Scientific Review Committee 2020 Rules and Guidelines

THINK BEYOND
Intel International Science and Engineering Fair
2020 Rule Clarifications and Changes
Introductions
SRC Members

- Ms. Michele Glidden
- Ms. Susan Appel
- Mr. Henry Disston
- Dr. Jennifer Green
- Dr. Paula Johnson
- Dr. Timothy Martin
- Mrs. Evelyn Montalvo
- Mr. Joseph Scott
- Dr. Jason Shuffitt
- Mrs. Andrea Spencer
Interesting Facts

- Total Projects = 1431
  - 1842 Participants from 80 Countries
  - No Shows = 16
  - Guests = 2
  - FTQ = 2
- Projects Competing = 1411
Changes to the Rules

• Rule book is a draft.

• Final edited version will be uploaded to the website by September.
Changes to the Rules

We are aware of the following issues:

1. Table of Content
   a. RRI Committee – Change from p.7 to p.6
   b. Human Participants – Exempt Studies – p.8 to p.9

2. Pages 9 & 14 – Numbering is off
Summary of Changes

➢ General

• Expanded Ethics Statement

• Roles and Responsibilities of the Students and Adults has been rewritten and reformatted

• Added Responsibilities for Qualified Scientist and Designated Supervisor
Summary of Changes

- Human Participants
  - Prohibit students from independently diagnosing diseases
  - Expanded definition of medical act
• Clarified PHBA rules

• Revised “Engineering Projects Guide”
Roles and Responsibilities of Students and Adults
Original Statement:

- Student researchers are expected to maintain the highest standards of honesty and integrity.
New Statement:

Student researchers, as well as adults who have a role in their projects, are expected to maintain the highest ethical standards.
Ethics Statement

These include, but are not limited to:

• Integrity.....

• Legality.....

• Respect for Confidentially and Intellectual Property.....
Ethics Statement

- Stewardship of the Environment
- Animal Care
- Human Participant Protection
- Potentially Hazardous Biological Agents
Qualified Scientist (QS)

Responsibilities:

The Qualified Scientist is responsible for:

- Reviewing the ISEF rules....
- Providing direct supervision throughout the timeline....
- Ensuring the proper training of the Student Researcher...
- Completing the required documentation.....
Designated Supervisor (DS)

Responsibilities:

- Providing direct supervision…..
- Completing the required documentation…..
- Reviewing and completing the Risk Assessment Form (3) when needed
Human Participants Rules

Ethics
Human
Subjects
IRB
Monitoring
Compliance
Justice
Beneficence
Respect
Education
Research
Original Item 6 under Rules:

Students are prohibited from administering medication and/or performing medical procedures…….
Human Participants Rules

New Item 6 under Rules:

Students are prohibited from independently diagnosing disease, administering medication and/or performing medical procedures.......
Original Item 6 under Rules:

The IRB must also confirm that the student is not violating the medical practice act of the state or country.....
New Item 6 under Rules:

The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc) of the state or country.....
Old version: Human participant involvement in Student-designed...

Rule 1. IRB review and pre-approval is necessary when the student-designed invention, prototype, application, etc. is tested by human participants other than the student researcher(s).
RULE 1. IRB REVIEW AND PRE-APPROVAL IS NECESSARY WHEN THE STUDENT-DESIGNED INVENTION, PROTOTYPE, APPLICATION, ETC. IS TESTED BY HUMAN PARTICIPANTS OTHER THAN THE STUDENT RESEARCHER(S) OR A SINGLE ADULT GUARDIAN, ADULT SPONSOR/QS/DS WHEN THE TESTING REQUIRES AN ADULT TESTER.

NEW VERSION: HUMAN PARTICIPANT INVOLVEMENT IN STUDENT-DESIGNED....
Vertebrate Animals
NO CHANGES
PHBAs
PHBAs

• Original Item 8 under Rules for ALL studies with PHBA

Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted. However, students may not genetically engineer organisms with multiple drug resistant traits........
PHBAs

• New Item 8 under Rules for ALL studies with PHBA

Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted, with the following exceptions:
PHBAs

a. Students are prohibited from the insertion of antibiotic resistance traits.....

b. Students are prohibited from designing or selecting for multiple drug resistance organisms.....
• Changed section heading from “Human Participants” to “Device Testing with Human Participants”
Most Common SRC Challenges
Frequent SRC Issues

Development of Medical Devices

- Improper Supervision
- Improper testing Location
Frequent SRC Issues

Conflict of Interest:

Any adult involved with the project cannot be on the approving committee.
Frequent SRC Issues

• Missing Forms
  – Form 1C – Regulated Research Institute/Industrial Setting
  – Form 3 – Risk Assessment
  – Human Informed Consent Form
  – Forms 6A & 6B – Potentially Hazardous Biological Agents
  – Form 7 – Continuation Projects Form
  – RRI letters of approval from IRB and/or IACUC
Frequent SRC Issues

Tissue Studies require both forms 6B and 6A
Frequent SRC Issues

- Improperly Completed Forms
  - Form 1A: Item 7 – Dates
  - Form 4: Human Participants Form
Frequent SRC Issues

• Missing Signatures
  – Qualified Scientist
    • Form 1C – Regulated Research Institute/Industrial Setting
    • Form 6A – Potentially Hazardous Biological Agents
  – IRB or SRC Chair/Members
    • Form 1B – Approval Form
    • Form 4 – Human Participants Form
    • Form 5A – Vertebrate Animal Form
    • Forms 6A – Potentially Hazardous Biological Agents Risk Assessment Form
Frequent SRC Issues

• Missing Information
  – Research Plan/Project Summary
  – Project Start and End Dates
  – Source of Cell Cultures
    • ATCC vs fresh tissue
  – Strain of Bacteria, esp. *E. coli*
  – Source of public available Data
Frequent SRC Issues

Too Much Information
- Previous Years Work described in Abstract
- Description of Mentor’s work versus Student’s experiment
- Signed Human Consent Forms
- References to Patents or Copyrights
- SDS Sheets
Video Killed the Science Fair Project
Reasons for FTQ

- No IRB approval
- Home lab
- Practicing medicine without proper medical supervision
- Contamination of the environment
Acknowledgements
Pat Zalo

You are truly appreciated and will be missed!
SUGGESTIONS FOR RULE CHANGES/CLARIFICATIONS ARE ALWAYS APPRECIATED AND CAN BE EMAILED TO:

SRC@SOCIETYFORSCIENCE.ORG