

## Rules for ALL Projects Involving Studies Involving Potentially Hazardous Biological Agents

1. The following types of studies are exempt from prior SRC review and require no additional forms:
  - a. Studies involving baker's yeast and brewer's yeast, except when used with rDNA studies.
  - b. 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.)
  - c. Studies involving water or soil not concentrated in media conducive to their growth. (Please review all rules below to ensure that there are not more specific rules that may apply.)
  - d. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold.
  - e. Studies of mushrooms and amoebozoia (slime mold).
  
2. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
  - a. Studies involving protists, archaea and similar microorganisms.
  - b. Research using manure for composting, fuel production, or other non-culturing experiments.
  - c. Commercially-available color change coliform water test kits. These kits must remain sealed and must be properly disposed.
  - d. Studies involving decomposition of vertebrate organisms (such as in forensic projects).
  - e. Studies with microbial fuel cells.
  
3. Prior review and approval is required for the use of potentially hazardous microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids:
  - a. An affiliated fair SRC, an IBC or an IACUC must approve all research before experimentation begins. The initial risk assessment determined by the student researcher and adults supervising the project must be confirmed by the SRC, IBC or IACUC.
  - b. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the affiliated fair SRC.
  - c. Research determined to be at Biosafety Level 1 (BSL-1) must be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Designated Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.

- d. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above (commonly limited to a Regulated Research Institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter or document from the Regulated Research Institution that the research does not require review. The research must be supervised by a Qualified Scientist.
  - e. Students are prohibited from designing or participating in an experiment associated with the following types of PHBA studies:
    - BSL-3 or BSL-4 Research
    - Culturing CRE (Carbapenem Resistant Enterobacteriaceae)
    - Studies that genetically engineer bacteria with multiple antibiotic resistance
  - f. Laboratory studies culturing known MRSA (Methicillin-resistant *Staphylococcus aureus*), VRE (Vancomycin-resistant enterococci) and KPC (Klebsiella pneumonia) must be conducted in a BSL-2 laboratory in a Regulated Research Institution with documented IBC Committee review and approval.
  - g. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms require at least BSL-2 containment.
  - h. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
  - i. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
  - j. All potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or 2 organisms the following disposal methods are acceptable: 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.
  - kl. Any proposed changes in the Research Plan by the student after initial local or affiliated fair SRC approval must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
- 4) The following forms are required:
- Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
  - Regulated Research Institution Form (1C) - when applicable.
  - Qualified Scientist (2), when applicable
  - Risk Assessment (3), when applicable
  - PHBA Risk Assessment Form (6A), when applicable
  - Human and Vertebrate Animal Tissue Form (6B) – for all studies involving tissues and body fluids.