

Roles and Responsibilities of Students and Adults

The Student Researcher(s)

The student researcher is responsible for all aspects of the research project including enlisting the aid of any required supervisory adults (Adult Sponsor, Qualified Scientist, etc.), obtaining necessary approvals (SRC, IRB, etc.), following the Rules & Guidelines of the Intel ISEF, and performing the experimentation, engineering, data analysis, etc.

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and the Intel ISEF. Society for Science & the Public reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

The Adult Sponsor

An Adult Sponsor may be a teacher, parent, professor, and/or other professional scientist in whose lab the student is working. This individual must have a solid background in science and should have close contact with the student during the course of the project.

The Adult Sponsor is responsible for working with the student to evaluate any possible risks involved in order to ensure the health and safety of the student conducting the research and the humans and/or animals involved in the study. The Adult Sponsor must review the student's **Student Checklist (1A)** and **Research Plan** to certify that that: a) experimentation is within local, state, and Federal laws and Intel ISEF rules; b) forms are completed by other required adults; and c) criteria for the Qualified Scientist adhere to those set forth below.

The Adult Sponsor must be familiar with the regulations that govern potentially dangerous research as they apply to a specific student project. These may include chemical and equipment usage, experimental techniques, research involving human and/or vertebrate animals, and cell cultures, microorganisms, or animal tissues. Some experiments involve procedures or materials that are regulated by state, federal or non-U.S. national laws. If not thoroughly familiar with the regulations, the Adult Sponsor should help the student enlist the aid of a Qualified Scientist.

The Adult Sponsor is responsible for ensuring the student's research is eligible for entry in the Blue Ridge Highlands Regional Science Fair and Intel ISEF.

The Qualified Scientist

A Qualified Scientist should have earned a doctoral/professional degree in a scientific discipline that relates to the student's area of research. Alternatively, the SRC may consider an individual with extensive experience and expertise in the student's area of research as a Qualified Scientist. The Qualified Scientist must be thoroughly familiar with local, state, and federal regulations that govern the student's area of research.

The Qualified Scientist and the Adult Sponsor may be the same person, if that person is qualified as described above. A student may work with a Qualified Scientist in a city, state or country that is not where the student resides. In this case, the student must work locally with a Designated Supervisor (see below) who has been trained in the techniques to be applied by the student.

The Designated Supervisor

The Designated Supervisor is an adult who is directly responsible for overseeing student experimentation. The Designated Supervisor need not have an advanced degree, but must be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Adult Sponsor may act as the Designated Supervisor.

If a student is experimenting with live vertebrates and the animals are in a situation where their behavior or habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

Review Committees

The Institutional Review Board (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 Intel ISEF-affiliated SRC can serve as an IRB as long as it has the required membership. An IRB must:

1. consist of a minimum of three members
2. include an educator

3. include a school administrator (preferably principal or vice principal), include an individual who is knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study. This may be a medical doctor, nurse practitioner, physician's assistant, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor.

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.

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 reviewing that project. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

Most projects require review by the full three member IRB.

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 the Intel ISEF rules.

An IRB is responsible for assessing risk and documenting the determination of risk level on Human Participant Form 4. However, 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 the Intel ISEF SRC in questionable cases.

IRB Waiver of Written Informed Consent: The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involved only minimal risk and anonymous data collection and if it is one of the following:

1. Research involving normal educational practices.
2. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.
3. Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

4. 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 than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is an 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.

Expedited Review: An expedited review by one member of the IRB may be conducted for the following types of projects. This person must have the expertise necessary to make such a decision and/or receive advisement from the appropriate expert.

1. Projects that involve testing by anyone other than the student researcher of student-designed invention or prototype where the feedback received is a direct reference to the design, where personal data is not collected, and where the testing does not pose a health or safety hazard.
2. Projects in which the student is the subject of their research and the research does not involve more than minimal risk.

The Affiliated Fair Scientific Review Committee

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. Directions for obtaining preapproval are available from the affiliated fair. A list of fairs is at: [http://apps2.societyforscience.org/ssp-affiliate-fair/.](http://apps2.societyforscience.org/ssp-affiliate-fair/))

Most proposed research projects involving vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved BEFORE experimentation. Local or regional SRC prior review is not required for human studies previously reviewed and approved by a properly constituted 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 Intel ISEF Affiliated Fair. Projects which were conducted at a Regulated Research Institution (not home, high school or field) and which were reviewed and approved by the proper institutional board before experimentation, must also be approved by the Intel ISEF Affiliated Fair SRC.

An Affiliated Fair SRC must:

1. include a minimum of three persons
2. include a biomedical scientist with an earned doctoral degree
3. include an educator
4. include at least one additional member

Additional expertise: many project evaluations require additional expertise (e.g., on biosafety and/or of human risk groups.) 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.

No Adult Sponsor, parent or other relative of the student(s), the Qualified Scientist, or the Designated Supervisor who oversees the project may serve on the SRC reviewing that project. Additional members are recommended to diversify and to increase the expertise of the committee.

A Scientific Review Committee (SRC) examines projects for the following:

1. evidence of literature search and appropriate attribution
2. evidence of proper supervision
3. use of accepted and appropriate research techniques
4. completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (where required)
5. evidence of search for alternatives to animal use
6. humane treatment of animals
7. compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents
8. documentation of substantial expansion for continuation projects
9. compliance with the ISEF ethics statement

Combined SRC/ IRB Committee

A combined committee is allowed as long as the membership meets both the SRC and IRB requirements listed above.

Regulated Research Institutions/Industrial Settings Review Committees

Regulated Research Institution: A Regulated Research Institution within the U.S. is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For project conducted outside of the United States, a Regulated Research Institution would be a comparable research institution that adheres to country laws governing the care and use of vertebrate animals.

Certain areas of research conducted in a regulated research institution or an industrial setting require review and approval by federally mandated committees that have been established at that institution. These committees include:

1. Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
2. Institutional Review Board (IRB); Human Subjects Participant Program (HSPP)
3. Institutional Biosafety Committee (IBC)
4. Embryonic Stem Cell Research Oversight Committee (ESCRO)
5. Safety Review Committee

The Blue Ridge Highlands Regional Science Fair Scientific Review Committee (BRHRSF SRC)

All projects are reviewed by the Scientific Review Committee prior to competition. The SRC is the final arbiter of the qualification of students to participate in the Blue Ridge Highlands Regional Science Fair. Before the fair, committee members review research plans and all required forms to confirm that applicable Intel ISEF rules have been followed. The SRC may request additional information from students prior to the science fair.

The SRC is made up of adults knowledgeable about research regulations. In addition to the review of all projects at the Regional Science Fair, committee members answer questions about the rules throughout the year from students and teachers.