Operational Guidelines for Scientific Review Committees (SRC) and Institutional Review Boards (IRB) updated 6/2022

For specific rules, please refer to: International Rules for Precollege Science Research: Guidelines for Science and Engineering Fairs

We also encourage you to address rules-related questions to the ISEF SRC: src@societyforscience.org

Scientific Review Committees (SRC)

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, certifications, research plans and exhibits for compliance with the rules, applicable laws and regulations at each level of science fair competition. Affiliated Fairs may authorize local SRCs to serve in this prior review capacity. The operation and composition of the local and Affiliated Fair SRCs must fully comply with the International Rules.

Most proposed research projects involving vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved by a local or regional SRC BEFORE experimentation. Prior SRC review is not required for human studies previously reviewed and approved by a properly constituted Institutional Review Board (IRB).

ALL projects, including those previously reviewed and approved by an IRB must be reviewed and approved by the SRC after experimentation and before competition in an Affiliated Fair.

Projects which were conducted at a Regulated Research Institution, industrial setting or any work site other than home, school or field and which were reviewed and approved by the proper IRB before experimentation, must also be approved by the Affiliated Fair SRC.

An SRC must consist of a minimum of three persons, including the following:

- a biomedical scientist with an earned graduate degree
- an educator
- at least one additional member

Additional expertise: Many project evaluations require additional expertise (e.g., in biosafety and/or of human risk groups). The SRC can add additional members to ensure the appropriate expertise is involved in evaluating the research project. If the SRC needs an expert as one of its members and one is not in the immediate area, all documented contact with an external expert must be submitted. If animal research is involved, at least one member must be familiar with proper animal care procedures. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied.

1) To avoid conflict of interest, no Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Designated Supervisor who oversees the project, may serve on the IRB or SRC reviewing that project or any other committee. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

2) SRCs can function on the local, regional, and/or state level. The Regeneron ISEF SRC reviews projects prior to competition at the Regeneron ISEF.

3) In many regions, the SRC also serves as the Institutional Review Board (IRB) and reviews projects involving human participants. A combined committee is allowed as long as the membership meets both the SRC and IRB requirements listed previously.

4) In reviewing projects just prior to a fair, if the SRC serving at that level of competition judges an IRB's decision as inappropriate, thereby

placing human participants in jeopardy, they may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with ISEF SRC in questionable cases.

5) These Operational Guidelines for SRCs/IRBs should be used in conjunction with the International Rules. The Rules are intended to ensure the safety of students, to protect the participants and environments studied, and to limit the liability of the adults who assist with the projects.

6) All SRC members must be familiar with the International Rules and the Operational Guidelines for SRCs/IRBs, as well as any pertinent federal regulations. When reviewing research plans, members are urged to use their best professional judgment and to consult other expertise as needed.

Registration of SRC Members

1) During the affiliation process, the affiliated fair director is responsible for registering the SRC members' names with Society for Science and attests that the affiliated fair has an active, properly constituted SRC.

2) The affiliated fair director is responsible for overseeing all local SRCs that feed into the affiliated fair when applicable.

SRC Approval Before Experimentation

1) All SRC members should convene for an initial meeting to review and discuss the current year's International Rules and forms. One purpose of this meeting is to ensure that committee members apply the International Rules in a consistent manner. The local/affiliated SRC should be ready to guide students and sponsors through the project approval process.

2) The SRC should be available on a regular basis to review projects that require approval before experimentation is started. (Refer to the International Rules for specific areas that require pre-approval.) The SRC should process these requests within two weeks of receipt, so students and sponsors can correct any plans in violation of the rules and begin experimentation as soon as possible. Because each fair has a different schedule, SRC meeting-time periods may vary. The affiliated fair director will inform the Society for Science of the meeting schedule at the end of the season with the Affiliated Fair Scientific Review Committee (SRC) Report.

3) Instead of meeting as a full committee, SRC members may individually review projects. If a project requires in-depth review or has a serious problem that could result in a violation, the entire SRC should meet to discuss the project.

4) A Scientific Review Committee (SRC) examines projects for the following:
   - Evidence of proper supervision
   - Completed forms, signatures, research dates, and preapproval dates (when required)
   - Evidence of proper team composition
   - Compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents and/or hazardous chemicals, activities or devices
   - Compliance with ISEF ethics statement
   - Use of accepted and appropriate research techniques
   - Evidence that risks have been properly assessed
   - Evidence of search for alternatives to animal use
   - Humane treatment of animals
   - Documentation of substantial expansion for continuation projects
   - Evidence of appropriate literature search and attribution

5) **Prohibited Studies**. Examples of prohibited studies include projects designed to kill

vertebrate animals and/or those involving more than momentary pain and distress, proposed use of potentially hazardous biological agents at home or in a laboratory that does not meet the biosafety level of the organisms or techniques being used. The SRC should notify the student and sponsor promptly and provide them with a full explanation of the core concerns and what to avoid/correct.

6) **For projects requiring prior SRC review (human participants; vertebrate animals;PHBAs;Hazardous Chemicals, Activities and Devices) the SRC should deliberate, resulting in one of the following decisions:**

   a) Approval of research done at home, school or field. If a project is approved, the SRC Chair signs the box in #2a on the Approval Form (1B). The approved forms should be returned to students as soon as possible, so that they can begin experimentation.

   b) Approval of research done at all Regulated Research Institutions with no prior fair SRC/IRB approval: If the project was conducted at a regulated research institution and was reviewed and approved by the proper institutional board before experimentation and complies with ISEF rules, sign box #2a on the approval Form (1B). **Attach (1C) and any required institutional approvals (e.g. IACUC, IRB).** If the approved project involved potentially hazardous biological agents, the SRC chair will also complete and sign the bottom section on Form 6A.

   c) Disapproval: The SRC Chair should provide the student and sponsor with a list of reasons for disapproval and suggestions for changes needed for approval. If suitable corrections are made, the revised project forms should be re-reviewed. If the revised project is then approved, the student and sponsor should be notified immediately so that the student can begin experimentation.

SRC Review Shortly Before Competition

1) An SRC is required to reconvene before the fair to review supporting documentation of all projects prior to competition. The SRC chair will document this approval by signing #3 at the bottom of Approval Form (1B).

2) Projects requiring pre-approval that were conducted at a Regulated Research Institution and were approved by the institution's approval bodies (IACUC, IRB, etc.) should be reviewed by the SRC/IRB to ensure documentation demonstrates pre-approval and compliance with the ISEF rules. If this review satisfies the pre-approval and compliance with the rules, the SRC chair will sign the box in #2b to indicate approval. If the approved project involved potentially hazardous biological agents, the SRC chair will also complete and sign the bottom section on Form 6A.

After Competition

1) Every affiliated SRC Chair must submit a summary report to the affiliated fair director immediately following the fair. The fair director should forward the report to Society for Science within 12 days of their fair and no later than June 1. The Society will not re- affiliate the fair in question until a report is received.

   The purpose of this report is to alert the Society to any problems that affiliated fairs are encountering and to assist in alleviating these problems. Staff welcomes comments and suggestions from the SRC Chair.

2) Society for Science provides an online form for the summary report. It includes the following:
   a) Name (and Fair ID number) of the

affiliated fair;
b) Dates of SRC/IRB meetings;
c) Major problems encountered;
d) Recommendations for correcting problems;
e) Data on how many projects were examined, approved, or failed to qualify;
f) Reasons for any projects failing to qualify.

Institutional Review Boards (IRB)

An Institutional Review Board (IRB), is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement. Therefore, it is advisable that an IRB be established at the school level to evaluate human research projects. If necessary, the local or ISEF-affiliated SRC can serve as an IRB as long as it has the required membership.

A School IRB must consist of a minimum of three members including the following:

- **An educator**
- **A school administrator (preferably principal or vice principal**
- **A medical or mental health professional.** The medical or mental health professional may be a medical doctor, nurse practitioner, physician's assistant, doctor of pharmacy, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor. The medical or mental health professional on the IRB may change depending on the nature of the study. This person must be knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study.
- No Adult Sponsor, Qualified Scientist, Designated Supervisor who oversees the project, parent or other relative of the student may serve on the IRB reviewing the project. Additional members are suggested to avoid conflict of interest.

Additional Expertise: If an expert is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of that expert.

1) IRBs exist at federally Regulated Research Institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research participants are incarcerated. The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor and the local IRB are responsible for ensuring that the project is appropriate for a pre-college student and adheres to ISEF rules.
2) It is the responsibility of the members of the IRB to thoroughly review the Research Plan and collectively decide whether to approve the project, request revisions to the methodology/ require more oversight (e.g., QS) to reduce risk to participants, or to determine that the project is not appropriate for student research. An IRB documents the determination of risk level on Human Participant Form 4.
3) An IRB generally makes the final determination of risk. However, in reviewing projects just prior to a fair, if an SRC judges an IRB's decision as inappropriate, thereby placing human participants in jeopardy, the SRC may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with ISEF SRC in questionable cases.

Informed Consent

1) The research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants give their consent. Research participants under 18 years of age or individuals not able to give consent (e.g.

mentally disabled) give their assent, with their parents/guardians giving parental permission. The IRB will determine whether the consent/assent/parental permission may be verbal or must be written depending on the level of risk and the type of study and will determine if a Qualified Scientist is required to oversee the project.

2) Documentation of written consent/ assent/ parental permission is required:
   a) When the IRB determines that a research study involves physical or psychological activities with more than minimal risk.
   b) When the IRB determines that the project could *potentially* result in emotional stress to research participants.
   c) When the IRB determines that the research participants belong to a risk group and the study does not meet any of the criteria below for a waiver.

3) The IRB may waive the requirement for documentation of written informed consent/assent/parental permission, if the research involves only minimal risk *and* anonymous data collection *and* if it is one of the following:
   a) Research involving normal educational practices. Research on individual or group behavior or characteristics of individuals where the researcher does <u>not</u> manipulate the participants' behavior and the study does not involve more than minimal risk.
   b) Surveys and questionnaires that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
   c) Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

Combined SRC/IRB

An ISEF-affiliated fair director can establish a local or regional committee, which serves as both an SRC and an IRB. This committee must include at least:

a) biomedical scientist with an earned doctoral degree
b) an educator
c) school administrator (preferably, a principal or vice principal)
d) and one of the following who is knowledgeable and capable of evaluating the physical and/or psychological risk involved in a given study: a medical doctor, physician's assistant, registered nurse, licensed psychologist, licensed professional clinical counselor or licensed social worker.

At least one member of the committee must be familiar with proper animal care procedures when reviewing projects using non-human vertebrate animals.

Please do not hesitate to reach out to Society staff or the ISEF SRC with any questions or concerns:
ISEF@societyforscience.org;
SRC@societyforscience.org