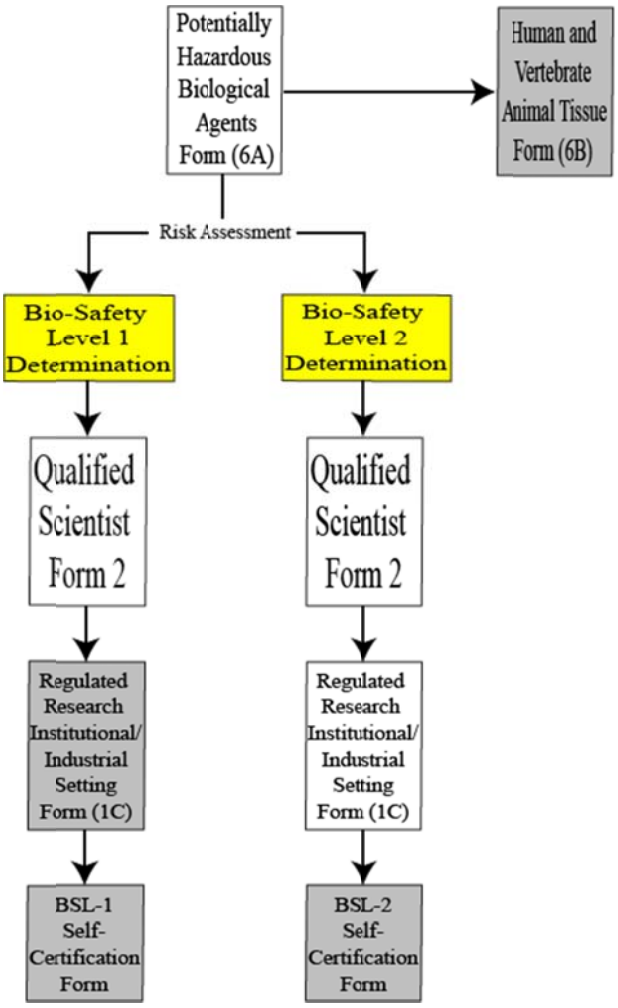
Potentially Hazardous Biological Agents Guidelines

Research using microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, parasites), recombinant DNA technologies or human or animal fresh/frozen tissue, blood, or bodily fluids may involve potentially hazardous biological agents.



When dealing with potentially hazardous biological agents, it is the responsibility of the Student Researcher(s) and ALL of the adults involved in a research project to conduct and document a risk assessment (Form 6A on page 29) 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 the biosafety level, which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training and supervision required.

Studies Exempt from Prior SRC Review/Approval

The following types of studies are exempt from prior SRC review and approval, but **MUST** be included on the Risk Assessment Form 3.

- Studies involving baker's yeast and brewer's yeast, except in rDNA studies.
- Studies involving *Lactobacillus* (starter cultures for controlled fermentation), *Bacillus thurgiensis* (typically found in insecticides), nitrogen-fixing/oil-eating bacteria, and algae-eating bacteria introduced into their NATURAL ENVIRONMENT. **None of these studies are exempt if they are cultured in a Petri dish.**
- Studies involving water or soil not purposely culturing bacteria.
- Studies of mold growth on food items, **IF the experiment is TERMINATED at the first sign of mold.**
- Studies of edible mushrooms and slime molds.
- Studies involving *E. coli K-12* which are done at school and are not rDNA studies.
- Studies involving protists, archaea and **KNOWN** nonpathogenic microorganisms.
- Studies using manure for composting, fuel production or other non-culturing experiments.
- Studies involving the use of commercially-available color change coliform water test kits. These kits must remain sealed and be properly disposed.
- Studies involving the decomposition of vertebrate organisms (such as in forensic projects).
- Studies with microbial fuel cells.

ALL Potentially Hazardous Biological Agent Study Guidelines

All other projects involving potentially hazardous biological agents must be reviewed and approved before experimentation begins by the appropriate review board: IBC (Institutional Biosafety Committee for studies done at a research institution) or SRC (Scientific Review Committee for studies done in a school setting).

- Experimentation involving the culturing of any organism (even BSL-1) is **PROHIBITED in a home environment**. Specimens may be collected at home or other field sites as long as they are immediately transported to a laboratory with the appropriate BSL containment as determined by the local/school SRC.
- The initial risk assessment determination done by the Student Researcher(s) and Qualified Scientist/Mentor must be confirmed by the appropriate review board.
- Student Researchers must be trained in standard microbiological practices.
- Once the study has been approved, a Student Researcher with any proposed changes to the methods and/or procedures must repeat the review process before continuing with data collection/ experimentation.
- ALL PHBAs must be properly disposed of at the end of experimentation in accordance with their biosafety level. Acceptable disposal methods for BSL-1 and BSL-2 organisms include:
  - Autoclave at 121°C for 20 minutes;
  - Use of a 10% bleach solution (1:10 dilution of domestic bleach);
  - Incineration;
  - Alkaline hydrolysis;
  - Biosafety pick-up; or
  - Other manufacturer recommendations.

Potentially Hazardous Biological Agent Study Biosafety Levels (BSL)

- BSL-1 – biological agents that pose low risk to personnel and the environment; highly unlikely to cause disease in healthy laboratory workers, animals or plants.
  - BSL-1 research projects must be conducted in a BSL-1 or higher laboratory. This MAY be a middle or high school science lab if it meets ALL of the standards for a BSL-1 lab (see the self-certification form at http://www.societyforscience.org/document.doc?id=330).
  - BSL-1 research projects must be reviewed by a Qualified Scientist/Mentor but can be directly supervised by a TRAINED Designated Supervisor at a verifiable BSL-1 laboratory.
  - Examples of BSL-1 Organisms: *Agrobacterium tumefaciens* (soil bacteria), *Micrococcus luteus, Neurospora crassa* (red bread mold), *Bacillus subtilis* (normal human gut bacteria).
  - Examples of BSL-1 Studies (this is not an exhaustive list):
    - Studies involving naturally-occurring plant pathogens where they are not cultured or introduced into the environment.
    - rDNA studies involving BSL-1 organisms and BSL-1 host vector systems such as the cloning of DNA in *E. coli K-12, S. cerevisiae,* and *B. subtilis* host vector systems.
    - Studies involving commercially available rDNA kits using BSL-1 organisms.
    - Studies of mold growth on food items where the project is NOT terminated at the first sign of mold.
    - Studies involving unknown microorganisms collected from the environment as long as **ALL of the following conditions are followed**:
      - Culturing is done in a plastic Petri dish and is **SEALED**.
      - The Petri dish remains **SEALED** throughout the experiment.

- The **SEALED** Petri dish is disposed of via autoclaving or disinfection by the Designated Supervisor or Qualified Scientist/Mentor.

- BSL-2 – biological agents that pose moderate risk to personnel and the environment; exposure in a lab situation would result in limited risk of spreading and it would rarely cause infection that would lead to serious disease; in the event that infection occurs, treatment and preventive measures are available
  - BSL-2 research projects must be conducted in a BSL-2 or higher laboratory. This is usually a regulated research institution, but a high school science lab MAY QUALIFY if it meets ALL of the standards for a BSL-2 lab (see the self-certification form on the SSP web site at http://www.societyforscience.org/document.doc?id=25).
  - BSL-2 research projects must be reviewed and directly supervised by a Qualified Scientist/ Mentor at a verifiable BSL-2 laboratory.
  - Examples of BSL-2 Organisms: *Mycobacterium* (typically found in water and food sources), *Streptococcus pneumoniae* (part of the normal upper respiratory tract flora), *Salmonella choleraesuis* (typically found in raw food sources such as eggs and meat).
  - Examples of BSL-2 Studies (this is not an exhaustive list):
    - Studies culturing known MRSA, VRE and KPC can only be done at a Regulated Research Institution and must include written justification for their usage with documented IBC review and approval.
    - Studies that select and subculture antibiotic-resistant organisms. Use **EXTREME CAUTION** when doing this type of project.
    - Studies that culture human or animal waste (including sewage sludge).
    - Studies that insert antibiotic resistant markers for the clonal selection of bioengineered organisms.
    - rDNA studies using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation.
    - rDNA studies involving BSL-2 organisms and/or BSL-2 host vector systems.
    - Studies involving unknown organisms collected from the environment where the culturing container (Petri dish) is opened for any purpose (except for disposal disinfection).
- BSL-3 - biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences.
- BSL-4 - biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable.

Prohibited PHBA Studies:

- Research that cultures Carbapenem Resistant Enterbacteriacae (CRE).
- Genetically engineered organisms with multiple drug resistance traits with the intended purpose of investigating the pathology or treatment of antibiotic-resistant infections.
- Insertion of antibiotic-resistant traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals or plants.
- BSL-3 AND BSL-4 research projects.
- Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses).

Potentially Hazardous Biological Agents Form (6A) – Middle School

This form is required for ALL projects involving microorganisms, rDNA, fresh/frozen tissue, blood, blood products and body fluids. SRC/IACUC/IBC approval is required PRIOR to experimentation.

This form is to be completed by the Qualified Scientist/Mentor in collaboration with the Student Researcher(s). All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____
2. Project Title:_____

_____

3. Identify ALL of the potentially hazardous biological agents to be used in this experiment. Include where you will obtain them, how much you are using and the biosafety level of each one.

4. Where will you be conducting the experimentation? Include the level of biosafety containment available at each site.

5. How will you minimize any risk associated in working with these agents? (What personal protective equipment will you be wearing; what type of hood is being used; will you be sealing the Petri dishes and not opening them; etc.)?

6. What biosafety level do you recommend for this project? ☐ **BSL-1** or ☐ **BSL-2**

7. How are you going to dispose of all cultured materials and other potentially hazardous biological agents?

8. What training will the Student Researcher(s) receive?

9. What experience/training does the Designated Supervisor (for BSL-1 studies only) have as it relates to the student's area of research?

Qualified Scientist/Mentor:

☐ I certify that experimentation **was not** conducted at a Regulated Research Institution, but was conducted at a (check one) ☐ BSL-1 or ☐ BSL-2 laboratory. The study has been reviewed by the local or school SRC and the procedures have been approved PRIOR to experimentation. **OR**

☐ I certify that experimentation **was** conducted at a Regulated Research Institution and was approved by the appropriate institutional board PRIOR to experimentation. Institutional approval forms are attached. Date of IACUC/IBC Approval:_____ **OR**

☐ I certify that experimentation **was** conducted at a Regulated Research Institution that does not require pre-approval for this type of study. The local or school SRC has reviewed that the student received appropriate training and the project complies with the CSEF Middle School rules.

Qualified Scientist's Printed Name	Qualified Scientist's Signature	Date of Acknowledgement (mm/dd/yy)

To be completed by the local or school Scientific Review Committee.

The SRC has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above.

SRC Chair's Printed Name	SRC Chair's Signature	Date of Approval (mm/dd/yy)