RULES FOR SCHOOLS

What follows is a synopsis of the ISEF rules. For the full rulebook, go to https://student.societyforscience.org/international-rules-pre-college-science-research

Not sure what forms you need? Check this out: https://apps2.societyforscience.org/wizard/index.asp

1. All projects must have
   - Checklist for Adult Sponsor (1)
   - Student Checklist (1A)
   - Research Plan
   - Approval Form (1B)
2. Abstract of 250 words maximum, 2 copies
3. If team project, each member must submit Approval Form 1B

Adult Sponsor: teacher, parent, professor, or scientist in lab where student is working; should have close contact with student doing project.

Qualified Scientist: holds a doctoral/professional degree in student's area of research; Qualified Scientist and Adult Sponsor may be the same person.

Designated Supervisor: adult directly responsible for overseeing student experimentation.

Affiliated Fair SRC: minimum of 3 persons

- Biomedical scientist with earned doctoral degree
- An educator
- At least one other person (someone from LSU Med)
- Veterinarian is recommended

HUMAN PARTICIPANTS PROJECTS

Studies exempt from preapproval from IRB (institutional review board) or human participants' paperwork include:

1. Data review studies – data taken from publically available sources
2. Behavioral observations in public places where
    a. Researcher has no interaction with subjects
    b. Researcher does not manipulate the environment
    c. Researcher does not record any personal identifying data

Other studies: require IRB pre-approval and may require written consent from all subjects include:

1. Students participating in physical activities
2. Surveys, questionnaires, tests
3. Researcher is subject of research
4. Testing of researcher designed invention or concept
5. Projects in which subjects are not anonymous
6. Behavioral studies in which
    a. Researcher has modified the environment
    b. Study occurs in non-public place
    c. Subjects are not anonymous

**Must complete Human Participation part of Research Plan and evaluate and minimize risks to subjects.
**Research must comply with FERPA and HIPPA laws.
**Researcher must have approval by IRB before beginning project
**Participants must give informed consent if 18 years of age or older and/or have parental permission if younger than 18 or unable to give consent. IRB determines if verbal or written consent is needed.

Student researcher may observe and collect data of medical procedures and medication administration under direct supervision of medical professional. Student researcher may NOT publish or display information in a report that identifies human participants directly or indirectly by identifiers without written consent of participants.

Forms Required:

1. Checklist for Adult Sponsor (1)
2. Student Checklist (1A)
3. Research Plan
4. Approval Form (1B)
5. Human Participants Form (4)
6. Regulated Research Institution Form (1C)
7. Qualified Scientist Form (2)

} When applicable

Level of Risk Assessment for Human Participants

Physical: Greater than minimal risk includes:

- Exercise greater than in everyday life
- Ingestion, tasting, smelling, or application of substance – IRB determines risk level
- Exposure to potentially hazardous substance

Psychological: Greater than minimal risk includes:

- Activity that could result in emotional stress (surveys questionnaires, viewing stimuli) [ex: sexual or physical abuse, divorce, low self-esteem, depression, anxiety, violent or disturbing video images]

Risk Groups (IRB will determine if special protections are warranted)

1. Pregnant women
2. Developmentally delayed persons
3. People with diseases (cancer, asthma, diabetes, AIDS, dyslexia, CV disorders, psychiatric disorders, learning disorders)
4. Economically or educationally disadvantaged persons
5. Minors, prisoner, students receiving disability services

"Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research." From FDA website

VERTEBRATE ANIMAL RULES

Encourage students to use alternatives to animal research!!

Vertebrate animals include:

1. Live vertebrate embryos or fetuses
2. Tadpoles
3. Bird and reptile eggs within 3 days of hatching
4. All vertebrates (including fish) at hatching or birth (**Zebrafish embryos are not considered vertebrate animals until 7 days post-fertilization.)

All vertebrate animal studies must be reviewed and approved before experimentation. SRC must include a veterinarian.

Behavioral studies of animals are exempt from prior SRC approval if:

- There is no interaction with animals being observed, and
- No manipulation of the environment, and
- Study complies with all state and federal laws and regulations.

Research projects must not:

- Cause animals pain or distress
- Cause illness or unexpected weight loss
- Cause animals to die
- Use toxic substances (alcohol, acid rain, pesticides, heavy metals, etc)
- Use conditioning with averse stimuli, mother-infant separation or induced helpless ness
- Study pain
- Predator/vertebrate prey studies

  The study must be terminated immediately if and when any of the above conditions exist.

**Experimental design with greater than 18 hour food or fluid restriction must be justified.
**Animals cannot be taken from or released into the wild without approval from wildlife officials. (Fish can be taken from wild only if released into the wild unharmed.)
**Animals must be properly cared for at all times. If illness or emergency occurs, veterinary care must be obtained. Student researcher must stop experimentation if death or unexpected weight loss (more than 15% control animal group) occurs.
**Livestock or fish raised for food using standard practices may be euthanized by qualified adult.

Forms required for Vertebrate Animal Projects:

1. Checklist for adult sponsor (1)
2. Student Checklist (1A)
3. Research Plan
4. Approval Form (1B)
5. Vertebrate Animal Form (5A) or 5B
6. Qualified Scientist Form (2) …. When applicable

Animal Studies Conducted in a Regulated Research Institution (research institution licensed to use animals)

- Institutional Animal Care and Use committee must approve project before it begins
- Research must be conducted under a principal investigator
- Student researchers cannot euthanize animals
- Animals must not be subjected to pain or distress without use of approved pain meds
- Research into diet or drugs of unknown effect is permitted until an animal shows signs of distress

Forms for animal studies in Regulated Research Institution:
In addition to above 6 forms,

7) Regulated Research Institution Form (1C)
8) PHBA Risk Assessment Form (6A) for tissues and body fluids
9) Human and Vertebrate Animal Tissue Form (6B) for tissues and body fluids

Potentially Hazardous Biological Agents (PHBA)

Includes:

- Microbes
- Recombinant DNA methods
- Human or animal tissues, blood, body fluids

Studies exempt from prior SRC approval (and need no additional forms):

1. use of bakers' or brewers' yeast (no recombinant studies)
2. use *of Lactobacillus, Bacillus thuringensis*, nitrogen fixers, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment but NOT cultured
3. mold growth on food if experiment terminates at first sign of mold
4. mushrooms and slime molds
5. use of *E. coli* K-12 in study done at school (no recombinant studies)

Studies exempt from prior SRC approval but requires Risk Assessment Form 3:

a) use of protists, archaea, and similar microbes
b) manure used for composting or fuel production – NOT being cultured
c) use of coliform water test kits
d) forensic studies involving decomposition of vertebrate animals
e) study of microbial fuel cells

All other studies involving PHBA are not exempt from prior SRC approval and need these forms:

1. Checklist for Adult Sponsor (1)
2. Student Checklist (1A)
3. Research Plan
4. Approval Form (1B)
5. PHBA Risk Assessment Form (6A)
6. Regulated Research Institution Form (1C)
7. Qualified Scientist (2) ***
8. Risk Assessment (3)
9. Human and Vertebrate Animal Tissue Form (6B)

When applicable

***** Requires PhD in microbiology or MS with years of experience in area of student's research.**

Other Rules to Remember:

- Cannot culture microbes at home.
- Cannot genetically engineer bacteria with multiple antibiotic resistances.
- Studies of MRSA, VRE, KPC must be done in BSL-2 facility with prior SRC approval.
- Plant pathogens may be studies but not cultured at home; Do not release them into the home or garden environment.
- Culturing of human or animal wastes is a BSL-2 activity.
- Cannot use BSL-3 or BSL-4 organisms.

For Region 1 Science and Engineering Fair, all cultured unknown microbes are considered BSL-2 and such studies must be conducted in a BSL-2 facility and BSL-2 guidelines followed.

Projects Involving recombinant DNA (rDNA):

- If microbe is BSL-1, study can be conducted at school under supervision of Qualified Scientist.
- All studies with BSL-2 organisms must be done in Regulated Research Institution and approved prior to experimentation.

These studies are not treated as PHBA:

1) Plant tissue
2) Plant and non-primate cell lines
3) Fresh or frozen meat, meat by-products, pasteurized milk, or eggs obtained from food stores, restaurants, or packing houses
4) Hooves, hair, nails, feathers
5) Teeth that have been sterilized
6) Fossilized tissue or specimens
7) Prepared fixed tissue

Other considerations:

- Human and non-human primate cell lines must be utilized in BSL-1 or BSL-2 labs
- Use of human or wild animal blood is a BSL-2 study and must follow OSHA, 29 CFR subpart Z regulations.
- Human breast milk and unpasteurized animal milk is BSL-2 study.
- Human body fluids where sample can be identified with specific person must have IRB review and approval and informed consent.

Project in which student uses his/her own body fluids (if not cultured):

- Is BSL-1
- May be done at home
- Must have IRB review if study is effect of experimental procedure on student researcher (ex: change of diet and blood sugar levels, etc)
- Must have SRC approval before experimentation.

Hazardous Chemicals, Activities, or Devices

Forms required:

1) Checklist for Adult Sponsor (1)
2) Student Checklist (1A)
3) Research Plan and Approval Form (1B)
4) Regulated Research Institution Form (1C)
5) Qualified Scientist Form (2)
6) Risk Assessment Form (3)

} When applicable

Hazardous chemicals, activities, or devices studies include:

- Prescription drugs
- Alcohol and tobacco
- Firearms and explosives

**Students can not give prescription drugs to human participants.
**Veterinarian must supervise student administration of prescription drugs to vertebrate animals.
**Designated Supervisor is responsible for acquisition, use, and disposal of alcohol or tobacco used in study.
**Adults can produce wine or beer in home using process that meets TTB regulations. Students can design and conduct research involving legal production of wine or beer (under direct parental supervision).
**Studies are permitted in which minute quantities of ethanol are produced.
**Students can distill alcohol for fuel or other non-consumable use if study is

a) Done at school, and
b) A TTB permit and school permit have been obtained.

**Students may conduct a project using firearms and explosives when the study is done with direct supervision of a Designated Supervisor who complies with all state, local, and federal laws.

Hazardous Chemicals: The Risk Assessment includes the chemical's

- Toxicity, reactivity, flammability, and corrosiveness
- Refer to MSDS
- Include proper disposal of chemical

Hazardous Devices: Need Risk Assessment Form
Examples of devices deemed hazardous include:

- NMR
- Ultra-centrifuge
- High vacuum equipment
- High temperature ovens and oil baths

Radiation: non-ionizing; Risk Assessment needed when student or subject exposure exceeds normal amount in everyday life

- Microwave waves

- UV rays
- Radiofrequency waves
- Infrared rays

Lasers: Classified I-IV based on safety

Radioisotopes: Exposure can not exceed 0.5 mrem/hr or 100 mrem/year

Not Allowed at Project:

1. Living organisms, including plants

2. Soil, sand, rocks, cement, waste samples
3. Taxidermy specimens
4. Preserved vertebrate or invertebrate animals
5. Human or animal food
6. Human/animal parts or body fluids
7. Plant materials
8. All chemicals including water
9. All hazardous substances or devices
10. Items that have been in contact with hazardous chemicals
11. 3-D printers
12. Dry ice
13. Sharp items
14. Flames or highly flammable materials
15. Batteries with open-top cells or wet cells
16. Glass or glass objects
17. Any other apparatus deemed unsafe by SRC or Display and Safety Committee