Operational Guidelines for Scientific Review Committees (SRC) and Institutional Review Boards (IRB)

Please refer to the *International Rules for Precollege Science Research: Guidelines for Science and Engineering Fairs for specific rules.*

We also encourage you to address rules-related questions to the Intel ISEF SRC listed at the end of this publication, email:

src@societyforscience.org

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Scientific Review Committee (SRC)

A Scientific Review Committee (SRC) is a group of adults knowledgeable about regulations concerning experimentation especially with vertebrate animals and potentially hazardous biological agents. The SRC must review and approve all projects in these areas before experimentation may begin. Local SRCs may be formed to assist the Fair SRC in reviewing and approving projects. Shortly before competition, the Fair SRC will also review the documentation for ALL projects to ensure that students have followed all applicable rules and that the project is eligible to compete.

1) An SRC consists of a minimum of three members. The SRC must include at least:
   a) biomedical scientist (*e.g.*, Ph.D., M.D., D.V.M., D.D.S., D.O.)
   b) an educator
   c) at least one other member

   Additional Expertise: Many projects will probably require additional expertise to be properly evaluated (for instance, extended knowledge of biosafety or of human risk groups). If animal research is involved, at least one member must be familiar with proper animal care procedures. If the SRC needs an expert as one of its members and one is not in the immediate area, then documented contact with an external expert is appropriate and encouraged.

2) In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor must not serve on the SRC reviewing that project. More than the minimum number of required members are recommended to help avoid this conflict of interest and to increase the expertise of the committee.

3) SRCs can function on the local, regional, and/or state level. The Intel ISEF has a permanent SRC that reviews projects prior to competition at the Intel ISEF. In many regions, the SRC also serves as the Institutional Review Board (IRB) and reviews projects involving human subjects. If a Fair SRC judges a local IRB's decision as inappropriate the SRC may override the IRB's decision. To serve as an IRB, an SRC must also include the members required in a properly constituted IRB (See page 3).

4) 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 subjects and environments studied, and to limit the liability of the adults who assist with the projects.

5) 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 coupled with good common sense. Members should counsel and instruct students and help them correct violations whenever possible.

Registration of SRC Members

1) The Intel ISEF-affiliated fair director is responsible for appointing members to the affiliated fair SRC. The Intel ISEF-affiliated fair director must register the members' names with Society for Science & the Public when submitting the affiliation paperwork.
2) The affiliated fair director is responsible for overseeing all local SRCs that feed into the affiliated fair SRC.

Approval Before Experimentation

1) All SRC members should convene in a central location 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 meet on a regular basis to review projects that require approval before experimentation is started. The SRC should process these requests within two weeks of receipt, so students and sponsors can correct any violations 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 Society for Science & the Public 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) SRCs should pay special attention to the following items:
   a) evidence of proper supervision
   b) use of appropriate research techniques
   c) completed forms, signatures and dates
   d) evidence of search for alternatives to animal use
   e) humane treatment of animals
   f) compliance with rules and laws governing proper care and housing of animals
   g) compliance with rules regarding potentially hazardous biological agents
   h) documentation of substantial expansion of continuing projects
   i) compliance with ISEF Ethics Statement.
5) The SRC should deliberate, resulting in one of the following decisions:
   a) Approval: 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. For the approval procedure for projects approved and conducted at regulated research sites, see SRC Reviw Shortly Before Competition, #2.
   b) 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.
6) Projects that are not allowed: Some projects are unethical, inhumane or have an unacceptable high risk and should not be done by pre-college students. Examples would be projects designed to kill vertebrate animals, toxicity studies using vertebrate animals, improper treatment of animals, proposed use of potentially hazardous biological agents at home, and lack of appropriate supervision. The SRC should notify the student and sponsor promptly and provide them with a complete list of reasons the project may not be done.

7) Biosafety level review and approval: If a project involves a potentially hazardous biological agent and is being conducted in a non-regulated site (e.g. school), the student researcher and the Qualified Scientist or Designated Supervisor who will be supervising the project must conduct a risk assessment and propose a biosafety level. The SRC will review the research plan, risk assessment, and proposed BSL and must confirm (or change, if needed) the Biosafety Level by completing and signing Potentially Hazardous Biological Agents Form 6A.

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.
3) SRC members must carefully review documents provided by the supervising professional in human subject studies with de-identified, anonymous data to ensure that data was appropriately de-identified.
   These studies did not require prior IRB review and approval.

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 & the Public within 12 days of their fair and no later than June 1. SSP will not re-affiliate the fair in question until a report is received.
   The purpose of this report is to alert SSP to any problems that affiliated fairs are encountering and to assist in alleviating these problems. SSP welcomes comments and suggestions from the SRC Chair.
2) Society for Science & the Public provides an online form for the summary report. Other forms are acceptable, as long as they include 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 Board (IRB)

1) 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 human subjects. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires

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2) Federal regulations require local community involvement, therefore an IRB should be established at the school level to evaluate human research projects. An IRB at the school or ISEF Affiliated Fair level must consist of a <u>minimum</u> of three members. In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor who oversee a specific project must not serve on the

IRB reviewing that project. Additional members are recommended to help avoid this conflict of interest and to increase the expertise of the committee. This IRB must include:

a) an educator
b) a school administrator (preferably, a principal or vice principal),
c) 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, psychologist, licensed clinical professional counselor or licensed social worker.

3) If the IRB needs an expert as one of its members and one is not in the immediate area, then documented contact with an external expert is appropriate and encouraged. A copy of the correspondence (e.g. email, fax, etc.) should be attached to Form 4 and can be used as the signature of that expert.

4) IRBs exist at federally registered institutions (e.g., universities, medical centers, NIH, correctional facilities). The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor is responsible for ensuring that the project is appropriate for a pre-college student and adheres to the ISEF rules.

5) 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 subjects in jeopardy, the SRC may override the IRB's decision and the project may fail to qualify for competition.

Informed Consent

1) The research subjects must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research subjects give their consent. Research subjects 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 a research subject.
   c) When the IRB determines that the research subjects 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.
   b) Research on individual or group behavior or characteristics of individuals where the researcher does <u>not</u> manipulate the subjects' behavior and the study does not involve more than minimal risk.
   c) 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. If there is any uncertainty regarding the appropriateness of waiving informed consent, it

is strongly recommended that informed consent be obtained.

d) 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 (e.g., Ph.D., M.D., D.V.M., D.D.S., D.O.)
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.

The ISEF Scientific Review Committee members will be glad to answer any questions or concerns about these guidelines or the International Rules

Please send email inquiries to:
SRC@societyforscience.org