ALL PROJECTS

Ethics Statement

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.

Eligibility/Limitations

- 1. Each Intel ISEF-affiliated fair may send the number of projects provided by their affiliation agreement.
- A student must be selected by an Intel ISEF-affiliated fair, and:
 a. be in grades 9–12 or equivalent;
 - b. not have reached age 20 on or before May 1 preceding the Intel ISEF.
- 3. English is the official language of the Intel ISEF. Student project boards and abstracts must be in English.
- 4. Each student is only allowed to enter one project. That project may include no more than 12 months of continuous research and may not include research performed before January 2017.
- 5. Team projects must have no more than three members. Teams competing at Intel ISEF must be composed of members who all meet Intel ISEF eligibility.
- 6. Students may compete in only one Intel ISEF affiliated fair, except when proceeding to a state/national fair affiliated with the Intel ISEF from an affiliated regional fair.
- 7. Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.
- 8. All sciences (physical, life, social) are represented at the Intel ISEF. Review a <u>complete list of categories and sub-categories</u> with definitions.
- 9. A research project may be a part of a larger study performed by professional scientists, but the project presented by the student must be only their own portion of the complete study.

Requirements

General

- 1. All domestic and international students competing in an Intel ISEF-affiliated fair must adhere to all rules as set forth in this document.
- 2. All projects must adhere to the Ethics Statement above.
- 3. It is the responsibility of the student and the Adult Sponsor to evaluate the study to determine if the research will require forms and/or review and approval prior to experimentation, especially projects that include human participants, vertebrate animals, or potentially hazardous biological agents.

- 4. Projects must adhere to local, state and U.S. Federal laws, regulations and permitting conditions. In addition, projects conducted outside the U.S. must also adhere to the laws of the country and jurisdiction in which the project was performed.
- 5. The use of non-animal research methods and alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project.
- 6. Introduction or disposal of non-native, genetically altered genetically-altered, and/or invasive species (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. It is recommended that students reference their local, state or national regulations and quarantine lists.
- 7. Intel ISEF exhibits must adhere to Intel ISEF <u>Display & Safety</u> requirements.
- 8. All projects must adhere to the requirements of the affiliated fair(s) in which it competes to qualify for participation in the Intel ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.

Approval and Documentation

- Before experimentation begins, a local or regional Institutional Review Board (IRB) or Scientific Review Committee (SRC) associated with the Intel ISEF-affiliated fair must review and approve most projects involving human participants, vertebrate animals, and potentially hazardous biological agents. Note: If a project involves the testing of a student designed invention, prototype or concept by a human, an IRB review and approval may be required prior to experimentation. See Human Participants Rules for details.
- Every student must complete the <u>Student Checklist (1A), a</u> <u>Research Plan/Project Summary</u> and <u>Approval Form (1B)</u> and review the project with the Adult Sponsor in coordination with completion by the Adult Sponsor of the <u>Checklist for Adult</u> <u>Sponsor (1)</u>.
- A <u>Qualified Scientist</u> is required for all studies involving Biosafety Lab-2 (BSL-2) potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.
- 4. After initial IRB/SRC approval (if required), any proposed changes in the <u>Student Checklist (1A)</u> and Research Plan/ Project Summary must be re-approved before laboratory experimentation/data collection resumes.
- 5. Projects which are continuations of a previous year's work and which require IRB/SRC approval must undergo the review process with the current year proposal prior to experimentation/data collection for the current year.
- 6. Any continuing project must document that the additional research is new and different. (<u>Continuation Projects Form (7)</u>).

- 7. If work was conducted in a regulated research institution, industrial setting or any work site other than home, school or field at any time during the current Intel ISEF project year, the <u>Regulated Research Institutional/Industrial Setting Form (1C)</u> must be completed and displayed at the project booth.
- After experimentation, each student or team must submit a (maximum) 250-word, one-page abstract which summarizes the current year's work. The abstract must describe research conducted by the student, not by the supervising adult(s).
- A project data book and research paper are not required, but are strongly recommended for judging purposes. Regional or local fairs may require a project data book and/or a research paper.
- All signed forms, certifications, and permits must be available for review by all regional, state, national and international affiliated fair SRCs in which the student(s) participate. This review must occur after experimentation and before competition.

Continuation/Research Progression of Projects

- 1. As in the professional world, research projects may build on work performed previously. A valid continuation project is a sound scientific endeavor. Students will be judged only on laboratory experiment/data collection performed over 12 continuous months beginning no earlier than January 2017 and ending May 2018.
- 2. Any project based on the student's prior research could be considered a continuation/research progression project. These projects must document that the additional research is a substantive expansion from prior work (e.g. testing a new variable or new line of investigation). Repetition of previous experimentation with the same methodology and research question, even with an increased sample size, is an example of an unacceptable continuation.
- 3. The display board and abstract must reflect the current year's work only. The project title displayed in the finalist's booth may mention years (for example, "Year Two of an Ongoing Study"). Previous year's databooks, research papers and supporting documents may be at the booth, but not openly displayed, if properly labeled as such.
- 4. Longitudinal studies are permitted as an acceptable continuation under the following conditions:
 - a. The study is a multi-year study testing or documenting the same variables in which time is a critical variable.
 (Examples: Effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time.)
 - b. Each consecutive year must demonstrate time-based change.
 - c. The display board must be based on collective past conclusionary data and its comparison to the current year data set. No raw data from previous years may be displayed.
- 5. All projects must be reviewed and approved each year and forms must be completed for the new year.
- 6. NOTE: For competition in the Intel ISEF, the <u>Continuation/</u> <u>Research Progression Project Form (7)</u> is required for projects

in the same field of study as a previous project. This form must be displayed at the project booth. Retention of all prior years' paperwork is required and must be presented to the Intel ISEF SRC upon request.

Team Projects

- Team projects compete and are judged in the scientific category of their research at the Intel ISEF. All team members must meet the eligibility requirements for Intel ISEF.
- 2. Teams must have no more than three members. A team with members from different geographic regions may compete at an affiliated fair of one of its members, but not at multiple fairs. However, each affiliated fair holds the authority to determine whether teams with members outside of a fair's geographic territory are eligible to compete, understanding that if the team wins the right to attend Intel ISEF, all team members' expenses must be supported by the fair.
 - a. Team membership cannot be changed during a given research year unless there are extenuating circumstances and the local SRC reviews and approves the change, including converting a team project to an individual project or vice versa. Such conversions must address rationale for the change and include a clear delineation between research preceding the change and that which will follow. A memorandum documenting this review and approval should be attached to Form 1A.
 - b. Once a project has competed in a science fair at any level, team membership cannot change and the project cannot be converted from an individual project to a team project or vice versa.
 - c. In a future year, any project may be converted from an individual to a team project, from a team to an individual project and/or have a change in team membership.
- 3. Each team is encouraged to appoint a team leader to coordinate the work and act as spokesperson. However, each member of the team should be able to serve as spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members and will be evaluated using the same judging criteria as individual projects.
- Each team member must submit an Approval Form (1B). Team members must jointly submit the Checklist for Adult Sponsor (1), one abstract, a Student Checklist (1A), a Research Plan/ Project Summary and other required forms.
- 5. Full names of all team members must appear on the abstract and forms.

Contact the <u>Science Education Programs</u> or the <u>Scientific</u> <u>Review Committee</u> with questions.

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 <u>Student Checklist (1A) and Research</u> <u>Plan/Project Summary</u> to insure 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 and/or a Designated Supervisor.

The Adult Sponsor is responsible for ensuring the student's research is eligible for entry in the 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 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.

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.

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

Expedited Review: An expedited review by one member of the IRB may be conducted for projects that meet one of the criteria listed below. The IRB member reviewing the project will determine whether appropriate safety precautions will be employed and whether the project meets criteria for expedited review. If a project submitted for expedited review does not meet the criteria specified below, the project must undergo full IRB review. The IRB member reviewing the project must have the expertise necessary to make such a decision and/or receive advisement from the appropriate expert.

 Student-designed Invention, Prototype, Computer Application, or Engineering/Design Project: The data received in these types of projects must be in direct reference to the design.
 Personal data are not collected and the testing does not pose a health or safety hazard. NOTE: The expedited review process may not be used if the invention is tested medically for treatment, diagnosis or intervention.

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 <u>Human Participant Form 4</u>. 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.

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: <u>https://apps2.</u> <u>societyforscience.org/ssp-affiliate-fair/</u>.

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 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 institutional board before experimentation, must also be approved by the Affiliated Fair SRC.

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

- 1. a biomedical scientist with an earned doctoral degree
- 2. an educator
- 3. 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.

To avoid conflict of interest, 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:

- evidence of literature search and appropriate attribution
- evidence of proper supervision
- use of accepted and appropriate research techniques
- completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (where required)
- evidence of search for alternatives to animal use
- humane treatment of animals
- compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents and hazardous chemicals, activities or devices
- documentation of substantial expansion for continuation projects
- compliance with the Intel 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 projects 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 ISEF Scientific Review Committee (Intel ISEF SRC)

All projects are reviewed by the Intel ISEF Scientific Review Committee prior to competition. The Intel ISEF SRC is the final arbiter of the qualification of students to participate in the Intel ISEF. Before the fair, committee members review research plans and all required forms to confirm that applicable Intel ISEF rules have been followed. The Intel ISEF SRC may request additional information from students prior to the Intel ISEF or may interview potential Intel ISEF participants at the fair to ensure that they qualify to compete. The Intel ISEF SRC, like an Affiliated Fair SRC, is made up of adults knowledgeable about research regulations. In addition to the review of all projects at the Intel ISEF, committee members answer questions about the rules throughout the year from students and teachers. The ISEF SRC can be contacted at SRC@societyforscience.org.

Members of the Intel ISEF Scientific Review Committee 2018:

Mrs. Christine Miller, Chair Ms. Susan Appel Mr. Henry Disston Dr. Jennifer Green Dr. Paula Johnson Dr. Timothy Martin Mrs. Evelyn Montalvo Dr. Jason Shuffitt Mrs. Andrea Spencer