

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

## **Changes for 2023-2024**

The following items were the key changes made to the International Rules for 2023-2024.

### **Human Participant Rules (pages 8-10)**

- Rule 6 modified to address the prohibition of conducting medical procedures on anyone except themselves (page 9)
  - 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. **Students are prohibited from drawing blood or conducting any other medical procedures on anyone except themselves.**
- In Human Participant Involvement in Student-Designed Invention, Rule 1 was modified to clarify the use of professional feedback (page 9)
  - IRB review and pre-approval is required when the student- designed invention, prototype, application, etc. is tested by human participants other than the student researcher(s) or single adult guardian/adult sponsor/QS/DS when the testing requires an adult tester. This includes surveys conducted regarding potential use or opinions of the invention or consumer product by the general public. **This is not intended to apply to professional feedback from experts in the field of study.**
- In Risk Groups under Human Participant & IRB Resources, Rule 4 (Page 11)
  - See the online Risk Assessment Guide and Online Survey Consent Procedures for more detailed information on risk assessment. **If the risk is more than minimal, a Risk Assessment Form 3 is required.**

### **Vertebrate Animal Rules (Pages 12-14)**

- Restructured the listing of vertebrate animals (page 12)
  - Vertebrate animals, as covered by these rules, are defined as:
    1. **All nonhuman vertebrates (including fish) at hatching or birth.**
    2. **Live nonhuman vertebrate mammalian embryos or fetuses**
    3. **Tadpoles**
    4. **Bird and reptile eggs starting three days (72 hours) prior to hatching**

Exception: Because of their delayed cognitive neural development, zebrafish embryos may be used up to seven days (168 hours) post-fertilization and not be considered a vertebrate. However, regardless of time of treatment, survival past the 7 days must be considered a vertebrate animal and the entire study is subject to all of the rules below.

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

In Rules for All Studies, Rule 10 (page 15) modified to prohibit the use of prions or prion-like proteins

- 10. All studies involving the use of prions or prion-like proteins are prohibited.

## Forms

### **Regulated Research Institutional/Industrial Setting Form (1C)**

- Clarified question 5 which now reads: Did the student(s) work on the project as part of a group? oYes oNo **Were there other high school students present? If yes, please list the student names and describe how their work was related or different from the work of this project.**

### **Risk Assessment Form (3)**

- Included human participants in the title box.
  - Text now reads: Must be completed before experimentation; recommended for all projects. **May be required for projects involving Human Participants, Hazardous Chemicals, Materials or Devices, or Potentially Hazardous Biological Agents**

### **Human Participants Form (4)**

- Under BELOW – IRB USE ONLY added text that risk assessment is required if project is more than minimal risk
  - More than Minimal Risk **(a risk assessment form 3 is required).**