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Intel International Science and Engineering Fair

International Rules and Guidelines 2012

International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs 2011-2012

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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 2012
Pittsburgh, Pennsylvania, USA, May 13–18, 2012

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

Please contact your local or regional Scientific Review Committee for pre-review and approval for your project. Find your fair at http://apps.societyforscience.org/find_a_fair

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

If you wish to speak to an Intel ISEF SRC member, please call SSP at (202) 785-2255.

Intel ISEF SRC

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 and 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 2011 and May 2012.
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/isef/project_categories.
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, a local or regional Institutional Review Board (IRB) or Scientific Review Committee (SRC) associated with your fair must review and approve most projects involving human participants, 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 participant studies and many vertebrate animal studies.
11) After initial IRB/SRC approval (if required), any proposed changes in the **Student Checklist (1A)** and **Research Plan** must be re-approved before laboratory experimentation/data collection resumes.
12) Projects which are continuations of 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. A valid continuation project is a sound scientific endeavor. 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 2011– May 2012.

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: 2010-2011). 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. In future years, the project may be converted from an individual to a team project, from a team to an individual project or have a change of team members.

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 and Adults

1) The Student Researcher(s)

The student researcher is responsible for all aspects of the research project including enlisting the aid of any 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 humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement, therefore 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. Contact your fair for information on how to receive pre-approval. (An online listing of fairs is available at: http://apps.societyforscience.org/isef/find_a_fair.)

Any proposed research in the following areas must be reviewed and approved BEFORE experimentation: projects involving vertebrate animals 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 (earned doctoral degree, such as 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. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied. 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
j) compliance with the ISEF ethics statement

7) Other Review Committees

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

a) Institutional Animal Care and Use Committee (IACUC)
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 at the Intel ISEF 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).

Human Participants

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 participants and the student researcher. When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB) and informed consent/assent from the research participant.

Exempt Studies

(Do Not Require IRB Preapproval or Human Participants Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. 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 humans or the collection of any data from a human participant for the purpose of the student's research project.
- Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which **all** of the following apply:
  a) the researcher has no interaction with the individuals being observed
  b) the researcher does not manipulate the environment in any way **and**
  c) the researcher does not record any personally identifiable data.
- Projects in which the student receives the data in a **de-identified/anonymous** format which complies with both 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 participants in science projects is allowable under the conditions and rules in the following sections. Based upon the Code of Federal Regulations (45 CFR 46), the definition of a **human participant** 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 participant research" requiring IRB preapproval include:
   - Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
   - Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
   - Studies in which the researcher is the subject of the research
   - Behavioral observations
     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 Participants portion of the Research Plan Instructions, #1 and evaluate and minimize the physical, psychological and privacy risks to their human participants. 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 participants, including any revisions, must be reviewed and approved by an **Institutional Review Board (IRB)** before the student may begin recruiting and/or interacting with human participants. 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) 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.

6) The research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants give their consent. Research participants 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 participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study which then allows the particiants, 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.

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 participants. 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 participants directly or through identifiers linked to the participants, (including photographs), without written consent (Public Health Service Act, 42, USC 241 (d)).

9) All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements including procurement of legal copies of the instrument.

10) Studies that involve the collection of data via use of the internet (e.g., email, web based surveys) are allowed but 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 Participants 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 participants' behavior and the study does not involve more than minimal risk.

c) Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

d) Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/ assent/parental permission, it is strongly recommended that documentation of written informed consent/ assent/parental permission be obtained.

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 participant 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 participants from any of the following groups, the IRB and student research must consider whether the nature of the study requires special protections or accommodations.
   a. Any member of a group that is naturally at-risk. (e.g. pregnant women, 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 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 the first priority.

SSP strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals 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
   - All other nonhuman vertebrates (including fish) at hatching or birth.

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

2) Alternatives to the use of vertebrate animals for research **must** be explored and discussed in the research plan. Alternatives include the following "4 R's":
   - **R**eplace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures or computer simulations
   - **R**educe the number of animals without compromising statistical validity
   - **R**efine the experimental protocol to lessen pain or distress to the animals.
   - **R**espect animals and their contribution to research.

3) All vertebrate animal studies must be reviewed and approved before experimentation begins. An IACUC is the review and approval body at a regulated research institution for all animal studies. The affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field and must include a veterinarian or an animal care provider with training and/or experience in the species being studied.

4) All vertebrate animal studies must have a research plan that includes:
   a. Justification why animals must be used, including the reasons for the choice of species, the source of animals and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.

   b. Description of how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.

5) Studies involving behavioral observations of animals are exempt from 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
   - Study meets all federal and state fish, game and wildlife laws and regulations.

6) Students performing vertebrate animal research must statisfy local, state, country and U.S. federal laws and regulations in the jurisdiction in which research is performed.

7) **Research projects which cause more than momentary or slight pain or distress are prohibited.** Projects that are designed to cause the death of the animal, as distinguished from humane euthanasia, are prohibited. (Humane euthanasia is permitted under certain conditions when the research is conducted at a regulated research institution. See Section B.)

8) Students **are prohibited** from designing or direct involvement in the following types of studies on vertebrate animals:
   a. Induced toxicity studies that involve known toxic substances 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.

   It is acceptable for a student to perform a tissue study involving the above types of research if the animal was euthanized for a purpose other than the student's project and the animal study was conducted by a Qualified Scientist with appropriate IACUC review and approval.

9) All animals must be monitored for signs of distress. If there is illness, unexpected weight loss, or death in either the control or experimental group, this unexpected outcome must be investigated and a veterinarian should be consulted to oversee any needed medical care. This review must be documented. If the illness or distress is caused by the study, the experiment must be stopped immediately.
   a. 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%.
   b. 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 such a project will fail to qualify for competition.
   c. Animals should be monitored for other clinical signs of distress such as: diarrhea, progressive dermatitis, rough hair coat, hunched posture, lethargy, coughing, labored breathing, nasal discharge, jaundice and/or anemia, neurological signs, bleeding, self-induced trauma, inability to eat or drink, self-isolation, etc.

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

11) 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.

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

13) 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.

NOTE: 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 Sections A & B below for site descriptions and additional vertebrate animal rules.

Sources of Information are available on page 24 and at www.societyforscience.org/isef/rulesandguidelines.

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

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

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

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

1) These projects must adhere to BOTH of the following guidelines:
   a. The research involves 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 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 required 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 **must** stop experimentation if there is unexpected weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors.

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 school/home/field 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 and may also be subject to Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and 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 if possible.

2) 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 or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.

4) Research in nutritional deficiency or research involving substances or drugs of unknown effects is permitted to the point that any clinical sign of distress is noted. 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 microrganisms, 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 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, 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, fuel production, or other non-culturing experiments.
      3) Commercially-available color change coliform water test kits which will remain sealed and will be properly disposed.

2) 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.

3) 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.

4) 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.

5) 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.

6) 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.

7) **Research determined to be biosafety levels 3 or 4 is prohibited for pre-college students.**

8) **Laboratory studies culturing known MRSA** (Methicillin resistant Staphlococcus aureus), **VRE** (Vancomycin-resistant enterococci) and **KPC** (Klebsiella pneumonia) must be conducted in a BSL-2 laboratory in a Registered Research Institution with documented IBC Committee review and approval.

9) **Studies intended to genetically engineer bacteria with multiple antibiotic resistance are prohibited.**

10) Extreme caution should be exercised when selecting and sub-culturing antibiotic resistant organisms. Studies using such organisms require at least BSL-2 containment.

11) Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.

12) Studies involving the culturing of human or animal waste, including sewage sludge, must be treated as a BSL-2 study.

13) 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 a 10% bleach solution (1:10 dillution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations.

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.

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, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.**

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

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

2) If tissues are obtained from an animal that was euthanized 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.

3) 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.)

4) Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products, see rule 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.

5) Biosafety level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or 2. These studies must be conducted in a regulated research institution in a BSL-2 laboratory under the supervision of a Qualified Scientist.

6) 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.

7) Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2.

8) Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or 4 is prohibited.

9) 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.

10) Self-sampling of capillary blood for analysis can be conducted in a home setting,(e.g. glucometer reading).

11) 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.

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**
  - 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.
  - 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 Groups

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

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment. Examples of BSL-1 organisms are: *Escherichia coli strain K12, Agrobacterium tumifaciens, 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 pneumonia, 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 in the Resource Section) 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.

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: displayandsafety@societyforscience.org

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.

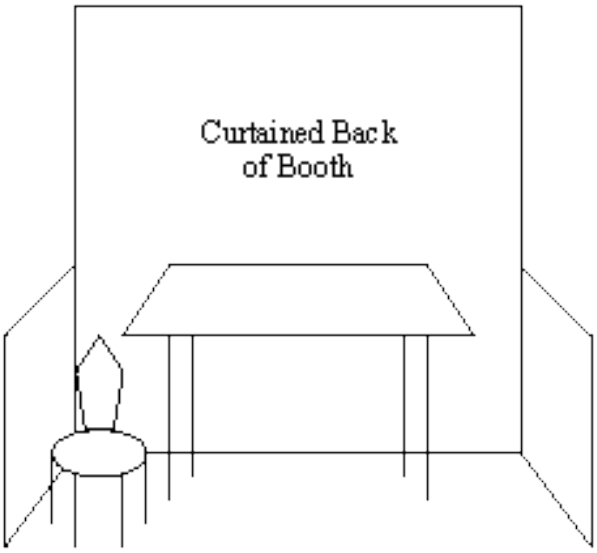
Maximum Size of Project

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

Note: Do not use glass if you frame the following documents for vertical display:

- 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

Forms including, but not limited to **Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, Approval Form (1B)** which are required for the project or for Scientific Review Committee approval do not have to be displayed as part of the project, but must be available in the booth in case asked for by a judge or other Intel ISEF official. Informed consents are confidential and must not be displayed. A photograph/video release form signed by the human participant is required for visual images of humans (other than the Finalist) displayed as part of the project.

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, DVDs, flash drives, brochures, booklets, nor endorsements, and/or acknowledgments** (graphic or written) unless the item(s) are an integral part of the project (Exception: Past and present 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. Postal addresses, world wide web and e-mail addresses, telephone and fax numbers of Finalist
17. Active Internet or e-mail connections as part of displaying or operating the project at the Intel ISEF
18. 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.
19. Glass or glass objects unless deemed by the Display and Safety Committee to be an integral and necessary part of the project (for example: glass that is an integral part of a commercial product such as a computer screen)
20. 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. Any photograph/visual image/chart/table and/or graph if:
   a. It is not deemed offensive or inappropriate by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. (Most frequently, visually offensive photographs/images show invertebrate or vertebrate animals/humans in improper conditions or situations.) The decision by any one of the groups mentioned above is final.
   b. It has a credit line of origin ("Photograph taken by..." or "Image taken from..." or "Graph/chart/table taken from ..."). (If all images,, etc. being displayed were taken or created by the Finalist or are from the same source, one credit line prominently and vertically displayed is sufficient.)
   c. It is from the Internet, magazine, newspaper, journal, etc., and credit lines are attached. (If all photographs, etc. are from the same source, one credit prominently and vertically displayed is sufficient.)
   d. It is a photograph or visual depiction of the Finalist.
   e. It is a photograph or visual depiction for which signed consent form is 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

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

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

- Animal Sciences ☐
- Behavioral and Social Science ☐
- Biochemistry ☐
- Cellular and Molecular Biology ☐
- Chemistry ☐
- Computer Science ☐
- Earth Science ☐
- Eng. Materials and Bioengineering ☐
- Engineering.: Electrical and Mechanical ☐
- Energy and 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
   ☐ vertebrate animals
   potentially hazardous biological agents:
   ☐ 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 Committee.

FOR INTEL ISEF OFFICIAL USE ONLY

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 Participants

1) *Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*
http://ohsr.od.nih.gov/guidelines/45cfr46.html

2) Dunn, C. M. and Chadwick, G. L., *Protecting Study Volunteers in Research: 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, "Protecting Human Research Participants" also provides similar information:
http://www.cancer.gov/clinicaltrials/conducting/protecting-participants/Page2

3) Penslar, R.L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH
http://www.hhs.gov/ohrp/archive/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.aspx

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

Vertebrate Animals
Animal Care and Use

1) Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
http://dels.nas.edu/ilar

2) *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/global/ilar/Guide

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
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)
2441 Village Green Place,
Champaign, IL 61822
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
http://www.fisheries.org/afs/docs/policy_16.pdf

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@ars.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

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@teh.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@jhsph.edu
   http://caat.jhsph.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; (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/biosafety/

5) World Health Organization Laboratory Safety Manual
   http://www.who.int/diagnostics_laboratory/guidance/en/

   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 (800) 227-5558
   email: pss@acs.org,
   website: http://www.acs.org/education

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/resources/

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/

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/biosafety/publications/index.htm

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

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

ALL Projects

1. United States Patent and Trade Office
   Customer Service: 1-800-786-9199 (toll-free); 571-272-1000 (local); 571-272-9950 (TTY)
   http://www.uspto.gov/
   http://www.uspto.gov/patents/process/index.jsp

2. European Patent Office
   http://www.epo.org/
   http://www.epo.org/applying/basics.html

Intel ISEF Categories and Subcategories

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

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

ANIMAL SCIENCES
Animal Husbandry
Development
Ecology
Pathology
Physiology
Populations Genetics
Systematics
Other

BEHAVIORAL & SOCIAL SCIENCES
Clinical & Developmental Psychology
Cognitive Psychology
Physiological Psychology
Sociology
Other

BIOCHEMISTRY
General Biochemistry
Metabolism
Structural Biochemistry
Other

CELLULAR AND MOLECULAR BIOLOGY
Cellular Biology
Cellular and Molecular Genetics
Immunology
Molecular Biology
Other

CHEMISTRY
Analytical Chemistry
General Chemistry
Inorganic Chemistry
Organic Chemistry
Physical Chemistry
Other

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

EARTH & PLANETARY SCIENCE
Climatology, Weather
Geochemistry, Mineralogy
Paleontology
Geophysics
Planetary Science
Tectonics
Other

ENGINEERING: Electrical & Mechanical
Electrical Engineering, Computer Engineering, Controls
Mechanical Engineering,
Robotics
Thermodynamics, Solar
Other

ENGINEERING: Materials & Bioengineering
Bioengineering
Chemical Engineering
Civil Engineering, Construction Eng.
Industrial Engineering, Processing
Material Science
Other

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

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

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

MATHEMATICAL SCIENCES
Algebra
Analysis
Applied Mathematics
Geometry
Probability and Statistics
Other

MEDICINE & HEALTH SCIENCES
Disease Diagnosis and Treatment
Epidemiology
Genetics
Molecular Biology of Diseases
Physiology and Pathophysiology
Other

MICROBIOLOGY
Antibiotics, Antimicrobials
Bacteriology
Microbial Genetics
Virology
Other

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

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

Checklist for Adult Sponsor (1)

This completed form is required for ALL projects.

To be completed by the Adult Sponsor in collaboration with the student researcher(s):

Student's Name(s): _____

Project Title: _____

1) ☐ I have reviewed the Intel ISEF Rules and Guidelines.
2) ☐ I have reviewed the student's completed Student Checklist (1A) and Research Plan.
3) ☐ I have worked with the student and we have discussed the possible risks involved in the project.
4) ☐ The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC:
   - ☐ Humans
   - ☐ Vertebrate Animals
   - Potentially Hazardous Biological Agents
     - ☐ Microorganisms ☐ rDNA ☐ Tissues
5) ☐ Items to be completed for **ALL PROJECTS**
   - ☐ Adult Sponsor Checklist (1)
   - ☐ Student Checklist (1A)
   - ☐ Research Plan
   - ☐ Approval Form (1B)
   - ☐ Regulated Research Institutional/Industrial Setting Form (1C) (when applicable after completed experiment)
   - ☐ Continuation Form (7) (when applicable)

6) **Additional forms required if the project includes the use of one or more of the following** (check all that apply):
   - ☐ **Humans** (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.)
     - ☐ Human Participants Form (4) or appropriate Institutional IRB documentation
     - ☐ Sample of Informed Consent Form (when applicable and/or required by the IRB)
     - ☐ Qualified Scientist Form (2) (when applicable and/or required by the IRB)
   - ☐ **Vertebrate Animals** (Requires prior approval, see full text of the rules.)
     - ☐ Vertebrate Animal Form (5A)—for projects conducted in a school/home/field research site (SRC prior approval required.)
     - ☐ Vertebrate Animal Form (5B)—for projects conducted at a Regulated Research Institution. (Institutional Animal Care and Use Committee (IACUC) approval required prior experimentation.)
     - ☐ Qualified Scientist Form (2) (Required for all vertebrate animal projects at a regulated research site or when applicable)
   - ☐ **Potentially Hazardous Biological Agents** (Requires prior approval by SRC, IACUC or Institutional Biosafety Committee (IBC), see full text of the rules.)
     - ☐ Potentially Hazardous Biological Agents Risk Assessment Form (6A)
     - ☐ Human and Vertebrate Animal Tissue Form (6B)—to be completed in addition to Form 6A when project involves the use of fresh or frozen tissue, primary cell cultures, blood, blood products and body fluids.
     - ☐ Qualified Scientist Form (2) (when applicable)
     - ☐ Risk Assessment Form (3) Required for projects involving protists, archae and similar microorganisms and for projects using manure for composting, fuel production or other non-culturing experiments (6A, 6B and 2 are not required)
   - ☐ **Hazardous Chemicals, Activities and Devices** (No prior approval required, see full text of the rules.)
     - ☐ Risk Assessment Form (3)
     - ☐ Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable)

Adult Sponsor's Printed Name	Signature	Date of Review

Phone	Email

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). Please include your name on each page.
The research plan for ALL projects is to include the following:

A. Question or Problem being addressed

B. Goals/Expected Outcomes/Hypotheses

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 participants research**:
   - **Participants.** 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 participants? 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?
   - **Risk Assessment**
     - **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, source, 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 Intel 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 and the Intel ISEF.

Student's Printed Name	Signature	Date Acknowledged (Must be prior to experimentation.)

b) Parent/Guardian Approval: I 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 Intel ISEF Rules. **Attach (1C) and required institutional approvals (e.g. IACUC, IRB)**

SRC Chair's Printed Name

Signature | Date of Approval

3) Final Intel 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 Intel ISEF Rules.

Regional SRC Chair's Printed Name	Signature	Date of Approval
State/National SRC Chair's Printed Name *(where applicable)*	Signature	Date of Approval

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(s)_____

Title of Project _____

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

The student(s) conducted research at my work site:

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

1) Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐ No

2) How did the student get the idea for her/his project? Was it a subset of your work? (e.g. Was the project assigned, picked from a list, an original student idea, etc.)

3) Did the student(s) 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(s) 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/students' 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 (must be after experimentaiton) _____

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(s) _____

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 Intel 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(s) _____

Title of Project _____

To be completed by the Student Researcher in collaboration with Designated Supervisor/Qualified Scientist: (All questions must be answered; additional page(s) may be attached.)

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

_____ _____
Position & Institution Phone or email contact information

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

Human Participants Form (4)

Required for all research involving human participants not conducted at a Registered Research Inst. (IRB approval required before experimentation.)

Student's Name(s) _____ Title of Project _____

Adult Sponsor _____ Contact Phone/Email _____

Must be completed by Student Researcher(s) 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 Participants Section of the Research Plan Instructions.
2. ☐ I have attached any surveys or questionnaires I will be using in my project.
   ☐ Any published instrument(s) used was /were legally obtained.
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: _____

Must 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 Participants 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 participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
4. Written Parental Permission required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Informed Consent required for participants 18 years or older:
   ☐ Yes ☐ No ☐ Not applicable (No participants 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/Professional License
Signature	Date of Approval

Educator	
Printed Name	Degree/Professional License
Signature	Date of Approval

Human Informed Consent Form

Instructions to the Student Researcher(s): 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 participant (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(s): _____

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:

Potential Risks of Study:

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
Printed Name of Research Participant: Date Reviewed & Signed: _____
Signature:

_____

Parental/Guardian Permission (if applicable) Date Reviewed & Signed: _____

Parent/Guardian Printed Name: Signature:

_____ _____

Vertebrate Animal Form (5A)

Required for all research involving vertebrate animals that is conducted in a school/home/field research site. (SRC approval required before experimentation.)

Student's Name(s) _____

Title of Project _____

_____

To be completed by Student Researcher:

1. Common name (or Genus, species) and number of animals used.

2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc.

3. What will happen to the animals after experimentation?

4. Attach a copy of wildlife licenses or approval forms, as applicable.

To be completed by Scientific Review Committee (SRC) BEFORE experimentation

Level of Supervision Required for agricultural, behavioral or nutritional studies:

☐ Designated Supervisor REQUIRED. Please have applicable person sign below.

☐ Veterinarian and Designated Supervisor REQUIRED. Please have applicable persons sign below.

☐ Veterinarian, Designated Supervisor and Qualified Scientist REQUIRED. Please have applicable persons sign below and have the Qualified Scientist complete Form (2).

The SRC has carefully reviewed this study and finds it is an appropriate study that may be conducted in a non-regulated research site.
SRC Pre-Approval Signature:

_____

SRC Chair Printed Name | Signature | Date of Approval

To be completed by Veterinarian:

☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation.

☐ I certify that I have approved the use and dosages of prescription drugs and/or nutritional supplements.

☐ I certify that I will provide veterinary medical and nursing care in case of illness or emergency.

Printed Name _____ Email/Phone _____

Signature _____ Date of Approval _____

To be completed by Designated Supervisor or qualified supervisor when applicable:

☐ I certify that I have reviewed this research and animal husbandry with the student before the start of experimentation and I accept primary responsibility for the care and handling of the animals in this project.

☐ I certify that I will directly supervise the experiment.

Printed Name _____ Email/Phone _____

Signature _____ Date of Approval _____

Vertebrate Animal Form (5B)

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

Student's Name(s) _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

_____

To be completed by Qualified Scientist or Principal Investigator:

1. Species of animals used: _____ Number of animals used: _____

2. a. Pain designation for the IACUC protocol: _____

   b. Pain designation for student's project: _____

3. Describe, in detail, the role of the student in this project: animal procedures and related equipment that were involved with, oversight provided and safety precautions employed. (Attach extra pages if necessary.)

4. Does the student's project also involve the use of tissues?
   - ◯ No
   - ◯ Yes, Be sure to complete Forms 6A and 6B

5. What laboratory training, including dates, was provided to the student?

6. 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

_____ _____

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

_____ _____ _____

Qualified Scientist/Principal Investigator Printed Name Signature Date

_____ _____ _____

IACUC Chair/Coordinator Printed Name Signature Date

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(s) _____

Title of Project _____

To be completed by Student Researcher(s) 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 procedures that will be used to minimize risk. (personal protective equip., hood type, etc.)

4. What final biosafety level do you recommend for this project given the risk assessment you conducted?

5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

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

QS/DS Printed Name	Signature	Date of Signature

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 Intel 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 Intel 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(s) _____

Title of Project _____

To be completed by Student Researcher(s):

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

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(s) _____

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 2008–2009 and earlier projects.

Components	Current Research Project	Previous Research Project
1. Title		2010–2011 2009–2010
2. Change in goal/purpose/ objective		2010–2011 2009–2010
3. Changes in methodology		2010–2011 2009–2010
4. Variables studied		2010–2011 2009–2010
5. Additional changes		2010–2011 2009–2010

Attached are:

☐ 2010–2011 Abstract and Research Plan ☐ 2009–2010 Abstract and Research Plan

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(s) Signature Date of Signature

Intel Corporation
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 3 million hours, toward improving education in more than 65 countries, regions, and territories. 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.

Through its acclaimed education competitions and its award-winning magazines, *Science News* and *Science News for Kids,* SSP is committed to inform, educate, and inspire.

www.societyforscience.org

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

www.societyforscience.org/isef

Intel International Science and Engineering Fair

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