International Rules for Pre-Collegiate Research:
Guideline for Science and Engineering Fairs

Changes for 2022-2023

The following items were the key changes made to the International Rules for 2022-2023.

ALL Projects

Regulated Research Institutions (RRI)/ Review Committees (page 7)

Added a section to address "private" laboratories and how to manage approvals.

Independent or private laboratories, such as those established to support student researchers do not meet the requirements of oversight or committee infrastructure to be considered Regulated Research Institutions (RRI). Therefore, such laboratories should be considered the same as high school laboratories as it pertains to the International Rules and the types of projects able to be conducted in this setting. For purposes of documentation, such facilities may complete the Regulated Research Institution/Industrial Setting Form 1C to address the adult supervision and conditions of research.

Human Participant Rules (pages 8-10)

- Rule 6 modified to address diagnostic applications in the prohibition of practicing medicine.

6. Students are prohibited from independently diagnosing disease, administering medication, and/or performing medical procedures on human participants.
   a. A student may observe and collect data for analysis of medical procedures, medication/treatment efficacy, and diagnosis of illness, only under the direct supervision of a licensed health care provider/professional.
   b. This Healthcare provider/professional must be named in the research plan/ protocol approved by the IRB. The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc.) of the state or country in which he/she is conducting the research.
   c. Students are prohibited from providing diagnostic or medical information to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.

- Rule 9 modified to better clarify online survey procedures.

9. Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in collecting anonymous data, obtaining informed consent, and ensuring that participants are of the appropriate age to give informed consent.
   a. Studies that involve the use of minors in conducting online surveys must have Informed Consent and the parent/guardian of the minor must provide written parental permission

before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.

b. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be delineated in the Research Plan.

Potentially Hazardous Biological Agents (PHBA) Rules (page 15-17)

Exempt Studies (no SRC pre-approval required) page 17

- Clarified two exemptions involving microbial fuel cells and baker's yeast.

1. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
   b. Studies involving protists and archaea
   c. Research using manure for composting, fuel production, or other non-culturing experiment
   d. Commercially available color change coliform detection test kits; these kits must remain sealed and must be properly disposed
   e. Studies involving decomposition of vertebrate organisms (such as in forensic projects)
   f. Studies with microbial fuel cells in which the device is sealed during experimentation and disposed of properly at the conclusion of the study

2. The following types of studies involve BSL-1 organisms and are exempt from prior SRC review and require no additional forms:
   a. Studies involving fermentation of baker's yeast and brewer's yeast, except in rDNA studies
   b. Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing, oil-eating, and algae-eating bacteria introduced into their natural environment (not exempt if cultured in a petri dish environment)
   c. Studies involving water or soil microbes not concentrated in media conducive to their microbial growth
   d. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold
   e. Studies of slime molds and edible mushrooms
   f. Studies involving *E. coli* k–12 (and other strains of *E. coli* used solely as a food source for *C. elegans*) that are performed at school and are not subject to additional rules for recombinant DNA studies or use of antibiotic resistant organisms

Hazardous Chemicals, Activities or Devices Rules (page 19- 20)

Rules for ALL Projects Involving Hazardous Chemicals, Activities and Devices page 19

- Prescription Drugs section rewritten to more tightly control the use of prescription drugs per current law.

B. Prescription Drugs

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.

1. Students are prohibited from the use of prescription drugs 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.
   a. Such studies must be conducted with a Qualified Scientist and a Risk Assessment Form 3 is required documentation
   b. Students are further prohibited from providing prescription drugs to human participants

2. In the case of prescription drugs administered to vertebrate animals, this may only be done under a veterinarian's supervision and with prescriptions provided for this specific purpose.

Forms

Changes to the forms were minimal and reflected the change of many projects not being conducted in a laboratory environment directly.

Regulated Research Institutional/Industrial Setting Form (1C)

- Adjusted the ordering of Question 1 a. and b. sections to allow more room for a response in those situations in which "no" is the response requiring additional descriptions.

Risk Assessment Form (3)

- Reordered the terminology of the title box.
  - Text now reads: Must be completed before experimentation. Required for projects involving hazardous chemicals, activities or devices and may be needed by other projects.

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

- Section 3 box to be completed by the Qualified Scientist or Designated Supervisor, first checkbox has been edited to clarify that a copy of the checklist
  - Experimentation on the microorganisms/cell lines/tissues to be used in this study will NOT be conducted at a Regulated Research Institution, but will be conducted at a (check one) __BSL-1 or __BSL-2 laboratory (include a copy of the checklist for BSL-2). [This study has been reviewed by the local SRC and the procedures have been approved prior to experimentation.]