Human Participant Rules (pages 8-10)

- Rule 6 modified to address the prohibition of conducting medical procedures on anyone except themselves (page 9)
  - 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? Yes No 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).