TXSEF
Junior and Senior Division
ISEF Rules Review

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Review of Rules

- 6th – 8th graders compete in the Junior Division.
- 9th – 12th graders compete in the Senior Division.
- Students can participate as Individuals or a Team of up to 3 students.
- All projects must abide by ISEF Rules and Guidelines and not break any laws
  - SRC Rules Quick Reference Document (Senior Division)
- May only contain one year of continuous research. Continuation projects are allowed, but can not be the exact same project. The previous year research plan and abstract must be submitted as well as Form 7 for Senior Division.

ISEF Rule Book

Review of Rules (continued)

- Students can only submit work done by themselves or their teammates for our competition. If they work in a research lab, it is important that only their work is submitted.
- All Senior Division Projects require ISEF Forms 1, 1A, and 1B, Research Plan, and Abstract. Additional paperwork may be required depending on the project.
- All Junior Division Projects in Texas require the MS Safety and Consent Form, Research Plan, and Abstract.
- All paperwork will need to be submitted for SRC approval in STEM Wizard.

ISEF Rule Book

Human Participant Studies

- Senior Division projects with human participants require a Form 4 and IRB pre-approval. If the study is done at a regulated research institution, IRB approval is required from the institution, not the school. A Qualified Scientist Form 2 may also be required.
- Junior Division projects with human participants require signatures from the Science Teacher, School Administrator, AND a Psychologist, Medical Doctor, or Registered Nurse on the MS Safety and Consent Form

- Examples:
    - Participants in physical activities
    - Surveys, Questionnaires, or Tests
        - On-line surveys require participant consent and must include a statement similar to the one provided by ISEF in the rule book and require participants to click a button or type a response indicating consent after the statement is read. *"There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question."*
    - Studies where the researcher is the subject of the research

ISEF Rule Book

Human Participant Studies (continued)

- Examples:
  - Data projects where the data is not de-identified
  - Behavioral observations where the the researcher interacts with the participant or modifies the environment, occurs in a non-public setting, or involves recording personally identifiable information
  - Testing of a student designed invention, prototype, or computer application (also requires risk assessment) with one exemption
    - If a student writes a computer program, creates an app, or produces some other type of technology where there is no risk to themself in testing it, and the researcher or the adult sponsor/parent/guardian (when an adult is required to test the product) is the only one testing/analyzing the product, then it is exempt from IRB approval. A risk assessment is still required.
    - This is just for engineering projects (where the student created a product) and not for experiments. If physical activity is involved or the collection of personally identifiable information, then it is not exempt.

ISEF Rule Book

Human Participant Studies (continued)

- Exemption Examples

Project Type	Project Explanation	Human Involvement	Form 4 Requirement	Form 3 Requirement
Engineering	Computer software created by student researcher	20 Students tested the software	Required	Required
Engineering	Computer software created by student researcher	Researcher or teacher tested software	Exempt	Required
Engineering	Student created system where video game only works when a bicycle is used	Researcher or teacher tested the system	Required	Required
Experiment	Blood pressure tested while playing different video games	Researcher	Required	Not for the human participants
Experiment	Bacteria cultured from hands after using different hand sanitizers	Researcher	Required	Not for the human participants

Vertebrate Animal Studies

- Senior Division projects with vertebrate animals require a Form 5A (if done at Home, School, Field) or 5B (regulated research institution) and SRC pre-approval or IACUC (Regulated Research Institution). A Qualified Scientist Form 2 may also be required.
- Junior Division projects with vertebrate animals require signatures from the Science Teacher AND a Veterinarian or other Biomedical/Biological Scientist (with animal experience) on the MS Safety and Consent Form

- Studies where the student works with tissue, samples, or data from vertebrate animals that is part of a larger study and where the student has no interaction with the animals is NOT a vertebrate animal study.
- Students are not allowed to cause pain, distress, or death to animals in their study. This may be allowed at a Regulated Research Institution, but it will not be allowed at our fair.

ISEF Rule Book

Potentially Hazardous Biological Agents Studies (PHBA)

- PHBA include bacteria, viruses, prions, fungi, parasites, rDNA technologies, human or animal fresh/frozen tissues, blood, or body fluids.
- Senior Division projects with PHBA require a Form 6A and SRC pre-approval. If they also involve human or animal vertebrate tissue such as cells, tissue, blood, or other body fluids, then a form 6B is also required. A Qualified Scientist Form 2 may also be required.
- Junior Division projects with PHBA require signatures from the Science Teacher AND a Biomedical/Biological Scientist on the MS Safety and Consent Form

- Culturing bacteria, mold, or other microorganisms can't be done at home.
- Must culture bacteria in the appropriate lab setting (BSL-1 or BSL-2).
- If environmental bacteria is cultured, it is only BSL-1 if the plates are sealed, not reopened, and disposed of properly.
- Must dispose of properly by autoclaving or treating with 10% bleach solution prior to disposal.
- Be careful with exempt items. If you culture in a petri dish or use rDNA technology, it isn't exempt

ISEF Rule Book

Hazardous Chemicals, Activities, or Devices (Risk Assessment)

- Includes DEA-controlled substances, prescription drugs, alcohol, tobacco, firearms, explosives, radiation, lasers, and any chemical or activity that involves a level of risk above that encountered in the student's everyday life. This is required for any student designed invention that has any human participant testing of the product.
- This does not include working with bacteria or mold. Those are PHBA. However, the chemicals or other aspects of the study may require a risk assessment.
- These Senior Division projects require a Form 3 and adult supervision by a Designated Supervisor or Qualified Scientist.
- These Junior Division projects require signatures from the Science Teacher AND a Designated Supervisor or Qualified Scientist who will monitor the student on the MS Safety and Consent Form.

ISEF Rule Book

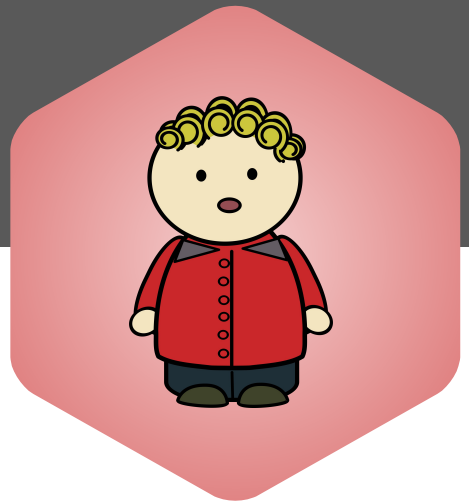
Location

- If a student works at a regulated research institution (RRI) or place of business, they need extra paperwork signed by whomever gave them permission to work in that location or whomever mentored them. This should not be the teacher or parent filling out the information.
- For Senior Division projects, the Form 1C must be completed by the supervising adult at the university or place of business where the research was done.
- Added in 2023* – A Form 1C should be filled out by any researcher at an institution who significantly assists a student with their project even if the student works remotely.
- For Junior Division projects, students should have the person who gave them permission to work in that location or monitored them write a letter stating that they had permission to work there and any other important information. This should be signed and dated.

ISEF Rule Book

Three Project Warning Flags!!!

Stop and read the rules or ask questions!!!



Human Participants: (Form 4)

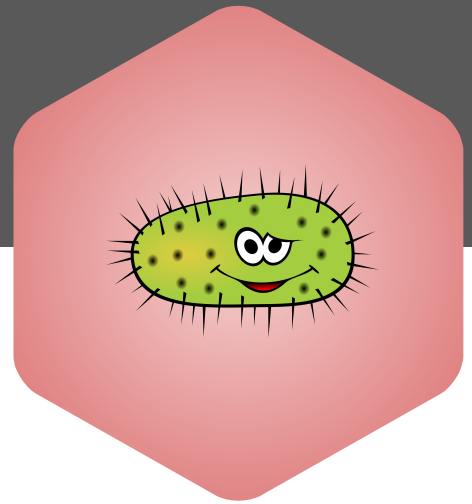
Humans as participants

require prior IRB approval

Vertebrate Animals: (Form 5)

Vertebrate Animal studies

require prior SRC approval



Microbiology PHBA (Form 6)

CAN'T BE DONE AT HOME

Requires prior SRC approval

ISEF Forms are not required for the **Junior Division**. However, these types of projects require additional signatures on the **MS Safety and Consent Form**.

ISEF Rule Book

IRB (Institutional Review Board)

- **Human Participant Studies – require pre-approval**
  - All three members must sign **ISEF Form 4 (Senior Division)**
    - School Administrator
    - Medical or Mental Health Professional (minimum of RN or licensed social worker)
    - Educator
  - You can have more than three members on the committee
  - One member signs **Form 1B, section 2a (Senior Division)**
  - For **Junior Division**, a School Administrator and a Medical/Mental Health Professional must sign the **MS Safety and Consent Form**
  - **Projects involving human participants that are done at a regulated research institution (RRI) require IRB approval from the RRI. The school IRB is not sufficient.**

ISEF Rule Book

SRC (Scientific Review Committee)

- **Vertebrate Animals and Microbiology(microorganisms, blood, bodily fluids, etc.) Projects – require pre-approval**
  - Three member on the SRC **(Senior Division)**
    - Biomedical Expert: graduate degree in Microbiology, Biomedical Research, related field or equivalent experience
    - Educator
    - One other member
  - Multiple people can be chairs of the SRC, but only 1 chair must sign **Forms 5A (vertebrate animals) and/or 6A (PHBA) and Form 1B, section 2a (Senior Division)**
  - For **Junior Division**, a Biomedical/Biological Scientist or a Veterinarian must sign the **MS Safety and Consent Form**
  - **For projects involving vertebrate animals that are done at a regulated research institution (RRI), a Form 5B and a copy of the IACUC for the project is required.**

ISEF Rule Book