

International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs 2012-2013

Table of Contents

For ALL Projects

Intel ISEF Ethics Statement	3
Intel ISEF Eligibility/Limitations	3
Intel ISEF Requirements	3
Continuation of Projects	4
Team Projects	4
Roles and Responsibilities of Students and Adults	
1) The Student Researcher(s)	5
2) The Adult Sponsor	5
3) The Qualified Scientist	5
4) The Designated Supervisor	5
5) The Institutional Review Board (IRB)	5
6) Local and Affiliated Fair Scientific Review Committees (SRC)	6
7) Other Review Committees	6
8) The Intel ISEF Scientific Review Committee	7
Human Participants Rules	8
1) Exempt Studies	8
2) Rules	8
3) IRB Waiver of Written Informed Consent	9
4) Human Participant Risk Assessment	10
Vertebrate Animal Rules	11
1) Rules for ALL Vertebrate Animal Studies	11
2) Additional Rules for Projects Conducted at School/Home/Field	12
3) Additional Rules for Projects Conducted in a Regulated Research Institution	13
Potentially Hazardous Biological Agents	
Rules for ALL Studies Involving Potentially Hazardous Biological Agents	14
Additional Rules for Projects Involving Unknown Microorganisms	15
Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies	15
Additional Rules for Projects Involving Tissues and Body Fluids Including Blood and Blood Products	15
Hazardous Chemicals, Activities or Devices Rules	18
Display and Safety Regulations	21
Sources of Information	25
Information on Required Abstract	28
Categories & Sub-Categories	29
Forms	30

www.societyforscience.org/isef/rulesandguidelines

The International Rules and Guidelines for Science Fairs is available at www.societyforscience.org in multiple formats. Familiarity with the rules is recommended for students, parents, teachers, mentors, fair directors and local and affiliated fair scientific review committees (SRC) and institutional review boards (IRB).

- International Rules and Guidelines — The full text of the International Rules and forms in html and as a downloadable pdf.
- The Intel ISEF Rules Wizard —An interactive tool which asks questions about your intended project and provides a list of forms required.
- Common SRC Problems — Frequent problems that emerge during Scientific Review Committee review for qualification at the Intel ISEF. Read these to learn what NOT to do.

These Rules are applicable for:

The Intel International Science and Engineering Fair 2013 Phoenix, Arizona, USA, May 12-17, 2013

The purpose of these rules is to:

- determine eligibility for competition in the Intel ISEF 2013
- protect the rights and welfare of the student researcher
- protect the rights and welfare of the human participant
- protect the health and welfare of the vertebrate animal subject
- ensure adherence to federal regulations
- ensure use of safe laboratory practices
- protect the environment

For pre-review and approval of your project, find your fair at
http://apps.societyforscience.org/find_a_fair

For Intel ISEF questions, contact:
Society for Science & the Public
Science Education Programs
1719 N Street, NW, Washington, DC 20036
office: 202-785-2255, fax: 202- 785-1243
email: sciedu@societyforscience.org

**For rules questions, contact the Intel ISEF Scientific Review Committee:
SRC@societyforscience.org**

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 up to the number of projects authorized by its affiliation agreement.
- 2) 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) Each student may enter only one project. That project may include no more than 12 months of continuous research and may not include research performed before January 2012.
- 4) Team projects may have two or three members. Teams may not have had more than three members at a local fair. Teams may not substitute members in a given research year.
- 5) 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.
- 6) Projects that are demonstrations, 'library' research, informational projects, 'explanation' models or kit-building are not appropriate for the Intel ISEF.
- 7) All sciences (physical, life, social) are represented at the Intel ISEF. A complete list of categories with descriptions is at www.societyforscience.org/isef/project_categories.
- 8) 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) All projects must adhere to the requirements of the affiliated fair(s) in which it competes to qualify for participation in the Intel ISEF. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.
- 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 the use of alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project.
- 6) Introduction or disposal of non-native species, pathogens, toxic chemicals or foreign substances into the environment is prohibited.
- 7) Intel ISEF exhibits must adhere to Intel ISEF display and safety requirements.

Approval and Documentation

- 8) 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.
- 9) Every student must complete the Student Checklist (1A), a Research Plan and Approval Form (1B) and review the project with the Adult Sponsor in coordination with completion by the Adult Sponsor of the Checklist for Adult Sponsor (1).
- 10) A Qualified Scientist is required for all studies involving BSL-2 potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.
- 11) After initial IRB/SRC approval (if required), any proposed changes in the Student Checklist (1A) and Research Plan must be re-approved before laboratory experimentation/ data collection resumes.
- 12) 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.

- 13) Any continuing project must document that the additional research is new and different (see Continuation Projects Form (7)).
 - 14) 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 Regulated Research Institutional/ Industrial Setting Form (1C) must be completed and displayed at the project booth.
 - 15) 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).
 - 16) A project data book and research paper are not required, but are recommended. Regional or local fairs may require a project data book and/or a research paper.
 - 17) 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.
- a. drought on soil in a given basin, return of flora and fauna in a burned area over time.)
 - b. Each consecutive year demonstrates time-based change.
 - c. The display board is based on collective past definitive data and its comparison to the current year data set. No raw data from previous years may be displayed.
- 5) All continuation projects must be reviewed and approved each year and forms must again be completed for the new year.

NOTE: For competition in the Intel ISEF, documentation must include the Continuation Project Form (7), the previous year's abstract and research plan and the abstract for all other prior years. Documentation must be labeled clearly with the year (ex: 2011-2012). Retention of all prior years' paperwork is required and must be presented to the Intel ISEF SRC upon request.

Team Projects

Continuation 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 2012 and ending May 2013.
 - 2) Any project based on the student's prior research could be considered a continuation project. If the current year's project could not have been performed without the outcome of a past year's research project, then it is considered a continuation for competition. 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) 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"). Supporting data books (not research papers) from previous related research may be exhibited 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
- 1) Team projects compete and are judged in the scientific category of their research at the Intel ISEF.
 - 2) Teams may have two or three members. Teams may not have had more than three members at any level of affiliated fair. Teams may not substitute members in a given research year.
 - 3) Team membership cannot be changed during a given research year, including converting from an individual project to a team project, or vice versa. In future years, the project may be converted from an individual to a team project, from a team to an individual project and/or change team members.
 - 4) 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 similar rules and judging criteria as individual projects.
 - 5) 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 and other required forms.
 - 6) Full names of all team members must appear on the abstract and forms.

Roles and Responsibilities of Students and Adults

1) 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.

2) 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. Regulations must be discussed with the student when completing the Research Plan. 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 Intel ISEF.

3) 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. A PhD, MD or a master's degree with additional experience and expertise in the student's area of research is acceptable

when approved by a Scientific Review Committee (SRC). 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.

4) 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, their behavior, or their habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

5) 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.
- include an educator
- 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, 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 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 oversee 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.

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.

6) 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 and applicable laws and regulations at each level of science fair competition. Local SRCs may be formed to assist the Affiliated Fair SRC in reviewing projects. 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://apps.societyforscience.org/isef/find_a_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:

- a. include a minimum of three persons
- b. include a biomedical scientist (earned doctoral degree, such as Ph.D., M.D., D.V.M., D.D.S., PharmD., or D.O.)
- c. include an educator
- d. 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 oversee the project may serve on the IRB 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:

- a. evidence of literature search and appropriate attribution
- b. evidence of proper supervision
- c. use of accepted and appropriate research techniques
- d. completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (where required)
- e. evidence of search for alternatives to animal use
- f. humane treatment of animals
- g. compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents
- i. documentation of substantial expansion for continuation projects
- j. compliance with the Intel ISEF ethics statement

7) Other Review Committees

Certain areas of research conducted in a Regulated Research Institution require review and approval by federally mandated committees that have been established at that institution. These committees include:

- a. Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
- b. Institutional Review Board (IRB) Human Subjects Research Board (HSRB)
- c. Institutional Biosafety Committee (IBC)
- d. Embryonic Stem Cell Research Oversight Committee (ESCRO)

8) The Intel 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 2013

Dr. Nancy Aiello, Chair

Mr. Henry Disston

Mr. Marcus Friskop

Dr. Paula Johnson

Dr. Maria Lavooy

Mrs. Christine Miller

Mrs. Evelyn Montalvo

Dr. Jason Shuffitt

Human Participants

Student researchers must follow federal guidelines (Code of Federal Regulations 45 CFR 46) to protect the human research participant and the student researcher. When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB) and informed consent/assent from the research participant.

Exempt Studies

(Do Not Require IRB Preapproval or Human Participants Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for the Intel ISEF and affiliated fairs are:

- Testing of a student-designed invention, program, concept, etc. where the feedback received is a direct reference to the product, where personal data is not collected, and where the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed.
 - Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.
 - Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
 - a. the researcher has no interaction with the individuals being observed;
 - b. the researcher does not manipulate the environment in any way, and
 - c. the researcher does not record any personally identifiable data.
 - Projects in which the student receives the data in a de-identified/anonymous format which complies with both of the following conditions:
 - a. the professional providing the data certifies in writing that the data have been appropriately de-identified and are in compliance with all privacy and HIPAA laws, and
 - b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).
- 2) Student researchers must complete ALL elements of the Human Participants portion of the Research Plan Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment below and the Risk Assessment Guide for additional guidance.
 - 3) The research study must be in compliance with all privacy and HIPAA laws as they apply to the project (e.g. the project involves medical information.)
 - 4) All research projects involving human participants, including any revisions, must be reviewed and approved by an Institutional Review Board (IRB) before the student may begin recruiting and/or interacting with human participants. The IRB must assess the risk and document its determination of risk on Form 4. After initial IRB approval, a student with any proposed changes in the Research Plan must repeat the approval process and regain approval before laboratory experimentation/ data collection resumes.
 - 5) Research conducted by a pre-college student at a federally Regulated Research Institution (e.g., university, medical center, government lab, correctional institution) must be reviewed and approved by that institution's IRB. A copy of the IRB approval for the entire project

is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), and/or (2) identifiable private information. These projects require IRB review and preapproval, and may also require documentation of written informed consent/assent/ parental permission. Examples of studies that are considered "human participant research" requiring IRB preapproval include:

- Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
- Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
- Studies in which the researcher is the subject of the research
- Behavioral observations that
 - a) involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., posts a sign, places an object).
 - b) occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
 - c) involve the recording of personally identifiable information
- Data/record review projects that include data that are not de-identified/anonymous (e.g., name, birth date, phone number and/or other identifying variables.)

Rules

- 1) The use of human participants in science projects is allowable under the conditions and rules in the following sections. Based upon the Code of Federal Regulations (45 CFR 46), the definition of a human participant

(which must include the research procedures/measures the student is using) and/or an official letter from the IRB attesting to approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.

- 6) Research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants may give their own consent. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing 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. See Risk Assessment below and the Risk Assessment Guide for further explanation of informed consent.
 - Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
 - Participants must be informed that their participation is voluntary (i.e., they may participate or decline to participate, with no adverse consequences of nonparticipation or aborted participation) and that they are free to stop participating at any time.
 - Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature.
 - When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
- 7) A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a medical professional. This medical professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medication and/or performing invasive medical procedures on human participants. The IRB must also confirm that the student is not violating the medical practice act of the state or country in which he/she is conducting the research.
- 8) Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).
- 9) All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument

publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.

- 10) Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in a) collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the Risk Assessment Guide and the Online Survey Consent Procedures.
- 11) After experimentation and before Intel ISEF competition, the Intel ISEF SRC reviews and approves previously-approved projects to ensure that students followed the approved Research Plan and all of the Intel ISEF rules.
- 12) The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b. Human Participants Form (4) with applicable consents and survey(s)
 - c. Regulated Research Institution Form (1C), when applicable
 - d. Qualified Scientist Form (2), when applicable

Sources of Information are available as a separate section at the end of the document.

IRB Waiver of Written Informed Consent

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 not manipulate the participants' behavior and the study does not involve more than minimal risk.
- c) Surveys, questionnaires, or activities 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.
- 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 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.

Projects involving no more than minimal risk and those with more than minimal risk are allowed under the following guidelines.

Human Participant Risk Assessment

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

1) Examples of Greater than Minimal Physical Risk

- a. Exercise other than ordinarily encountered in everyday life
- b. Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
- c. Exposure to any potentially hazardous material.

2) Examples of Greater than Minimal Psychological Risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing video images.

3) Privacy Concerns

The student researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4) Risk Groups

If the research study includes participants from any of the following groups, the IRB and student research must consider whether the nature of the study requires special protections or accommodations:

- a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
- b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA)).

See the online Risk Assessment Guide and Online Survey Consent Procedures for more detailed information on risk assessment.

Vertebrate Animals

The following rules were developed to help pre-college student researchers adhere to the federal regulations governing professional scientists and to protect the welfare of both animal subjects and the student researcher. When students conduct research with animal subjects, health and well-being is of high priority.

SSP strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals.

All projects involving vertebrate animals must adhere to the rules below AND to either Section A or Section B rules, depending on the nature of the study and the research site.

A project is considered a tissue study and not a vertebrate animal study if tissue is obtained from an animal that was euthanized for a purpose other than the student's project. (Documentation is required of the IACUC approval for the original animal study from which tissues are obtained.) In tissue studies, a student may observe the vertebrate study, but may not manipulate or have any direct involvement in the vertebrate animal experimental procedures.

Rules for ALL Vertebrate Animal Studies

1) The use of vertebrate animals in science projects is allowable under the conditions and rules in the following sections. Vertebrate animals, as covered by these rules, are defined as:

- Live, nonhuman vertebrate mammalian embryos or fetuses
- Tadpoles
- Bird and reptile eggs within three days (72 hours) of hatching
- All other nonhuman vertebrates (including fish) at hatching or birth.

Exception: Because of their delayed cognitive neural development, zebrafish embryos are not considered vertebrate animals until 7 days (168 hours) post-fertilization.

2) Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following "Four R's":

- **Replace** vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible.
- **Reduce** the number of animals without compromising statistical validity.
- **Refine** the experimental protocol to minimize pain or distress to the animals.
- **Respect** animals and their contribution to research.

- 3) All vertebrate animal studies must be reviewed and approved before experimentation begins. An Institutional Animal Care and Use Committee, known as an IACUC, is the institutional animal oversight review and approval body for all animal studies at a Regulated Research Institution. The affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any affiliated fair SRC serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.
- 4) All vertebrate animal studies must have a research plan that includes:
 - a. Justification why animals must be used, including the reasons for the choice of species, the source of animals and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.
 - b. Description of how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.
- 5) Studies involving behavioral observations of animals are exempt from advance SRC review if ALL of the following apply:
 - There is no interaction with the animals being observed,
 - There is no manipulation of the animal environment in any way, and
 - The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.
- 6) Students performing vertebrate animal research must satisfy local, state, country laws and regulations of the jurisdiction in which research is performed as well as U.S. federal law.
- 7) Research projects which cause more than momentary or slight pain or distress are prohibited. If there is illness or unexpected weight loss this must be investigated and a veterinarian must be consulted to oversee any indicated medical care. This investigation must be documented by the Qualified Scientist, Designated Supervisor who is qualified to determine the illness or a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.

- 8) No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup. Such a project will fail to qualify for competition.
 - a. Studies that are designed or anticipated to cause vertebrate animal death are prohibited.
 - b. Any death that occurs must be investigated by a veterinarian, the Qualified Scientist or the Designated Supervisor who is qualified to determine the cause of death. The project must be suspended until such investigation occurs and the results must be documented in writing.
 - c. If death was the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.

- 9) All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.

- 10) Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:
 - a. Induced toxicity studies with known toxic substances that could impair health or end life, including, but not limited to, alcohol, acid rain, pesticides, or heavy metals.
 - b. Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
 - c. Studies of pain.
 - d. Predator/vertebrate prey experiments.

- 11) Justification is required for an experimental design that involves food or fluid restriction and must be appropriate to the species. If the restriction exceeds 18 hours, the project must be reviewed and approved by an IACUC and conducted at a regulated research institution.

- 12) Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. Fish may be obtained from the wild only if the researcher releases the fish unharmed, has the proper license, and adheres to state, local and national fishing laws and regulations. Students are prohibited from performing electrofishing.

- 13) A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.

- 14) After initial SRC approval, a student with any proposed changes in the Research Plan of the project must repeat the approval process before laboratory experimentation/ data collection resumes.

A. Additional Rules for Projects Conducted at School/Home/Field

Vertebrate animal studies may be conducted at a home, school, farm, ranch, in the field, etc. This includes:

- Studies of animals in their natural environment.
- Studies of animals in zoological parks.
- Studies of livestock that use standard agricultural practices.

These projects must be reviewed and approved by an SRC in which one member is either a veterinarian and/or an animal care provider/expert with training and/or experience in the species being studied.

- 1) These projects must adhere to BOTH of the following guidelines:
 - a. The research involves only agricultural, behavioral, observational or supplemental nutritional studies on animals.

AND

 - b. The research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

All studies meeting the general guidelines but not meeting the above criteria specifically for home, school or field must be conducted at a Regulated Research Institution. See Section B.

- 2) Animals must be treated kindly and cared for properly. Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species. They must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned frequently. Proper care must be provided at all times, including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and well-being. A Designated Supervisor is required to oversee the daily husbandry of the animals. Any of the following U.S. documents provide further guidance for animal husbandry:
 - *Federal Animal Welfare Regulation*
 - *Guide for the Care and Use of Laboratory Animals*
 - *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag-Guide)*

- 3) The affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research plan and animal husbandry plans is required. This certification is required before experimentation and SRC approval and is documented on Vertebrate Animal Form 5A. A veterinarian must certify experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.

Sources of Information are available as a separate section at the end of the document.

- 4) If an illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian. A student researcher must stop experimentation if there is unexpected weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors. If death is the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
- 5) The final disposition of the animals must be described on Vertebrate Animal Form 5A. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site.
- 6) The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b. Vertebrate Animal Form (5A)
 - c. Qualified Scientist Form (2), when applicable

B. Additional Rules for Projects Conducted in a Regulated Research Institution

All studies not meeting the criteria in Section A. but are otherwise permissible under Intel ISEF rules must be conducted in a Regulated Research Institution (RRI). 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.

Some protocols permitted in a Registered Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

- 1) The Institutional Animal Care and Use Committee (IACUC) or the comparable animal oversight committee must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local and regional SRC must also review

the project to certify that the research project complies with Intel ISEF Rules. This local and regional SRC review should occur before experimentation begins, if possible.

- 2) Student researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
- 3) Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.
- 4) Research in nutritional deficiency or research involving substances or drugs of unknown effect is permitted to the point that any clinical sign of distress is noted. In the case that distress is observed, the project must be suspended and measures must be taken to correct the deficiency or drug effect. A project can only be resumed if appropriate steps are taken to correct the causal factors.
- 5) The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b. Regulated Research Institution Form (1C)
 - c. Vertebrate Animal Form (5B)
 - d. Qualified Scientist Form (2)

Potentially Hazardous Biological Agents

Rules for use of microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids.

Research using microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids may involve potentially hazardous biological agents. Students are permitted to do some research projects with potentially hazardous biological agents meeting the conditions and rules described below which were designed to protect students and to ensure adherence to federal and international biosafety regulations and guidelines.

When dealing with potentially hazardous biological agents, it is the responsibility of the student and all of the adults involved in a research project to conduct and document a risk assessment (Form 6A) to define the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The risk assessment determines a biosafety level which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training, and supervision required.

All projects involving microorganisms, recombinant DNA technologies and human or animal fresh/frozen tissues, blood or body fluids must adhere to the rules below AND, depending on the study, to the additional rules in Section A, B or C.

Rules for ALL Studies with Potentially Hazardous Biological Agents

- 1) The following types of studies are exempt from prior SRC review and require no additional forms:
 - a. Studies involving baker's yeast and brewer's yeast, except when used with rDNA studies.
 - b. Studies involving *Lactobacillus*, *Bacillus thurgensis*, nitrogen-fixing, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment.)
 - c. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold.
- 2) The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
 - a. Studies involving protists, archaea and similar microorganisms.
 - b. Research using manure for composting, fuel production, or other non-culturing experiments.
 - c. Commercially-available color change coliform water test kits. These kits must remain sealed and must be properly disposed.
 - d. Studies involving decomposition of vertebrate organisms (such as in forensic projects).
- 3) The use of potentially hazardous microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids, is allowable as follows:
 - a. An affiliated fair SRC, an IBC or an IACUC must approve all research before experimentation begins. The initial risk assessment determined by the student researcher and adults supervising the project must be confirmed by the SRC, IBC or IACUC.
 - b. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the affiliated fair SRC.
 - c. Research determined to be at Biosafety Level 1 (BSL-1) must be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Designated Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.
 - d. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above (commonly limited to a Regulated Research Institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter or document from the Regulated Research Institution that the research does not require review. The research must be supervised by a Qualified Scientist.
 - e. BSL-3 or -4 research is prohibited.
 - f. Laboratory studies culturing known MRSA (Methicillin-resistant *Staphylococcus aureus*), VRE (Vancomycin-resistant enterococci) and KPC (*Klebsiella pneumoniae*) must be conducted in a BSL-2 laboratory in a Regulated Research Institution with documented IBC Committee review and approval.
 - g. Studies that genetically engineer bacteria with multiple antibiotic resistance are prohibited.
 - h. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms require at least BSL-2 containment.
 - i. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
 - j. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
 - k. All potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or

BSL 2 organisms: Autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable.

- i. Any proposed changes in the Research Plan by the student after initial local or affiliated fair SRC approval must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
- 4) The following forms are required:
 - Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - Regulated Research Institution Form (1C) - when applicable.
 - Qualified Scientist (2), when applicable
 - Risk Assessment (3), when applicable
 - PHBA Risk Assessment Form (6A), when applicable
 - Human and Vertebrate Animal Tissue Form (6B) - for all studies involving tissues and body fluids. Sources of Information are available as a separate section at the end of the document.

A. Additional Rules for Projects Involving Unknown Microorganisms

Studies involving unknown microorganisms present a challenge because the presence, concentration and pathogenicity of possible agents are unknown. In science fair projects, these studies typically involve the collection and culturing of microorganisms from the environment (e.g. soil, household surfaces, skin.)

- 1) Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
 - a. Organism is cultured in a plastic petri dish (or other standard non-breakable container) and sealed. Other acceptable containment includes two heavy-duty (2-ply) sealed bags.
 - b. Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
 - c. The sealed Petri dish is disposed of via autoclaving or disinfection under the supervision of the Designated Supervisor.
- 2) If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.

B. Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies

Studies involving rDNA technologies in which microorganisms have been genetically modified require close review to assess the risk level assignment. Some rDNA studies can be safely conducted in a BSL-1 high school laboratory with prior review by a knowledgeable SRC:

- 1) All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems must be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or Designated Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems.
- 2) Commercially available rDNA kits using BSL-1 organisms may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation.
- 3) An rDNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.
- 4) All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the IBC prior to experimentation.
- 5) Propagation of recombinants containing DNA coding for oncogenes or other human, plant or animal toxins (including viruses) is prohibited.

C. Additional Rules for Projects with Tissues and Body Fluids, including Blood and Blood Products

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

- 1) *The following types of tissue do not need to be treated as potentially hazardous biological agents:*
 - a. Plant tissue
 - b. Plant and non-primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures must be identified in the Research Plan.
 - c. Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses.
 - d. Hair.
 - e. Teeth that have been sterilized to kill any blood-borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended.
 - f. Fossilized tissue or archeological specimens.
 - g. Prepared fixed tissue.

- 2) Research involving human and/or non-human primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection) must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/or catalog number of the cultures must be identified in the Research Plan.
- 3) If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.
- 4) If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and is subject to the vertebrate animal rules for studies conducted at a Regulated Research Institution. (See vertebrate animal rules.)
- 5) Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 7) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.
- 6) Biosafety level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or -2. These studies must be conducted in a Regulated Research Institution in a BSL-2 laboratory under the supervision of a Qualified Scientist.
- 7) All studies involving human or wild animal blood or blood products should be considered a Biosafety level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Studies involving domestic animal blood may be considered a BSL-1 level study. All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z. Any tissue or instruments with the potential of containing blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation.
- 8) Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2.
- 9) Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or -4 is prohibited.
- 10) Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent. Student researchers using their own body fluids are exempt from this requirement.
- 11) Self-sampling of capillary blood for analysis (e.g. glucometer reading) may be conducted in a home setting.
- 12) Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

Potentially Hazardous Biological Agents Risk Assessment

Use this information to complete PHBA Risk Assessment Form 6A

Risk assessment defines the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The end result of a risk assessment is the assignment of a biosafety level which then determines the laboratory facilities, equipment, training, and supervision required.

Risk assessment involves:

- Assignment of the biological agent to a risk group
 - Studies involving a known microorganism must begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
 - The study of unknown microorganisms and the use of fresh tissues relies on the expertise of the supervising adult(s).
- Determination of the level of biological containment available to the student researcher to conduct the experimentation. (See "Levels of Biological Containment" for details.)

- Assessment of the experience and expertise of the adult(s) supervising the student.
- Assignment of a biosafety level for the study based on risk group of biological agent, level of biological containment available and the expertise of the Qualified Scientist or Designated Supervisor who will be supervising the project.

If a study is conducted at a non-regulated site (e.g. school), the biosafety level must be confirmed by the local or affiliated fair SRC. If the research is conducted at a Regulated Research Institution, the biosafety level must be assigned by an Institutional Biosafety Committee (IBC) or equivalent approval body or a letter from an institutional representative certifying that the research does not require review. If no approval body exists at the Regulated Research Institution, a letter or document from the Regulated Research Institution that the research does not require review is required and the local or affiliated fair SRC must review the project and assign a biosafety level. If possible, this review should be before experimentation.

Classification of Biological Agents Risk Groups

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory, or growth of agents in small volumes for diagnostic and experimental purposes.

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: *Escherichia coli* strain K12, *Agrobacterium tumefaciens*, *Micrococcus leuteus*, *Neurospora crassa*, *Bacillus subtilis*.

BSL-2 risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and it rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. Examples of BSL-2 organisms are: *Mycobacterium*, *Streptococcus pneumoniae*, *Salmonella choleraesuis*.

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. Projects in the BSL-3 group are prohibited.

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are prohibited.

Levels of Biological Containment

There are four levels of biological containment (Biosafety Level 1-4). Each level has guidelines for laboratory facilities, safety equipment and laboratory practices and techniques.

BSL-1 containment is normally found in water-testing laboratories, in high schools, and in colleges teaching introductory microbiology classes. Work is done on an open bench or in a fume hood. Standard microbiological practices are used when working in the laboratory. Decontamination can be achieved by treating with chemical disinfectants or by steam autoclaving. Lab coats are required and gloves recommended. The laboratory work is supervised by an individual with general training in microbiology or a related science.

BSL-2 containment is designed to maximize safety when working with agents of moderate risk to humans and the environment. Access to the laboratory is restricted. Biological safety cabinets (Class 2, type A, BSC) must be available. An autoclave should be readily available for decontaminating waste materials. Lab coats, gloves and face protection are required. The laboratory work must be supervised by a scientist who understands the risk associated with working with the agents involved.

BSL-3 containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. Projects in the BSL-3 group are prohibited.

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Projects in the BSL-4 group are prohibited.

Hazardous Chemicals, Activities or Devices

(Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms and explosives, radiation, lasers, etc.)

The following rules apply to research using hazardous chemicals, devices and activities. These include substances and devices that are regulated by local, state, country, or international law, most often with restrictions of their use by minors such as DEA-controlled substances, prescription drugs, alcohol, tobacco, firearms and explosives. Hazardous activities are those that involve a level of risk above and beyond that encountered in the student's everyday life.

These rules are intended to protect the student researcher by ensuring proper supervision and the consideration of all potential risks so that the appropriate safety precautions are taken. Students are required to meet all standards imposed by Intel ISEF, school, local, and/or regional fair(s).

Rules for ALL Projects Involving Hazardous Chemicals, Activities and Devices

- 1) The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Designated Supervisor, except those involving DEA-controlled substances, which require supervision by a Qualified Scientist.
- 2) The student researcher must conduct a risk assessment in collaboration with a Designated Supervisor or Qualified Scientist prior to experimentation. This risk assessment is documented on the Risk Assessment Form 3.
- 3) Student researchers must acquire and use regulated substances in accordance with all local, state, U.S. federal and country laws. For further information or classification for these laws and regulations, contact the appropriate regulatory agencies.
- 4) For all chemicals, devices or activities requiring a Federal and/or State Permit, the student/supervisor must obtain the permit prior to the onset of experimentation. A copy of the permit must be available for review by adults supervising the project and the local and affiliated and the ISEF Scientific Review Committee in their review prior to competition.
- 5) The student researcher must minimize the impact of an experiment on the environment. Examples include using minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner and in accordance with good laboratory practices.
- 6) The following forms are required:
 - a. **Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan and Approval Form (1B)**
 - b. **Regulated Research Institution Form (1C), when applicable**

- c. **Qualified Scientist Form (2), when applicable**
- d. **Risk Assessment Form (3)**

Additional Rules for Specific Regulated Substances

There are additional rules for the following regulated substances:

- A. DEA-controlled Substances
- B. Prescription Drugs
- C. Alcohol & Tobacco
- D. Firearms and Explosives

A. DEA-Controlled Substances

The U.S. Drug Enforcement Administration (DEA) regulates chemicals that can be diverted from their intended use to make illegal drugs. Other countries may have similar regulatory bodies; students outside of the U.S. must adhere to their own country's drug regulatory agency requirements in addition to U.S. DEA regulations. DEA-controlled substances and their schedule number are at the DEA website under Sources of Information. It is the responsibility of the student to consult this list if there is a possibility that substances used in experimentation could be regulated.

- 1) All studies using DEA-controlled substances must be supervised by a Qualified Scientist who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.
- 2) All studies using DEA Schedule 1 substances must have the research protocol approved by DEA before research begins. Schedule 2, 3 and 4 substances do not require protocol approval by DEA.

B. Prescription Drugs

Prescription drugs are drugs regulated by federal or country laws and are available only through a pharmacy to protect against inappropriate or unsafe use. Special precautions must be taken in their use for a science project as follows:

- 1) Students are prohibited from administering prescription drugs to human participants.
- 2) A veterinarian must supervise student administration of any prescription drugs to vertebrate animals.

C. Alcohol and Tobacco

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the production of alcohol and distribution of alcohol and tobacco products. Many such products are restricted by age for purchase, possession and consumption. Students outside of the U.S. must adhere to U.S. regulations and to their local and country laws and regulations.

1. The Designated Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
2. Production of ethyl alcohol (wine or beer) is allowable in the home under parental supervision and must meet the TTB home production regulations.
3. Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
4. Students are allowed to distill alcohol for fuel or other non-consumable products. To do so, the work must be conducted at school and a TTB permit must be obtained by school authorities. Details regarding this process are available from the Alcohol and Tobacco Tax and Trade Bureau (TTB) website.

D. Firearms and Explosives

The U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), along with state agencies, regulates the purchase and use of firearms and explosives. A firearm is defined as a small arms weapon from which a projectile is fired by gunpowder. An explosive is any chemical compound, mixture or device, the primary purpose of which is to function by explosion. Explosives include, but are not limited to, dynamite, black powder, pellet powder, detonators, and igniters.

The purchase of a firearm by a minor is generally unlawful. The use of a firearm, without proper state certification, is illegal. Students should check the training and certification requirements of individual states and countries.

- 1) Projects involving firearms and explosives are allowable when conducted with the direct supervision of a Designated Supervisor and when in compliance with all federal, state and local laws.
- 2) A fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.
- 3) Potato guns and paintball guns are not firearms unless they are intended to be used as weapons. They must be treated as hazardous devices.

Guidance for Risk Assessment

Please find below guidance on conducting risk assessment when using the following:

- A. Hazardous Chemicals
- B. Hazardous Devices
- C. Radiation

A. Hazardous Chemicals

A proper risk assessment of chemicals must include review of the following factors:

Toxicity – the tendency of a chemical to be hazardous to health when inhaled, swallowed, injected or in contact with the skin.

Reactivity – the tendency of a chemical to undergo chemical change.

Flammability – the tendency of a chemical to give off vapors which readily ignite when used under normal working conditions.

Corrosiveness – the tendency of a chemical, upon physical contact, to harm or destroy living tissues or physical equipment.

When assessing risk, the type and amount of exposure to a chemical must be considered. For example, an individual's allergic and genetic disposition may have an influence on the overall effect of the chemical. The student researcher must refer to Material Safety Data Sheets provided by the vendor (MSDS) to ensure that proper safety precautions are taken. Some MSDS sheets (e.g., Flinn) rank the degree of hazard associated with a chemical. This rating may assist students and adult sponsors in determining risk associated with the use of a chemical.

A risk assessment must include proper disposal methods for the chemicals used in an experiment. The Flinn Catalog (referenced in the Sources of Information section) provides information for the proper disposal of chemicals. If applicable, the student researcher must incorporate in the research plan disposal procedure required by federal and state guidelines.

Environmentally Responsible Chemistry

The mission of environmentally responsible (green) chemistry is to avoid the use or production of hazardous substances during a chemical process. The principles of green chemistry are described on the EPA website in the Sources of Information section. The following principles must be incorporated into the research plan:

- Waste prevention
- Use of the safest possible chemicals and products
- Design of the least possible hazardous chemical syntheses
- Use of renewable materials
- Use of catalysts in order to minimize chemical usage
- Use of solvents and reaction conditions that are as safe as possible
- Maximization of energy efficiency
- Minimization of accident potential

B. Hazardous Devices

The documentation of risk assessment (Form 3) is required when a student researcher works with potentially hazardous/dangerous equipment and/or other devices, in or outside a laboratory setting that require a moderate to high level of expertise to ensure their safe usage. Some commonly used devices (Bunsen burners, hot plates, saws, drills, etc.) may not require a documented risk assessment, assuming that the student researcher has experience working with the device. Use of other potentially dangerous devices such as high vacuum equipment, heated oil baths, NMR equipment, and high temperature ovens must have documentation of a risk assessment. It is recommended that all student designed inventions also have documentation of a risk assessment.

C. Radiation

A risk assessment must be conducted when a student uses non-ionizing radiation beyond that normally encountered in everyday life. Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (MW), radiofrequency (RF) and extremely low frequency (ELF). Lasers usually emit visible, ultraviolet or infrared radiation. Lasers are classified into four classes based upon their safety. Manufacturers are required to label Classes II - IV lasers.

Class I lasers - those found in CD players, laser printers, geological survey equipment and some laboratory equipment. There are no known risks associated with using a Class I laser.

Class II lasers - found in laser pointers, aiming and range-finding devices. These pose a risk if the beam is viewed directly over a long period of time.

Class III lasers - found in higher-powered laser pointers, printers and spectrometers. They are hazardous devices which can cause eye damage when the beam is viewed directly even for a short period of time.

Class IV lasers - high powered lasers used in surgery, research, and industry. They are extremely hazardous and can cause eye and skin damage from both direct and indirect exposure. The beam is also a fire hazard.

Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study. Depending upon the level of exposure, radiation released from these sources can be a health hazard. Most research institutions have a Radiation Safety Office which oversees the use of ionizing radiation and ensures compliance with state and federal regulations.

Sources of Information are available as a separate section at the end of the document.

Intel ISEF Display and Safety Regulations

Please address any questions regarding Intel ISEF Display and Safety Regulations to:
John O. Cole, Display and Safety Committee Chair, E-mail: displayandsafety@societyforscience.org

Display and Safety Authority

The Intel ISEF Display and Safety Committee is the final authority on display and safety issues for projects approved by the SRC to compete in the Intel ISEF. Occasionally, the Intel ISEF Display and Safety Committee may require students to make revisions to conform to display and safety regulations. The Regulations that follow have been divided into two main categories to separate those that deal specifically with display regulations and those that pertain to safety regulations.

Display Regulations

The following regulations must be adhered to when a finalist exhibits a project at Intel ISEF.

Display Content for Research Institution and/or Continuation Projects

The project display summarizes the research project and must focus on the student(s) work for this year's study with only minimal reference to previous research. Longitudinal studies may present only conclusionary data from prior years. [Exception: the project title of the display board may mention years or which year the project is (for example, "Year Two of an Ongoing Study").] Continuation projects must have the Continuation Project Form (7) vertically displayed.

In addition, the project display must be limited to the work conducted by the student(s) for the project. The mentor's research, even if it was a precursor to student experimentation (e.g. animal research from which tissue was obtained for the project) is not a part of the student research project and must not be included in the display. Very minimal reference to work done by a mentor or others may be included only for background information or clarification of what the student's research covered and must clearly indicate that it was not part of the student's work.

Maximum Size of Project

- Depth** (front to back): 30 inches or 76 centimeters
- Width** (side to side): 48 inches or 122 centimeters
- Height** (floor to top): 108 inches or 274 centimeters

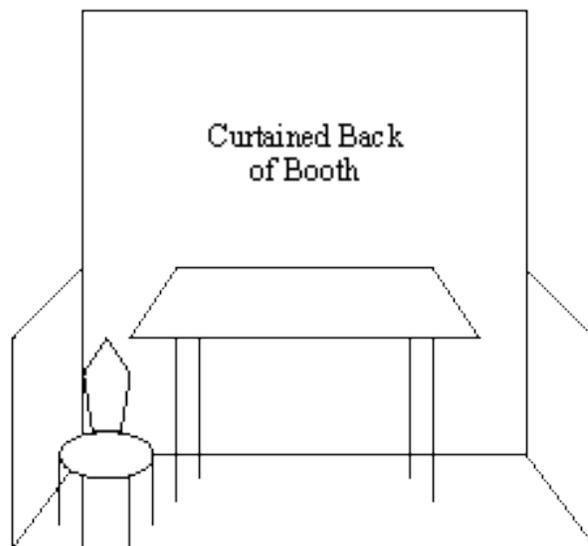
At the Intel ISEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters). Maximum project sizes include all project materials, supports, and demonstrations for public and judges. If a table is used, it becomes part of the project and must not itself exceed the allowed dimensions nor may the table plus any part of the project exceed the allowed dimensions.

Nothing can be attached to the rear curtain for display, and any framework supporting the display must be within the allowable dimensions.

At the Intel ISEF, any project with a component that will be demonstrated by the finalist must be demonstrated only within the confines of the finalist's booth. When not being demonstrated, the component plus the project must not exceed the maximum size dimensions for a project.

Position of Project

Table or freestanding display must be parallel to, and positioned at, the back curtain of the booth.



Forms Required to be Visible and Vertically Displayed

The only items that may be displayed on the front of the tables provided are the forms listed below.

- All finalists must display vertically the following documents:
- 1) Original of official Abstract and Certification as approved and stamped/embossed by the Intel ISEF Scientific Review Committee.
 - 2) Completed Intel ISEF Project Set-up Approval Form SRC/DS2 (Received on-site at the Fair)

If either of the following documents is required, it must be displayed vertically.

- 1) Regulated Research Institutional/Industrial Setting Form(1C) — if applicable
- 2) Continuation Projects Form (7) — if applicable

Forms Required at Project but not Displayed

Forms including, but not limited to, **Checklist for Adult Sponsor (1)**, **Student Checklist (1A)**, **Research Plan and Approval Form (1B)** which are required for the project or for Scientific Review Committee approval do not have to be

displayed as part of the project but must be available in the booth in case asked for by a judge or other Intel ISEF official. A photograph/video release form signed by the subject is required for visual images of humans (other than the finalist) displayed as part of the project.

Informed Consent Forms not to be Displayed

When human participants are involved in a project, consent forms may be required by SRC but should not be displayed as they are confidential documents.

Photograph/Image Display Requirements

Display of photographs other than that of the finalist must have a photo release signed by the subject, and if under 18 years of age, also by the guardian of the subject. Sample consent text: *"I consent to the use of visual images (photos, videos, etc.) involving my participation/my child's participation in this research."*

Finalists using audio-visual or multi-media presentations (for example, 35mm slides; videotapes; images, graphics, animations, etc., displayed on computer monitors; or other non-print presentation methods) must be prepared to show the entire presentation to the Display and Safety inspectors before the project is approved.

Any photograph/visual image/chart/table and/or graph is allowed if:

- a. It is not deemed offensive or inappropriate (*which includes images/photographs showing invertebrate or vertebrate animals/humans in surgical, necrotizing or dissection situations*) by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. The decision made by any one of the groups mentioned above is final.
- b. It has a credit line of origin ("Photograph taken by..." or "Image taken from..." or "Graph/Chart/Table taken from..."). (If all images, etc. being displayed were taken or created by the finalist or are from the same source, one credit line prominently and vertically displayed on the backboard/poster or tabletop is sufficient.)
- c. It is from the Internet, magazine, newspaper, journal, etc., and a credit line is attached. (If all photographs, etc. are from the same source, one credit prominently and vertically displayed is sufficient.)
- d. It is a photograph or visual depiction of the finalist.
- e. It is a photograph or visual depiction for which a signed consent form is at the project or in the booth.

Note: Images used as backgrounds must also be credited.

Handouts Allowed at Project Official Abstract

Handouts to judges and to the public must be limited to **UNALTERED photocopies** of the official abstract and certification.

The Intel ISEF Scientific Review Committee defines the "official abstract and certification" as an **UNALTERED** original abstract and certification as stamped/embossed by the Intel

ISEF Scientific Review Committee. If the Scientific Review Committee requires a finalist to make changes to the abstract and certification submitted with registration papers, the revised version will be stamped/embossed, will replace the earlier version, and will become the finalist's official abstract and certification.

The only abstract allowed anywhere at a project is the official abstract. The term "abstract" may not be used as a title or reference for any information on a finalist's display or in a finalist's materials at the project except as part of displaying the official abstract. **An original stamped/embossed official abstract and certification must appear on the display board or in a vertical position at the project.**

Any disks, CDs, printed materials, etc. (including unofficial abstracts) designed to be distributed to judges or the public will be confiscated by the Display and Safety Committee and will be discarded immediately.

Items/Materials Not Allowed at Project

The following is a list of what cannot be displayed at the project:

- 1) **Awards, medals, business cards, flags, logos, CDs, DVDs, Flash Drives, brochures, booklets, nor endorsements, give-away items (pens, key chains, etc.), and/or acknowledgments (graphic or written).** (Exceptions: Flash drives, CDs, DVDs that are an integral part of the project and used for judging only with prior approval given during inspection; past and present Intel ISEF medals worn by the finalists.)
- 2) Postal addresses, World Wide Web, e-mail and/or social media addresses, QR codes, telephone, and/or fax numbers of a finalist.
- 3) Active Internet or e-mail connections as part of displaying or operating the project at the Intel ISEF
- 4) Prior years' written material or visual depictions on the vertical display board. [Exception: the project title displayed in the finalist's booth may mention years or which year the project is (for example, "Year Two of an Ongoing Study")]. Continuation projects must have the Continuation Project Form (7) vertically displayed.

Other Display Regulations

- 1) No changes, modifications, or additions to projects may be made after approval by the Display and Safety Committee and the Scientific Review Committee. Finalists who do not adhere to the signed agreement on the SRC/DS2 Form regarding this regulation will fail to qualify for competition. *A project data book and research paper are not required* but are highly recommended.
- 2) If a project fails to qualify and is not removed by the finalist, Society for Science & the Public will remove the project in the safest manner possible but is not responsible for damage to the project.

Safety Regulations

The following regulations must be adhered to when a Finalist exhibits a project at the Intel ISEF.

Not Allowed at Project or Booth

- 1) Living organisms, including plants
- 2) Soil, sand, rock, and/or waste samples, **even if permanently encased in a slab of acrylic**
- 3) Taxidermy specimens or parts
- 4) Preserved vertebrate or invertebrate animals
- 5) Human or animal food
- 6) Human/animal parts or body fluids (for example, blood, urine)
- 7) Plant materials (living, dead, or preserved) that are in their raw, unprocessed, or non-manufactured state (Exception: manufactured construction materials used in building the project or display)
- 8) All chemicals including water (Projects may not use water in any form in a demonstration.)
- 9) All hazardous substances or devices [for example, poisons, drugs, firearms, weapons, ammunition, reloading devices, and lasers]
- 10) Dry ice or other sublimating solids
- 11) Sharp items (for example, syringes, needles, pipettes, knives)
- 12) Flames or highly flammable materials
- 13) Batteries with open-top cells
- 14) Glass or glass objects unless deemed by the Display and Safety Committee to be an integral and necessary part of the project (for example, glass that is an integral part of a commercial product such as a computer screen)
- 15) Any apparatus deemed unsafe by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public (for example, large vacuum tubes or dangerous ray-generating devices, empty tanks that previously contained combustible liquids or gases, pressurized tanks, etc.)

Electrical Regulations at Intel ISEF

- 1) Cord-connected electrical appliances shall be UL/CSA-approved. Cord components should be listed with UL or CSA.
- 2) Electrical devices must be protectively enclosed. Any enclosure must be non-combustible. All external non-current carrying metal parts must be grounded using the above listed UL/CSA connection and materials.
- 3) Finalists requiring 120 or 220 Volt A.C. electrical circuits must provide a **UL/CSA-listed 3-wire extension cord** which is appropriate for the load and equipment. Only UL/CSA-approved extension cords in good repair shall be used.
- 4) Electrical power is supplied to projects; therefore, the maximum allowed for projects is **120 or 220 Volt, A.C., single phase, 60 cycle**. No multi-phase will be available or shall be used. Maximum circuit amperage/

wattage available is determined by the electrical circuit capacities of the exhibit hall and may be adjusted on-site by the Display and Safety Committee. For all electrical regulations, "**120 Volt A.C.**" or "**220 Volt A.C.**" is intended to encompass the corresponding range of voltage as supplied by the facility in which the Intel ISEF is being held.

- 5) All electrical work must conform to the Exhibit Hall regulations or the National Electrical Code. (www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=70&cookie_test=1). The guidelines presented in these D & S regulations are general ones, and other rules may apply to specific configurations. The on-site electrician may review electrical work on any project.
- 6) All electrical connectors, wiring, switches, extension cords, fuses, etc. must be **UL/CSA-listed** and must be appropriate for the load and equipment. Connections must be soldered or made with **UL/CSA-listed** connectors. Wiring, switches, and metal parts must have adequate insulation and over-current safety devices (such as fuses) and must be inaccessible to anyone other than the finalist. Exposed electrical equipment or metal that possibly may be energized must be shielded with a non-conducting material or with a grounded metal box to prevent accidental contact.
- 7) All lighting used for decoration or illumination must be UL/CSA approved. Lamp wattage must not exceed ratings. Lighting must not pose risk of injury if touched. As low a voltage as possible must be used.
- 8) At the end of the day or the viewing period, all electrical exhibits must be disconnected, and power bars must be switched off.
- 9) Where practical and necessary, it is recommended that indicator lights be used to indicate that the voltage is on.
- 10) An insulating grommet is required at the point where the wire or cable enters any enclosure.
- 11) No exposed live parts over 36 volts are allowed. Current (amperage) must be low so as not to cause any discomfort or danger if touched.
- 12) There must be an accessible, clearly visible on/off switch or other means of quickly disconnecting from the **120 or 220 Volt** power source.
- 13) Wet cells shall not be used because of the hazardous chemicals involved

Laser Requirements

Lasers may be used in a finalist's display under the following guidelines. Display and Safety Inspectors may revoke the privilege and require lasers to be removed if careless or indiscriminate use is observed. Serious offenses may result in revoking the right to display.

- 1) Class 1: A class 1 laser is safe under all conditions of normal use. It is allowed provided a finalist avoids indiscriminate exposure to other finalists, judges or visitors.
- 2) Class 1M: A class 1M laser is safe for all conditions of use except when passed through magnifying optics such as microscopes and telescopes. It is allowed provided the finalist avoids indiscriminate exposure to others and does not utilize magnifying optics in the area of the laser.
- 3) Class 2: A class 2 laser is safe because the blink reflex will limit the exposure to no more than 0.25 seconds. This only applies to visible-light lasers (400–700 nm).
- 4) Class 2M: A class 2M laser is safe because of the blink reflex if not viewed through optical instruments. This applies only to visible-light lasers (400–700 nm). It is allowed provided the finalist avoids indiscriminate exposure to others and does not utilize magnifying optics in the area of the laser. Class 3R: A class 3R laser has a risk of injury if viewed directly. It cannot be used or displayed.
- 5) Class 3B: A class 3B laser has a risk of injury if viewed directly. It cannot be used or displayed.
- 6) Class 4: A class 4 laser has a risk of injury if viewed directly. It cannot be used or displayed.

Other Safety Regulations

- 1) Any inadequately insulated apparatus producing extreme temperatures that may cause physical burns is not allowed.
- 2) Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points must be for display only.
- 3) Society for Science & the Public, the Scientific Review Committee, and/or the Display and Safety Committee reserve the right to remove any project for safety reasons or to protect the integrity of the Intel ISEF and its rules and regulations.
- 4) Project sounds, lights, odors, or any other display items must not be distracting. Exceptions to this rule may be permitted for judging demonstrations. Approval must be given prior to judging.

Sources of Information

ALL Projects

1. United States Patent and Trade Office
Customer Service: 1-800-786-9199 (toll-free);
571-272-1000 (local); 571-272-9950 (TTY)
www.uspto.gov/
www.uspto.gov/patents/process/index.jsp
2. European Patent Office
www.epo.org/
www.epo.org/applying/basics.html
3. The Mad Scientist Network at Washington University
School of Medicine:
www.madsci.org
4. ANS Task Force
www.anstaskforce.gov

Aquatic Nuisance Species (ANS) Task Force
www.anstaskforce.gov
www.anstaskforce.gov/Documents/ISEF.pdf
5. *Success with Science: The Winner's Guide to High School Research*
Gagliani, S. and DeObaldia, G. (2011). Research
Corporation for Science Advancement.
ISBN 0-9633504-8-X

Human Participants

- 1) *Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*
<http://ohsr.od.nih.gov/guidelines/45cfr46.html>
- 2) Dunn, C. M. and Chadwick, G. L., *Protecting Study Volunteers in Research*, 3rd Edition (2004). Boston, MA: Thomson Centerwatch. ISBN 1-930624-44-1.

Can be purchased from:
www.amazon.com
- 3) NIH tutorial, "Protecting Human Research Participants" also provides similar information:
www.cancer.gov/clinicaltrials/conducting/protecting-participants/Page2
- 4) Belmont Report, April 18, 1979
<http://ohsr.od.nih.gov/guidelines/belmont.html>
- 5) *Standards for Educational and Psychological Testing*. (1999). Washington, DC: AERA, APA, NCME.
www.apa.org/science/programs/testing/standards.aspx

- 6) American Psychological Association
750 First Street, NE
Washington, DC 20002-4242
phone: 202-336-5500; 800-374-2721
www.apa.org

Information for students:
www.apa.org/science/leadership/students/information.aspx

Information regarding publications:
www.apa.org/pubs/index.aspx
- 7) Educational and Psychological Testing
Testing Office for the APA Science Directorate
phone: 202-336-6000
email: testing@apa.org
www.apa.org/science/programs/testing/index.aspx
- 8) The Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. §§ 6501-6506)
www.ftc.gov/privacy/coppafaqs.shtml

Vertebrate Animals Animal Care and Use

- 1) *Laboratory Animals*, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
<http://dels.nas.edu/ilar>
- 2) *Guide for the Care and Use of Laboratory Animals (2010)*
<http://dels.nas.edu/global/ilar/links-care>
- 3) *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003)*, Institute for Laboratory Animal Research (ILAR).
dels.nas.edu/report/guidelines-carey/10732

To order these ILAR publications contact:
National Academies Press
500 Fifth Street, NW
Washington, DC 20055
phone: 888-624-8373 or 202-334-3313
fax: 202-334-2451; www.nap.edu
- 4) Federal Animal Welfare Act (AWA)
7 U.S.C. 2131-2157
Subchapter A - Animal Welfare (Parts I, II, III)
www.nal.usda.gov/awic/legislat/awicregs.htm

Above document is available from:
USDA/APHIS/AC
4700 River Road, Unit 84
Riverdale, MD 20737-1234
email: ace@aphis.usda.gov
Tel: 301-734-7833
Fax: 301-734-4978'
<http://awic.nal.usda.gov>

- 5) *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*
Federation of Animal Science Societies (FASS)
1800 S. Oak Street, Suite 100
Champaign, IL 61820-6974
phone: 217-356-3182
email: fass@assoqh.org; www.fass.org
- 6) *Guidelines for the Use of Fish in Research* (2004),
American Fisheries Society.
www.fisheries.org
www.fisheries.org/afs/docs/policy_16.pdf
- 7) Euthanasia Guidelines
AVMA Guidelines on Euthanasia (June 2007)
American Veterinary Medical Association.
www.avma.org/issues/animal_welfare/euthanasia.pdf
- 4) Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing may be obtained from:
Specialized Information Services
NLM/NIH
2 Democracy Plaza, Suite 510
6707 Democracy Blvd., MSC 5467
Bethesda, MD 20892-5467
phone: 301-496-1131; Fax: 301-480-3537
Toll Free: 888-FIND NLM or 888-346-3656
email: tehip@tehip.nlm.nih.gov
www.sis.nlm.nih.gov;
http://toxnet.nlm.nih.gov/altbib.html
- 5) John's Hopkins Center for Alternatives to Animal Testing (CAAT) has worked with scientists since 1981 to find new methods to replace the use of laboratory animals in experiments, reduce the number of animals tested, and refine necessary tests to eliminate pain and distress.
email: caat@jhsp.edu
http://caat.jhsp.edu/

Alternative Research and Animal Welfare

- 1) The National Library of Medicine provides computer searches through MEDLINE:
Reference & Customer Services
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
888-FIND-NLM or 888-346-3656
301-594-5983; email: info@ncbi.nlm.nih.gov
www.nlm.nih.gov
www.ncbi.nlm.nih.gov/sites/entrez
- 2) National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.
Animal Welfare Information Center
National Agriculture Library
10301 Baltimore Avenue, Room 410
Beltsville, MD 20705-2351
phone: 301-504-6212, fax: 301-504-7125
email: awic@ars.usda.gov
www.nal.usda.gov/awic
- 3) Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in ILAR Journal.
ILAR
The Keck Center of the National Academies
500 Fifth Street, NW, Keck 687
Washington, DC 20001
phone: 202-334-2590, fax: 202-334-1687
email: ILAR@nas.edu
http://dels.nas.edu/ilar

Potentially Hazardous Biological Agents

- 1) American Biological Safety Association: ABSA Risk Group Classification – list of organisms
www.absa.org
- 2) American Type Culture Collection (ATCC)
www.atcc.org
- 3) Bergey's Manual of Systematic Bacteriology website – follow the links for resources and microbial databases for a collection of international websites of microorganisms and cell cultures: www.bergeys.org/resources.html
- 4) Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 4th Edition. Published by CDC-NIH,
www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf
- 5) World Health Organization Laboratory Safety Manual
www.who.int/diagnostics_laboratory/guidance/en/
- 6) Canada – Agency of Public Health – list of non-pathogenic organisms
www.phac-aspc.gc.ca/lab-bio/index_eng.php
www.phac-aspc.gc.ca/lab-bio/res/index-eng.php
- 7) Microorganisms for Education Website – list of organisms
www.science-projects.com/safemicrobes.htm
- 8) *NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health.*
http://oba.od.nih.gov/oba/index.html

9) OSHA - Occupational Health and Safety Administration
www.osha.gov

9) Occupational Safety and Health Administration
www.osha.gov
Safety and Health Topics:
www.osha.gov/SLTC/
www.osha.gov/SLTC/reactivechemicals/index.html
www.osha.gov/SLTC/laserhazards/index.html
www.osha.gov/SLTC/radiationionizing/index.html

Hazardous Chemicals, Activities or Devices

General Lab/Chemical Safety

1) *Safety in Academic Chemistry Laboratories, Volumes 1 and 2, 2003.* Washington, DC: American Chemical Society.

Order from (first copy free of charge):
American Chemical Society
Publications Support Services
1155 16th Street, NW
Washington, DC 20036
phone: 202-872-4000 or 800-227-5558
email: help@acs.org,
www.acs.org/education

10) U.S. Nuclear Regulatory Commission
Material Safety and Inspection Branch
One White Flint North
11555 Rockville Pike
Rockville, MD 20852
phone: 301-415-8200; 800-368-5642
www.nrc.gov

2) *General*
Howard Hughes Medical Institute as a resource for
working with cell cultures, radioactive materials and
other laboratory materials.
www.hhmi.org/resources/

3) Environmental Protection Agency (EPA) website for
green chemistry
www.epa.gov/greenchemistry

4) Material Safety and Data Sheets (MSDS)
MSDS should be collected by your laboratory or available
from the manufacturer. The internet also has a range of
free resources:
www.flinnsci.com/sections/msds-search..aspx

A directory of MSDS sheets from Flinn Scientific Inc. that
includes a ranking of hazard level and disposal methods
www.ilpi.com/msds/index.html - A listing of numerous
sites that have free downloads of MSDS sheets

5) DEA Controlled Substances
Drug Enforcement Agency website:
www.justice.gov/dea/index.htm
Controlled Substance Schedules - a list of controlled
substances : www.dea.gov/divisions/oc/ocdiversion.usdoj.gov/schedules/

6) Alcohol, Tobacco Firearms and Explosives
Alcohol and Tobacco Tax and Trade Bureau
www.ttb.gov/
Bureau of Alcohol, Tobacco, Firearms and Explosives
www.atf.gov

7) Radiation
Radiation Studies Information (CDC)
www.cdc.gov/nceh/radiation/default.htm

8) CDC Laboratory Safety Manuals
www.cdc.gov/biosafety/publications/index.htm

Intel ISEF Categories and Subcategories

The categories have been established with the goal of better aligning judges and student projects for the judging at the Intel ISEF. Local, regional, state and country fairs may or may not choose to use these categories, dependent on the needs of their area. Please check with your affiliated fair(s) for the appropriate category listings at that level of competition.

Please visit our website at www.societyforscience.org/isef/students/project_categories for a full description and definition of the Intel ISEF categories:

ANIMAL SCIENCES

Animal Husbandry
Development
Ecology
Pathology
Physiology
Populations Genetics
Systematics
Other

BEHAVIORAL & SOCIAL SCIENCES

Clinical & Developmental Psychology
Cognitive Psychology
Physiological Psychology
Sociology
Other

BIOCHEMISTRY

General Biochemistry
Metabolism
Structural Biochemistry
Other

CELLULAR AND MOLECULAR BIOLOGY

Cellular Biology
Cellular and Molecular Genetics
Immunology
Molecular Biology
Other

CHEMISTRY

Analytical Chemistry
General Chemistry
Inorganic Chemistry
Organic Chemistry
Physical Chemistry
Other

COMPUTER SCIENCE

Algorithms, Data Bases
Artificial Intelligence
Networking and Communications
Computational Science, Computer Graphics
Computer System, Operating System
Software Engineering, Programming Languages
Other

EARTH & PLANETARY SCIENCE

Climatology, Weather
Geochemistry, Mineralogy
Paleontology
Geophysics
Planetary Science
Tectonics
Other

ENGINEERING: Electrical & Mechanical

Electrical Engineering, Computer Engineering, Controls
Mechanical Engineering, Robotics
Thermodynamics, Solar
Other

ENGINEERING: Materials & Bioengineering

Bioengineering
Chemical Engineering
Civil Engineering, Construction Eng.
Industrial Engineering, Processing
Material Science
Other

ENERGY & TRANSPORTATION

Aerospace and Aeronautical Engineering, Aerodynamics
Alternative Fuels
Fossil Fuel Energy
Vehicle Development
Renewable Energies
Other

ENVIRONMENTAL MANAGEMENT

Bioremediation
Ecosystems Management
Environmental Engineering
Land Resource Management, Forestry
Recycling, Waste Management
Other

ENVIRONMENTAL SCIENCES

Air Pollution and Air Quality
Soil Contamination and Soil Quality
Water Pollution and Water Quality
Other

MATHEMATICAL SCIENCES

Algebra
Analysis
Applied Mathematics
Geometry
Probability and Statistics
Other

MEDICINE & HEALTH SCIENCES

Disease Diagnosis and Treatment
Epidemiology
Genetics
Molecular Biology of Diseases
Physiology and Pathophysiology
Other

MICROBIOLOGY

Antibiotics, Antimicrobials
Bacteriology
Microbial Genetics
Virology
Other

PHYSICS AND ASTRONOMY

Astronomy
Atoms, Molecules, Solids
Biological Physics
Instrumentation and Electronics
Magnetics and Electromagnetics
Nuclear and Particle Physics
Optics, Lasers, Masers
Theoretical Physics, Theoretical or Computational Astronomy
Other

PLANT SCIENCES

Agriculture/Agronomy
Development
Ecology
Genetics
Photosynthesis
Plant Physiology (Molecular, Cellular, Organismal)
Plant Systematics, Evolution
Other