

Intel International Science and Engineering Fair 2011

International Rules & Guidelines



INSPIRED TO CHANGE
OUR WORLD.

Society for Science & the Public

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International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs 2010-2011

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www.societyforscience.org/isef/rulesandguidelines

The International Rules and Guidelines for Science Fairs is available on the Society for Science & the Public website in a number of formats to better aid all of those involved in the process: students, parents, teachers, mentors, fair directors and local, regional and state scientific review committees (SRC) and institutional review boards (IRB).

- [International Rules and Guidelines](#) - The full text of the International Rules and the forms both in html and in a downloadable format.
- The [Intel ISEF Rules Wizard](#) - This “wizard” asks a series of questions about your planned project and will provide a list of forms that you need to complete.
- [Common SRC Problems](#) - This list was generated from the SRC reviews leading up to the Intel ISEF. Read these to get pointers on what NOT to do.

**These Rules apply to the
Intel International Science and Engineering Fair 2011
Los Angeles, California, USA, May 8-13, 2011**

In addition to providing the rules of competition, these rules and guidelines for conducting research were developed to facilitate the following:

- protect the rights and welfare of the student researcher and human subjects
- protect the health and well-being of vertebrate animal subjects
- follow federal regulations governing research
- offer guidance to affiliated fairs
- use safe laboratory practices
- address environmental concerns

**Please address any general questions regarding the Intel ISEF to:
Society for Science & the Public**

Science Education Programs
1719 N Street, NW, Washington, DC 20036
office: 202/785-2255, fax: 202/785-1243, sciedu@societyforscience.org

**For specific rules questions, please email:
SRC@societyforscience.org**

The ISEF SRC members listed below will be using the above email address to respond to rules inquiries.

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ALL PROJECTS

Ethics Statement

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include 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 or the Intel ISEF.

Eligibility/Limitations

- 1) Each ISEF-affiliated fair may send the number of projects provided by their affiliation agreement.
- 2) A student must be selected by an ISEF-affiliated fair and be in grades 9-12 or equivalent to be eligible, none of whom has reached age 21 on or before May 1 preceding the Intel ISEF.
- 3) Each student may enter only **one** project which covers research done over a maximum of 12 continuous months between January 2010 and May 2011.
- 4) Team projects may have a maximum of three members. Teams may not have more than 3 members at a local fair and then eliminate members at regional, state or international competition.
- 5) Students may compete in only one 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 or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.
- 7) There is a broad range of categories in which students can complete science fair projects. A list of the Intel ISEF categories and subcategories with definitions can be found at www.societyforscience.org/Page.aspx?pid=470
- 8) A research project may be a part of a larger study done by professional scientists, but the project presented by the student must only be their portion of the complete study.

Requirements

General

- 1) All domestic and international students competing in an ISEF-affiliated fair must adhere to all of the rules as set forth in this document.
- 2) All projects must adhere to the Ethics Statement above.
- 3) Projects must adhere to local, state, country and U.S. Federal laws, regulations and permitting conditions.
- 4) 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.

- 5) Introduction or disposal of non-native species, pathogens, toxic chemicals or foreign substances into the environment is prohibited. See www.anstaskforce.gov/documents/isef.pdf.
- 6) Intel ISEF exhibits must adhere to Intel ISEF display and safety requirements.
- 7) **It is the responsibility of the student and adult sponsor to check with their affiliated fair for any additional restrictions or requirements.**

Approval and Documentation

- 8) Before experimentation begins, an Institutional Review Board (IRB) or Scientific Review Committee (SRC) must review and approve most projects involving human subjects, vertebrate animals, and potentially hazardous biological agents. See the appropriate sections of the Rules Book.
- 9) Every student must complete **Student Checklist (1A)**, a **Research Plan** and **Approval Form (1B)** and review the project with the Adult Sponsor as the **Checklist for Adult Sponsor (1)** is completed.
- 10) A Qualified Scientist is required for all studies involving BSL-2 potentially hazardous biological agents, DEA-controlled substances, many human subject 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 previous year's work and which require IRB/SRC approval must be reapproved 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 ISEF project year, **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 adult supervisors.
- 16) A project data book and research paper are not required, but are recommended. (See *Student Handbook*; Regional fairs may have different requirements).
- 17) All signed forms, certifications, and permits must be available for review by a SRC just before each fair a student enters.

Continuation of Projects

- 1) As in the professional world, research projects may be done that build on work done in previous years. Students will be judged only on the most recent year's research. The project year includes research conducted over a maximum of 12 continuous months from January 2010- May 2011.
- 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 done without what was learned from the past year's research, then it is a continuation project for competition. These projects must document that the additional research is an expansion from prior work (e.g. testing a new variable or new line of investigation, etc.) Repetition of previous experimentation with the exact same methodology and research question or increasing sample size are examples of unacceptable continuations.
- 3) Display boards and the 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 on the table properly labeled as such.
- 4) Longitudinal studies are permitted as an acceptable continuation under the following conditions:
 - a. The study is a multi-year study testing or documenting the same variables in which time is a critical variable. (Examples: Effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time.)
 - b. Each consecutive year must demonstrate **time-based** change.
 - c. The display board must be based on collective past conclusionary data and its comparison to the current year data set. No raw data from previous years may be displayed.
- 5) All continuation projects must be reviewed and approved each year and forms must 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. The documentation should be clearly labeled with the year (ex: 2009-2010). Please retain all prior years' paperwork in case a SRC requests additional documentation.

Team Projects

- 1) At the Intel ISEF, team projects will compete within the scientific category of their research and will no longer be a separate judged category.
- 2) Teams may have up to three members. Teams may not have more than three members at a local fair and then eliminate members to qualify for the Intel ISEF.
- 3) Team membership cannot be changed during a given research year including converting from an individual project or vice versa, but may be altered in subsequent years.
- 4) Each team should 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)**. However, 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 & Adults

1) The Student Researcher(s)

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

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include 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 or the Intel ISEF.

2) The Adult Sponsor

An Adult Sponsor may be a teacher, parent, university professor, or 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 or animals involved in the study. The Adult Sponsor must review the student's **Student Checklist (1A)** and **Research Plan** to make sure that: a) experimentation is done within local, state, and federal laws and these International Rules; b) that forms are completed by other adults involved in approving or supervising any part of the experiment; and c) that 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 or vertebrate animals, and cell cultures, microorganisms, or animal tissues. The issues must be discussed with the student when completing the **Research Plan**. Some experiments involve procedures or materials that are regulated by state and federal 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 possess an earned doctoral/professional degree in the biological or medical sciences as it relates to the student's area of research. However, a master's degree with equivalent experience and/or 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 the 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 outlined above. A student may work with a Qualified Scientist in another city or state. In this case, the student must work locally with a Designated Supervisor (see below) who has been trained in the techniques the student will use.

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 should be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Adult Sponsor may act as the Designated Supervisor.

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

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 human subjects. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement, therefore an IRB should be established at the school level to evaluate human research projects. An IRB at the school or ISEF Affiliated Fair level must consist of a minimum of three members.

An IRB must include:

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

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

In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor who oversee a specific project must not serve on the IRB reviewing that project. Additional members are recommended to help avoid this conflict of interest and to increase the expertise of the committee.

IRBs exist at federally regulated institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research subjects are at a correctional facility. 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 ISEF rules.

An IRB generally makes the final determination of risk. However, in reviewing projects just prior to a fair, if a SRC judges an IRB's decision as inappropriate, thereby placing human subjects in jeopardy, the SRC may override the IRB's decision and the project may fail to qualify for competition.

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 pertinent laws and regulations. Local SRCs may be formed to assist the Affiliated Fair SRC in reviewing and approving projects. The operation and composition of the local and Affiliated Fair SRCs must fully comply with the International Rules.

Any proposed research in the following areas must be reviewed and approved BEFORE experimentation: projects involving vertebrates and potentially hazardous biological agents. (Human studies reviewed and approved by a properly constituted IRB do not have to be reviewed by the SRC until just prior to the Fair competition.)

ALL projects must be reviewed and approved by the SRC after experimentation and shortly before competition in an Affiliated Fair competition. (Projects requiring preapproval which were conducted at a regulated research institution (not home or high school, etc.) and which were reviewed and approved by the proper institutional board before experimentation must also be reviewed by the Fair SRC for rules compliance.)

A SRC must consist of a minimum of three persons. The SRC must include:

- a) a biomedical scientist (Ph.D., M.D., D.V.M., D.D.S., or D.O.)
- b) an educator
- c) at least one other member

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

In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor must not serve on the

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

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

- a) evidence of literature search
- 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 (when needed)
- e) evidence of search for alternatives to animal use
- f) humane treatment of animals
- g) compliance with rules and laws governing human, animal research and those involving potentially hazardous biological agents
- i) documentation of substantial expansion for continuation projects

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)**
- b) **Institutional Review Board (IRB)**
- c) **Institutional Biosafety Committee (IBC)**
- d) **Embryonic Stem Cell Research Oversight Committee (ESCRO)**

8) The Intel ISEF Scientific Review Committee (Intel ISEF SRC)

A Scientific Review Committee exists at the Intel ISEF level. The ISEF SRC reviews the forms and the research plan for all projects to ensure that students have followed all applicable Rules.

The Intel ISEF SRC, like an Affiliated Fair SRC, is made up of a group of adults knowledgeable about research regulations. The Intel ISEF SRC reviews the **Checklist for Adult Sponsor (1), Abstract, Student Checklist (1A), Research Plan and Approval Form (1B)** in addition to all other required forms for students who enter the Intel ISEF. They also identify problems local fairs may be having and work with fair directors and teachers to resolve them.

A fair director or Affiliated Fair SRC member with any questions regarding the process, should contact the Society for Science & the Public or a member of the Intel ISEF SRC.

The Intel ISEF SRC is the final authority on projects that are qualified to compete in the Intel ISEF. In some cases, the Intel ISEF SRC may have questions about particular projects. Usually, after students explain their procedures and research to the Intel ISEF SRC, a simple corrective measure is prescribed (e.g., contacting the Designated Supervisor to confirm a detail, or rewriting an abstract for purposes of clarification).

It is important that students retain all original signed forms. Do not send original forms to the Society for Science & the Public.

Human Subjects

The following rules were developed to help pre-college student researchers follow federal guidelines (Code of Federal Regulations 45 CFR 46) designed to protect the human research subjects and the student researcher. When students conduct research with human subjects, the rights and welfare of the participants must be protected. Most human subject studies require preapproval from an Institutional Review Board (IRB) and informed consent/assent from the research subject.

Exempt Studies (Do Not Require IRB Preapproval or Human Subjects Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human subjects forms. Examples of exempt projects for ISEF and affiliated fairs include the following:

- 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 hazard. It is recommended that 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 or published and do not involve any interaction with human subjects or the collection of any data from a human subject 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 conditions below:
 - a) the professional providing the data must certify in writing that the data have been appropriately de-identified and are in compliance with all privacy and HIPAA laws and
 - b) during the final SRC review and approval process, the SRC must ensure that the data were appropriately de-identified by review of the written documentation provided by the supervising professional.

Rules

- 1) The use of human subjects 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 subject** is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), 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 subjects 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
 - a) that involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
 - b) that occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
 - c) that involve the recording of personally identifiable information
 - Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables.)
- 2) Student researchers must complete ALL elements of the Human Subjects portion of the Research Plan Instructions, #1 and evaluate and minimize the physical, psychological and privacy risks to their human subjects. See risk assessment below and the online Risk Assessment Guide for additional guidance.
- 3) The research study should be in compliance with all privacy and HIPAA laws when they apply to the project (e.g. the project involves medical information.)
- 4) All research projects involving human subjects, 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 subjects. After initial IRB 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.
- 5) The research subjects must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research subjects give their consent. Research subjects under 18 years of age or individuals not able to give consent (e.g. mentally disabled) give their assent, with their parents/guardians giving parental permission. **The IRB will determine**

whether the consent/assent/parental permission may be verbal or must be written depending on the level of risk and the type of study and will determine if a Qualified Scientist is required to oversee the project. See Risk Assessment below and the online Risk Assessment Guide for further explanation of informed consent.

- As part of the process of obtaining informed consent, the researcher will provide information to the subject (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study which then allows the subject, parents or guardians to make an educated decision about whether or not to participate.
 - Participants will also be informed that their participation is voluntary (i.e., they may decide whether or not to participate) 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 on a page.
 - When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
- 6) Research conducted by a pre-college student at federally regulated research institutions (e.g., universities, medical centers, NIH, correctional institutions, etc.) must be reviewed and approved by that institution's IRB. A copy of the IRB approval for the entire project (which must include the research procedures/ measures the student is using) or an official letter from the IRB attesting to this approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.
- 7) A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medications and performing invasive medical procedures on human subjects. The IRB must confirm that the student is not violating the medical practice act of the particular 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 subjects directly or through identifiers linked to the subjects, (including photographs), without written consent (Public Health Service Act, 42, USC 241 (d)).
- 9) All standardized tests 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 will 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 online Risk Assessment Guide for more detailed procedures.
- 11) After experimentation and shortly before fair competition, the SRC reviews and approves previously approved projects to make sure that students followed the approved **Research Plan** and the rules.
- 12) The following forms are required:
- a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Human Subjects Form (4)** w/applicable consents and survey(s)
 - f. **Regulated Research Institution Form (1C)** - when applicable
 - g. **Qualified Scientist Form (2)** - when applicable
- 13) **Sources of Information** are available on page 24 and at www.societyforscience.org/isef/rulesandguidelines.

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 subjects' 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.

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 DAILY 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. These studies should require documented informed consent/minor assent/parental permission (as applicable).

1) Physical Risks

- a. **Exercise** other than ordinarily encountered in DAILY LIFE would be considered more than minimal risk
- b. **Ingestion, tasting, smelling, or application of a substance** would typically be considered more than minimal risk. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB who will determine risk level based upon the nature of the study and local norms.
- c. **Exposure to any potentially hazardous material** would be considered more than minimal risk.

2) Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress would be considered more than minimal risk. For example, answering questions related to personal experiences such as sexual, physical or child 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) Invasion of Privacy

The student researcher and IRB must consider whether any activity could potentially result in negative consequences for the subject due to invasion of privacy or breach of confidentiality. Protecting confidentiality involves taking 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 truly anonymous. Anonymity involves collecting 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 subjects 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, mentally 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 covered by federal regulations. (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act).

See the online Risk Assessment Guide for a more detailed discussion of Risk Assessment.

www.societyforscience.org/isef/rulesandguidelines

Vertebrate Animals

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

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 keeping the health and well-being of the animal subjects as a first priority.

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.

Rules for ALL Studies Involving Vertebrate Animals

- 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, and all other nonhuman vertebrates (including fish) at hatching or birth.
- 2) Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following "3 R's":
 - Replace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures or computer simulations
 - Reduce the number of animals without compromising statistical validity
 - Refine the experimental protocol to lessen pain or distress to the animals.
- 3) **Research projects which cause more than momentary pain or suffering to vertebrate animals or which are designed to kill vertebrate animals are prohibited.** (Note: Humane euthanasia is permitted under certain conditions when the research is conducted at a regulated research institution. See Section B.)
- 4) Students **are prohibited** from designing or being directly involved in the following types of studies on vertebrate animals:
 - a. All induced toxicity studies involving a poison or toxin that could impair health or destroy life, including, but not limited to, alcohol, acid rain, insecticide, herbicide, or heavy metals.
 - b. Behavioral experiments involving conditioning with aversive stimuli, mother/infant separation or induced helplessness
 - c. Studies of pain
 - d. Predator/vertebrate prey experiments
- 5) Because weight loss is one significant sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.
- 6) If an experimental design requires food or water restriction, it must be appropriate to the species, but may not exceed 18 hours.
- 7) If there are unexpected deaths in either the experimental or control groups, the cause of the death must be investigated. If the experimental procedure is responsible for the deaths, the experiment must be immediately terminated. A death rate of 30% or greater in any group or subgroup is not permitted and the project will fail to qualify for competition.
- 8) Students performing vertebrate animal research must follow local, state, country and U.S. federal regulations.
- 9) Except for observational studies, a Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals.
- 10) A Scientific Review Committee (SRC) and/or an Institutional Animal Care and Use Committee (IACUC) must approve all research before experimentation begins. (An IACUC is the review and approval body at a regulated research institution for all animal studies.) The research plan for vertebrate animal studies must include the following:
 - a. Justify why animals must be used, including the reasons for the choice of species 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. Describe in detail, 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.
- 11) 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.

- 12) Studies involving behavioral observations of animals are exempt from prior SRC review if **ALL** of the following apply:
- There is no interaction with the animals being observed,
 - There is no manipulation of the environment in any way and
 - All federal or state fish, game and wildlife laws and regulations are followed.
- 13) Certain types of vertebrate animal studies may be conducted at home, school or other non-regulated research sites, whereas other studies must be conducted at a regulated research institution. See A. Non-regulated Research Site and B. Regulated Research Site below for rules and site descriptions.
- 14) **Sources of Information** are available on page 24 and at www.societyforscience.org/isef/rulesandguidelines.
- husbandry of the animals. The following documents offer space requirements and additional husbandry information:
- *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 Scientific Review Committee must determine when a veterinarian is required to certify that the research plan and animal husbandry are appropriate. This certification is required before experimentation and the prior SRC approval. A veterinarian must be consulted in experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.
- 4) If an unexpected illness or emergency occurs, the affected animals must have proper medical and nursing care that is directed by a veterinarian. A student researcher is expected to stop experimentation if there is significant 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.

A. Additional Rules for Projects Conducted in a Non-regulated Site

Vertebrate animal studies may be conducted at a **non-regulated** research site (home, school, farm, ranch, in the field, etc.). This includes:

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

- 1) These projects must adhere to BOTH of the following guidelines:
- a. The research involves 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.
- (Note: All studies not meeting the above criteria 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 compatible with the standards and requirements appropriate for the species used. 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
- 5) 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 and local fishing laws and regulations. Students are prohibited from performing electrofishing.
- 6) The final disposition of the animals must be considered and explained on **Vertebrate Animal Form (5A)**. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a non-regulated site.
- 7) **The following forms are required:**
- a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Vertebrate Animal Form (5A)**
 - f. **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 must be conducted in a regulated research institution. A regulated research institution 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. 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 that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and program structured in compliance with U.S. federal laws are included in this definition.

(NOTE: Some research that is permissible for professionals in research institutions is not appropriate for pre-college students.)

- 1) The Institutional Animal Care and Use Committee (IACUC) must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local SRC must also review the project to certify that the research project complies with ISEF Rules. This SRC review should occur before experimentation begins.
- 2) Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. Student researchers are prohibited from performing euthanasia. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
- 3) Research projects that cause more than momentary pain or suffering to vertebrate animals are prohibited. Potentially painful experiments or procedures conducted on laboratory animals without the appropriate use of anesthetics, analgesics and/or tranquilizers are prohibited.
- 4) Research in nutritional deficiency, ingestion, inoculation or exposure to unknown or potentially hazardous materials or drugs is permitted to proceed only to the point where the first sign of the deficiency or effect appear. Appropriate measures must then be taken to correct the deficiency or drug effect, if such action is feasible. If not, the animal(s) must be euthanized.
- 5) The following forms are required:
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Regulated Research Institution Form (1C)**
 - f. **Vertebrate Animal Form (5B)**
 - g. **Qualified Scientist Form (2)**

Potentially Hazardous Biological Agents

(includes rules involving microorganisms, rDNA, and human and vertebrate animal tissues)

Projects involving **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 working with potentially hazardous biological agents. Students are permitted to do research projects with potentially hazardous biological agents as long as every effort is made to ensure that they work safely and that the projects meet the conditions and rules described below. The following rules were developed to protect students and to help them adhere 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 final biosafety level which then determines the laboratory facilities, equipment, training, and supervision required for the research project to proceed.

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 Involving Potentially Hazardous Biological Agents

- 1) 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 under the conditions and rules that follow. All of these areas of research may involve potentially hazardous biological agents and require special precautions.
- 2) An appropriate review and approval committee (SRC, IBC, 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.
- 3) Experimentation involving culturing of potentially hazardous biological agents, even BSL-1 organisms, **is prohibited in a home environment**. However, specimens are allowed to be collected at home as long as they are immediately transported to a laboratory with the appropriate level of biosafety containment.
- 4) **Research determined to be biosafety levels 3 or 4 is prohibited for pre-college students.**
- 5) **Laboratory studies utilizing MRSA** (Methicillin resistant Staphylococcus aureus) **and VRE** (Vancomycin-resistant enterococci) must be conducted in a Registered Research Institution under the supervision of a qualified scientist.
- 6) **Studies intended to genetically engineer bacteria with multiple antibiotic resistance are prohibited.** Extreme caution should be exercised when selecting out antibiotic resistant organisms. Studies using such organisms require at least BSL-2 containment.
- 7) Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
- 8) A risk assessment must be conducted by the student and adult supervisors prior to experimentation and a final biosafety level must be determined or confirmed by the SRC.
- 9) Research determined to be at Biosafety Level 1 (BSL-1) may 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.
- 10) Research determined to be a Biosafety Level 2 (BSL-2) **MUST** be conducted in a laboratory rated BSL-2 or above (commonly found in a regulated research institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter obtained from an institutional representative that the research does not require review. The research must be supervised by a Qualified Scientist. The student researcher must receive extensive training, demonstrate competency and be directly supervised while conducting microbiological procedures.
- 11) All potentially hazardous biological agents must be properly disposed of at the end of experimentation in accordance with their biosafety level. Following are acceptable procedures for disposal of cultured materials: Autoclaving at 121 degrees Celsius for 20 minutes, use of 10% bleach solution, incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations.
- 12) Studies involving the culturing of human or animal waste, including sewage sludge, must be treated as a BSL-2 study.
- 13) The following types of studies are exempt from prior SRC review:
 - A. No additional forms required:
 - 1) Studies involving baker's yeast and brewer's yeast, except when involved with rDNA studies
 - 2) Studies involving Lactobacillus, Bacillus thurgensis, nitrogen-fixing, oil-eating bacteria, slime mold and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment that could potentially be contaminated.)
 - 3) Studies of mold growth on food items if the experiment is terminated at the first evidence of mold.

- B. Require completed Risk Assessment Form 3:
- 1) Studies involving protists, archaea and similar microorganisms
 - 2) Research using manure for composting or other non-culturing experiments and fuel production.
 - 3) Commercially-available color change coliform water test kits which will remain sealed and will be properly disposed.
- 14) Any proposed changes in the **Research Plan** by the student after initial SRC approval must have subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
- 15) 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 appl.
 - c. **Qualified Scientist (2)**, when applicable
 - d. **Risk Assessment (3)**, when applicable
 - e. **PHBA Risk Assessment Form (6A)**
 - f. **Human and Vertebrate Animal Tissue Form (6B)** - for all studies involving tissues and body fluids.
- 16) **Sources of Information** are available on page 25 and at www.societyforscience.org/isef/rulesandguidelines.

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, etc.)

- 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 include doubled heavy-duty (2-ply) sealed bags.
 - b) Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (i.e. counting presence of organisms or colonies).
 - c) The sealed Petri dish is disposed of in the appropriate manner under the supervision of the Designated Supervisor.
- 2) **If a culture container is opened for any purpose, 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 risk level assignment. There are a few rDNA studies that 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 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. 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) A rDNA technology study that involves 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 Involving Tissues & 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) If tissues are obtained from an animal that was sacrificed for a purpose other than the students' 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.
- 2) If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and adhere to the vertebrate animal rules for studies conducted at a regulated research institution. (See the vertebrate animal rules.)
- 3) Biosafety level 1 studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products, see rule 5) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies can be conducted in a BSL-1 laboratory and must be supervised by a Qualified Scientist or trained Designated Supervisor.
- 4) Biosafety level 2 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.
- 5) 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. All 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 bloodborne pathogens (eg. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed of after experimentation.
- 6) Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2.
- 7) Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or 4 is prohibited.
- 8) Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and informed consent. Student researchers using their own body fluids are exempt from this requirement.

- 9) 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.
- 10) The following types of tissue do not need to be treated as potentially hazardous biological agents:
 - a. Plant tissue
 - b. Established cell and tissue cultures (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures should be identified in the Research Plan
 - c. 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 a recommended procedure.
 - f. Fossilized tissue or archeological specimens
 - g. Prepared fixed tissue

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 final biosafety level which then determines the laboratory facilities, equipment, training, and supervision required for the research project to proceed.

Risk assessment involves:

- **Assignment of the biological agent to a risk group**
 - o Studies involving a known microorganism should begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
 - o The study of unknown microorganisms and the use of fresh tissues should rely on the expertise of qualified adults supervising the project.

- **Determination of the level of biological containment** available to the student researcher to conduct the experimentation. (Please see Levels of Biological Containment below for more details.)
- **Assessment of the experience and expertise of the adult(s)** supervising the student.
- **Assignment of a final 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 final biosafety level must be confirmed by the SRC. If the research is conducted at a regulated site, the final biosafety level must be assigned by an Institutional Biosafety Committee (IBC) or equivalent approval body or a letter obtained from an institutional representative that the research does not require review. If no approval body exists at the regulated site, the SRC should review the project and assign a final biosafety level.

Classification of Biological Agents Risk

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. **PROHIBITED**

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. **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 competent 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. **PROHIBITED**

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. **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 that involves the use of hazardous chemicals, devices and activities. The rules 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 and tobacco and 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 that the proper supervision is provided and that all potential risks are considered so that the appropriate safety precautions are taken. Before beginning research involving hazardous chemicals, activities or devices, be sure to check with your school, local, or regional fair as more strict rules and guidelines may be in effect.

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 will be expected to have the permit prior to the onset of experimentation. A copy of the permit should be available for review by adults supervising the project and/or the Scientific Review Committee in their review prior to competition.
- 5) The student researcher must design experiments to minimize the impact that an experiment has on the environment, for instance using minimal quantities of chemicals that must subsequently be disposed of in an environmentally safe manner in accordance with good laboratory practices.
- 6) The following forms are required:
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Reg. Research Institution Form (1C)** - when applicable
 - f. **Qualified Scientist Form (2)** - when applicable
 - g. **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 a number of chemicals that can be diverted from their regular use to make illegal drugs. Other countries may have similar regulatory bodies; students outside of the U.S. should consult the drug regulatory agency in their country in addition to being aware of DEA regulations. DEA-controlled substances and their schedule number can be found at the DEA website listed in the Sources of Information at the end of the section. If a student is uncertain whether chemicals involved in a project are controlled by the DEA, he/she should consult the listing of DEA-controlled substances.

- 1) All studies using DEA-controlled substances must be supervised by a Qualified Scientist who is licensed by the DEA (or other appropriate 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. Therefore, special precautions must be taken in their use for a science project.

- 1) Students are prohibited from administering prescription drugs to human subjects.
- 2) Administering any prescription drug to vertebrate animals must be done under all appropriate vertebrate animal rules and guidelines. A veterinarian is required.

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 have an age restriction for purchase, possession and consumption. Students outside of the U.S. must additionally adhere to their local and country laws and regulations.

The Designated Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.

- 1) Production of ethyl alcohol (wine or beer) is allowable in the home under the supervision of the parents and must meet the TTB home production regulations.

2. Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
3. Students are allowed to conduct science fair experiments involving the distillation of alcohol for fuel or other non-consumable products. However, 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 ignitors.

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.

Note: Potato guns or 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 should include review of factors such as the degree of toxicity, reactivity, flammability or corrosiveness.

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 doing a risk assessment 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 the chemical may have. The student researcher must refer to Material Safety Data Sheets (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 below) provides good 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 chemical process. The principles of green chemistry are described on the EPA website in the Sources of Information section. Whenever possible the following principles should be incorporated into the research plan.

- Prevent waste
- Use safer chemicals and products
- Design less hazardous chemical syntheses
- Use renewable materials
- Use catalysts
- Use safer solvents and reaction conditions
- Increase energy efficiency
- Minimize the potential for accident

B. Hazardous Devices

The documentation of a 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 are 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 are found in laser pointers, aiming and range finding devices and pose a risk if the beam is directly viewed over a long period of time.
- Class III lasers are found in higher powered laser pointers, printers and spectrometers. They are to be considered hazardous devices which can cause eye damage when the beam is directly viewed even for a short period of time.
- Class IV lasers are high powered lasers used in surgery, research, and industrial settings. They are extremely hazardous and can cause eye and skin damage from both direct and indirect exposure. The beam is also a fire hazard.

A risk assessment must be conducted when a student uses **ionizing radiation** beyond that normally encountered in everyday life. 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.

Additional **Sources of Information** are available on page 26 and at www.societyforscience.org/isef/rulesandguidelines.

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: dejavu60@msn.com

General Requirements

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 in their display to conform to display and safety regulations.

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

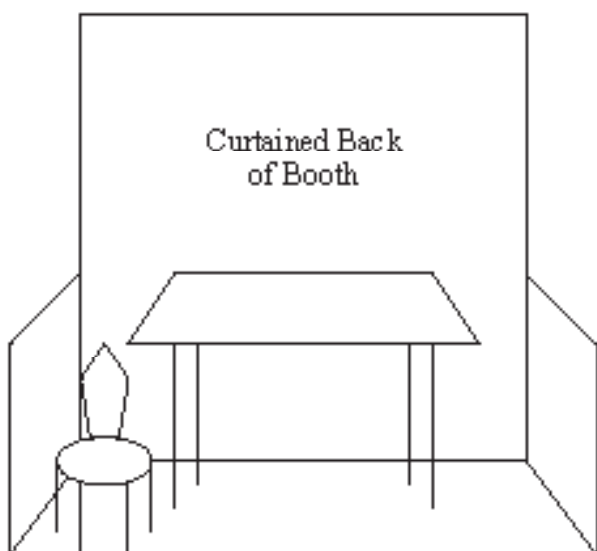
At the Intel ISEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters).

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.

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 allowed dimensions. Water is no longer permitted in demonstrations.

Position of Project

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



Required to Be Visible and Vertically Displayed at the Intel ISEF

- Original of official Abstract and Certification as approved and stamped/embossed by the Intel ISEF Scientific Review Committee
- Completed Intel ISEF Project Set-up Approval Form SRC/DS2 (Received on-site at the Fair)
- Regulated Research Institutional/Industrial Setting Form (1C) — when applicable
- Continuation Projects Form (7) — when applicable
- Photograph / image credits

Required to Be at the Project But Not Displayed at the Intel ISEF

All forms required for Scientific Review Committee approval including, but not limited to **Checklist for Adult Sponsor (1)**, **Student Checklist (1A)**, **Research Plan, Approval Form (1B)**, and **Human Subjects (4)**, 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 officials. In addition, the Display & Safety Committee requires a photograph/video release form signed by the human subject for visual images of humans (other than the Finalist) displayed as part of the project. These forms and any informed consents forms should not be displayed.

Handouts/Official Abstract and Certification at the Intel ISEF

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

Not Allowed for Display at Project or in 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 (as indicated in item 5 in the section of these rules entitled "Allowed at Project or in Booth BUT with the Restrictions Indicated")]
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. **Awards, medals, business cards, flags, logos, CDs, endorsements, and/or acknowledgments** (graphic or written) unless the item(s) are an integral part of the project (Exception: Intel ISEF medal(s) may be worn at all times.)
15. Photographs or other visual presentations depicting vertebrate animals in surgical techniques, dissections, necropsies, or other lab procedures
16. Active Internet or e-mail connections as part of displaying or operating the project at the Intel ISEF
17. 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.
18. Glass or glass objects unless deemed by the Display and Safety Committee to be an integral and necessary part of the project (Exception: glass that is an integral part of a commercial product such as a computer screen)
19. 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.)

Allowed at Project or in Booth for Display BUT with the Restrictions Indicated

1. Photographs and/or visual depictions **if**:
 - a. They are not deemed offensive or inappropriate by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. This includes, but is not limited to, visually offensive photographs or visual depictions of invertebrate or vertebrate animals, including humans. The decision by any one of the groups mentioned above is final.
 - b. They have credit lines of origin ("Photograph taken by..." or "Image taken from..."). (If all photographs being displayed were taken by the Finalist or are from the same source, one credit line prominently and vertically displayed is sufficient.)
 - c. They are from the Internet, magazines, newspapers, journals, etc., and credit lines are attached. (If all photographs/images are from the same source, one credit prominently and vertically displayed is sufficient.)
 - d. They are photographs or visual depictions of the Finalist.
 - e. They are photographs of human subjects for which signed consent forms are at the project or in the booth.
2. Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points **if for display only and not operated.**
3. Any demonstration for judges or the public must be performed within the maximum size of the project permitted, an area 30"(Depth) by 48"(Width) by 108" (Height)
4. Class II lasers **if**:
 - a. The output energy is < 1 mW and is operated only by the Finalist
 - b. Operated only during the Display and Safety inspection and during judging
 - c. Labeled with a sign reading "**Laser Radiation: Do Not Look into Beam**"
 - d. Enclosed in protective housing that prevents physical and visual access to beam
 - e. Disconnected when not operating

Note: Class II lasers are found in laser pointers and in aiming and range-finding devices. They pose a risk if the beam is directly viewed over a long period of time.
5. Class III and IV lasers if for display only and not operated (See the description of Class III and Class IV lasers in the Radiation section of the Hazardous Chemicals, Activities, or Devices.
6. Any apparatus producing temperatures that will cause physical burns if adequately insulated
7. The only items that may be displayed on the front of the provided tables are the forms listed in the section of these rules entitled "Required to be Visible and Vertically Displayed at the Intel ISEF:"

Electrical Regulations at the Intel ISEF

1. Finalists requiring 120 or 220 Volt A.C. electrical circuits must provide a **UL-listed 3-wire extension cord** which is appropriate for the load and equipment.
2. Electrical power supplied to projects and, therefore, the maximums allowed for projects is **120 or 220 Volt, A.C., single phase, 60 cycle**. 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.
3. All electrical work must conform to the National Electrical Code or exhibit hall regulations. The guidelines presented here are general ones, and other rules may apply to specific configurations. The on-site electrician may review electrical work on any project.
4. All electrical connectors, wiring, switches, extension cords, fuses, etc. must be **UL-listed** and must be appropriate for the load and equipment. Connections must be soldered or made with **UL-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.
5. Wiring not part of a commercially available **UL-listed** appliance or piece of equipment must have a clearly visible fuse or circuit breaker on the supply side of the power source and prior to any project equipment.
6. There must be an accessible, clearly visible on/off switch or other means of disconnect from the **120 or 220 Volt** power source.
7. Any lighting that generates considerable and excessive amounts of heat (high-intensity lamps, halogen lights, etc.) must be turned off when the Finalist is not present.

Other Intel ISEF Information and Requirements

1. *Finalists must be present at their projects for the Display and Safety inspection. The inspection is a process that takes place between the Finalist and inspector; therefore, no other persons should be present representing the Finalist except for an interpreter if necessary.*
2. Returning items that have been removed through a violation and/or adding items that are not permitted after final clearance by the Display and Safety Committee and the Scientific Review Committee is prohibited.
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. A project data book and research paper are not required but are highly recommended.
5. *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.'*
6. 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.
7. 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.
8. 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.
9. Project sounds, lights, odors, or any other display items must not be distracting.
10. No food or drinks, except small containers of bottled water for personal consumption, are allowed in the Exhibit Hall.

Information on Required Abstract & Certification for ALL Projects at the Intel ISEF

* This form may not be relevant for your regional or state fair; please refer to instructions from your affiliated fair.*

In ADDITION to the basic form requirements for ALL Projects and any other requirements due to specific areas of research, an Abstract & Certification is required at the conclusion of research. Details on this requirement follow.

Completing the Abstract

After finishing research and experimentation, you are required to write a (maximum) 250 word, one-page abstract. This should be written on the Official Abstract and Certification Form as provided by Society for Science & the Public. The abstract **should include the following:**

- a) purpose of the experiment
- b) procedure
- c) data
- d) conclusions

It may also include any possible research applications. Only minimal reference to previous work may be included. An abstract **must not include the following:**

- a) acknowledgments (including naming the research institution and/or mentor with which you were working), or self-promotions and external endorsements
- b) work or procedures done by the mentor

Completing the Certification

At the bottom of the Abstract & Certification form there are six questions. Please read each carefully and answer appropriately. The Intel ISEF Scientific Research Committee will review and approve the abstract and answers to the questions.

Revisions or questions will be resolved via a SRC appointment on site at the Intel ISEF. Please bring a copy of your Abstract & Certification to the fair. Only after final Intel ISEF SRC approval has been obtained via a stamped/embossed copy of this Abstract & Certification may a Finalist make copies to hand out to the judges and the public. (SSP provides the first 30 copies.)

Intel ISEF Sample Abstract & Certification

Title
Finalist's Name
School Name, City and State, Country

Category
Pick one only--
mark an "X" in
box at right

Start Typing the Body of Your Abstract Here Beginning at the Left Margin

- Animal Sciences
- Behavioral and Social Science
- Biochemistry
- Cellular & Molecular Biology
- Chemistry
- Computer Science
- Earth Science
- Eng. Materials & Bioengineering
- Eng: Electrical & Mechanical
- Energy & Transportation
- Environmental Sciences
- Environmental Management
- Mathematical Sciences
- Medicine and Health
- Microbiology
- Physics & Astronomy
- Plant Sciences

1. As a part of this research project, the student directly handled, manipulated, or interacted with (check all that apply):
 human subjects potentially hazardous biological agents:
 vertebrate animals microorganisms rDNA tissue
2. This abstract describes only procedures performed by me/us, reflects my/our own independent research, and represents one year's work only. yes no
3. I/We worked or used equipment in a regulated research institution or industrial setting. yes no
4. This project is a continuation of previous research. yes no
5. My display board includes non-published photographs/visual depictions of humans (other than myself): yes no
6. I/We hereby certify that the abstract and responses to the above statements are correct and properly reflect my/our own work. yes no

This embossed seal attests that this project is in compliance with all federal and state laws and regulations and that all appropriate reviews and approvals have been obtained including the final clearance of the Intel ISEF Scientific Review



NOTE: Your abstract must be on the Intel International Science and Engineering Fair Abstract & Certification form and embossed/stamped by the Intel ISEF Scientific Review Committee before it is displayed or handed out. No pasted or taped text will be permitted. No other format or version of your approved Abstract & Certification will be allowed for any purpose at the Intel ISEF.

Sources of Information

Human Subjects

- 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: A Manual for Investigative Sites* (2002). Boston, MA: Thomson Centerwatch. ISBN 1-930624-36-0.
Can be purchased from:
<http://www.amazon.com>
NIH tutorial also provides similar information:
<http://www.cancer.gov/clinicaltrials/learning/page2>
- 3) Penslar, R.L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
- 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.
To order call: (800) 628-4094. If outside US, call (717) 632-3535, Ext. 8087
<http://www.apa.org/science/programs/testing/standards.asp>
- 6) American Psychological Association
750 First Street, NE
Washington, DC 20002-4242
phone: 202-336-5500; 1-800-374-2721
<http://www.apa.org>

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

Information regarding publications:
<http://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
<http://www.apa.org/science/programs/testing/index.aspx>

Many of the documents above are also available by contacting:

Office for Human Research Protections
Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
phone: 240-453-6900; toll free in U.S. 866-447-4777
email: ohrp@osophs.dhhs.gov

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_n/ilarhome/reports.shtml
- 2) *Principles and Guidelines for the Use of Animals in Pre-college Education* (a free pamphlet from ILAR)
Can be found online:
http://dels.nas.edu/ilar_n/ilarhome/reports.shtml
- 3) *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research* (2003), Institute for Laboratory Animal Research (ILAR).

To order these ILAR publications contact:
National Academies Press
500 Fifth Street, NW
Lockbox 285
Washington, DC 20055
phone: 888-624-8373 or 202-334-3313
fax: 202-334-2451; <http://www.nap.edu>
- 4) Federal Animal Welfare Act (AWA)
7 U.S.C. 2131-2157
Subchapter A - Animal Welfare (Parts I, II, III)
<http://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)
1111 N. Dunlap Avenue
Savoy, IL 61874
phone: (217) 356-3182
email: fass@assochq.org
<http://www.fass.org>
- 6) *Guidelines for the Use of Fish in Research* (2004), American Fisheries Society.
<http://www.fisheries.org/afs/publicpolicy.html>
- 7) Euthanasia Guidelines
AVMA Guidelines on Euthanasia (June 2007)
American Veterinary Medical Association.
http://www.avma.org/issues/animal_welfare/euthanasia.pdf

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
1-888-FIND-NLM or 1-888-346-3656
(301) 594-5983; email: custserv@nlm.nih.gov
<http://www.nlm.nih.gov>
<http://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@nal.usda.gov
<http://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_n/ilarhome
- 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
Ph: 301-496-1131; Fax: 301-480-3537
Toll Free: 1-888-FIND NLM or 1-888-346-3656
Email: tehip@tehip.nlm.nih.gov
<http://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/>

Potentially Hazardous Biological Agents

- 1) American Biological Safety Association: ABSA Risk Group Classification – list of organisms
<http://www.absa.org>
- 2) American Type Culture Collection
(703) 365-2700; 1(800) 638-6597 (US, Canada, & PR)
<http://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: <http://www.bergeys.org/resources.html>
- 4) Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 4th Edition. Published by CDC-NIH,
To order: Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop F05
Atlanta, GA 30333

<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>
- 5) World Health Organization Laboratory Safety Manual-3rd Edition
<http://www.who.int/csr/resources/publications/biosafety/biosafety7.pdf>

Available online in English, French, Spanish, & Portuguese. Provides practical guidance on biosafety techniques for use in laboratories at all levels. Includes risk assessment and safe use of recombinant DNA technology, and provides guidelines for the commissioning and certification of laboratories.

Canada – Agency of Public Health – list of non-pathogenic organisms
http://www.phac-aspc.gc.ca/ols-bsl/pathogen/organism_e.html
- 6) Microorganisms for Education Website – list of organisms
<http://www.science-projects.com/safemicrobes.htm>
- 7) NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health.
<http://oba.od.nih.gov/oba/index.html>
- 8) OSHA – Occupational Health and Safety Administration
<http://www.osha.gov>
- 9) The Mad Scientist Network at Washington University School of Medicine: <http://www.madsci.org>

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) 872-4554 or 1-800-227-5558
email: pss@acs.org,
website: <http://www.acs.org/publications>
- 2) *Safety in the Research Laboratory*
A free DVD from Howard Hughes Medical Institute that includes sections on working with cell cultures, radioactive materials and other laboratory materials. Other free safety DVD's are also available: order from the website:
<http://www.hhmi.org/catalog/main?action=home>
- 3) Environmental Protection Agency (EPA) website for green chemistry: <http://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:
<http://www.flinnsci.com/sections/safety/safety.asp> - A directory of MSDS sheets from Flinn Scientific Inc. that includes a ranking of hazard level and disposal methods
<http://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:
<http://www.justice.gov/dea/index.htm>

Controlled Substance Schedules - a list of controlled substances : <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>
- 6) Alcohol, Tobacco Firearms and Explosives
Alcohol and Tobacco Tax and Trade Bureau
<http://www.ttb.gov/>
Bureau of Alcohol, Tobacco, Firearms and Explosives
<http://www.atf.gov>
- 7) Radiation
Radiation Studies Information (CDC)
<http://www.cdc.gov/nceh/radiation/default.htm>
- 8) CDC Laboratory Safety Manuals
<http://www.cdc.gov/od/ohs/safety/SUPSAFE.PDF>
<http://www.cdc.gov/od/ohs/safety/S2.pdf>
- 9) Occupational Safety and Health Administration Documents available from:
OSHA Publications
P.O. Box 37535
Washington, DC 20013-7535
phone: (202) 693-1888; fax: (202) 693-2498
<http://www.osha.gov>
PUB 8-1.7 - Guidelines for Laser Safety and Hazard Assessment
STD 1-4.1 - OSHA Coverage of Ionizing Radiation Sources Not Covered by Atomic Energy Act of 1954
- 10) U.S. Nuclear Regulatory Commission
Material Safety and Inspection Branch
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738
phone: (301) 415-8200; (800) 368-5642
<http://www.nrc.gov>

Student Checklist (1A)

This form is required for ALL projects.

1) a. Student/Team Leader: _____ Grade: _____

Email: _____ Phone: _____

b. Team Member: _____ c. Team Member: _____

2) Title of Project: _____

3) School: _____ School Phone: _____

School Address: _____

4) Adult Sponsor: _____ Phone/Email: _____

5) Is this a continuation from a previous year? Yes No

If Yes:

a) Attach the previous year's **Abstract** and **Research Plan**

b) Explain how this project is new and different from previous years on **Continuation Form (7)**

6) **This year's** laboratory experiment/data collection: (must be stated (mm/dd/yy))

Start Date: _____ End Date: _____

7) Where will you conduct your experimentation? (check all that apply)

Research Institution School Field Home Other: _____

8) List name and address of all non-school work site(s):

Name: _____

Address: _____

Phone: _____

9) **Complete a Research Plan following the Research Plan instructions and attach to this form.**

10) **An abstract is required for all projects after experimentation.**

Research Plan Instructions

A complete research plan is required and must accompany Checklist for Student (1A)

Provide a typed research plan and attach to Student Checklist (1A).

The research plan for ALL projects is to include the following:

A. Question or Problem being addressed

B. Hypothesis/Engineering Goals

C. Description in detail of method or procedures (The following are important and key items that should be included when formulating ANY AND ALL research plans.)

- **Procedures:** Detail all procedures and experimental design to be used for data collection
- **Data Analysis:** Describe the procedures you will use to analyze the data that answer research question or hypothesis

D. Bibliography: List at least five (5) major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.

- Choose one style and use it consistently to reference the literature used in the research plan
- Guidelines can be found in the Student Handbook

Items 1-4 below are subject-specific guidelines for additional items to be included in your research plan as applicable:

1. Human subjects research:

- **Subjects.** Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
- **Recruitment.** Where will you find your subjects? How will they be invited to participate?
- **Methods.** What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
- **Risks.** What are the risks or potential discomforts (physical, psychological, time involved, social, legal etc) to participants? How will you minimize the risks?
- **Benefits.** List any benefits to society or each participant.
- **Protection of Privacy.** Will any identifiable information (e.g., names, telephone numbers, birthdates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?
- **Informed Consent Process.** Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

2. Vertebrate animal research:

- Briefly discuss potential **ALTERNATIVES** to vertebrate animal use and present a detailed justification for use of vertebrate animals
- Explain potential impact or contribution this research may have
- Detail all procedures to be used
 - Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experimentation
 - Detailed chemical concentrations and drug dosages
- Detail animal numbers, species, strain, sex, age, etc.
 - Include justification of the numbers planned for the research
- Describe housing and oversight of daily care
- Discuss disposition of the animals at the termination of the study

3. Potentially Hazardous Biological Agents:

- Describe Biosafety Level Assessment process and resultant BSL determination
- Give source of agent, source of specific cell line, etc.
- Detail safety precautions
- Discuss methods of disposal

4. Hazardous Chemicals, Activities & Devices:

- Describe Risk Assessment process and results
- Detail chemical concentrations and drug dosages
- Describe safety precautions and procedures to minimize risk
- Discuss methods of disposal

Approval Form (1B)

A completed form is required for each student, including all team members.

1) To Be Completed by Student and Parent

a) Student Acknowledgment:

- I understand the risks and possible dangers to me of the proposed research plan.
- I have read the ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.
- I have read and will abide by the following Ethics statement

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include 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 or the Intel ISEF.

Student's Printed Name

Signature

Date Acknowledged

(Must be prior to experimentation.)

b) Parent/Guardian Approval: have read and understand the risks and possible dangers involved in the **Research Plan**. I consent to my child participating in this research.

Parent/Guardian's Printed Name

Signature

Date of Approval

(Must be prior to experimentation.)

2) To be completed by the Fair SRC

(Required for projects requiring prior SRC/IRB APPROVAL. Sign 2a or 2b as appropriate.)

a) Required for projects that need prior SRC/IRB approval BEFORE experimentation

(humans, vertebrates or potentially hazardous biological agents)

The SRC/IRB has carefully studied this project's **Research Plan** and all the required forms are included. My signature indicates approval of the **Research Plan** before the student begins experimentation.

SRC/IRB Chair's Printed Name

Signature

Date of Approval

(Must be prior to experimentation.)

OR

b) Required for research conducted at all Regulated Research Institutions with no prior fair SRC/IRB approval.

This project was conducted at a regulated research institution (**not home or high school, etc.**), was reviewed and approved by the proper institutional board before experimentation and complies with the ISEF Rules. **Attach (1C) and required institutional approvals (e.g. IACUC, IRB)**

SRC Chair's Printed Name

Signature

Date of Approval

3) Final ISEF Affiliated Fair SRC Approval (Required for ALL Projects)

SRC Approval After Experimentation and Shortly Before Competition at Regional/State/National Fair

I certify that this project adheres to the approved **Research Plan** and complies with all ISEF Rules.

Regional SRC Chair's Printed Name

Signature

Date of Approval

State/National SRC Chair's Printed Name

Signature

Date of Approval

(where applicable)

Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed after experimentation by the adult supervising the student research conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

This form MUST be displayed with your project; Responses must be on the form

Student's Name _____

Title of Project _____

To be completed by the Supervising Adult in the Setting (NOT the Student) after experimentation:
(Responses must remain on the form as it is required to be displayed at student's project booth.)

The student conducted research at my work site:

- a) to use the equipment b) to perform experiment(s)/conduct research

1) How did the student get the idea for her/his project?
(e.g. Was the project assigned, picked from a list, an original student idea, etc.)

2) Have you reviewed the ISEF rules relevant to this project? Yes No

3) Did the student work on the project as a part of a research group? Yes No
If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)

4) What specific procedures or equipment did the student actually use for the project.
Please list and describe. (Do not list procedures student **only** observed.)

5) How independent or creative was the student's work?

*Student research projects dealing with human subjects, vertebrate animals or potentially hazardous biological agents require review and approval by an institutional regulatory board (IRB/IACUC/IBC). **Copy of approval(s) must be attached, if applicable.***

Supervising Adult's Printed Name

Signature

Title

Institution

Date Signed

Address

Email/ Phone

Qualified Scientist Form (2)

May be required for research involving human subjects, vertebrate animals, potentially hazardous biological agents, and DEA-controlled substances. Must be completed and signed before the start of student experimentation.

Student's Name _____

Title of Project _____

To be completed by the Qualified Scientist:

Scientist Name: _____

Educational Background: _____ Degree(s): _____

Experience/Training as relates to the student's area of research: _____

Position: _____ Institution: _____

Address: _____ Email/Phone: _____

1) Have you reviewed the ISEF rules relevant to this project? yes no

2) Will any of the following be used?

a) Human subjects yes no

b) Vertebrate animals yes no

c) Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products) yes no

d) DEA-controlled substances yes no

3) Will you directly supervise the student? yes no

a. If no, who will directly supervise and serve as the Designated Supervisor? _____

b. Experience/Training of the Designated Supervisor: _____

4) Describe the safety precautions and training necessary for this project:

To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the **Research Plan** prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the **Research Plan**. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my direct supervision.

Qualified Scientist's Printed Name

Signature

Date of Approval

To be completed by the Designated Supervisor when the Qualified Scientist cannot directly supervise.

I certify that I have reviewed the **Research Plan** and have been trained in the techniques to be used by this student, and I will provide direct supervision.

Designated Supervisor's Printed Name

Signature

Date of Approval

Phone

Email

Risk Assessment Form (3)

Required for projects using hazardous chemicals, activities or devices.
Must be completed before experimentation.

Student's Name _____

Title of Project _____

To be completed by the Student Researcher in collaboration with Designated Supervisor/Qualified Scientist:

1. List/identify the hazardous chemicals, activities, devices or microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules) that will be used.
2. Identify and assess the risks involved.
3. Describe the safety precautions and procedures that will be used to reduce the risks.
4. Describe the disposal procedures that will be used (when applicable).
5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):

I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the **Research Plan** and will provide direct supervision.

Designated Supervisor's Printed Name

Signature

Date of Review
(must be prior to experimentation.)

Position & Institution

Phone or email contact information

Experience/Training as relates to the student's area of research

Human Subjects Form (4)

Required for all research involving human subjects. (IRB approval required before experimentation.)

Student's Name _____ Title of Project _____

Adult Sponsor: _____ Contact Phone/Email: _____

To be completed by Student Researcher in collaboration with the Adult Sponsor/Designated Supervisor/Qualified Scientist:

1. I have submitted my Research Plan which addresses ALL areas indicated in the Human Subjects Section of the Research Plan Instructions.
2. I have attached any surveys or questionnaires I will be using in my project.
3. I have attached an informed consent that I would use if required by the IRB.
4. Yes No Are you working with a Qualified Scientist?
 Name: _____ Degree: _____
 Email Address/Phone Number: _____
 Experience/Training as it relates to this project: _____

To be completed by Institutional Review Board (IRB) after review of the research plan. The submitted Research Plan must address all areas indicated on the Human Subjects section of the Research Plan Instructions.

Check one of the following:

- Research project requires revisions and is **NOT approved** at this time. IRB will attach document indicating concerns and/or requested revisions.
- Research project is **Approved** with the following conditions below: (All 5 must be answered)
 1. Risk Level (check one): Minimal Risk More than Minimal Risk
 2. Qualified Scientist (QS) Required: Yes No
 3. Written Minor Assent required for minor subjects:
 Yes No Not applicable (No minors in this study)
 4. Written Parental Permission required for minor subjects:
 Yes No Not applicable (No minors in this study)
 5. Written Informed Consent required for subjects 18 years or older:
 Yes No Not applicable (No subjects 18 yrs or older in this study)

IRB SIGNATURES (All 3 signatures required) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project and agree with the above IRB determinations.

Medical or Mental Health Professional (a psychologist, psychiatrist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)	
Printed Name	Degree/Professional License
Signature	Date of Approval

School Administrator	
Printed Name	Degree
Signature	Date of Approval

Educator	
Printed Name	Degree
Signature	Date of Approval

Sample Informed Consent Form

Instructions to the Student Researcher: An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist.

This form is used to provide information to the research subject (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form or may copy ALL elements of it into a new document.
- If the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.

Student Researcher:

Title of Project:

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

Purpose of the project:

If you participate, you will be asked to:

Time required for participation:

Risks:

Benefits:

How confidentiality will be maintained:

If you have any questions about this study, feel free to contact:

Adult Sponsor: _____ Phone/email: _____

Voluntary Participation:

Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent or Minor Assent

Date Reviewed & Signed: _____

Printed Name of Research Subject:

Signature:

Parental/Guardian Permission (if applicable)

Date Reviewed & Signed: _____

Parent/Guardian Printed Name:

Signature:

Vertebrate Animal Form (5B)

Required for all research involving vertebrate animals that is conducted at a Regulated Research Institution.
(IACUC approval required before experimentation.)

Student's Name _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

1. Was this a student-generated idea or was it a subset of your work?
2. Have you reviewed the ISEF Rules relevant to this project?
3. What laboratory training, including dates, was provided to the student?
4. Species of animals used: _____ Number of animals used: _____
5. a. Pain designation for the IACUC protocol: _____
b. Pain designation for student's project: _____
6. Describe, in detail, the role of the student in this project: procedures and equipment they were involved with, oversight provided and safety precautions employed. (Attach extra pages if necessary.)
7. If the student's project also involves the use of tissues, please describe the tissues to be used and how they were obtained. (If these tissues are covered in the above IACUC protocol, the student does not need to complete Form 6A or Form 6B)
8. **Attach a copy of the Regulated Research Institution IACUC Approval.** A letter from the Qualified Scientist or Principal Investigator is not sufficient.

Certification or Documentation of Student Researcher Training

_____ Date(s) of Training _____
List Certificate Number or Attach Documentation

_____ Signature _____ Date _____
Qualified Scientist/Principal Investigator Printed Name

_____ Signature _____ Date _____
IACUC Chair/Coordinator Printed Name

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, fresh/frozen tissue, blood and body fluids.

SRC/IACUC/IBC approval required before experimentation.

Student's Name _____

Title of Project _____

To be completed by Student Researcher in collaboration with Qualified Scientist/Designated Supervisor:

(All questions are applicable and must be answered; additional page(s) may be attached.)

- 1) Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism.
- 2) Describe the site of experimentation including the level of biological containment.
- 3) Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.
- 4) Describe the procedures that will be used to minimize risk. (personal protective equip., hood type, etc.)
- 5) What final biosafety level do you recommend for this project given the risk assessment you conducted?

To be completed by Qualified Scientist or Designated Supervisor

- 1) What training will the student receive for this project?
- 2) Do you concur with the biosafety information and recommendation provided by the student researcher above?
Yes No If no, please explain.

QS/DS Printed Name

Signature

Date of Signature

Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable)

To be completed by SRC: (Check all that apply.)

- The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-1 study, which must be conducted at a BSL-1 or above laboratory.
Date of SRC approval (before experimentation) _____
- The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-2 study, which must be conducted at a BSL-2 or above laboratory.
Date of SRC approval (before experimentation) _____
- This project was conducted at a Research Institution and was reviewed and approved by the appropriate institutional board (e.g. IACUC, IBC) before experimentation at a BSL-1 or BSL-2 laboratory and complies with the ISEF rules. The required institutional forms are attached.
Date of SRC approval (after experimentation) _____
- The Research Institution where this study was conducted does not require approval for this type of study. The student has received proper training and the project complies with ISEF rules. Attached is a letter from an institutional representative certifying the above. Date of SRC approval _____

SRC Chair's Printed Name

Signature

Human and Vertebrate Animal Tissue Form (6B)

Required for projects using fresh/frozen tissue, primary cell cultures, blood, blood products and body fluids. If the research involves living organisms, please ensure that the proper human or animal forms are completed.

All projects using any tissue listed above, must also complete Form 6A.

Student's Name _____

Title of Project _____

To be completed by Student Researcher:

1) What tissue(s), organ(s), or part(s) will be used?

2) Where will the above tissue, organ, or part be obtained (identify each separately):

3) If the tissue is obtained from a source within a research institution, please provide information regarding the vertebrate study from which the tissue was obtained. Attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.

To be completed by the Qualified Scientist or Designated Supervisor:

I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.

AND/OR

I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

Printed Name _____ Signature _____ Date Signed _____
(Must be prior to experimentation.)

Title _____ Phone/Email _____

Institution _____

Continuation Projects Form (7)

Required for projects that are a continuation in the same field of study as a previous project.
This form must be accompanied by the previous year's abstract and Research Plan.

Student's Name _____

To be completed by Student Researcher:

List all components of the current project that make it new and different from previous research. The information must be on the form; use an additional form for 2007-2008 and earlier projects.

Components	Current Research Project	Previous Research Project
1. Title		2009-2010: 2008-2009:
2. Changes in Goal/Purpose/Objective		2009-2010: 2008-2009:
3. Changes in Methodology		2009-2010: 2008-2009:
4. Variables Studied		2009-2010: 2008-2009:
5. Additional Changes		2009-2010: 2008-2009:

Attached are:

2009- 2010 Abstract and Research Plan

2008-2009 Abstract

I hereby certify that the above information is correct and that the current year Abstract & Certification and project display board properly reflect work done only in the current year.

Student's Printed Name

Signature

Date of Signature

2011 Student Handbook

Science Research and the Process of Science

Research is a process by which people discover or create new knowledge about the world in which they live. The Intel ISEF and Affiliated Fairs are research (data) driven. Students design research projects that provide quantitative data through experimentation followed by analysis and application of that data. Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for research based science fairs.

Questioning is probably the most important part of a scientific investigation and is often followed by an "if...then" statement. Students are encouraged to design 'controlled' experiments, ones that allow them to set up a standard and then change only one variable at a time to see how that variable might affect the original condition tested as the standard. Thus, questioning usually leads to experiments or observations.

Good scientists, both young and old, frequently use a process to study what they see in the world. This process has been referred as the 'Scientific Method' or more recently as the 'Inquiry Cycle'. The following stages listed below will help you produce a good scientific experiment:

- 1) Be curious, choose a limited subject, ask a question; identify or originate/define a problem. It is important that this question be a 'testable' question - one in which data is taken and used to find the answer. A testable question can further be identified as one in which one or more variables can be identified and tested to see the impact of that variable on the original set of conditions. The question should not merely be an 'information' question where the answer is obtainable through literature research.
- 2) Review published materials related to your problem or question. This review should also include reviewing the International Rules and Guidelines (www.societyforscience.org/isef/rulesandguidelines). This is called background research.
- 3) Evaluate possible solutions and guess why you think it will happen (hypothesis).
- 4) Experimental design (procedure). In designing the experiment, it is critical that only one variable - a condition that may effect the results of the experiment - is changed at a time. This makes the experiment a 'controlled' experiment.
- 5) Challenge and test your hypothesis through your procedure of experimentation (data collection) and analysis of your data. Use graphs to help see patterns in the data.
- 6) Draw conclusions based on empirical evidence from the experiment.
- 7) Prepare your report and exhibit.

- 8) Review and discuss the findings with peer group/ professional scientists

- 9) New question(s) may arise from your discussions.

This sets the stage for another research project as new questions are raised from others and the process repeats itself. The hypothesis often changes during the course of the experiment. Supporting or not supporting your hypothesis is secondary to what is learned and discovered during the research.

Non Inquiry Based Research

Not all areas of study are best served by scientific method based research. Because engineers, inventors, mathematicians, theoretical physicists, and computer programmers have different objectives than those of other scientists, they follow a different process in their work. The process that they use to answer a question or solve a problem is different depending on their area of study. Each one uses their own criteria to arrive at a solution.

Engineering Projects

"Scientists try to understand how nature works; engineers create things that never were." An engineering project should state the engineering goals, the development process and the evaluation of improvements. Engineering projects may include the following:

- 1) Define a need or "How can I make this better?"
- 2) Develop or establish design criteria (could be more than one)
- 3) Do background research and search the literature to see what has already been done or what products already exist that fill a similar need. What makes them good and what makes them weak?
- 4) Prepare preliminary designs and a materials list. Consider costs, manufacturing and user requirements.
- 5) Build and test a prototype of your best design. Consider reliability, repair and servicing.
- 6) Retest and redesign as necessary. Product testing.
- 7) Present results.

Computer Science Projects

These often involve creating and writing new algorithms to solve a problem or improve on an existing algorithm. Simulations, models or 'virtual reality' are other areas on which to conduct research.

Mathematics Projects

These involve proofs, solving equations, etc. Math is the language of science and is used to explain existing phenomena or prove new concepts and ideas.

Theoretical Projects

These projects may involve a thought experiment, development of new theories and explanations, concept formation or designing a mathematical model.

Getting Started

1) **Pick your topic:** This is perhaps the most difficult part. Get an idea of what you want to study or learn about. Ideas should come from things in your areas of interest. A hobby might lead you to a good topic. What is going on in the world that you would like to know more about? Most importantly, pick a question or problem that is not too broad and that can be answered through scientific investigation.

2) **Research Your Topic:** Go to the library or internet to learn more about your topic. Always ask Why or What if... Look for unexplained or unexpected results. Also, talk to professionals in the field.

3) **Organize:** Organize everything you have learned about your topic. At this point, you should narrow your thinking by focusing on a particular idea.

4) **Make a Time Table:** Choose a topic that not only interests you, but can be done in the amount of time you have. Identify your 'testable question'. Develop a time line to manage your time efficiently. You will need time to fill out the necessary forms and to review the research plan with your sponsor. Certain projects will require more time because they need prior approval from the Scientific Review Committee (SRC) or Institutional Review Board (IRB). Allow plenty of time to experiment and collect data. You will also need time to write a paper and put together a display or 'board'.

5) **Plan Your Experiment:** Give careful thought to experimental design. Once you have a feasible project idea, write a research plan. This plan should explain how you will do your experiments and exactly what will be involved. Remember you must design your experiment so that it is a 'controlled' experiment. This is one in which only one variable is changed at a time. The results are then compared to the 'standard' data you take originally before you change that one variable. Thus, you have designed an investigation with adequate control and limited variables to investigate a question. Also, in your experimental design, make sure you include sufficient numbers in both control (if applicable) and experimental groups to be statistically valid. The experimental design should also include a list of materials. Once finished with the experimental design (called 'procedure') all students are required to fill out the appropriate forms.

6) **Consult with Your Adult Sponsor and Get Approvals:** You are required to discuss your research plan with an Adult Sponsor and obtain a signature of approval. In reviewing your research plan, you should determine if additional forms and prior approval are needed.

7) **Conduct Your Experiment:** During experimentation, keep detailed notes of each and every experiment, measurement and observation in a log book. Do not rely on memory. Besides, judges love logbooks! Use data tables or charts to record your quantitative data.

8) **Analyze Your Results:** When you complete your experiments, examine and organize your findings. Use appropriate graphs to make 'pictures' of your data. Identify patterns from the graphs. This will help you answer your testable question. Did your experiments give you the expected results? Why or why not? Was your experiment performed with the exact same steps each time? Are there other explanations that you had not considered or observed? Were there experimental errors in your data taking, experimental design or observations? Remember, that understanding errors is a key skill scientists must develop. In addition, reporting that

a suspected variable did not change the results can be valuable information. That is just as much a 'discovery' as if there was some change due to the variable. In addition, statistically analyze your data using the statistics that you can understand and explain their meaning.

9) **Draw Conclusions:** Did the variable(s) tested cause a change when compared to the standard you are using? What patterns do you see from your graph analysis that exist between your variables? Which variables are important? Did you collect enough data? Do you need to conduct more experimentation? Keep an open mind - never alter results to fit a theory. If your results do not support your hypothesis, that's ok and in some cases good! Try to explain why you obtained different results than your literature research predicted for you. Were there sources of error that may have caused these differences? If so, identify them. Even if the results do differ, you still have accomplished successful scientific research because you have taken a question and attempted to discover the answer through quantitative testing. This is the way knowledge is obtained in the world of science. Think of practical applications that can be made from this research. How could this project be used in the real world? Finally, explain how you would improve the experiment and what would you do differently.

Elements of a Successful Project

1) Project Data Book:

A project data book is your most treasured piece of work. Accurate and detailed notes make a logical and winning project. Good notes show consistency and thoroughness to the judges and will help you when writing your research paper. Data tables are also helpful. They may be a little 'messy' but be sure the quantitative data recorded is accurate and that units are included in the data tables. Make sure you date each entry.

2) Research Paper:

A research paper should be prepared and available along with the project data book and any necessary forms or relevant written materials. A research paper helps organize data as well as thoughts. A good paper includes the following sections.

- a) **Title Page and Table of Contents:** The title page and table of contents allows the reader to follow the organization of the paper quickly.
- b) **Introduction:** The introduction sets the scene for your report. The introduction includes the purpose, your hypothesis, problem or engineering goals, an explanation of what prompted your research, and what you hoped to achieve.
- c) **Materials and Methods:** Describe in detail the methodology you used to collect data, make observations, design apparatus, etc. Your research paper should be detailed enough so that someone would be able to repeat the experiment from the information in your paper. Include detailed photographs or drawings of self-designed equipment. *Only include this year's work.*
- d) **Results:** The results include data and analysis. This should include statistics, graphs, pages with your raw collected data, etc.
- e) **Discussion:** This is the essence of your paper. Compare your results with theoretical values, published data, commonly held beliefs, and/or expected results. Include a discussion of possible errors. How did the data vary between repeated observations of similar events? How were your results

affected by uncontrolled events? What would you do differently if you repeated this project? What other experiments should be conducted?

- f) **Conclusions:** Briefly summarize your results. State your findings in relationships of one variable with the other. Support those statements with empirical data (one average compared to the other average, for example). Be specific, do not generalize. Never introduce anything in the conclusion that has not already been discussed. Also mention practical applications.
- g) You should always credit those who have assisted you, including individuals, businesses and educational or research institutions. However, acknowledgments listed on a project board are a violation of D & S Display rules and must be removed.
- h) **References/Bibliography:** Your reference list should include any documentation that is not your own (i.e. books, journal articles, websites, etc.). See an appropriate reference in your discipline for format or refer to the Instructions to Authors of the appropriate publication.

Three common reference styles are:

APA (American Psychological Association) **Style :**

<http://apastyle.apa.org/>
<http://www.calvin.edu/library/knightcite/index.php>
<http://owl.english.purdue.edu/owl/resource/560/01/>
This resource offers examples for the general format of APA research papers, in-text citations, endnotes/footnotes, and the reference page.

MLA (Modern Language Association) **Format:**

<http://www.mla.org/style>
<http://www.calvin.edu/library/knightcite/index.php>
<http://owl.english.purdue.edu/owl/resource/557/01/>
This resource offers examples for the general format of MLA research papers, in-text citations, endnotes/footnotes, and the Works Cited page.

Chicago Manual of Style

<http://www.chicagomanualofstyle.org/home.html>
<http://www.calvin.edu/library/knightcite/index.php>

The Chicago Manual of Style presents two basic documentation systems. The more concise author-date system has long been used by those in the physical, natural, and social sciences. In this system, sources are briefly cited in the text, usually in parentheses, by author's last name and date of publication. The short citations are amplified in a list of references, where full bibliographic information is provided.

Patent and Copyright Information

You may want to consider applying for a patent or copyright if you want to protect your work. You can contact the Office of Public Affairs, U.S. Patent Office, at 1-800-786-9199 for Patent information or the Library of Congress at 202-707-3000 for copyright information.

3) Abstract:

After finishing research and experimentation, you need to write an abstract. The abstract needs to be a maximum of 250 words on one page. An abstract should include the a) purpose of the experiment, b) procedures used, c) data, and conclusions. It also may include any possible research applications. Only minimal reference to previous work may be included. The abstract must focus on work done in the current year and should not include a) acknowledgments, or b) work or procedures done by the mentor. See below for an example of an appropriately written abstract. See page 23 of the International Rules for the proper formatting of an Official Intel ISEF Abstract and Certification. Please Note: The Official abstract form is only for those participating in ISEF and may not be required for many Affiliated or local fairs.

Sample Abstract

Effects of Marine Engine Exhaust Water on Algae
Mary E. Jones
Hometown High School, Hometown, PA, United States

This project in its present form is the result of bioassay experimentation on the effects of two-cycle marine engine exhaust water on certain green algae. The initial idea was to determine the toxicity of outboard engine lubricant. Some success with lubricants eventually led to the formulation of "synthetic" exhaust water which, in turn, led to the use of actual two-cycle engine exhaust water as the test substance.

Toxicity was determined by means of the standard bottle or "batch" bioassay technique. *Scenedesmus quadricauda* and *Ankistrodesmus* sp. were used as the test organisms. Toxicity was measured in terms of a decrease in the maximum standing crop. The effective concentration - 50% (EC50) for *Scenedesmus quadricauda* was found to be 3.75% exhaust water; for *Ankistrodesmus* sp. 3.1% exhaust water using the bottle technique.

Anomalies in growth curves raised the suspicion that evaporation was affecting the results; therefore, a flow-through system was improvised utilizing the characteristics of a device called a Biomonitor. Use of a Biomonitor lessened the influence of evaporation, and the EC 50 was found to be 1.4% exhaust water using *Ankistrodesmus* sp. as the test organism. Mixed populations of various algae gave an EC 50 of 1.28% exhaust water.

The contributions of this project are twofold. First, the toxicity of two-cycle marine engine exhaust was found to be considerably greater than reported in the literature (1.4% vs. 4.2%). Secondly, the benefits of a flow-through bioassay technique utilizing the Biomonitor was demonstrated.

International Rules & Guidelines

www.societyforscience.org/isef/rules&guidelines

The rules were developed to facilitate the following:

- protect the rights and welfare of the student researcher and human subjects
- protect the health and well-being of vertebrate animal subjects
- follow federal regulations governing research
- offer guidance to affiliated fairs
- use of safe laboratory practices
- address environmental concerns

4) Visual Display:

You want to attract and inform. Make it easy for interested spectators and judges to assess your study and the results you have obtained. You want to 'catch the eye' of the judges and convince them that the research is of sufficient quality to deserve closer scrutiny. Most displays or boards have three sections and are free standing. For the most part, the displays are put on a table. Most Intel ISEF judges get a chance to look at the board before the interviews. Make the most of your space using clear and concise displays. You never get a second chance to make a first impression! Please be sure to reference the Display and Safety Rules in the International Rules and Guidelines; this information is also available on the Society for Science & the Public website at www.societyforscience.org.

Helpful hints for display:

- a) **Current Year:** Make sure the board reflects the current year's work only. Prior year's data books are permitted at your project.
- b) **Good Title:** Your title is an extremely important attention-grabber. A good title should simply and accurately present your research and depict the nature of the project. The title should make the casual observer want to know more.
- c) **Take Photographs:** Many projects involve elements that may not be safely exhibited at the Fair, but are an important part of the project. You might want to take photographs of important parts/phases of your experiment to use in your display. Photograph or other visual images of human test subjects must have signed consent forms. Credit must be given for all photographs.
- d) **Be Organized:** Make sure your display follows a sequence and is logically presented and easy to read. Reach out to the 'skim-reader'. A glance should permit anyone (particularly the judges) to locate quickly the title, abstract, experiments, results and conclusions. When you arrange your display, imagine that you are seeing it for the first time. Highlight your results using key graphs that show the relationships of the two variables tested. Use the graphs to give a 'picture' of the data for your viewers. These graphs will provide an easier method of viewing the data rather than just seeing the recorded quantitative data.
- e) **Eye-Catching:** Make your display stand out. Use neat, colorful headings, charts and graphs to present your project. Pay special attention to the labeling of graphs, charts, diagrams, photographs, and tables to ensure that each has a title and appropriate label describing what is being demonstrated. Anyone should be able to understand the visuals without further explanation.
- f) **Correctly Presented and Well-Constructed:** Be sure to adhere to the size limitations and safety rules when preparing your display. Display all required forms for your project. Make sure your display is sturdy, as it will need to remain intact for quite a while. You must also consider the weight of the project for shipping. It can be very costly to ship a heavy board. Keep your materials light, but strong.

Please Note: The judges are judging your research, not the display. So don't spend an excessive amount of time or money on the board. You are being judged on the science not the show!

5) Judging

Judges evaluate and focus on 1) what the student did in the current year; 2) how well a student followed the scientific, engineering, computer programming or mathematical methodologies; 3) the detail and accuracy of research as documented in the data book; and 4) whether experimental procedures were used in the best possible way.

Judges look for well thought-out research. They look at how significant your project is in it's field; how thorough you were, and how much of the experiment thought and design is your own work.

Initially, judges get their information from your board, abstract and research paper to learn what the project is about, but it is the **Interview** that will be the final determination of your work. Judges applaud those students who can speak freely and confidently about their work. They are not interested in memorized speeches or presentations – they simply want to **talk** with you about your research to see if you have a good grasp of your project from start to finish. It is important to start the interview off right. Greet the judges and introduce yourself. You want to make a good first impression. Appearance, good manners, appropriate attire, and enthusiasm for what you are doing will impress the judges.

Judges often ask questions to test your insight into your projects such as: "How did you come up with this idea?" "What was your role?", "What didn't you do?", "What further plans do you have to continue research?" and "What are the practical applications of your project?" Remember that the judges need to see if you understand the basic principles of science behind your project or topic area. They want to determine if you have correctly measured and analyzed the data. They want to know if you can determine possible sources of error in your project and how you might apply your findings to the 'real' world. Finally, the judges seek to encourage you in your scientific efforts and your future goals/career in science. Relax, smile and enjoy your time to learn from them and accept their accolades for your fine work.

Intel ISEF Judging Criteria (points)

	<u>Individual</u>	<u>Team</u>
Creative Ability	30	25
Scientific Thought and Engineering Goals	30	25
Thoroughness	15	12
Skill	15	12
Clarity	10	10
Teamwork	---	16

Intel International Science and Engineering Fair 2011

International Rules & Guidelines



INSPIRED TO CHANGE
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The foundation of tomorrow's innovation is education. That's why making quality education available to more students around the world—with the help of technology—has inspired Intel's commitment to education for 40 years. We do more than make contributions. Intel gets directly involved in developing and helping to change policy, training teachers, offering free curricula, providing kids with a place to explore technology, and encouraging young innovators. Intel believes that students at all levels everywhere deserve to have the skills they need to become part of the next generation of innovators.

In the last decade, Intel has invested more than \$1 billion, and Intel employees have donated over 2.5 million hours, toward improving education in 50 countries. We are actively involved in education programs, advocacy, and technology access to help tomorrow's innovators.

The Intel International Science and Engineering Fair and Intel Science Talent Search encourage students to tackle challenging scientific questions and develop the skills needed to solve the problems of tomorrow.

www.intel.com/education

Society for Science & the Public

Society for Science & the Public (SSP) is one of the oldest nonprofit organizations in the U.S. dedicated to public engagement in science and science education. Established in 1921, SSP is a membership organization and a leading advocate for the understanding and appreciation of science and the vital role it plays in human advancement.

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To learn more about the Intel International Science and Engineering Fair, visit:

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Intel International Science and Engineering Fair

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