

# POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS AND HAZARDOUS MATERIALS/ACTIVITIES

Potentially Hazardous Biological Agents (PHBAs) include microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi and parasites) and recombinant DNA technologies.

Hazardous materials include hazardous chemicals, devices and radiation. Hazardous activities are those that involve a level of risk above and beyond that encountered in daily life.

It is the responsibility of the student and all of the adults involved in a PHBA and hazardous material-related research project to conduct and document a risk assessment to define the potential level of harm, injury or disease to plants, animals and humans that may occur. The risk assessment determines which hazards and/or biosafety level which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training, and supervision required.

1. Risk Assessment: Students who worked with PHBAs and Hazardous Materials (including prescription drugs or controlled substances) will be asked to upload a Risk Assessment Form in the online application, completed by an adult who supervised the study. The Risk Assessment Form is available in Appendix 11.
2. Students are prohibited from designing or participating in any research involving biosafety levels above BSL-2. (This includes BSL-2+, BSL-3 and BSL-4.) Studies involving viral vectors should also remain at or below BSL-2 at all stages of the study where student is involved (the vector cannot be BSL-2+ or above).
3. Research involving PHBAs is permitted when conducted at a RRI or a certified BSL-2 laboratory, or a BSL-1 laboratory at a high school depending on the classification of the biological agents used (see page 28 for more details). Research must be closely supervised and should follow all Institutional Biosafety Committee (IBC) requirements as applicable (understanding that most high schools will not have an IBC)
  - a. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. This includes the use of *E. coli* k-12, studies involving fermentation of baker's and brewer's yeast, algae-eating bacteria, soil microbes, mold growth, slime molds and edible mushrooms. These BSL-1 studies are permitted in a school lab and require a Risk Assessment form, but cannot be conducted in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the appropriate BSL containment.
  - b. Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions, if not stored in a home environment as of June 2020:
    - i. If experimentation occurred in the home environment prior to 2020, this research is eligible for STS as long as all conditions of rule 3b are met. Student must provide documentation to demonstrate the dates of experimentation. All at home PHBA research is prohibited post-2020.
    - ii. Organism is cultured in a plastic petri dish (or other standard non-breakable container) and sealed and experiment only involves procedures in which petri dish remains sealed throughout.
    - iii. The sealed petri dish is disposed of via autoclaving or disinfection under the supervision of the mentor/supervising scientist/PI.
    - iv. If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory precautions.
  - c. Research involving human or vertebrate animal tissues/blood/breast milk/other bodily fluids from established cell lines or were freshly collected are considered PHBA studies and student researcher should complete a Risk Assessment form before working with these materials. Any study involving the collection and examination of body fluids that may contain biological agents belonging to biosafety level over 2 is prohibited.

- d. All studies involving the use of prions or commercially available prion-like proteins are prohibited. This includes studies working with amyloid- $\beta$  ( $A\beta$ ), tau,  $\alpha$ -synuclein, transactive response DNA-binding protein of 43 kDa, Huntingtin protein and amyloid fibrils.
  - e. Studies involving plasmids that contain genes encoding prion-like proteins are also prohibited. Work involving the lysis of cells or cell lines and/or purification of prion-like proteins is prohibited in laboratories besides those designated as BSL-2.
  - f. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
  - g. Students are prohibited from the insertion of antibiotic-resistance traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals or plants. Students are prohibited from designing or selecting for multidrug-resistant organisms (MDROs) to investigate the pathology, development or treatment of antibiotic-resistant infections.
4. Research involving Hazardous Materials is permitted when the research meets the following requirements:
- a. Student researcher, with an adult supervisor, has completed a risk assessment process, and a supervising adult can verify that student identified potential risks prior to experimentation, and followed proper safety precautions and disposal methods.
  - b. Project remains within local, state and federal laws. This includes but is not limited to all drone projects (which may require registration with state or national authorities), adherence to trespassing and privacy laws, etc.
  - c. Chemicals should be assessed for toxicity, reactivity, flammability and corrosiveness. The type and amount of exposure to a chemical must be considered in the risk assessment. Student researcher must refer to the Materials Safety Data Sheets provided by the vendor (SDS) to ensure proper safety precautions are taken. A risk assessment must include proper disposal methods for the chemicals used in an experiment.
  - d. All projects using chemicals in a home, school, or lab setting must be conducted under the following conditions:
    - i. Obtain and read the Safety Data Sheets (SDS) for each chemical being used. \*
    - ii. Follow standard lab practices for chemical handling, safety, ventilation, and specific disposal procedures as outlined in the Safety Data Sheets (SDS).
    - iii. Cannot reuse any cookware, utensils, and/or equipment used during the experimentation for regular household use.
    - iv. Be conducted with a Direct Supervisor with proper training and knowledge of the chemicals being used.
- \*NOTE: Safety Data Sheets can be found online and provide Globally Harmonized System (GHS) ratings for chemicals. These ratings use different categories to define a chemical's physical, health, and environmental hazards. The GHS rating should be factored into a student's risk assessment and safety precautions. Chemicals may also be rated on the National Fire Protection Association (NFPA) scale. This scale runs from 0-4, with 4 being the most hazardous. A GHS rating of 1 is equivalent to an FPA of 4.
- e. Projects starting after June 2026 involving chemicals that are listed as carcinogenic, teratogenic, or reproductive system damaging on the SDS must be conducted at an RRI with a direct supervisor that has training in their usage.
  - f. Devices including potentially hazardous/dangerous equipment or other devices, in or outside a laboratory setting that require a moderate to high level of expertise to ensure their safe usage (high vacuum equipment, heated oil baths, NMR equipment, high-temperature ovens, etc.) require a risk assessment. It is recommended that all student-designed inventions also have documentation of a risk assessment.
  - g. The culturing of samples from fresh/frozen tissues or body fluids or meat and meat by-products obtained from food stores, restaurants or packing houses must be considered biosafety Level 1 studies and must be conducted in a BSL-1 laboratory or higher.

- a. All projects involving ionizing radiation may not exceed the personal exposure limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
5. Research involving prescription drugs and controlled substances is permitted under the following situations:
- a. In the United States, the Food and Drug Administration tightly regulates the issuance of prescriptions and thus they are controlled substances. State laws further regulate the use of prescription drugs and it is unlawful for any person knowingly or intentionally to possess a controlled substance unless it was obtained directly from a valid prescription or order of a practitioner while acting in the course of their professional practice. It is also unlawful to use the prescription for persons or purposes outside of the original prescription. All applicable federal, state and country laws must be followed.
  - b. Students are prohibited from the use of prescription drugs or other controlled substances in their study outside of the authority of a practitioner or researcher that has obtained the controlled substance with appropriate approvals and is using the substance for the purpose for which it was prescribed.
  - c. A risk assessment is required.
  - d. Students are prohibited from providing prescription drugs or controlled substances to human participants or vertebrate animals.
  - e. Students may not conduct research involving DEA controlled substances in a school or home setting.
6. Research involving firearms and explosives are allowable under the following circumstances:
- a. When conducted under the direct supervision of an adult and when in compliance with all federal, state and local laws. Any use of a firearm must be conducted with proper state certification and training.
  - b. Note that underage researchers are prohibited from purchasing firearms, ammunition, black powder or explosives.

# CLASSIFICATION OF BIOLOGICAL AGENTS

## RISK GROUPS AND EXAMPLES

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes.

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: *Agrobacterium tumefaciens*, *Micrococcus leuteus*, *Neurospora crassa*, *Bacillus subtilis*, non-pathogenic strains of *E. coli*.

BSL-2 risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. Examples of BSL-2 organisms are: *Mycobacterium*, *Streptococcus pneumoniae*, *Salmonella choleraesuis*.

- Projects involving water samples collected from Active Harmful Algal Blooms are considered BSL-2.
- Culturing of human or animal waste, including sewage, is considered BSL-2.
- An rDNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. Projects in the BSL-3 group are prohibited.

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are prohibited.

## LEVELS OF BIOLOGICAL CONTAINMENT

There are four levels of biological containment (Biosafety Level 1–4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques. This type of research is not permitted in a home environment.

BSL-1 containment is normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in an appropriate biosafety hood. Standard microbiological practices are used when working in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats and gloves are required. The laboratory work is supervised by an individual with general training in microbiology or a related science.

BSL-2 containment is designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats and gloves are required; eye protection and face shields must also be worn as needed. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

BSL-2+ and BSL-3 containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Projects in the BSL-2+ and BSL-3 groups are prohibited.

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Projects in the BSL-4 group are prohibited.

## DISPOSAL

All potentially hazardous biological agents must be properly disposed of at the end of experimentation in accordance with their biosafety level. For BSL 1 or BSL 2 organisms: Autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable.