POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS AND HAZARDOUS MATERIALS

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.

It is the responsibility of the student and all of the adults involved in a PHBA-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 when working with biological agents. The risk assessment determines a biosafety level which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training, and supervision required.

1. 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 next page 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 studies are permitted in a school lab and require a Risk Assessment form, but cannot be conducted in a home environment.
    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 1b are met. Student must provide documentation to demonstrate the dates of experimentation.
        ii. Organism is cultured in a plastic petri dish (or other standard non-breakable container) and sealed.
        iii. Experiment involves only procedures in which the petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
        iv. The sealed petri dish is disposed of via autoclaving or disinfection under the supervision of the mentor/supervising scientist/PI.
        v. 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 freshly collected are considered PHBA studies and student researcher should complete a Risk Assessment form before working with these materials.
2. Research involving Hazardous Materials is permitted when the research meets the following requirements:
    a. Student researcher 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. Hazardous chemicals, devices and radiation carry significant legal and safety regulations and should be approved via the risk assessment by a supervising adult in advance of experimentation.
3. Risk Assessment

a. Students who worked with PHBAs and Hazardous Materials will be asked to upload a Risk Assessment Form in the online application. The Risk Assessment Form is available in Appendix 9.
b. Hazardous Materials
    i. 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.
    ii. 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). It is recommended that all student designed inventions also have documentation of a risk assessment.
    iii. A risk assessment must be conducted when a student's project involves radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (NW), radiofrequency (RF) and extremely low frequency (ELF).

CLASSIFICATION OF BIOLOGICAL AGENTS

RISK GROUPS

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 tumifaciens, 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 pneumonia, Salmonella choleraesuis.

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-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-3 group 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.