. Pathogenicity or virulence is the ability of a biohazardous material to produce or develop a rapid, severe, or deadly disease. Some materials are highly pathogenic, even in healthy adults, whereas others are opportunistic pathogens able to infect only hosts with lowered immunity or sites other than their normal habitat. Some biohazardous materials are attenuated, or weakened, and do not produce significant disease. The more severe the potentially-acquired disease, the higher the risks.

Recombinant DNA (rDNA). A series of procedures used to join together (recombine) DNA segments. A recombinant DNA molecule is constructed (recombined) from segments from 2 or more different DNA molecules. Under certain conditions, a recombinant DNA molecule can enter a cell and replicate there, autonomously (on its own) or after it has become integrated into a chromosome.

Recombinant DNA Molecules. *NIH Guidelines* characterize these molecules as those constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.

Registered User. The registered user is typically the Principal Investigator or Supervisor of a project that includes the use of biohazardous materials.

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

Routes of Entry. An infection occurs when pathogenic microorganisms enter the human body in sufficient numbers and by a particular route, which overcomes the body's defense system. By understanding the mode of transmission (pathway from source to you) and route of entry (entry route into body), procedures or controls to prevent exposure and infection can be developed.

Select Agents. Select agents are the biological agents or toxins listed in 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121, or the HHS and USDA Select Agents and Toxins List. Investigators who possess or use a select agent must register with and get approval

from either the CDC Select Agent Program or USDA APHIS Agricultural Select Agent Program, depending on the agent.

Unaffiliated Person. Individuals who work with biohazardous materials who are not formally affiliated with the University; e.g., faculty members on sabbatical, employees in start-up companies, etc.

4.0 APPLICABILITY

This policy applies to all faculty, staff, students, or unaffiliated personnel who work on ASU research protocols that require the use of biohazardous materials.

5.0 REGULATIONS

5.1 INFECTIOUS AGENTS AND BIOLOGICAL TOXINS

The following contains source information concerning infectious agents and toxins:

Possession, Use, and Transfer of Select Agents and Toxins, 42 CFR Parts 72 and 73, Department of Health and Human Services, http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf.

Biological Safety in Microbiological and Biomedical Laboratories - 4th Edition (BMBL): Prudent Biological Safety Level 1-4 practices, procedures, and facilities described for manipulations of infectious agents in laboratory settings and animal facilities.

American Biological Safety Association Risk Group Classification for Infectious Agents: Risk group classifications that are primarily used in the research environment for comprehensive Biological Safety risk assessment: http://www.absa.org/

U.S. Public Health Service (USPHS) Foreign Quarantine (42 CFR 71): CDC Importation Permits for Etiologic Agents @ http://www.cdc.gov/od/eaipp/

CDC Additional Requirements for Facilities Transferring or Receiving Select Agents Regulation (42 CFR 72.6):Registration program for shipping infectious agents and biological toxins designated as Select Agents: http://www.cdc.gov/od/sap

U.S. Occupational Safety Department and Health Administration (OSHA) Blood-borne Pathogens Standard (29 CFR 1910.1030): Covers human blood, other potentially infectious human body fluids or tissues and human cell lines. Reference http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

5.2 OTHER BIOLOGICAL SAFETY INFORMATION RESOURCES

Other resources include:

American Biological Safety Association Resources: http://www.absa.org/index.shtml.

American Industrial Hygiene Association (AIHA) Resources:
http://www2.umdnj.edu/eohssweb/aiha/

Biological Safety Reference Document - Second Edition (AIHA Publications):

- Information to address questions about laboratory, health care, and biotechnology biohazards in the workplace.
- Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets
  http://www.cdc.gov/od/ohs/biosfty/IBC/IBC.htm
- Anti-microbial Pesticides, EPA Office of Pesticide Programs
  http://www.epa.gov/oppad001/

References for Inactivation of HIV and Herpes B:

- http://www.cdc.gov/od/ohs/biosfty/inacthiv.htm
- http://www.cdc.gov/od/ohs/biosfty/herpesBinfo.htm

6.0 GOVERNING PRINCIPLES

ASU is committed to protecting students, faculty, staff, and the public from exposure to biohazardous materials that are used in research and teaching activities. The Biological Safety Program is designed to:

- Enhance biological safety knowledge among University stakeholders;
- Assist researchers in protecting personnel, the environment, and property from exposure.
- Provide the process and tools to assess safety needs and precautions for emergency response, planning, initiation, and termination of activities involving biohazardous materials.
- Provide an environment for high-quality research while maintaining a safe work place.
- Comply with applicable federal, state, and local requirements.

6.1 INSTITUTIONAL BIOSAFETY COMMITTEE

The Institutional Biosafety Committee administers the ASU-Jonesboro Biological Safety Program. Its mission is to work with the campus community to develop and implement an efficient, convenient, comprehensive, and forward-looking Biological Safety Program.

The Institutional Biological Safety Committee is appointed by the Vice Chancellor for Academic Affairs and Research and is composed of nine members as follows:

- At least one member with expertise in rDNA;
- At least one member with expertise in animal care and use;
- At least one member with expertise in plants;

- At least one member with expertise in containment issues;
- At least two members from the community who have interests in regional health issues and the environment;
- The Associate Vice Chancellor for Research who serves in an ex officio capacity but retains voting rights;
- The Director of Environmental Health and Safety, who is also a voting member.

A quorum is required for the Committee to conduct business. A quorum for purposes of the IBC is four members, one of which must be from the community. Members serve three-year rotating appointments.

6.2 BIOLOGICAL SAFETY OFFICER (BSO)

The BSO will be appointed to oversee management of biosafety risks in the event that ASU decides to develop BL-2 or greater capacity. (NIH Guidelines require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BL-3 or BL-4). The BSO will be appointed by the Vice Chancellor for Academic Affairs and Research and will provide administrative support to the IBC..

The BSC will serve as the BSO until such time as a BSO is appointed.

6.3 IBC PROGRAM APPLICATION

6.3.1 Overview. The PI or supervisor is responsible for preparing an IBC Program Application whenever s/he proposes use of biohazardous materials at biohazard levels 1-4. Components of these procedures include, but are not limited to:

- A risk assessment,
- A description of the proposed experiments and protocol to ensure safety and containment,
- Development of laboratory-specific emergency plans, and
- Training of laboratory personnel in emergency response procedures.

6.3.3 IBC Program Application

The IBC Program Application includes the following elements:

- A written assessment providing information on exposure prevention of personnel, environment, and property, with preparations to contain and disinfect the release.
- Types and levels of potential research program risks including a review of work assignments to determine employee potential for exposure to lab-acquired infections.
- A training plan to minimize the risk of exposure.
- Established decontamination practices for the type of biohazards involved and type of disinfectant needed for the biohazardous material.

- An understanding of the air handling and drainage systems as they relate to biohazardous materials.
- Layout of lab furniture, sinks, floor drains, and emergency equipment.
- Storage locations and security of biohazard materials.
- Appropriate work practices; e.g., personal hygiene, labeling, sharps handling, use of Personal Protective Equipment, etc.
- Description of recordkeeping procedures for biohazardous materials and rDNA.

6.3.3 Training

The principal investigator or program director must ensure that all persons working with biohazardous material(s) must:

- Be instructed in the laboratory specific exposure or release control plan; entry control procedures; the meanings of the various signs, signals, or other controls used; applicable emergency procedures applying to their work activities and area, recognition and prevention of dangerous situations and/or exposures and the symptoms (acute and chronic) of possible exposures.
- Receive documented training in basic biosafety controls; applicable directives (including use of this handbook); and specific methods and requirements of their work and work area.
- Participate in introductory to biohazardous materials management training and in a refresher every two years. Participate in initial Blood Borne Pathogen Training – Universal Precautions
- Participate in Annual Blood Borne Pathogen Training and in an annual refresher course
- Participate in autoclave safety training.
- Participate in biosafety cabinet training

All ancillary employees who work around biohazardous material(s) and/or blood or body fluids must participate in initial and bi-annual biohazardous materials and bloodborne pathogens training. The Principal Investigator or Program Director are responsible for ensuring that all ancillary personnel receive appropriate training when working around hazardous materials.

7.0 RESPONSIBILITIES

The roles and responsibilities of ASU employees are categorized as follows:

- ASU-Jonesboro Institutional Biological Safety Committee (IBC)
- Department of Environmental Health and Safety
- Principal Investigators and Supervisors (Registered Users)
- Biohazard Workers
- Ancillary Workers (Non-Biohazard Qualified Personnel) Deans, Directors, Administrators, and Department Heads

7.1 Institutional Biological Safety Committee (IBC)

The Biological Safety Committee's responsibilities include:

- Registering the IBC with the NIH Office of Biotechnology Activities including: 1) a roster of IBC members indicating their principal role on the committee (e.g., chair, contact person, expert in areas identified in the *NIH Guidelines* and 2) biosketches of committee members. Biosketches should reflect the professional background and perspective of the individual.
- Filing a report at least annually that updates the committee roster and biosketches;
- Meeting as needed and maintaining a permanent record of IBC meetings and activities.
- Ensuring that it fulfills all administrative, oversight, review, and reporting functions as described in Sections IV-B-2-a and IV-B-2-b of the *NIH Guidelines* including:

    - Reviewing and recommending policies and guidelines that ensure biological safety procedures, equipment, facilities, and training are appropriate for the biohazard risk;
    - Working collaboratively with principal investigators (PIs) to review laboratory security, safety, emergency plans, and other activities;
    - Providing guidance to PIs and reviewing reports or proposals prepared for submission to the NIH Office for Recombinant DNA Activities (ORDA) and the NIH Recombinant DNA Advisory Committee (RAC).
    - Reviewing and approving the use of rDNA or Biological Safety Level 2 materials before work commences, and conducting periodic assessments of registered users;
    - Ensuring that the University offers appropriate and sufficient employee training concerning the risks and use of biohazardous materials;
    - Maintaining records of projects and/or proposals involving the use of recombinant DNA;
    - Investigating reports of non-compliance, alerting the ASU Vice President for Research (or other administration officials as appropriate) and the PI of any violations, and monitors corrective action.
    - Performing periodic inspections of the Biological Safety program on the Jonesboro campus;
    - Conducting periodic assessments of Registered rDNA users, and assisting in resolving problems that may arise;
    - Developing an annual report concerning all activities for the previous year including summaries of proposals reviewed and the decisions that were rendered, status of any compliance or containment issues that arose during the course of the year, emergency procedures that were reviewed or instituted, and, other relevant topics discussed by the members of the IBC during the course of the year.
    - Providing a campus forum to address issues involving biohazardous materials.
    - Other responsibilities as indicated in the *NIH Guidelines*.

7.2 BIOLOGICAL SAFETY OFFICER (BSO)/ENVIRONMENTAL SAFETY

When a BSO is appointed, s/he will have primary responsibility for monitoring the use of biohazardous materials on campus with specific responsibilities as follows:

- Develops guidelines for the campus community so that biohazardous materials are used safely and in compliance with federal, state and local regulations.
- Maintains databases that document ASU-Jonesboro Biological Safety programs.
- Conducts or supervises annual inspections and reviews of recombinant DNA laboratories or facilities,
- Provides PIs and the IBC with technical advice concerning safety procedures and lab containment;
- Interprets safety and regulatory requirements and develops procedural documentation;
- Reports safety and/or noncompliance issues to the AVP, Chair of the IBC, and to appropriate federal/state agencies.
- Provides or arranges appropriate training programs to meet campus and community needs.
- Advises the campus community on biological safety matters.
- Conducts inspections, identifies and reports safety problems to the AVP, IBC, PI, and others to assure that program guidelines are met.
- Collects and disposes of unwanted biohazardous materials in an environmentally sound manner.
- Serves as liaison to regulatory agencies such as Center of Disease Control and Prevention, National Institutes of Health, Department of Transportation, Department of Agriculture, and the Arkansas Departments of Health and Labor.
- Assisting in arrangement for the proper shipping and transportation of biohazardous materials.
- Assists the IBC chair with preparation of interim and annual reports.

7.3 PRINCIPAL INVESTIGATORS & SUPERVISORS (REGISTERED USERS)

Principal Investigators and supervisors (Registered Users) have primary responsibility for safety when work is conducted with biohazardous materials including:

- Registering the locations of rDNA or biohazardous materials with the Environmental Health and Safety Department.
- Submitting the initial research protocol and any subsequent changes to the IBC for review and approval prior to initiating rDNA or biohazardous research activities.
- Submitting renewal forms to the IBC for all rDNA and biohazardous research activities before prior approvals expire;
- Reporting any newly-identified select agents, high-consequence livestock pathogens, toxins, or plant pathogens to the Environmental Health and Safety Department immediately.

- Notifying the Environmental Health and Safety Department of all persons who use biohazardous material in their work locations and ensuring that these individuals receive appropriate training.
- Maintaining a current and up-to-date inventory of biohazardous materials. Completing and posting appropriate biohazard signs, labels, and Emergency Notification Signage.
- Assuring appropriate use of laboratory equipment in manufacturer's guidelines. This includes maintaining, certifying, labeling, and providing PPE and UV hazard training for all exposed to the IBC w/ UV lamps (laboratory and Campus Facilities staff).
- Requesting collection of biohazardous materials in a timely manner.
- Ensuring the availability of reference information concerning biological hazards, and ensuring that affected staff understand how to use these references.
- Conducting risk assessments of each task involving biohazardous materials and setting the Biological Safety Level for the proposed work.
- Making an initial determination of the required levels of physical and biological containment in accordance with the ASU-Jonesboro Biological Safety Governing Principles and NIH Guidelines;
- Selecting appropriate microbiological practices and laboratory techniques to be used for the research.
- Working with institutional officials to maintain safe work areas that comply with University policies and federal, state & local regulations.
- Ensuring that all workers under their supervision use proper personal protective equipment as required;
- Understanding and following institutional and regulatory procedures in the event of a biocontainment failure or in any other emergency situation.
- Complying with shipping requirements for recombinant DNA and biohazardous materials.
- Controlling ancillary worker access to areas where biological hazards may be present.
- Completing biohazardous materials laboratory closure documentation prior to termination of work.

7.4 BIOHAZARD WORKERS

Biohazard workers' responsibilities include:

- Completing an introduction to biological safety training course and Biological Safety refresher coursework every two years thereafter, at minimum.
- Promptly reporting all accidents, biohazardous exposures, possible work-related illnesses, hazardous circumstances, and incidents to their supervisor.
- Understanding and following all proper protocols and procedures for acquisition, use, storage, and disposal of biohazardous materials.
- Understanding where to find and how to properly use reference information and resources on biohazardous materials.

- Knowing how to respond to biocontainment failures and other emergencies involving biohazardous materials.
- Familiarizing themselves with the use of personal protective equipment when required;
- Working with the Environmental Health and Safety Department to maintain safe work areas that comply with University policies and federal, state and local regulations.

7.5 ANCILLARY WORKERS (NON-BIOHAZARD QUALIFIED PERSONNEL)

Ancillary Workers are persons who work in areas that contain biohazardous materials, but do not normally work directly with these biohazardous materials. Examples of ancillary workers are custodial staff, maintenance staff, delivery and University Police Officers and visiting personnel. Their responsibilities include:

- Attending the ancillary worker biological safety training course and subsequent refresher training every year thereafter.
- Taking precautions to avoid disturbing biohazardous materials.
- Promptly reporting releases and other unsafe conditions involving biohazardous materials to the Principal Investigator or Program Director.
- Familiarizing themselves with the use of personal protective equipment as needed for safety purposes.
- Requesting assistance from his/her Supervisor and the Principal Investigator or Program Director when uncertain about risks related to biohazardous materials.

7.6 DEANS, DIRECTORS, ADMINISTRATORS, & DEPARTMENT HEADS

Deans, Directors, Administrators, and Department heads' responsibilities include:

- Familiarizing themselves with the ASU-Jonesboro Biological Safety program guidelines and provide leadership in the development of safe practices.
- Assisting the IBC in communicating major announcements and identifying appropriate personnel for Registered User status.
- Reviewing biological safety inspections and assisting in the resolution of problem situations where relevant.
- Identifying funding sources to correct safety hazards and ensuring that appropriate facilities are available to control biohazards.
- Assuring that the principal investigator and all personnel have necessary training.
- Assuring that laboratories are closed appropriately before termination of any programs that required use and/or storage of biohazardous materials.

APPENDIX A
BIOSAFETY CABINET SUMMARY CHART

The summary chart below compares the different biological safety cabinet types for performance characteristics and applications of use. Biological safety cabinets are among the most effective and most common primary containment devices used in laboratories with biohazardous material.

Type	Face Velocity	Airflow Pattern	Radionuclides/ Toxic chemicals	Biosafety Levels	Product Protection
Class I Open front	75	In at front; rear and top through hepa filter	No	2,3	No
Class II Type A	75	70% recirculated through hepa; exhaust through hepa	No	2,3	Yes
Class II Type B1	100	30% recirculated through hepa; exhaust via hepa and hard ducted	Yes (low levels/volatility)	2,3	Yes
Class II Type B2	100	No recirculation; total exhaust via hepa and hard ducted	Yes	2,3	Yes
Class II Type B3	100	Same as iia, but plena under negative pressure to room and exhaust air is ducted	Yes	2,3	Yes
Class III	Na	Supply air inlets and exhaust	Yes	3,4	Yes

APPENDIX B
SAFETY-LEVEL CRITERIA

Laboratory biological safety-level criteria

Federal biological safety-level criteria [1] include the following:

- Biological safety level 1-4 (BL1 to BL4): standard research laboratory experiments.
- Biological safety level 1-4 large scale (BL1-large scale to BL4-large scale): large-scale (over 10 liters) research and production with good large scale practices (GLSP).
- Biological safety level 1-4 plants (BL1-P to BL4-P): standard plant greenhouse facility experiments.
- Biological safety level 1-4 animals (BL1-N to BL4-N): standard whole animal facility experiments.

Biological safety levels 1 and 2 (BL-1, BL-2)

BL-1

- Suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.
- Special containment equipment or facility design is neither required nor generally used.
- Laboratory personnel have specific training in the procedures conducted in the laboratory.
- Supervision by a scientist with general training in microbiology or a related science.

BL-2

- Suitable for work involving agents of moderate potential hazard to laboratory personnel and the environment.
- Laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists.
- Access to the laboratory is limited when work is being conducted.
- Extreme precautions are taken with contaminated sharp items.
- Certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

[1] ASU-Jonesboro allows only BL-1 and BL-2 laboratories.

ABL	**Agents**	**Practices**	**Safety equipment (primary barriers)**	**Facilities (secondary barriers)**
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench top sink required
2	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure	BL-1 practice plus: Limited access Biohazard warning signs "sharps" precautions Biosafety document defining any needed waste decontamination or medical surveillance policies	Primary barriers = class I or II IBCS or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves and face protection is needed.	BL-1 plus: Autoclave available

VERTEBRATE ANIMAL BIOLOGICAL SAFETY LEVEL CRITERIA (BL1-N, BL2-N)

There are two recommended vertebrate animal biological safety levels. The recommendations below describe practices, safety equipment and facilities for experiments with animals infected with agents that cause, or may cause, human infection. In general, the biological safety level recommended for working with biohazardous material in vivo and in vitro are comparable.

BL1-N
Suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to personnel handling the animals and the environment.

BL2-N
This level involves work with agents associated with human disease. It addresses the practices, procedures, containment equipment, and facility requirements of ABLS-1.

BL2-N is suitable for work involving agents of moderate potential hazard to laboratory personnel, animals, and the environment.

Laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists.

Access to the animal facility is limited to the fewest number of individuals possible. Personnel who must enter the room for program or service purposes when work is in progress are advised of the potential hazard.

Certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

BL-N	Agents	Practices	Safety equipment (primary barriers)	Facilities (secondary barriers)
1	Not known to consistently cause disease in healthy adults	Standard animal care and management practices, including appropriate medical surveillance programs.	As required for normal care of each species	Standard animal facility No recirculation of exhaust air Directional air flow recommended Hand washing sink recommended
2	Associated with human disease; hazard = percutaneous exposure, ingestion, mucous membrane exposure	BL1-N practice plus: Limited access Biohazard warning signs "sharps" precautions Biosafety document Decontamination of all infectious waste and of animal cages prior to washing	BL1-N equipment plus primary barriers: containment equipment appropriate for animal species; PPE: laboratory coats, gloves and respiratory protection as needed.	BL1-N facility plus: Autoclave available Hand washing sink available in the animal room Mechanical cage washer used

RECOMBINANT DNA BIOLOGICAL SAFETY LEVEL CRITERIA

NIH requires that: 1) investigators conduct initial risk assessments based upon the risk group of an agent (as indicated below) and, 2) all physical and biological containment for recombinant DNA research involving humans, animals, plants that use standard or

special microbiological practices, containment equipment, or laboratory facilities adhere to its guidelines (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html).

Agents are separated into four risk groups (RGS) based upon their relative pathogenicity for healthy adult humans. Criteria for each group are as follows: Risk group 1 (RG1): agents are not associated with disease in healthy adults. Risk group 2 (RG2): agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.[2]

[2] BL 3 & 4 research activities are not currently allowed on the ASU – Jonesboro campus.

APPENDIX C
LABORATORY SECURITY ISSUES

In response to national concerns and recent catastrophic events, the following measures are recommended to improve laboratory security:

1. All areas of the university having electronic locking devices of any type, should make whatever changes to their systems necessary to fully enable the system which results in access by such device at all times.
2. All areas where research is conducted utilizing hazardous material, radioactive material, biohazardous material, and other sensitive materials should have controlled access for authorized personnel only.

Laboratories using biohazardous materials must be kept secured at all times. Several federal, state and consensus standards required that the laboratory doors and hazardous material areas have at a minimum, limited access and required the areas be kept locked when no laboratory staff are present. Security recommendations also include having a routine intra-laboratory inventory mechanism for identifying missing biological, hazardous or radioactive material inventory. This requires an ongoing inventory be maintained.

Laboratories have also experience thefts, many of which occurred because doors were left open and laboratories were unattended. Computers, wallets, and other personal items have been stolen. There has been "unauthorized sharing of supplies" from laboratories. There is also the potential for sabotage to ongoing research. Laboratory principal investigators or supervisors need to take these steps in order provide security against terrorism, larceny, and to remain in compliance with various regulations:

1. Approach any visitors that appear to be wandering in laboratory areas and ask if you can help direct them.
2. Lock all equipment (e.g. freezers, cabinets, incubators and scintillation counters) that may contain biohazardous material and are located in hallways or areas outside of laboratories.
3. Keep laboratory doors closed at all times (they also provide correct air flow and fire safety).
4. Lock laboratory doors when no one is present.
5. Post and keep current the "emergency notification signage" on laboratory doors. Include name of responsible person, a second person knowledgeable with the laboratory and a 24-hour contact number (ASU).

Take an inventory of all hazardous and biohazardous material. Track the use of this material and report any missing inventory to ASU and Environmental Health and Safety.

APPENDIX D
SIGNAGE[3]

PLANTS

BL2-P AND BL3-P

A sign shall be posted indicating that a restricted experiment is in progress and shall indicate: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for use of the area.

BL4-P

A sign shall be posted indicating that a restricted experiment is in progress and shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for use of the area. If organisms are used have the potential to seriously damage natural ecosystems, their presence shall be indicated by a sign posted on the Greenhouse access doors. If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

ANIMALS: BL2-N, BL3-N, AND BL4-N

When the animal research requires special provisions for entry (e.g., vaccination), a warning sign incorporating the universal biosafety symbol shall be posted on all access doors to the animal work area. The sign shall indicate: (i) the agent, (ii) the animal species, (iii) the name and telephone number of the Animal Facility Director or other responsible individual, and (iv) any special requirements for entering the laboratory.

UNIVERSAL BIOHAZARD SYMBOL

[3] Source: *NIH Guidelines for Research Involving Recombinant DNA Molecules* (April 2002).