Safety issues (3)

Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies

- All **rDNA technology** studies involving **BSL-1 organisms** and **BSL-1 host vector systems** must be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or Designated Supervisor prior to experimentation.

  Examples include **cloning of DNA in *E. coli* K-12**, ***S. cerevesiae*,** and ***B. subtilis*** host-vector systems.

- 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.**

- All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a **Regulated Research Institution** and approved prior to experimentation.

- Propagation of recombinants containing **DNA coding for human, plant or animal toxins (including viruses)** is prohibited.

- All **genome editing studies** that include **alteration of germline cells,** and **insertion of gene drives,** should be categorized as a **BSL-2 study** and must be conducted after approval.

  Qualified scientists are expected to ensure that student research protocols address appropriate intrinsic and extrinsic containment precautions.

- **Introduction or disposal of non-native, genetically-altered and/or invasive species (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited.**

  Students and adult sponsors should reference their local, state and national regulations and quarantine lists.

Additional Rules for Projects with Tissues and Body Fluids, including Blood and Blood Products

- Studies involving **fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates** may contain microorganisms and have the **potential of causing disease**.

- Therefore, a **proper risk assessment** is required.

- Research involving **human and/or non-human primate established cell lines and tissue culture collections** (e.g., obtained from the American Type Culture Collection) must be considered a **BSL-1 or BSL-2 level organism** as indicated by source information and treated accordingly.

  The source and/or catalog number of the cultures **must be identified** in the Research Plan/Project Summary.

- The collection and examination of **fresh/frozen tissue and/or body fluids, (not including blood or blood products) from a non-infectious source** with little likelihood of microorganisms present must be considered **Biosafety level 1** studies.

- The collection and examination of fresh/frozen tissues or body fluids or meat, meat byproducts, pasteurized milk or eggs **NOT obtained** from food stores, restaurants, or packing houses **may contain microorganisms.**

- Because of the increased risk from unknown potentially hazardous agents, these studies must be considered **biosafety level 2 studies conducted in a BSL-2 laboratory** under the supervision of a Qualified Scientist.

- **Human breast milk of unknown origin**, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered **BSL-2.**

- All studies involving **human or wild animal blood or blood products** should be considered at a minimum a **Biosafety level 2 study** and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist.

- **Known BSL-3 or BSL-4 blood is prohibited.**

- Studies involving **domestic animal blood** may be considered a **BSL-1 level study**.

- Any tissue or instruments with the **potential of containing blood-borne pathogens** (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be **properly disposed** after experimentation.

- Studies of human body fluids, where the **sample can be identified with a specific person**, must have **approval, and informed consent.**

- Any study involving the collection and examination of body fluids which may contain biological agents belonging to **BSL-3 or -4 is prohibited.**

- Studies involving **embryonic human stem cells** must be conducted in a **Registered Research Institution**.

The following types of studies are **exempt from prior approval**:

- Studies involving **protists** and **archaea**.
- Research **using manure** for composting, fuel production, or other non-culturing experiments.
- Commercially-available color change **coliform water test kits**. These kits must remain sealed and must be properly disposed.
- Studies involving **decomposition of vertebrate organisms** (such as in forensic projects).
- Studies with **microbial fuel cells**.

*A microbial fuel cell (MFC) is a device that converts chemical energy to electrical energy by the action of microorganisms.

- Studies involving **baker's yeast** and **brewer's yeast**, **except in rDNA** studies.

- Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment).

- Studies involving **water or soil microbes** not concentrated in media conducive to their microbial growth.

- Studies of **mold growth** on food items if the experiment is terminated at the first evidence of mold.

- Studies of **slime molds** and **edible mushrooms**.

- Studies involving ***E. coli* K-12,** the most commonly used laboratory reference organism.

Exempt Tissues (no pre-approval required):

1) The following types of tissue **do not need** to be treated as potentially hazardous biological agents:

- **Plant tissue** (except those known to be toxic or hazardous)
- **Plant and non-primate established cell lines** and **tissue culture collections** (e.g., obtained from the American Type Culture Collection).
- **Fresh or frozen meat**, **meat by-products**, **pasteurized milk** or **eggs** obtained from food stores, restaurants, or packing houses.

- Hair, hooves, nails and feathers.
- Teeth that have been sterilized to kill any blood- borne pathogen that may be present.
- Fossilized tissue or archeological specimens.
- Prepared fixed tissue.

Potentially Hazardous Biological Agents Risk Assessment

- **Risk assessment defines the potential level of harm, injury or disease** to plants, animals and humans that may occur when **working with biological agents**.

- The **end result** of a risk assessment is the **assignment of a biosafety level** which then determines the laboratory facilities, equipment, training, and supervision required.

Risk assessment **involves**:

- **Assignment** of the biological agent to a risk group.

- Studies involving a known microorganism must begin with an initial assignment of the microorganism to a **biosafety level risk group** based on **information available through a literature search**.

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

- 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*.

BSL-2 risk group

- 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.

- These agents require Biosafety Level 2 containment.

  Examples of BSL-2 organisms are: *Mycobacteria* other than *M.tb*, *Streptococcus pneumonia*, *Salmonella typhi*.

BSL-3 risk group

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

- Examples include *Francisella tularensis*, *Mycobacterium tuberculosis*, *Chlamydia psittaci*, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, SARS coronavirus, *Coxiella burnetii*, Rift Valley fever virus, *Rickettsia rickettsii*, several species of Brucella, chikungunya, yellow fever virus, and West Nile virus.

BSL-4 risk

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

  Examples include Marburg virus, Ebola virus, Lassa virus, Crimean-Congo hemorrhagic fever, Hendra virus, Nipah virus, and some Flaviviruses.


Thank You!