

International Rules for Precollege Science Research: Guidelines for Science and Engineering Fairs 2009-2010

A Publication of

Society for Science & the Public

1719 N Street, NW

Washington, DC 20036-2888

Tel: 202/785-2255; Fax: 202/785-1243

email: sciedu@societyforscience.org

specific rules questions: src@societyforscience.org

Available online: <http://www.societyforscience.org/isef/primer/rules.asp>

Downloadable at: www.societyforscience.org/isef/document/index.asp

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Acknowledgments

Fair directors, teachers, scientists, parents, and adult volunteers inspire and encourage students to explore and investigate their world through hands-on research. Those of you who work with these young people are rarely recognized and never can be adequately thanked. Without you, precollege science and engineering projects and science and engineering fairs would not be possible. We applaud your commitment and appreciate your hard work. We sincerely hope that our efforts to enhance these Rules will serve you in working with students.

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

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

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

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

Intel ISEF SRC

Dr. Nancy Aiello, Chairperson (EST)
home: 540-554-8748

Dr. James Stevens (MST)
office: 303-724-0424, home: 303-696-1504, cell: 303-921-1076, fax: 303-724-3005

Mr. Henry Disston (EST)
office: 215-895-5840, fax: 215-895-5842

Mrs. Christine Miller (PST)
home: 775-847-7129, cell: 775-722-3134

Mrs. Evelyn Montalvo (EST)
(English or Spanish inquiries)
school: 787-834-2150, home: 787-833-0287, fax: 787-265-2500

Dr. Paula Johnson (PST)
office: 520-621-3483

Dr. Patricia Bossert (EST)
home: 631-757-5411; cell: 631-793-8237

Dr. Jennifer Green (EST)
office: 513-529-2448

Mr. Marcus Friskop (CST)
school: 701-242-7138; home: 701-242-7650

Mr. Jason Shuffitt (CST)
home: 270-843-6635; cell: 270-792-2557

**These Rules apply to the
Intel International Science and Engineering Fair 2010
San Jose, California, USA, May 9-15, 2010**

PERMISSION TO REPRINT WITH CREDIT GRANTED
Available on our website at www.societyforscience.org/isef/

*This is the last printed version of the International Rules and Guidelines;
The Rules will continue to be updated annually and made available on the website.*

❖ Changes & Modifications for 2009-May 2010 ❖

Human Subjects

- Reorganization of the human subjects rules; additional resources are on the website.
- Reorganization of Human Subjects Form 4; Form 4 no longer serves as an informed consent document.
- Student researcher/Qualified Scientist can develop their own informed consent form based on sample provided.
- Clarification of waiver of informed consent/assent/parental permission by IRB.

Vertebrate Animals

- A veterinarian must be consulted in experiments involving prescription drugs and/or nutritional supplements in a non-regulated setting.

Potentially Hazardous Biological Agents

- Commercially available coliform test kits require a Risk Assessment Form 3
- Laboratory studies utilizing MRSA and VRE are prohibited

Form and Other Changes

- Human Subjects Form 4 is no longer to be used as a photo consent; guidance on creating a photo consent is in the Display & Safety section of the rules.
- “Educator” replaces “science educator” for membership on IRB’s and SRC’s.

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

❖ The Rules on the Web ❖

www.societyforscience.org/isef/primer/rules.asp

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.

❖ 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/Page.aspx?pid=470 for a full description and definition of the Intel ISEF categories:

ANIMAL SCIENCES

Development
Ecology
Animal Husbandry
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
Software Engineering., Programming Languages
Computer System, Operating System
Other

EARTH & PLANETARY SCIENCE

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

ENGINEERING: Electrical & Mechanical

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

ENGINEERING: Materials & Bioengineering

Bioengineering
Civil Engineering, Construction Eng.
Chemical Engineering
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

Atoms, Molecules, Solids
Astronomy
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

❖ Intel ISEF Display and Safety Regulations ❖

Please address any questions regarding Intel ISEF Display and Safety Regulations to:
John O. Cole, Display and Safety Committee Chair, E-mail: dejavu60@msn.com

General Requirements

The Intel ISEF Display and Safety Committee is the final authority on display and safety issues for projects approved by the SRC to compete in the Intel ISEF. Occasionally, the Intel ISEF Display and Safety Committee may require students to make revisions in their display to conform to display and safety regulations.

Maximum Size of Project

Depth (front to back): 30 inches or 76 centimeters

Width (side to side): 48 inches or 122 centimeters

Height (floor to top): 108 inches or 274 centimeters

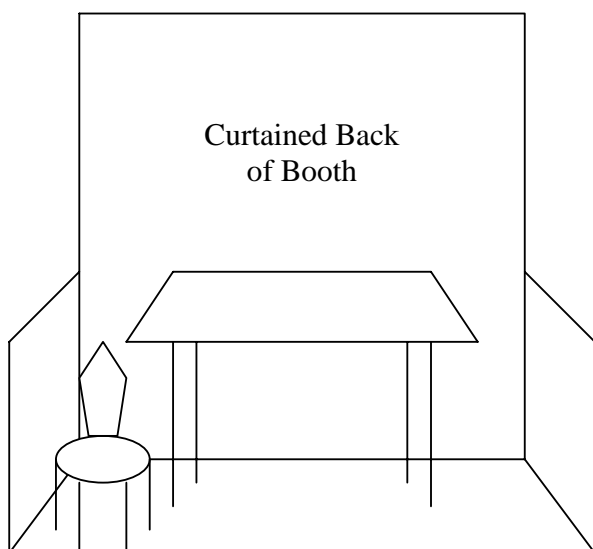
At the Intel ISEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters).

Maximum project sizes include all project materials, supports, and demonstrations for public and judges. If a table is used, it becomes part of the project and must not itself exceed the allowed dimensions nor may the table plus any part of the project exceed the allowed dimensions.

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

Position of Project

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



Required to Be Visible and Vertically Displayed at the Intel ISEF

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

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

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

Handouts/Official Abstract and Certification at the Intel ISEF

The Intel ISEF Scientific Review Committee defines the "official abstract and certification" as an **UNALTERED** original abstract and certification as stamped/embossed by the Intel ISEF Scientific Review Committee. If the Scientific Review Committee requires a Finalist to make changes to the abstract and certification submitted with registration papers, the revised version will be stamped/embossed, will replace the earlier version, and will become the Finalist's official abstract and certification.

The only abstract allowed anywhere at a project is the official abstract. The term "abstract" may not be used as a title or reference for any information on a Finalist's display or in a Finalist's materials at the project except as part of displaying the official abstract.

An original stamped/embossed official abstract and certification must appear on the display board or in a vertical position at the project. Handouts to judges and to the public must be limited to **UNALTERED photocopies** of the official abstract and certification.

Not Allowed at Project or in Booth

1. Living organisms, including plants
2. Taxidermy specimens or parts
3. Preserved vertebrate or invertebrate animals
4. Human or animal food
5. Human/animal parts or body fluids (for example, blood, urine)
6. 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)
7. All chemicals including water (Exceptions: water integral to an enclosed, sealed apparatus.)
8. 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”)]
9. Dry ice or other sublimating solids
10. Sharp items (for example, syringes, needles, pipettes, knives)
11. Flames or highly flammable materials
12. Batteries with open-top cells
13. **Awards, medals, business cards, flags, logos, endorsements, and/or acknowledgments** (graphic or written) unless the item(s) are an integral part of the project (Exception: Intel ISEF medal(s) may be worn at all times.)
14. Photographs or other visual presentations depicting vertebrate animals in surgical techniques, dissections, necropsies, or other lab procedures
15. Active Internet or e-mail connections as part of displaying or operating the project at the Intel ISEF
16. 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.
17. Glass or glass objects unless deemed by the Display and Safety Committee to be an integral and necessary part of the project (Exception: glass that is an integral part of a commercial product such as a computer screen)
18. 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 BUT with the Restrictions Indicated

1. Soil, sand, rock, and/or waste samples **if permanently encased in a slab of acrylic**
2. Postal addresses, World Wide Web and e-mail addresses, telephone and fax numbers **of Finalist only**
3. Photographs and/or visual depictions **if:**
 - a. They are not deemed offensive or inappropriate by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. This includes, but is not limited to, visually offensive photographs or visual depictions of invertebrate or vertebrate animals, including humans. The decision by any one of the groups mentioned above is final.
 - b. They have credit lines of origin (“Photograph taken by...” or “Image taken from...”). (If all photographs being displayed were taken by the Finalist or are from the same source, one credit line prominently and vertically displayed is sufficient.)
 - c. They are from the Internet, magazines, newspapers, journals, etc., and credit lines are attached. (If all photographs/images are from the same source, one credit prominently and vertically displayed is sufficient.)
 - d. They are photographs or visual depictions of the Finalist.
 - e. They are photographs of human subjects for which signed consent forms are at the project or in the booth.
4. Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points **if for display only and not operated.**
5. 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)
6. 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.
7. 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, p. 27.*)
8. Any apparatus producing temperatures that will cause physical burns if adequately insulated
9. 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. No changes, modifications, or additions to projects may be made after approval by the Display and Safety Committee and the Scientific Review Committee.
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.

❖ ALL PROJECTS ❖

❖ Ethics Statement

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs or the Intel ISEF.

❖ Eligibility/Limitations

- 1) Each ISEF-affiliated fair may send up to two Individual Project Finalists and one Team Project of two or three Finalists to the Intel ISEF.
- 2) Any student selected by an ISEF-affiliated fair must 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 2009 and May 2010.
- 4) 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.
- 5) Team projects may have a maximum of three members.
- 6) Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.
- 7) A research project may be a part of a larger study done by professional scientists, but the project presented by the student may 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) 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.
- 5) Intel ISEF exhibits must adhere to Intel ISEF display and safety requirements.
- 6) **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

- 7) Before experimentation begins, an Institutional Review Board (IRB) or Scientific Review Committee (SRC) must review and approve most projects involving human subjects, vertebrate animals, and potentially hazardous biological agents. See the appropriate sections of the Rules Book.
- 8) 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.
- 9) A Qualified Scientist is required for all studies involving BSL-2 potentially hazardous biological agents, DEA-controlled substances, many human subject studies and many vertebrate animal studies.
- 10) 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.
- 11) 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.
- 12) Any continuing project must document that the additional research is new and different. (See **Continuation Projects Form (7)**)
- 13) 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.
- 14) 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.
- 15) A project data book and research paper are not required, but are recommended. (See *Student Handbook*; Regional fairs may have different requirements).
- 16) All signed forms, certifications, and permits must be available for review by an SRC just before each fair a student enters.

❖ Continuation of Projects

- 1) As in the professional world, research projects may be done that build on work done in previous years. Students will be judged only on the most recent year's research. The project year includes research conducted over a maximum of 12 continuous months from January 2009- May 2010.
- 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 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.

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 in the upper right hand corner with the year (ex: 2008-2009). Please retain all prior years' paperwork in case an SRC requests additional documentation.

❖ Team Projects

- 1) Team Projects compete in a separate "team" category against all other Team Projects. An ISEF Affiliated Fair has the option of sending a team project, in addition to two individual projects, to the Intel ISEF. ISEF-Affiliated Fairs are not required to have Team Projects, but are encouraged to do so.
- 2) Teams may have up to three members. **NOTE:** Teams may not have more than three members at a local fair and then eliminate members to qualify for the Intel ISEF.
- 3) Team membership cannot be changed during a given research year including converting from an individual project or vice versa, but may be altered in subsequent years.
- 4) Each team should appoint a team leader to coordinate the work and act as spokesperson. However, each member of the team should be able to serve as spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members and will be evaluated using similar rules and judging criteria as individual projects.
- 5) Each team member must submit an **Approval Form (1B)**. However, team members must jointly submit the **Checklist for Adult Sponsor (1)**, one abstract, a **Student Checklist (1A)**, a **Research Plan** and other required forms.
- 6) Full names of all team members must appear on the abstract and forms.

❖ Roles and Responsibilities of Students & Adults ❖

1) The Student Researcher(s)

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

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs or the Intel ISEF.

2) The Adult Sponsor

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

The Adult Sponsor is responsible for working with the student to evaluate any possible risks involved in order to ensure the health and safety of the student conducting the research and the humans or animals involved in the study. The Adult Sponsor must review the student's **Student Checklist (1A)** and **Research Plan** to make sure that: a) experimentation is done within local, state, and federal laws and these International Rules; b) that forms are completed by other adults involved in approving or supervising any part of the experiment; and c) that criteria for the Qualified Scientist adhere to those set forth below.

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

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

3) The Qualified Scientist

A Qualified Scientist should possess an earned doctoral/professional degree in the biological or medical sciences as it relates to the student's area of research. However, a master's degree with equivalent experience and/or expertise in the student's area of research is acceptable when approved by a Scientific Review Committee (SRC). The Qualified Scientist must be thoroughly familiar with the local, state, and federal regulations that govern the student's area of research.

The Qualified Scientist and the Adult Sponsor may be the same person, if that person is qualified as outlined above. A student may work with a Qualified Scientist in another city or state. In this case, the student must work locally with a Designated Supervisor (see below) who has been trained in the techniques the student will use.

4) The Designated Supervisor

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

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

5) The Institutional Review Board (IRB)

An Institutional Review Board (IRB) is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving human subjects. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

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

An IRB must include:

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

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

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

IRBs exist at federally regulated institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research subjects are at a correctional facility. The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor and the local IRB are responsible for ensuring that the project is appropriate for a pre-college student and adheres to the ISEF rules.

An IRB generally makes the final determination of risk. However, in reviewing projects just prior to a fair, if an 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 ISEF Affiliated Fair SRC in reviewing and approving projects. The operation and composition of the local and ISEF-Affiliated Fair SRCs must fully comply with the International Rules.

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

ALL projects must be reviewed and approved by the SRC after experimentation and shortly before competition in an ISEF-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.)

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

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

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

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

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

- a) evidence of literature search
- b) evidence of proper supervision
- c) use of accepted and appropriate research techniques
- d) completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (when needed)
- e) evidence of search for alternatives to animal use
- f) humane treatment of animals
- g) compliance with rules and laws governing human, animal research and those involving potentially hazardous biological agents
- i) documentation of substantial expansion for continuation projects
- 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 ISEF Scientific Review Committee (ISEF SRC)

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

The ISEF SRC, like an ISEF Affiliated Fair SRC, is made up of a group of adults knowledgeable about research regulations. The 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 ISEF Affiliated Fair SRC member with any questions regarding the process, should contact the Society for Science & the Public or a member of the ISEF SRC. (See page 3.)

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

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

❖ Human Subjects ❖

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

Exempt Studies

(Do Not Require IRB Preapproval or Human Subjects Paperwork)

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

- Testing of a student designed invention, program, concept, etc. where the feedback received is a direct reference to the product, where personal data is not collected and where the testing does not pose a health hazard. It is recommended that Risk Assessment Form (3) be completed.
- Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available or published and do not involve any interaction with human subjects or the collection of any data from a human subject for the purpose of the student's research project.
- Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which **all** of the following apply:
 - a) the researcher has no interaction with the individuals being observed
 - b) the researcher does not manipulate the environment in any way **and**
 - c) the researcher does not record any personally identifiable data.
- Projects in which the student receives the data in a **de-identified/anonymous** format which complies with both conditions below:
 - a) the professional providing the data must certify in writing that the data have been appropriately de-identified and are in compliance with all privacy and HIPAA laws and
 - b) during the final SRC review and approval process, the SRC must ensure that the data were appropriately de-identified by review of the written documentation provided by the supervising professional.

Rules

- 1) The use of human subjects in science projects is allowable under the conditions and rules in the following sections. Based upon the Code of Federal Regulations (45 CFR 46), the definition of a **human subject** is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information. **These projects require IRB review and preapproval** and may also require documentation of written informed consent/assent/parental permission. Examples of studies that are considered "human subjects research" requiring IRB preapproval include:
 - Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
 - Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
 - Studies in which the researcher is the subject of the research
 - Behavioral observations
 - a) that involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
 - b) that occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
 - c) that involve the recording of personally identifiable information
 - Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables.)
- 2) Student researchers must complete ALL elements of the Human Subjects portion of the Research Plan Instructions on p. 31, #1 and evaluate and minimize the physical, psychological and privacy risks to their human subjects. See risk assessment below and the online Risk Assessment Guide for additional guidance.
- 3) The research study should be in compliance with all privacy and HIPAA laws when they apply to the project (e.g. the project involves medical information.)
- 4) All research projects involving human subjects, including any revisions, must be reviewed and approved by an **Institutional Review Board (IRB)** before the student may begin recruiting and/or interacting with human subjects. After initial IRB approval, a student with any proposed changes in the **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.
- 5) The research subjects must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research subjects give their consent. Research subjects under 18 years of age or individuals not able to give consent (e.g. mentally disabled) give their assent, with their parents/guardians

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

- As part of the process of obtaining informed consent, the researcher will provide information to the subject (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study which then allows the subject, parents or guardians to make an educated decision about whether or not to participate.
 - Participants will also be informed that their participation is voluntary (i.e., they may decide whether or not to participate) and that they are free to stop participating at any time.
 - Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature on a page.
- 6) Research conducted by a pre-college student at federally regulated research institutions (e.g., universities, medical centers, NIH, correctional institutions, etc.) must be reviewed and approved by that institution's IRB. A copy of the IRB approval for the entire project (which must include the research procedures/measures the student is using) or an official letter from the IRB attesting to this approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.
 - 7) A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medications and performing invasive medical procedures on human subjects. The IRB must confirm that the student is not violating the medical practice act of the particular state or nation in which he/she is conducting the research.
 - 8) Student researchers may NOT publish or display information in a report that identifies the human subjects directly or through identifiers linked to the subjects, (including photographs), without written consent. (Public Health Service Act, 42, USC 241 (d)).
 - 9) All standardized tests that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements including procurement of legal copies of the instrument.
 - 10) Studies that involve the collection of data via use of the internet (e.g., email, web based surveys) are allowed but will pose challenges in a) collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the online Risk Assessment Guide for more detailed procedures.

- 11) After experimentation and shortly before fair competition, the SRC reviews and approves previously approved projects to make sure that students followed the approved **Research Plan** and the rules.
- 12) The following forms are required:
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Human Subjects Form (4)**
 - f. **Regulated Research Institution Form (1C)** - when applicable
 - g. **Qualified Scientist Form (2)** - when applicable

IRB Waiver of Written Informed Consent

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

- a) Research involving normal educational practices
- b) Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the subjects' behavior and the study does not involve more than minimal risk.
- c) Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
- d) Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

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

Risk Assessment

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

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

1) Physical Risks

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

2) Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress would be considered more than minimal risk. For example, answering questions related to personal experiences such as sexual, physical or child abuse, divorce, depression, anxiety, answering questions that could result in feelings of depression, anxiety or low self-esteem or viewing violent or distressing video images.

3) Invasion of Privacy

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

Risk level can be reduced by protecting confidentiality or collecting data that is truly anonymous.

Anonymity involves collecting research in such a way that it is impossible to connect research data with the individual who provided the data.

4) Risk Groups

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

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

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

www.societyforscience.org/isef/primer/rules.asp

Sources of Information

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

2) Dunn, C. M. and Chadwick, G. L., *Protecting Study Volunteers in Research: A Manual for Investigative Sites* (2002). Boston, MA: Thomson Centerwatch. ISBN 1-930624-36-0.

Can be purchased from:

<http://www.amazon.com>

NIH tutorial also provides similar information:

<http://www.cancer.gov/clinicaltrials/learning/page2>

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

4) *Belmont Report*, April 18, 1979
<http://ohsr.od.nih.gov/guidelines/belmont.html>

5) *Standards for Educational and Psychological Testing*. (1999). Washington, DC: AERA, APA, NCME.
To order call: (800) 628-4094. If outside US, call (717) 632-3535, Ext. 8087
<http://www.apa.org/science/standards.html>

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/infostu.html>

Information regarding publications:

<http://www.apa.org/publications/>

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/testing.html>

Many of the documents above are also available by contacting:

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

❖ Vertebrate Animals ❖

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

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

Rules for ALL Studies Involving Vertebrate Animals

- 1) The use of vertebrate animals in science projects is allowable under the conditions and rules in the following sections. Vertebrate animals, as covered by these rules, are defined as live, nonhuman vertebrate mammalian embryos or fetuses, tadpoles, bird and reptile eggs within three days (72 hours) of hatching, and all other nonhuman vertebrates (including fish) at hatching or birth.
- 2) Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following “3 R’s”:
 - Replace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures or computer simulations
 - Reduce the number of animals without compromising statistical validity
 - Refine the experimental protocol to lessen pain or distress to the animals.
- 3) **Research projects which cause more than momentary pain or suffering to vertebrate animals or which are designed to kill vertebrate animals are prohibited.** (Note: Humane euthanasia is permitted under certain conditions when the research is conducted at a regulated research institution. See Section B.)
- 4) The following types of studies on vertebrate animals are **prohibited**:
 - a. All induced toxicity studies involving a poison or toxin that could impair health or destroy life, including alcohol, acid rain, insecticide, herbicide, or heavy metals.
 - b. Behavioral experiments involving operant conditioning with aversive stimuli, mother/infant separation or induced helplessness
 - c. Studies of pain
 - d. Predator/vertebrate prey experiments
- 5) Because weight loss is one significant sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.
- 6) If an experimental design requires food or water restriction, it must be appropriate to the species, but may not exceed 18 hours.
- 7) If there are unexpected deaths in either the experimental or control groups, the cause of the death must be investigated. If the experimental procedure is responsible for the deaths, the experiment must be immediately terminated. A death rate of 30% or greater in any group or subgroup is not permitted and the project will fail to qualify for competition.
- 8) Students performing vertebrate animal research must follow local, state, country and U.S. federal regulations.
- 9) Except for observational studies, a Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals.
- 10) A Scientific Review Committee (SRC) and/or an Institutional Animal Care and Use Committee (IACUC) must approve all research before experimentation begins. (An IACUC is the review and approval body at a regulated research institution for all animal studies.) The research plan for vertebrate animal studies must include the following:
 - a. Justify why animals must be used, including the reasons for the choice of species and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.
 - b. Describe in detail, how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.
- 11) After initial SRC approval, a student with any proposed changes in the **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.
- 12) Studies involving behavioral observations of animals are exempt from prior SRC review if **ALL** of the following apply:
 - There is no interaction with the animals being observed,
 - There is no manipulation of the environment in any way and
 - All federal or state fish, game and wildlife laws and regulations are followed.
- 13) Certain types of vertebrate animal studies may be conducted at home, school or other non-regulated research sites, whereas other studies must be conducted at a regulated research institution. See A. Non-regulated Research Site and B. Regulated Research Site below for rules and site descriptions.

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

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

- Studies involving animals in their natural environment
 - Studies involving animals in zoological parks
 - Studies involving livestock that use standard agricultural practices.
- 1) These projects must adhere to BOTH of the following guidelines:
 - a. The research involves agricultural, behavioral, observational or supplemental nutritional studies on animals.
AND
 - b. The research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

(Note: All studies not meeting the above criteria must be conducted at a Regulated Research Institution. See Section B. below.)

- 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 prior SRC approval. A veterinarian must be consulted in experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.
- 4) If an unexpected illness or emergency occurs, the affected animals must have proper medical and nursing care that is directed by a veterinarian. A student researcher is expected to stop experimentation if there is significant weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors.

- 5) Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. Fish may be obtained from the wild only if the researcher releases the fish unharmed, has the proper license, and adheres to state and local fishing laws and regulations.
- 6) The final disposition of the animals must be considered and explained on **Vertebrate Animal Form (5A)**. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a non-regulated site.
- 7) **The following forms are required:**
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Vertebrate Animal Form (5A)**
 - f. **Qualified Scientist Form (2), when applicable**

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

All studies not meeting the criteria in Section A. must be conducted in a regulated research institution. A regulated research institution is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers For Disease Control. In addition, pharmaceutical and biotechnology companies that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and program structured in compliance with U.S. federal laws are included in this definition.

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

- 1) The Institutional Animal Care and Use Committee (IACUC) must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local SRC must also review the project to certify that the research project complies with ISEF Rules. This SRC review should occur before experimentation begins.

- 2) Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. Student researchers are prohibited from performing euthanasia; only the Qualified Scientist or an institutional representative may perform the euthanasia. All methods of euthanasia must adhere to current AVMA Guidelines.
- 3) Research projects that cause more than momentary pain or suffering to vertebrate animals are prohibited. The following table relates the USDA Pain Categories and the permissibility of studies for science fair projects.

USDA Pain Categories	Definition	ISEF Guidelines
Category A	Live animals will receive non-painful manipulation. Animals may be euthanized to obtain tissues, cells, etc.	Permitted
Category B	Live animals will receive momentary pain or stressful stimulus without anesthesia, which results in a short-term response. Examples include but are not limited to: injections, field trapping/tagging, blood sampling and standard agricultural husbandry practices.	Permitted
Category C	Live animals will have significant manipulations, surgery, etc., performed while anesthetized. The animals will be euthanized at the termination of the procedure without regaining consciousness.	Permitted only with proper training and certification
Category D	Live animals will have manipulations performed while anesthetized and are allowed to recover and/or animals will develop discernable clinical signs indicating pain, distress, or significant physiological changes <u>spontaneously</u> or <u>as a result of specific experimental procedures</u> . Examples include, but are not limited to: Survival surgical procedures of any type and some studies which would include tumor development. ALL SUCH STUDIES MUST INCLUDE TREATMENT TO ALLEVIATE PAIN OR DISTRESS.	Limited Category D procedures are permitted with proper training and certification. The project must adhere to all ISEF rules. Most Category D projects would be deemed inappropriate for high school students.
Category E	Live animals will experience significant/severe pain or distress, without benefit of anesthetics, tranquilizers or analgesics.	PROHIBITED

- 4) Research in nutritional deficiency, ingestion, inoculation or exposure to unknown or potentially hazardous materials or drugs is permitted to proceed only to the point where the first sign of the deficiency or effect appear. Appropriate measures must then be taken to correct the deficiency or drug effect, if such action is feasible. If not, the animal(s) must be euthanized.
- 5) The following forms are required:
 - a. **Checklist for Adult Sponsor (1)**
 - b. **Student Checklist (1A)**
 - c. **Research Plan**
 - d. **Approval Form (1B)**
 - e. **Regulated Research Institution Form (1C)**
 - f. **Vertebrate Animal Form (5B)**
 - g. **Qualified Scientist Form (2)**

Sources of Information for Animal Care and Use

1) *Guide for the Care and Use of Laboratory Animals*, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
http://dels.nas.edu/ilar_n/ilarhome/reports.shtml

2) *Principles and Guidelines for the Use of Animals in Precollege Education* (a free pamphlet from ILAR)

Can be found online:

http://dels.nas.edu/ilar_n/ilarhome/reports.shtml

3) *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research* (2003), Institute for Laboratory Animal Research (ILAR).

To order these ILAR publications contact:

National Academies Press
 500 Fifth Street, NW
 Lockbox 285
 Washington, DC 20055
 phone: 888-624-8373 or 202-334-3313
 fax: 202-334-2451; <http://www.nap.edu>

4) Federal Animal Welfare Act (AWA)
 7 U.S.C. 2131-2157
 Subchapter A - Animal Welfare (Parts I, II, III)
<http://www.nal.usda.gov/awic/legislat/awicregs.htm>

Above document is available from:

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

5) *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*
 Federation of Animal Science Societies (FASS)
 1111 N. Dunlap Avenue
 Savoy, IL 61874
 phone: (217) 356-3182
 email: fass@assochq.org
<http://www.fass.org>

6) *Guidelines for the Use of Fish in Research* (2004), American Fisheries Society.
<http://www.fisheries.org/afs/publicpolicy.html>

7) Euthanasia Guidelines
AVMA Guidelines on Euthanasia (June 2007)
 American Veterinary Medical Association.
http://www.avma.org/issues/animal_welfare/euthanasia.pdf

Sources of Information for 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/entrez/query.fcgi>
- 2) National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.
Animal Welfare Information Center
National Agriculture Library
10301 Baltimore Avenue, Room 410
Beltsville, MD 20705-2351
phone: (301) 504-6212, fax: (301) 504-7125
email: awic@nal.usda.gov
<http://www.nal.usda.gov/awic>
- 3) Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in ILAR Journal.
ILAR
The Keck Center of the National Academies
500 Fifth Street, NW, Keck 687
Washington, DC 20001
phone: (202) 334-2590, fax: 202-334-1687
email: ILAR@nas.edu
<http://dels.nas.edu/ilar/>
- 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@tehl.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 ❖

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

Projects involving **microorganisms** (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), **recombinant DNA (rDNA) technologies** or **human or animal fresh/frozen tissues, blood, or body fluids** may involve working with potentially hazardous biological agents. Students are permitted to do research projects with potentially hazardous biological agents as long as every effort is made to ensure that they work safely and that the projects meet the conditions and rules described below. The following rules were developed to protect students and to help them adhere to federal and international biosafety regulations and guidelines.

When dealing with potentially hazardous biological agents it is the responsibility of the student and all of the adults involved in a research project to conduct and document a **risk assessment, (Form 6A)** to define the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The risk assessment determines a final biosafety level which then determines the laboratory facilities, equipment, training, and supervision required for the research project to proceed. See page 23.

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

Rules for ALL Studies Involving Potentially Hazardous Biological Agents

- 1) The use of potentially hazardous microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids is allowable under the conditions and rules that follow. All of these areas of research may involve potentially hazardous biological agents and require special precautions.
- 2) An appropriate review and approval committee (SRC, IBC, IACUC) must approve all research before experimentation begins. The initial risk assessment determined by the student researcher and adults supervising the project must be confirmed by the SRC.
- 3) Experimentation involving culturing of potentially hazardous biological agents, even BSL-1 organisms, **is prohibited in a home environment**. However, specimens are allowed to be collected at home as long as they are immediately transported to a laboratory with the appropriate level of biosafety containment.
- 4) **Research determined to be biosafety levels 3 or 4 is prohibited for precollege students.**
- 5) **Laboratory studies utilizing MRSA** (Methicillin resistant *Staphylococcus aureus*) **and VRE** (Vancomycin-resistant enterococci) **are prohibited.**
- 6) **Studies intended to genetically engineer bacteria with multiple antibiotic resistance are prohibited.** Extreme caution should be exercised when selecting out antibiotic resistant organisms. Studies using such organisms require at least BSL-2 containment.
- 7) Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
- 8) A risk assessment must be conducted by the student and adult supervisors prior to experimentation and a final biosafety level must be determined or confirmed by the SRC. See p. 23.
- 9) Research determined to be at Biosafety Level 1 (BSL-1) may be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Designated Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.
- 10) Research determined to be a Biosafety Level 2 (BSL-2) **MUST** be conducted in a laboratory rated BSL-2 or above (commonly found in a regulated research institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter obtained from an institutional representative that the research does not require review. The research must be supervised by a Qualified Scientist. The student researcher must receive extensive training, demonstrate competency and be directly supervised while conducting microbiological procedures.
- 11) All potentially hazardous biological agents must be properly disposed of at the end of experimentation in accordance with their biosafety level. Following are acceptable procedures for disposal of cultured materials: Autoclaving at 121 degrees Celsius for 20 minutes, use of 10% sodium hypochlorite, incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations.
- 12) Studies involving the culturing of human or animal waste, including sewage sludge, must be treated as a BSL-2 study.
- 13) The following types of studies are exempt from prior SRC review:
 - A. No additional forms required:
 - 1) Studies involving baker's yeast and brewer's yeast, except when involved with rDNA studies
 - 2) Studies involving *Lactobacillus*, *Bacillus thuringensis*, nitrogen-fixing, oil-eating bacteria, slime mold and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment that could potentially be contaminated).
 - B. Require completed Risk Assessment Form 3:
 - 1) Studies involving protists, archae and similar microorganisms
 - 2) Research using manure for composting or other non-culturing experiments and fuel production.
 - 3) Commercially-available color change coliform water test kits which will remain sealed and will be properly disposed.
- 14) Any proposed changes in the **Research Plan** by the student after initial SRC approval must have subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.

- 15) The following forms are required:
- Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)**
 - Regulated Research Institution Form (1C)** - when appl.
 - Qualified Scientist (2)**, when applicable
 - Risk Assessment (3)**, when applicable
 - PHBA Risk Assessment Form (6A)**
 - Human and Vertebrate Animal Tissue Form (6B)** – for all studies involving tissues and body fluids.

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.)

- Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
 - 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.
 - Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (i.e. counting presence of organisms or colonies).
 - The sealed Petri dish is disposed of in the appropriate manner under the supervision of the Designated Supervisor.
- If a culture container is opened for any purpose, it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.**

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

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

- All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli K12*, *S. cerevisiae*, and *B. subtilis* host-vector systems.
- 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.
- 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.

- 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.
- 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 vertebrate may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

- If tissues are obtained from an animal that was sacrificed for a purpose other than the students' project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.
- 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, pg 17.)
- Biosafety level 1 studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products, see rule 5) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies can be conducted in a BSL-1 laboratory and must be supervised by a Qualified Scientist or trained Designated Supervisor.
- Biosafety level 2 studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or 2. These studies must be conducted in a regulated research institution in a BSL-2 laboratory under the supervision of a Qualified Scientist.
- 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.
- Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2. Pasteurized domestic animal milk may be considered BSL-1.
- Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or 4 is prohibited.
- Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and informed consent. Students using their own body fluids are exempt from this requirement.

- 9) Studies involving human embryonic human stem cells must be conducted in a registered research institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.
- 10) The following types of tissue do not need to be treated as potentially hazardous biological agents:
- Plant tissue
 - Established cell and tissue cultures (e.g., obtained from the American Type Culture Collection). The source and catalog

- number of the cultures should be identified in the Research Plan
- Meat or meat by-products obtained from food stores, restaurants, or packing houses
 - Hair
 - 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.
 - Fossilized tissue or archeological specimens
 - Prepared fixed tissue

Risk Assessment

(Use this information to complete PHBA Risk Assessment Form 6A)

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

Risk assessment involves:

- **Assignment of the biological agent to a risk group**
 - 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 tumefaciens*, *Micrococcus leuteus*, *Neurospora crassa*, *Bacillus subtilis*.

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

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

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

Levels of Biological Containment

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

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

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

BSL-3 containment is required for infectious agents that may cause serious or potentially lethal diseases as a result of exposure by inhalation. **PROHIBITED**

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. **PROHIBITED**

Sources of Information

American Biological Safety Association: ABSA Risk Group
Classification – list of organisms
<http://www.absa.org>

American Type Culture Collection
(703) 365-2700; 1(800) 638-6597 (US, Canada, & PR)
<http://www.atcc.org>

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>

Biosafety in Microbiological and Biomedical Laboratories
(BMBL) - 4th Edition. Published by CDC-NIH,
To order: Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop F05
Atlanta, GA 30333

<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>

World Health Organization
Laboratory Safety Manual-3rd Edition
<http://www.who.int/csr/bioriskreduction/>

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](http://www.phac-aspc.gc.ca/ols-bsl/pathogen/organism_e.html)

Microorganisms for Education Website – list of organisms
<http://www.science-projects.com/safemicrobes.htm>

NIH Guidelines for Research Involving Recombinant DNA
Molecules. Published by National Institutes of Health.
<http://oba.od.nih.gov/oba/index.html>

OSHA – Occupational Health and Safety Administration
<http://www.osha.gov>

The Mad Scientist Network at Washington University
School of Medicine: <http://www.madsci.org>

❖ 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 listed below.
- 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. **Regulated 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. (see p. 14)
- 2) Administering any prescription drug to vertebrate animals must be done under all appropriate vertebrate animal rules and guidelines. (see p. 17) 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 referenced in the Sources of Information section below.

D. Firearms and Explosives

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

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

- 1) Projects involving firearms and explosives are allowable when conducted with the direct supervision of a Designated Supervisor and when in compliance with all federal, state and local laws.
- 2) A fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.

Note: Potato guns or paintball guns are not firearms unless they are intended to be used as weapons. They must be treated as hazardous devices.

Guidance for Risk Assessment

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

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

A. Hazardous Chemicals

A proper risk assessment of chemicals should include review of factors such as the degree of toxicity, reactivity, flammability or corrosiveness.

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

Reactivity - the tendency of a chemical to undergo chemical change

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

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

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

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

Environmentally Responsible Chemistry

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

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

B. Hazardous Devices

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

C. Radiation

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

- Class I lasers are those found in CD players, laser printers, geological survey equipment and some laboratory equipment. There are no known risks associated with using a Class I laser.
- Class II lasers are found in laser pointers, aiming and range finding devices and pose a risk if the beam is directly viewed over a long period of time.
- Class III lasers are found in higher powered laser pointers, printers and spectrometers. They are to be considered hazardous devices which can cause eye damage when the beam is directly viewed even for a short period of time.
- Class IV lasers are high powered lasers used in surgery, research, and industrial settings. They are extremely hazardous and can cause eye and skin damage from both direct and indirect exposure. The beam is also a fire hazard.

A risk assessment must be conducted when a student uses **ionizing radiation** beyond that normally encountered in everyday life. Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study. Depending upon the level of exposure, radiation released from these sources can be a health hazard. Most research institutions have a Radiation Safety Office which oversees the use of ionizing radiation and ensures compliance with state and federal regulations.

Sources of Information

General Lab/Chemical Safety

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

Order from (first copy free of charge):

American Chemical Society
Publications Support Services
1155 16th Street, NW
Washington, DC 20036
phone: (202) 872-4554 or 1-800-227-5558
email: pss@acs.org
website: <http://www.acs.org/publications>

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://catalog.hhmi.org/index.jsp>

Environmental Protection Agency (EPA) website for green chemistry: <http://www.epa.gov/greenchemistry>

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

DEA Controlled Substances

Drug Enforcement Agency website:
<http://www.usdoj.gov/dea>

Controlled Substance Schedules – a list of controlled substances : <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>

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>

Radiation

Radiation Studies Information (CDC)
<http://www.cdc.gov/nceh/radiation/default.htm>

CDC Laboratory Safety Manuals
<http://www.cdc.gov/od/ohs/safety/SUPSAFE.PDF>
<http://www.cdc.gov/od/ohs/safety/S2.pdf>

Occupational Safety and Health Administration Documents available from:

OSHA Publications
P.O. Box 37535
Washington, DC 20013-7535
phone: (202) 693-1888; fax: (202) 693-2498
<http://www.osha.gov>

PUB 8-1.7 - Guidelines for Laser Safety and Hazard Assessment
STD 1-4.1 - OSHA Coverage of Ionizing Radiation Sources Not Covered by Atomic Energy Act of 1954

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>

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 an 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.

Intel ISEF Sample Abstract & Certification

<p>Title _____</p> <p>Finalist's Name _____</p> <p>School Name, City and State, Country _____</p> <hr/> <p>Start Typing the Body of Your Abstract Here Beginning at the Left Margin</p>	<p>Category</p> <p>Pick one only-- mark an "X" in box at right</p> <ul style="list-style-type: none"> Animal Sciences <input type="checkbox"/> Behavioral and Social Science <input type="checkbox"/> Biochemistry <input type="checkbox"/> Cellular & Molecular Biology <input type="checkbox"/> Chemistry <input type="checkbox"/> Computer Science <input type="checkbox"/> Earth Science <input type="checkbox"/> Eng. Materials & Bioengineering <input type="checkbox"/> Eng.: Electrical & Mechanical <input type="checkbox"/> Energy & Transportation <input type="checkbox"/> Environmental Sciences <input type="checkbox"/> Environmental Management <input type="checkbox"/> Mathematical Sciences <input type="checkbox"/> Medicine and Health <input type="checkbox"/> Microbiology <input type="checkbox"/> Physics & Astronomy <input type="checkbox"/> Plant Sciences <input type="checkbox"/>
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1. As a part of this research project, the student directly handled, manipulated, or interacted with (check all that apply):

<input type="checkbox"/> human subjects	<input type="checkbox"/> potentially hazardous biological agents:
<input type="checkbox"/> vertebrate animals	<input type="checkbox"/> microorganisms <input type="checkbox"/> rDNA <input type="checkbox"/> 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

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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.

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.