International Rules for Precollege Science Research:

Guidelines for Science and Engineering Fairs

2006-2007

A Publication of

Science Service

1719 N Street, NW
Washington, DC 20036-2888
Tel: 202/785-2255; Fax: 202/785-1243
email: sciedu@sciserv.org
specific rules questions: src@sciserv.org

Available online: http://www.sciserv.org/isef/primer/rules.asp
Downloadable at: www.sciserv.org/isef/document/index.asp

Table of Contents

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. Science Service applauds your commitment and appreciates 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: Science Service

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

For specific rules questions, please email:
SRC@sciserv.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)
office: 787-834-2150, home: 787-833-0287, fax: 787-265-2500

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

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

These Rules apply to the
Intel International Science and Engineering Fair 2007 presented by Agilent Technologies
Albuquerque, New Mexico, USA, May 13-19, 2007

A Science Service educational program
1719 N Street, NW, Washington, DC 20036-2888
Tel: 202/785-2255, Fax: 202/785-1243

Price: $1.25 per copy (Visa/Mastercard Accepted)

❖ Changes & Modifications for 2006-May 2007 ❖

General

- The Categories and subcategories for the Intel ISEF have been modified. Local, regional and state fairs may or may not choose to use these new categories, dependent on the needs of their area.

Hazardous Chemicals, Activities or Devices

- The previously termed sections of "Controlled Substances" and "Hazardous Substances or Devices" have been combined in one section termed "Hazardous Chemicals, Activities or Devices."
- All projects in this section must be supervised by a Designated Supervisor except for those involving DEA-controlled substances that require supervision by a Qualified Scientist.
- A **risk assessment** is required for all projects in this research area (see page 26).

Human Subjects

- There is a clarification of rules involving review of medical records.
- There is a clarification of the types of projects which are exempt from IRB review and approval.
- There is an expansion of guidelines for conducting surveys on the internet.

Form Changes

- Changes have been made in Forms 1, 1A, 1B, 1C and 2.
- Form 3 has become a Risk Assessment Form required for all projects involving Hazardous Chemicals Activities or Devices.
- Form 7 has been expanded to include more information about previous research.

In addition to providing the rules of competition, these rules and guidelines for conducting research were developed with the intent to do 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.sciserv.org/isef/primer/rules.asp

The International Rules and Guidelines for Science Fairs is available on the Science Service 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 2006. Read these to get pointers on what NOT to do.

❖ Intel ISEF Categories and Subcategories ❖

The categories have been modified 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 new 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.sciserv.org/isef/students/rules/rules4.asp** for a full description and definition of the Intel ISEF categories (subcategories may adjust):

ANIMAL SCIENCES
Development
Ecology
Genetics
Animal Husbandry
Pathology
Physiology
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
Inorganic Chemistry
Organic Chemistry
Physical Chemistry
General 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 SCIENCE
Climatology, Weather
Geochemistry, Mineralogy
Paleontology
Geophysics
Planetary Science
Tectonics
Other

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

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

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

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

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

MATHEMATICAL SCIENCES
Algebra
Analysis
Applied Mathematics
Geometry
Probability and Statistics
Other

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

MICROBIOLOGY
Antibiotics, Antimicrobials
Bacteriology
Microbial Genetics
Virology
Other

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

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

❖ Intel ISEF Display and Safety Regulations ❖

Please address any questions regarding Intel ISEF Display and Safety Regulations to:
William A. Greene, Science Service, E-mail: bgreene@sciserv.org
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

30 inches deep front to back (76 centimeters);

48 inches (122 centimeters) **side to side**;

108 inches (274 centimeters) **floor to top**

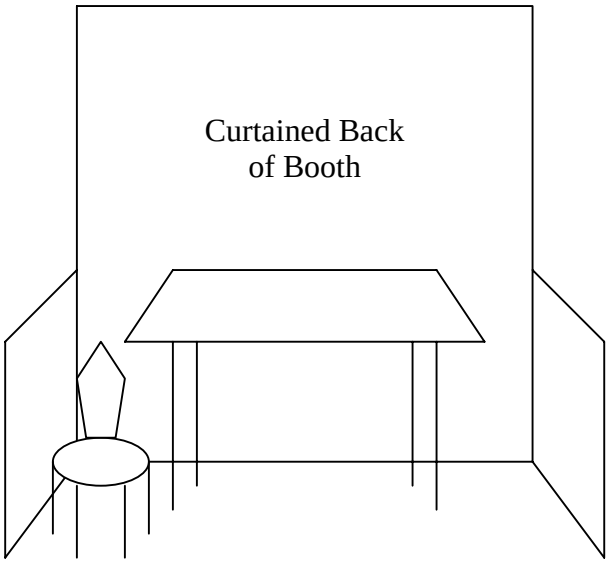
At the Intel ISEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters).

Maximum project sizes include all project materials and supports. 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.



Items 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) — if applicable
- Continuation Projects Form (7) — if applicable

Items Required to be at the Project But Not Displayed at the Intel ISEF

Forms including, but not limited to, **Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan** and **Approval Form (1B)** which are required for the project or for Scientific Review Committee approval do not have to be displayed as part of the project but must be available in the booth in case asked for by a judge or other Intel ISEF official.

Human Subjects Form (4) (or equivalent form provided by a regulated research institution) for human subjects of the research, surveys, photographs, etc. (if applicable) are confidential information, must **not** be displayed, but **must be available in the booth** in case requested by a judge or other Intel ISEF official. Human Subjects Form (4) or an equivalent photograph release signed by the human subject is required for visual images of humans (other than the Finalist) displayed as part of the project.

Handouts/Official Abstract and Certification at the Intel ISEF

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

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

display or in a Finalist's materials at the project except as part of displaying the official abstract.

An original stamped/embossed official abstract and certification must appear on the display board or in a vertical position at the project.

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

Items 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 apparatus or water supplied by the Display and Safety Committee)
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 "Items 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, 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 Science Service (for example, large vacuum tubes or dangerous ray-generating devices, empty tanks that previously contained combustible liquids or gases, pressurized tanks, etc.)

Items 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 numbers, 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 Science Service. 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. Credit lines of their origins ("Photograph taken by..." or "Image taken from...") are attached. (If all photographs being displayed were taken by the Finalist or are from the same source, one credit line prominently 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 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. (Human Subjects Form 4 or equivalent photograph release signed by the human subject must be included in the paperwork and must be properly checked on the Intel ISEF Official Abstract and Certification.)

4. Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points **if for display only and not operated**
5. 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
6. Class III and IV lasers if for display only and not operated
7. Any apparatus producing temperatures that will cause physical burns if adequately insulated.

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, certain 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. A project data book and research paper are not required but are highly recommended.
4. The only acceptable informed consent form for use at the Intel ISEF is the official Human Subjects Form (4) in the International Rules for Precollege Science Research or an equivalent form provided by a regulated research institution (see Form 1C) or, in the case of display of photographs only, an equivalent photograph release signed by the human subject.
5. 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.
6. If a project fails to qualify and is not removed by the Finalist, Science Service will remove the project in the safest manner possible but is not responsible for damage to the project.
7. 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.
8. Project sounds, lights, odors, or any other display items must not be distracting.
9. 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) Any student in grades 9-12 or equivalent is eligible, none of whom has reached age 21 on or before May 1 preceding the Intel ISEF.

2) Each student may enter only **one** project which covers research done over a maximum of 12 continuous months between January 2006 and May 2007.

3) 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.

4) Team projects may have a maximum of three members.

5) 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.

❖ Requirements

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) Projects that are demonstrations, 'library' research or informational projects, 'explanation' models or kit building are not appropriate for the Intel ISEF.

3) 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.

4) Before experimentation begins, an Institutional Review Board (IRB) or Scientific Review Committee (SRC) must review and approve all projects involving: human subjects, vertebrate animals, and potentially hazardous biological agents.

5) 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.

6) A Qualified Scientist is required for all studies involving BSL-2 potentially hazardous biological agents, DEA-controlled substances, more than minimal risk in human subjects and for most vertebrate animal studies.

7) 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 (see *Student Handbook*).

8) A project data book and research paper are not required, but are recommended. (see *Student Handbook;* Regional fairs may have different requirements).

9) All signed forms, certifications, and permits must be available for review by an SRC just before each fair a student enters.

10) After initial IRB/SRC approval (if required), a student with any proposed changes in the **Student Checklist (1A)** and **Research Plan** of the project must repeat the approval process 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 an institutional or industrial setting any time during the current ISEF project year, **Regulated Research Institutional/Industrial Setting Form (1C)** must be completed.

14) Projects must adhere to local, state, country and U.S. Federal laws and regulations.

15) All projects must adhere to the Ethics Statement above.

16) Intel ISEF exhibits must adhere to Intel ISEF display and safety requirements.

17) Introduction or disposal of foreign or non-native substances or species, toxic chemicals or pathogenic substances into the environment is prohibited.

16) It is the student's responsibility to check with their affiliated fair for any additional restrictions or requirements.

❖ Continuation of Projects

1) As in the professional world, research projects may be done that build on previous work and are in the same field of study. Students will be judged only on the most recent year's research. This project year includes research conducted over a maximum of 12 continuous months from January 2006 to May 2007.

2) 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.

3) Any project based on prior research in the same field of study as a previous year's project is considered a continuation for competition. These projects must document that the additional research is new and different from prior work (e.g. testing a new variable or new line of investigation, etc.) Repetition of previous experimentation or increasing sample size are examples of unacceptable continuations.

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 the critical variable. (Examples: Effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned period 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 prior year's abstract and **Student Checklist (1A)** and **Research Plan** or equivalent documentation. Copies must be attached behind the current year's **Student Checklist (1A)** and **Research Plan** and forms. Each page of the previous year's forms must be clearly labeled in the upper right hand corner with the year (ex: 2005-2006). Retain all previous years' paperwork in case an SRC requests documentation of experimentation conducted in other prior years.

❖ 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 -Team (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 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.

The student must be in grades 9-12 or equivalent and must not have reached age 21 on or before May 1 preceding the Intel ISEF. Students may compete as a team of up to 3 members.

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 ultimately responsible not only for the health and safety of the student conducting the research, but also for the humans or animals used as subjects. 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 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. **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. This IRB must include:

a) a science teacher
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, or licensed social worker.

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.

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) a science teacher
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 and animal research
h) compliance with rules regarding 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 are:

a) Institutional Animal Use and Care Committee (IACUC)

b) Institutional Biosafety Committee (IBC)

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 regulations concerning experimentation in restricted areas. 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.

If a fair director or ISEF Affiliated Fair SRC member has any questions concerning the process, feel free to contact Science Service 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. Even though copies may have been sent with registration papers, students must bring original signed forms to the Intel ISEF in case an SRC interview is necessary. **Do not send original forms to Science Service.**

❖ Human Subjects ❖

When students conduct research with human subjects, the rights and welfare of those participating in the study must be protected. There are federal regulations protecting human subjects that require the prior review of human subjects research by an Institutional Review Board and, in most cases, the informed consent of research subjects. The following rules were developed to help student researchers adhere to the Federal regulations and to, therefore, protect the rights and welfare of both the research subjects and the student researcher.

Rules

1) All research projects involving human subjects, including any revisions, must be reviewed and approved by an **Institutional Review Board (IRB)** before the research begins.

2) The use of human subjects in science projects is allowable under the conditions and rules in the following sections. Based upon CFR (Code of Federal Regulations) 45, the definition of a **human subject** is a living individual about whom a investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information.
   A) Examples of studies that are considered "human subjects research" and require IRB approval 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, questionnaire, tests)
   - Studies in which the researcher is the subject of the research
   - Behavioral observations
     - o 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) in any way.)
     - o that occur in a non public or restricted access settings (e.g., day care setting, doctor's office)
     - o that involve the recording of personally identifiable information
   - Data/record review projects that include identifiable data (see #3)

   B) Examples of projects that are **NOT** considered human subjects research and do not require IRB pre-approval include:
   - Product testing of engineering projects
   - Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from pre-existing data sets that are publicly available or published (see #3-c)
   - Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which **all** of the following apply:
     - o The researcher has no interaction with the individuals being observed,
     - o The researcher does not manipulate the environmental in any way **and**
     - o The researcher does not record any personally identifiable data.

3) Projects involving pre-existing data sets or data obtained through record review fall into one of three categories (a, b, and c below) and must adhere to the regulations detailed below. Pre-existing data set/review projects are projects that 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. These projects may involve the student analyzing data given to the student researcher in paper or electronic form.
   a) Projects in which the data are **not de-identified/ anonymous** (e.g., data set that includes patient name, birth date, phone number or other identifying variables; student gathers data from patient files that include identifiers) are considered human subjects projects. These projects require prior IRB review and pre-approval and may require informed consent. Student researchers and adult mentors (Designated Supervisor or Qualified Scientist) should be familiar with and in compliance with all privacy and HIPAA laws.
   b) Projects in which the student receives the data in a **de-identified/anonymous** format will not require IRB pre approval, but must comply with BOTH conditions below:
      i) 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.
      ii) 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.
   c) Projects in which the records/data are **publicly available** (print, electronic or internet) do not require IRB review or approval. Examples of such projects include examination of sports teams or individual athlete statistics or crime statistics.

4) When developing the Research Plan, student researchers must evaluate and minimize the physical and/or psychological risks to their human subjects.

5) The documentation of written **Informed Consent** is required for most projects. **Children/Minors participating in most research will require special consent procedures including assent of the child/minor and consent of the parent/guardian.** Children/Minors are persons who have not attained the legal age for consent; in most jurisdictions the legal age is 18 and in some jurisdictions this may include all students still in secondary school.

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 to be specifically 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 collect data via use of the internet (e.g., email, web based surveys) require special consideration from the IRB which should have at least one member with professional expertise in conducting human subjects research. The use of the internet and email for data collection will pose challenges in collecting a) anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. The research plan and Form 4 must explicitly address how these challenges were evaluated and addressed.

    It is permissible to develop a process of obtaining informed consent that is conducive to internet research. Researchers will want to provide information to potential participants about the purpose of the study and nature of their participation, potential risks, the voluntary nature of the study and the participant's right to withdrawal from the study at any time. A sample informed consent statement for adult participants is available on the web at www.sciserv.org/isef/document/index.asp.

    Recruiting and utilizing participants who are under the age of 18 for a research study conducted on the internet is permissible under the two following conditions.

    a. If the IRB has determined that informed consent is required, the parent/legal guardian must give consent through a traditional Form 4 and informed consent procedures. In this situation, parents/guardians review and sign a Form 4 before the minor participant completes the online or email survey.
    b. If the IRB determines that informed (parental) consent is not necessary for a study that poses very minimal risk, the student researcher can use an assent procedure similar to the sample consent form available on the web. The researcher should provide information to potential participants describing the nature of the study and what the participant will be asked to do, informing the participant of his/her right to withdrawal at any time and indicating that by typing I AGREE or checking a box on the survey and completing the survey, he/she has agreed to participate in the study.

11) After initial IRB/SRC approval (if required), a student with any proposed changes in the **Student Checklist (1A)** and **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.

Risk Assessment

Once a study population is chosen, the student researcher must consider any potential physical and/or psychological risks when developing the research plan. In evaluating risk, students and IRBs must use the following federal definition of minimal risk as a guide: **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.**

Risk Groups: The following risk groups require additional safeguards because they have been judged as vulnerable to coercion or undue influence:

1) 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, cardiac disorders, psychiatric disorders, dyslexia, AIDS, etc.)
2) Special vulnerable groups that are covered by federal regulations (*e.g.* children/minors, prisoners, pregnant women).

Risk Activities: The following are examples of activities that contain **more than minimal risk:**

1) **Physical**
    a. **Exercise** other than ordinarily encountered in DAILY LIFE by that subject.
    b. **Ingestion of any substance** or exposure to any potentially hazardous materials.

2) **Psychological**
    a. Any activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress**. For example, answering questions related to personal experiences such as sexual, physical or child abuse, divorce and/or psychological well-being (e.g. depression, anxiety, suicide) must be considered more than minimal risk. Additionally, research activities that involve exposing

subjects to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk. Examples include violent or distressing video images, distressing written materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in subjects.

b. Any activity that could potentially result in negative consequences for the subject due to **invasion of privacy or breech of confidentiality**. Confidentiality involves taking careful measures to ensure that the research data and/or responses are not disclosed to the public or unauthorized individuals with identifiable information. When research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints) or health-related data (genetic material, blood, tissue) the researcher must consider risks related to invasion of privacy and possible breech of confidentiality. Ways to reduce these risks include collecting data anonymously or developing data collection procedures that make it impossible to link any identifying information (e.g. subject's name) with his/her responses or data. Anonymity involves collecting research data in such a way that it is impossible to connect research data (e.g. responses, questionnaires) with the individual who provided the data. That is, personal identifiers (e.g. names, birthdates, social security numbers) are not collected or linked with the data.

Informed Consent

The process of obtaining informed consent provides information to the subject (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study and allows the subject (and where applicable, parents or guardians) to make an educated decision about whether or not to participate. Informed consent is an on-going process, not a single event that ends with a signature on a page. It must incorporate procedures that do not involve coercion or deception.

Section A. Informed Consent Required

Documentation of informed consent is required for the following as long as the study does not meet any of the criteria for a waiver as described in Section B.:

1) When the IRB determines that a research study involves physical or psychological activities with more than minimal risk.
2) When the IRB determines that the project could *potentially* result in emotional stress to a research subject.
3) When the IRB determines that the research subjects belong to a risk group and the study does not meet any of the criteria below for a waiver.

Section B. Informed Consent May Be Waived

The IRB may waive the requirement for documentation of written informed consent 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 and questionnaires 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. If there is any uncertainty regarding the appropriateness of waiving informed consent, it is strongly recommended that informed consent be obtained.

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 (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If the documentation of informed consent is not required or obtained, all subjects must still give their consent/assent to participate in the study. Research subjects under 18 years of age or other individuals not able to give consent (e.g. mentally disabled) give their assent, whereas adults give their consent. The researcher must inform potential subjects about the purpose of the study and what they will be asked to do. The potential subjects must also be informed that their participation is voluntary and that they may withdraw from the study at any time. This information and the consent/assent can be either verbal or written. The procedure for obtaining consent/assent should be included in the research plan.

If a research subject is under 18 years of age, it is recommended that, in all cases, informed consent be obtained. Both the parent/legal guardian and the school age research subject must sign **Human Subjects Form (4)**. However, an IRB may decide that informed consent is not required because of the allowable exceptions listed above. **When the IRB waives informed consent of research subjects under the age of 18 for studies involving surveys or questionnaires, justification of this waiver must be stated on Human Subjects Form (4).**

Review Process

1) A student interested in doing a human subjects research project must first **review the rules**, choose a study group and consider the risks of their proposed research. The student must work with their Adult Sponsor who can guide them to a Qualified Scientist, if necessary, to help in the development of their research plan.

2) The student must complete the **Student Checklist (1A)**, **Research Plan**, and **Human Subjects Form (4)** and submit this information along with a copy of any questionnaire, survey or instrument used to collect human data to the Institutional Review Board (IRB). Submission of the appropriate forms does not give the student permission to begin the research. The IRB must **sign the Approval Form (1B) and Human Subjects Form (4)**, approving the project, before the research can begin.

3) To complete the IRB review process, the IRB must designate the risk-status of the project and other requirements by checking the appropriate box(es) on **Human Subjects Form (4).** The IRB may require one or more of the following:

   a. Documentation of written Informed Consent on the **Human Subjects Form (4).** When the IRB waives informed consent of research subjects under the age of 18 for studies involving surveys or questionnaires, justification of this waiver must be stated on Form 4.

   b. **Qualified Scientist Form (2)** – The IRB will require the project to be overseen by a Qualified Scientist when there is more than minimal risk involved. If the Qualified Scientist is unable to directly supervise the project, a trained **Designated Supervisor** will also be required.

   c. Changes to the **Research Plan** – If the IRB requires changes or modifications of the Research Plan, the student must incorporate those changes into the written **Research Plan** before the IRB approves the project.

4) After the IRB has approved the project and **all committee members have signed the Human Subjects Form (4),** the student may begin recruiting and/or interacting with human subjects.

5) 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.

6)

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)** - if applicable
- **g. Qualified Scientist Form (2)** - if applicable

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.ahcpub.com/products_and_services/

NIH tutorial also provides similar information:
http://www.cancer.gov/clinicaltrials/learning/page3

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: 202-336-5500
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: 301-496-7005
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, bird and reptile eggs within three days (72 hours) of hatching, and all other nonhuman vertebrates 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":
   - **R**eplace vertebrate animals with invertebrates, lower life forms, tissue/cell cultures or computer simulations
   - **R**educe the number of animals without compromising statistical validity
   - **R**efine the experimental protocol to lessen pain or distress to the animals.

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 such as those using alcohol, acid rain, insecticide, herbicide, heavy metals, etc.
   b. Behavioral experiments involving operant conditioning with aversive stimuli, mother/infant separation or induced helplessness
   c. Studies of pain
   d. Predator/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.

Research Sites

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. 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.

A. Non-regulated site
Vertebrate animal studies may be conducted at a **non-regulated** research site (home, school, farm, ranch, in the field, etc.), ONLY if each of the following applies:

- The research involves behavioral, observational or supplemental nutritional studies on animals.

  AND

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

All such studies must adhere to the additional rules listed in Section A to ensure the proper care and treatment of the animals in the study.

B. Regulated Research Institutions
All other studies using vertebrate animals must be conducted in a **regulated research institution** and must follow the additional rules in Section B.

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

1) 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)

2) 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. It is highly recommended that a veterinarian be consulted in experiments that involve supplemental nutrition and/or activities that would not be ordinarily encountered in the animal's daily life.

3) 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.

4) 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.

5) Studies involving animals in their natural environment, as well as animals in zoological parks, where there is no interaction between the experimenter and the subject animals, must have SRC pre-approval but do not require a **Qualified Scientist Form (2) .**

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) After initial SRC approval, a student with any proposed changes in the **Student Checklist (1A)** and **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.

8) **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)**

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

Some research that is permissible for professionals in research institutions is not appropriate for pre-college students. The following are additional rules for projects conducted in a regulated research institution:

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. 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 spontaneously or as a result of specific experimental procedures. 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) 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/index.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/prin_guide.asp

To order contact:
National Academies Press
500 Fifth Street, NW
Lockbox 285
Washington, DC 20001
phone: 888-624-8373 or 202-334-3313
fax: 202-334-2451; http://www.nap.edu

3) 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://www.aphis.usda.gov/ac/info.html

4) *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
(217) 356-3182
http://www.fass.org

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, 4th Floor
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/

Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing may be obtained from:

Specialized Information Services
NLM/NIH
2 Democracy Plaza, Suite 510
6707 Democracy Blvd., MSC 5467
Bethesda, MD 20892-5467
Ph: 301-496-1131; Fax: 301-480-3537
Toll Free: 1-888-FIND-NLM or 1-888-346-3656
Email: tehip@teh.nlm.nih.gov
http://www.sis.nlm.nih.gov;
http://toxnet.nlm.nih.gov/altbib.html

4) Euthanasia Guidelines

2000 Report of the AVMA Panel on Euthanasia.
Journal of the American Veterinary Medical Association (JAVMA), Vol. 218, No.52: 669-696, March 2001.
http://www.avma.org/resources/default.asp

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 ❖

(previously classified as pathogenic and potentially pathogenic agents, recombinant DNA, and human and vertebrate animal tissues)

Projects incorporating **microorganisms** (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), **recombinant DNA (rDNA) technologies** or **human or animal fresh 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 a **risk assessment** (See page 23). A 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. A more complete discussion of the factors associated with risk assessment can be found on page 23.

All projects involving microorganisms, recombinant DNA technologies and human or animal fresh 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 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 with 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) 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 page 23.
5) Research determined to be at Biosafety Level 1(BSL-1) may be conducted in a BSL-1 or higher laboratory. The research must be supervised by a Qualified Scientist or a trained Designated Supervisor. The student must be properly trained in standard microbiological practices.
6) Research determined to be a Biosafety Level 2 (BSL-2) MUST be conducted in a laboratory rated BSL-2 or above (commonly found in a regulated research institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter obtained from a institutional representative that the research does not require review. The research must be supervised by a Qualified Scientist. The student researcher must receive extensive training, demonstrate competency and be directly supervised while conducting microbiological procedures.
7) **Research determined to be biosafety levels 3 or 4 is prohibited for precollege students.**
8) **Studies intended to produce or 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.
9) 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, and biosafety pick-up.
10) Studies involving the culturing of human or animal waste, including sewage sludge, must be treated as a BSL-2 study.
11) The following types of studies are exempt from these rules:
    a) Studies involving baker's yeast and brewer's yeast, except when involved with rDNA studies
    b) Studies involving most protists, archae bacteria and similar microorganisms
    c) Research using manure for composting or other non-culturing experiments and fuel production
12) Any proposed changes in the **Student Checklist (1A)** and **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.
13) 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) - if applicable
    f. Qualified Scientist (2), if applicable
    g. Hazardous Risk Assessment Form (6A)
    h. 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.)

1) Research with unknown microorganisms can be treated as a BSL-1 study under the following conditions:
   a) Organism **is cultured** in a plastic Petri dish (or other standard non-breakable container) **and sealed**. Other acceptable containment include petro film and doubled heavy-duty (2-ply) sealed bags.
   b) Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (i.e. counting presence of organisms or colonies).
   c) The sealed Petri dish is disposed of in the appropriate matter under the supervision of the Designated Supervisor.
2) If a culture is opened for identification, sub-culturing or isolation, it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.

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

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

1) All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli K12*, *S. cerevesiae*, and *B. subtilis* host-vector systems.
2) All rDNA technology studies using the following DNA insert molecules 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) DNA molecules that are not in the DNA of organisms or viruses, (b) DNA from single non-chromosomal or non-viral sources and (c) DNA that is entirely from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in the host.
3) A rDNA technology study that involves BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.
4) All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a regulated research institution and approved by the IBC prior to experimentation.
5) **Propagation of recombinants containing DNA coding for oncogenes or other human, plant or animal toxins** (including viruses) **are prohibited.**

C. Additional Rules for Projects Involving Tissues Including Blood and Blood Products

Studies involving fresh 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.

1) If tissues are obtained from an animal that was sacrificed for a purpose other than the students' project, it may be considered a tissue study. 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 vertebrate animal rules, pg 17.)
2) Biosafety level 1 studies involve the collection and examination of fresh tissue and/or body fluids, (not including blood or blood products, see rule 4) 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.
3) Biosafety level 2 studies involve the collection and examination of fresh tissues or body fluids that may contain microorganisms belonging to BSL-1 or 2. These studies must be conducted in a regulated research institution under the supervision of a Qualified Scientist.
4) 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.
5) Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, should be considered BSL-2. Domestic animal milk may be considered BSL-1.
6) Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or 4 is prohibited for high school students.
7) 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.
8) The following types of tissue do not need to be treated as potentially hazardous biological agents:
   a. Plant tissue
   b. Established cell and tissue cultures (*e.g.*, those obtained from the American Type Culture Collection). The source and catalog number of the cultures should be identified in the **Research Plan**
   c. Meat or meat by-products obtained from food stores, restaurants, or packing houses
   d. Hair
   e. Teeth that have been sterilized to kill any blood borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is a recommended procedure.
   f. Fossilized tissue or archeological specimens
   g. Prepared fixed tissue slides

Risk Assessment

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. 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: *Aspergillus niger, Bacillus thuringiensis, Escherichia coli strain K12, Lactobacillus acidophilus, Micrococcus leuteus, Neurospora crassa, Pseudomonas fluorescens, Serratia marcescens*.

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

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. These agents are usually not spread by casual contact. The agents require Biosafety Level 3 containment. **PROHIBITED**

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. These agents are usually easily transmitted from one individual to another, from animal to human or vice-versa, either directly or indirectly, or by casual contact. The agents require Biosafety Level 4 containment. **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. The laboratory must be a separate building or isolated zone, with double-door entry, directional inward airflow. Many special procedures and protective devices are required when working with these agents. **PROHIBITED**

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Numerous special facilities and precautions are required when working with these agents. **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/resources/publications/biosafety/Biosafety7.pdf

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

Canada – Agency of Public Health – list of non-pathogenic organisms
http://www.phac-aspc.gc.ca/ols-bsl/pathogen/organism_e.html

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://www4.od.nih.gov/oba/

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, please contact the 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)** - if applicable
- **f. Qualified Scientist Form (2) -** if 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 and 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. 18)

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 consumable ethyl alcohol is prohibited for anyone under the age of 18. Yeast fermentation studies where minute quantities of ethyl alcohol are produced, are exempt from these rules.

2. Students are allowed to conduct science fair experiments involving the distillation of alcohol for fuel production. 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 resource 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 ignitors.

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

1. All persons receiving explosives must obtain a license or permit from the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) or international equivalent regulatory body.
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: A "potato gun" is not a firearm unless it is intended to be used as a weapon. A "potato" gun used in a science fair project should be treated as a hazardous device.

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 Resource 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

A risk assessment for the use of hazardous devices must consider all potential risks for the student researcher using the device. While many household items (iron, saw, drill, etc.) can be hazardous if used improperly, the documentation of a risk assessment (Form 3) is required when a student researcher works with potentially dangerous laboratory equipment and other devices that require a moderate to high level of expertise to ensure their safe usage.

Certain laboratory equipment may present a greater risk than other equipment. For example, hot plates and Bunsen burners may not require a documented risk assessment, whereas other devices such as high vacuum equipment, heated oil baths, NMR equipment, UV lights, lasers and high-temperature ovens require documentation of a risk assessment (Form 3.)

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 1 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://pubs.acs.org/

http://www.practicingsafescience.org/

Online course from Howard Hughes Medical Institute on practicing safe science. Includes sections on general lab safety, chemical safety, and safety concerns when dealing with cell cultures, human blood, radioactive materials and X-ray diffraction.

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 - A directory of MSDS sheets from Flinn Scientific Inc. that includes a ranking of hazard level and disposal methods

http://www.hhmi.org/about/labsafe/lcss.html - Laboratory chemical safety summaries from Howard Hughes Medical Institute

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/contactus

Bureau of Alcohol, Tobacco, Firearms and Explosives
http://www.atf.gov

Radiation

Radiation Manual from the Center of Disease Control (CDC): www.cdc.gov/od/ohs/manual/radman.htm

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 Science Service. The abstract **should include:**

a) purpose of the experiment
b) procedures used,
c) data, and
d) conclusions.

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

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

Completing the Certification

At the bottom of the Abstract & Certification form there are five questions. Please read each carefully, answer appropriately, and sign in the signature box to certify your answers. 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

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

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

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

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

1. As a part of this research project, the student directly handled, manipulated, or interacted with (check all that apply): ☐ human subjects ☐ potentially hazardous biological agents ☐ vertebrate animals ☐ microorganisms ☐ rDNA ☐ tissue
2. Student independently performed all procedures as outlined in this abstract. ☐ yes ☐ no
3. A Regulated Research Institution was a work site for some or all of this project. ☐ yes ☐ no
4. This project is a continuation. ☐ yes ☐ no
5. My display board includes photographs/visual depictions of humans (other than myself): ☐ yes ☐ no

I/We hereby certify that the above statements are correct and the information provided in the Abstract is the result of one year's research. I/We also attest that the above properly reflects my/our own work.

Finalist or Team Leader Signature _____ Date _____

FOR INTEL ISEF OFFICIAL USE ONLY

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 by the Intel ISEF Scientific Review Committee.

Sample Intel ISEF Official Abstract & Certification

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.