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❖ Acknowledgment ❖

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.

To request copies or for questions regarding the Intel ISEF please contact:

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For questions specifically about the rules, please contact any of the following:

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❖ Quick Rules Reference ❖

(The following is a partial list of rules and is not meant to replace the full contents of this booklet. It will identify and locate specific rules in this booklet. Page numbers are identified.)

■ ATTENTION ALL PROJECTS

- All students must meet with their sponsor to complete **Checklist for the Adult Sponsor** before beginning experimentation.➔**33**
- Any proposed changes in the **Research Plan (1A)** after initial IRB and/or SRC approval must have subsequent IRB and/or SRC approval before experimentation begins/resumes. ➔ **8**
- All studies involving nonhuman vertebrate animals, pathogenic agents, controlled substances, non-exempt recombinant DNA, certain tissue studies and more than minimal risk in human subjects studies must have a Qualified Scientist. ➔ **12, 16, 19, 20, 20, 22**
- Adult Sponsor, Parents and Qualified Scientists cannot serve on IRB/SRC reviewing their student's project. ➔ **10**
- The use of hazardous chemicals and equipment, firearms, radioactive substances and radiation require proper supervision by a Designated Supervisor. ➔ **24**
- The use of photographs of persons requires **Informed Consent Form 4B**. ➔ **11**

■ HUMAN SUBJECTS

- Research must be reviewed and approved by an IRB before experimentation begins. ➔ **11**
- Psychological and physical risks must be carefully evaluated by both the student and the IRB. ➔ **11**
- Informed consent is strongly recommended for all projects using human subjects, and is required for all subjects when more than minimal risk is determined by the IRB. ➔ **11**

■ RECOMBINANT DNA

- Non-exempt rDNA studies must be conducted in a federally registered research institution under the direct supervision of a Qualified Scientist. ➔ **21**
- Exempt rDNA studies may be conducted in a non-federally registered laboratory (including school laboratory) under direct supervision of a trained teacher or Qualified Scientist. ➔ **21**

■ CONTROLLED SUBSTANCES

- Students must adhere to all federal and state regulations governing controlled substances. ➔ **19**
- Students under 21 may not purchase and/or handle smokeless powder or black powder for science projects. ➔ **19**

■ HAZARDOUS SUBSTANCES or DEVICES

- Students must adhere to federal and state regulations governing hazardous substances or devices. ➔ **24**
- Experiments must have oversight by a trained Designated Supervisor. ➔ **24**

■ NONHUMAN VERTEBRATE ANIMALS

- Research must be reviewed and approved by an SRC before experimentation begins. ➔ **11**
- Alternatives to the use of vertebrate animals for research **must** be explored. ➔ **15**
- All animals must be legally acquired from reputable animal breeders. ➔ **15**
- Experiments involving laboratory animals cannot be conducted in a student's home; exceptions can be made by the governing SRC for behavioral studies. ➔**15**
- Proper animal care must be provided daily including weekends, holidays and vacations. ➔ **15**
- Experimental procedures that cause unnecessary pain or discomfort are prohibited. ➔ **15**
- Experiments designed to kill vertebrate animals are not permitted. ➔ **15**
- Students may not perform euthanasia, except in emergency situations. ➔ **15**
- LD(50) or higher in any group or subgroup is not permitted. ➔ **15**
- Alcohol, acid rain, insecticide, herbicide, and heavy metal toxicity studies are prohibited. ➔ **15**

■ HUMAN AND ANIMAL TISSUE

- Human blood (and products) must be documented free of HIV and hepatitis viruses and/or must be handled by acceptable containment procedures applicable to blood borne pathogens. ➔ **23**
- Students using their own blood do not need HIV or hepatitis certifications. ➔ **23**
- For the purposes of student research, all body fluids, including saliva and urine (but excluding hair), are to be considered tissues. ➔ **23**

■ PATHOGENIC AGENTS

- Microorganisms collected, isolated, and/or cultured from any environment should be considered potentially pathogenic. ➔ **19**

❖ Highlights for 2000-May 2001 ❖

- ✓ The **Checklist for Adult Sponsor/Safety Assessment Form** must be part of the student papers.
- ✓ All projects involving human subjects must be approved by a PROPERLY constituted Institutional Review Board (IRB) BEFORE experimentation begins.
- ✓ **Informed Consent Form (4B)** is required for all subjects in projects involving more than minimal risk and is recommended for all projects involving human subjects. A copy of any test, survey, or questionnaire must be provided for parental review for subjects under 18 years of age.
- ✓ **Human and Animal Tissue Form (6)** must be submitted to an SRC for review and approval before student begins experimentation.
- ✓ The use of **alcohol**, acid rain, insecticide, herbicide, and heavy metals in toxicity or behavioral studies on live vertebrates is prohibited.
- ✓ Studies involving pathogenic agents are prohibited in a home environment, but specimens may be collected at home.
- ✓ Non-invasive (behavioral) studies involving pets and livestock may be done at home.
- ✓ Projects involving human subjects, nonhuman vertebrate animals, rDNA, pathogens, controlled substances, and human and animal tissue require prior approval by an IRB/SRC before experimentation begins.
- ✓ A project with a death rate of 50 percent or greater in any group or subgroup of vertebrates will fail to qualify for competition.
- ✓ Students should retain all original signed forms. When a student sends the **Checklist for Adult Sponsor, Research Plan (1A)** and **Approval Form (1B)** to the ISEF Affiliated Fair for approval, the ISEF Affiliated Fair should return the signed forms to the student. Do not send original forms to the Intel ISEF.
- ✓ **This project year includes research conducted over a maximum, continuous 12 month period between January 2000 and May 2001.**
- ✓ If you have questions, please contact a member of the ISEF Scientific Review Committee.

These Rules apply to

The 2001 Intel International Science and Engineering Fair (Intel ISEF)
San Jose, California, USA, May 6-12, 2001

A Science Service educational program
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Price: $1.25 per copy
(Visa/Mastercard the Only Credit Cards Accepted)

❖ Intel ISEF Category Descriptions ❖

1) Behavioral and Social Sciences
Human and animal behavior, social and community relationships—psychology, sociology, anthropology, archaeology, ethology, ethnology, linguistics, learning, perception, urban problems, reading problems, public opinion surveys, educational testing, etc.

2) Biochemistry
Chemistry of life processes—molecular biology, molecular genetics, enzymes, photosynthesis, blood chemistry, protein chemistry, food chemistry, hormones, etc.

3) Botany
Study of plant life—agriculture, agronomy, horticulture, forestry, plant taxonomy, plant physiology, plant pathology, plant genetics, hydroponics, algae, etc.

4) Chemistry
Study of nature and composition of matter and laws governing it—physical chemistry, organic chemistry (other than biochemistry), inorganic chemistry, materials, plastics, fuels, pesticides, metallurgy, soil chemistry, etc.

5) Computer Science
Study and development of computer hardware, software engineering, internet networking and communications, graphics (including human interface), simulations / virtual reality or computational science (including data structures, encryption, coding and information theory).

6) Earth and Space Sciences
Geology, minerology, physiography, oceanography, meteorology, climatology, astronomy, speleology, seismology, geography, etc.

7) Engineering
Technology; projects that directly apply scientific principles to manufacturing and practical uses—civil, mechanical, aeronautical, chemical, electrical, photographic, sound, automotive, marine, heating and refrigerating, transportation, environmental engineering, etc.

8) Environmental Science
Study of pollution (air, water, and land) sources and their control; ecology.

9) Gerontology
Study of the aging process in living organisms.

10) Mathematics
Development of formal logical systems or various numerical and algebraic computations, and the application of these principles—calculus, geometry, abstract algebra, number theory, statistics, complex analysis, probability.

11) Medicine and Health
Study of diseases and health of humans and animals—dentistry, pharmacology, pathology, ophthalmology, nutrition, sanitation, pediatrics, dermatology, allergies, speech and hearing, etc.

12) Microbiology
Biology of microorganisms—bacteriology, virology, protozoology, fungi, bacterial genetics, yeast, etc.

13) Physics
Theories, principles, and laws governing energy and the effect of energy on matter—solid state, optics, acoustics, particle, nuclear, atomic, plasma, superconductivity, fluid and gas dynamics, thermodynamics, semiconductors, magnetism, quantum mechanics, biophysics, etc.

14) Zoology
Study of animals—animal genetics, ornithology, ichthyology, herpetology, entomology, animal ecology, paleontology, cellular physiology, circadian rhythms, animal husbandry, cytology, histology, animal physiology, invertebrate neurophysiology, studies of invertebrates, etc.

15) Team Projects
Study conducted by two or three students in any discipline.

❖ Intel ISEF Display and Safety Regulations ❖

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) (Exceptions: teeth, hair, nails, dried animal bones, histological dry mount sections, and completely sealed wet mount tissue slides)
6. Plant materials (living, dead, or preserved) usually which were part of the scientific experimentation and which are in their raw, unprocessed, or non-manufactured state (Exception: manufactured construction materials used in building the project or display)
7. Laboratory/household chemicals including water (Exceptions: water integral to an enclosed apparatus or water supplied by the Display and Safety Committee)
8. Poisons, drugs, controlled substances, hazardous substances or devices (for example, firearms, weapons, ammunition, reloading devices)
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, etc. (Exception: The current year Intel ISEF medal may be worn at all times.)
14. Photographs or other visual presentations depicting vertebrate animals in surgical techniques, dissections, necropsies, other lab techniques, improper handling methods, improper housing conditions, etc.

Allowed at Project or in Booth BUT with the Restrictions Indicated

1. Soil or waste samples if permanently encased in a slab of acrylic
2. Empty tanks that previously contained combustible liquids or gases must be certified as having been purged with carbon dioxide.
3. Accomplishments, acknowledgments, addresses other than the Finalist's address, telephone and FAX numbers, and e-mail and Web addresses are allowed only inside research papers or data books.
4. The only photographs or visual depictions of identifiable or recognizable people allowed are photographs of the Finalist, the Finalist's family, or persons for which consent forms [Informed Consent Form (4B) or an equivalent form provided by a registered research institution] are readily visible on the table or in front of the vertical display board.
5. Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points may not be operated.
6. Class II lasers:
   a. May be operated only by the Finalist.
   b. May be operated only during Display and Safety inspection and during judging.
   c. Posted sign must read "Laser Radiation: Do Not Stare Into Beam."
   d. Must have protective housing that prevents physical and visual access to beam.
   e. Must be disconnected when not operating.
7. Class III and IV lasers may not be operated.
8. Large vacuum tubes or dangerous ray-generating devices must be properly shielded.
9. Pressurized tanks that contained noncombustibles may be allowed if properly secured.
10. Any apparatus producing temperatures that will cause physical burns must be 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. See "Additional Electrical Regulations at the Intel ISEF" for other electrical rules.

Maximum Size of Project at the Intel ISEF

30 inches (76 centimeters) deep
48 inches (122 centimeters) wide
108 inches (274 centimeters) high including table

Notes: At the Intel ISEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters). Display area consists of a draped table and curtained back against which the project must be positioned.

Handouts and Official Abstract at the Intel ISEF

The official abstract is defined as an UNALTERED photocopy or the original abstract as stamped/embossed by the Intel ISEF Scientific Review Committee. If the Scientific Review Committee requires a Finalist to make changes to his or her abstract, the new version will be stamped/embossed and will become the Finalist's new official abstract.

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 on the official abstract.

The original or an unaltered copy of the Finalist's official abstract 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 a copy of the official abstract.

Items Required to be Visible at Project at the Intel ISEF

- Official abstract as approved and stamped/embossed by the Intel ISEF Scientific Review Committee
- Scientific Review Committee approval form (Green-printed form received on-site at the Fair)
- Completed Intel ISEF Exhibit Approval Form DS2 (Received on-site at the Fair)
- Forms which must be visible at all times on the table or in front of the vertical display board *if they apply to the project*:
    - Registered Research Institutional/Industrial Setting Form (1C)—if applicable
    - Informed Consent Forms (4B) (or equivalent form provided by a registered research institution) for any identifiable and/or recognizable people (except the Finalist or the Finalist's family members) who are included in any photographs or visual depictions anywhere at the project or in the booth.

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

- Informed Consent Forms (4B) (or equivalent form provided by a registered research institution) for human subjects of the research, surveys, etc. (if applicable) are confidential information, must ***not*** be displayed, but ***must be available in the booth*** in case asked for by a judge or other Intel ISEF official.
- Other forms [including, but not limited to, Checklist for Adult Sponsor/Safety Assessment Form, Research Plan (1A), 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 should be available in the booth in case asked for by a judge or other Intel ISEF official.

Additional Electrical Regulations at the Intel ISEF

- See the "Display and Safety Regulations" for other electrical rules.
- 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 be requested to review electrical work.
- 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 overcurrent safety devices (such as fuses) and must be inaccessible to anyone but the Finalist. Exposed electrical equipment or metal that is liable to be energized must be shielded with a nonconducting material or with a grounded metal box or cage to prevent accidental contact.
- There must be an accessible, clearly visible on/off switch or other means of disconnect from the 120 or 220 Volt power source.
- Wiring which is not part of a commercially available UL-listed appliance or piece of equipment must have a fuse or circuit breaker on the supply side of the power source and prior to any project equipment.

General Intel ISEF Information and Requirements

- No changes, modifications, or additions to projects may be made after approval by the Display and Safety Committee and the Scientific Review Committee.
- A project data book and research paper are not required but are recommended.
- The only acceptable informed consent form for use at the Intel ISEF is the official Form 4B in the International Rules for Precollege Science Research or an equivalent form provided by a registered research institution (see Form 1C).
- Prior years' written material or visual depictions may not be displayed on the vertical display board, except that 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").
- 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.
- No photographs or any other visual depictions may be included in any manner at a project or in the booth if they are deemed visually offensive 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.
- 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.
- Any copies of printed materials (including unofficial abstracts) designed to be distributed to judges or members of the public which are confiscated by the Display and Safety Committee will be discarded and will not be returned to the Finalist.
- Project sounds must not be distracting to surrounding Finalists or judges.
- No food or drinks, except small containers of bottled water for the Finalist's consumption during judging, are allowed in the exhibit hall.

❖ Eligibility ❖

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. 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.

❖ Requirements ❖

1) Every student must complete **Research Plan (1A)** and **Approval Form (1B)** and review with Adult Sponsor as sponsor completes Checklist for Adult Sponsor (1).
2) Certain projects require additional forms. Experiments that involve human subjects, nonhuman vertebrate animals, pathogenic agents, controlled substances, recombinant DNA, or human/animal tissue require approval from an Institutional Review Board (IRB) or Scientific Review Committee (SRC) **before** experimentation begins (see Item #8, **Research Plan (1A)**).
3) All studies involving nonhuman vertebrate animals, pathogenic agents, controlled substances, nonexempt recombinant DNA, certain tissue studies and all studies involving more than a minimal risk in human subjects must have a Qualified Scientist.
4) 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*).
5) Each student should display a project data book and research paper (see *Student Handbook*).
6) All signed forms, certifications, and permits must be available for review by an SRC just before each fair a student enters. We recommend these be kept in a notebook or folder.
7) Any proposed changes in the **Research Plan (1A)** by the student after initial IRB/SRC approval must have subsequent IRB/SRC approval before experimentation begins/resumes.
8) Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.
9) If work was conducted in an institutional or industrial setting any time during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.
10) Any continuing project must document new and different research.
11) Projects must adhere to all Federal, State and local laws and regulations.

❖ Limitations ❖

1) Each student may enter only **one** project which covers research done over a maximum, continuous 12 month period between January 2000 and May 2001.
2) Team projects may have a maximum of three members (see below).
3) Intel ISEF exhibits must adhere to Intel ISEF safety and size requirements (see page 6).
4) Students may compete in only one ISEF Affiliated Fair, except when proceeding to a state/national fair affiliated with the Intel ISEF from an affiliated regional fair.

❖ Continuation of Projects

Students will be judged only on the most recent year's research (example: 2000-May 2001). Display boards must reflect the current year's work only. However, supporting data books (not research papers) from previous related research may be exhibited on the table properly labeled as such. Any continuing project must document new and different research (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. Documentation must include the prior year's abstract and **Research Plan (1A)** including the response to #9. Copies must be attached behind the current year's **Research Plan (1A)** and forms. Each page of prior work must be clearly labeled in the upper right hand corner with the years (ex: 1999-2000).

❖ Team Projects

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. Team Projects are not required, but are encouraged. 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. A Team Project cannot be converted to an individual project or vice versa. A new member may not be added to a continuing Team Project, but two original team members may continue their research if the third member no longer participates.

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 the same rules and judging criteria as individual projects (see *Student Handbook*, Judging). Each team member must submit **1B Forms**. However, team members must jointly submit the **Checklist for Adult Sponsor**, one abstract, a Team **Research Plan (1A)** and other required forms. Full names of all team members must appear on the abstract and forms.

❖ Adults Involved in a Science Project ❖

1) 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 **Research Plan (1A)** 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 in the Operational Guidelines.

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 nonhuman animals, and cell cultures, microorganisms, or animal tissues. The issues must be discussed with the student when completing the **Research Plan (1A)**. 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 International Science and Engineering Fair.

2) The Qualified Scientist

A Qualified Scientist should possess an earned doctoral/ professional degree in the biomedical sciences. 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.

3) The Designated Supervisor

The Designated Supervisor is an adult who supervises a student's experiment. In the case of hazardous substances or devices, a Designated Supervisor is directly responsible for overseeing student experimentation. A Qualified Scientist may or may not be necessary. 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. If the Designated Supervisor is not knowledgeable, the Adult Sponsor must ensure that the student enlists the help of an Animal Care Supervisor.

4) The Animal Care Supervisor

The Animal Care Supervisor is required for all nonhuman vertebrate animal projects and must be familiar with the proper care and handling of research animals used in the project. The Qualified Scientist or Designated Supervisor or animal care professional usually serves as the Animal Care Supervisor.

5) The Institutional Review Board (IRB)

An Institutional Review Board (IRB) is a committee that, according to federal law, must evaluate the potential physical 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.

An IRB at the school or ISEF Affiliated Fair level must consist of a minimum of three members. Additional members are recommended to avoid conflict of interest. The IRB should include:

a) a science teacher
b) a school administrator
c) and one of the following: a psychologist, psychiatrist, medical doctor, physician's assistant, or registered nurse

Due to the federal regulations requiring local community involvement, an IRB should be established at the school level to deal with human research projects. If it is impossible to establish an IRB at each school, the teacher/school should contact the ISEF-Affiliated Fair Director for assistance in evaluating human research prior to experimentation.

■ *Special Notes on the IRB*

(a) If the project is behavioral, a psychologist, psychiatrist, or individual with human behavioral training must serve on the IRB.

(b) For subjects under 18, student researchers must obtain written informed consent from all subjects and their parent/guardian when more than minimum risk is involved.

(c) Neither the Adult Sponsor, parents, nor the Qualified Scientist who oversees a specific project is permitted to serve on the SRC or IRB reviewing that project. Consequently, neither the Adult Sponsor nor the Qualified Scientist may sign the SRC portion of Approval Form (1B). This eliminates conflict of interest.

6) The Affiliated Fair Scientific Review Committee (SRC)

An SRC must consist of a minimum of three persons. Additional members are recommended to avoid conflict of interest. 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

■ *Special Notes on the SRC*

(1) If the student lives in a rural area and does not have access to a degreed biomedical scientist, the student or SRC must enlist the services of someone from another geographic area. The Rules and necessary forms should be sent to that person so he or she is familiar with the procedures.

(2) One of the SRC members must be familiar with proper animal care procedures when animal research is involved.

(3) Local SRCs may be formed to assist an ISEF Affiliated Fair SRC in reviewing and approving projects. The operation and composition of the local SRCs must fully comply with these International Rules.

(4) Neither the Adult Sponsor, parents, nor the Qualified Scientist who oversees a specific project is permitted to serve on the SRC or IRB reviewing that project. Consequently, neither the Adult Sponsor nor the Qualified Scientist may sign the SRC portion of Approval Form (1B). This eliminates conflict of interest.

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

a) evidence of library search
b) evidence of proper supervision
c) use of accepted research techniques
d) completed forms, signatures and dates
e) humane treatment of animals
f) compliance with rules and laws governing human and animal research
g) appropriate use of recombinant DNA, pathogenic organisms, controlled substances, tissues and hazardous substances and devices
h) appropriate documents and substantial expansion for continuation projects

The SRC follows this three-step process:

1) **BEFORE EXPERIMENTATION**, the SRC reviews and approves experimental procedures for projects involving human subjects, nonhuman vertebrates, pathogenic agents, controlled substances, recombinant DNA, and human/animal tissue to make sure they comply with the Rules and any pertinent laws. Human studies reviewed and approved by a properly constituted IRB do not have to be reviewed by the SRC until ISEF-Affiliated Fair competition.

2) **AFTER EXPERIMENTATION AND SHORTLY BEFORE THE ISEF-AFFILIATED FAIR**, the SRC reviews and approves those same projects to make sure that students followed the approved **Research Plan (1A)** and the Rules.

3) **AFTER EXPERIMENTATION AND SHORTLY BEFORE THE ISEF-AFFILIATED FAIR**, the SRC also reviews all remaining projects to make sure students followed the applicable Rules.

7) 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.

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 and approves the **Checklist for Adult Sponsor**, **Abstract, Research Plan (1A)**, 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 p. 2 for phone numbers). The ISEF SRC is the final authority on projects that are eligible 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 should 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 ❖

An Institutional Review Board (IRB) must review and approve all research involving human subjects **before** experimentation begins. The International Rules, which follow federal regulations, exist to safeguard the rights and welfare of individuals who participate as research subjects and to protect the student researcher. When students conduct biomedical or behavioral research, they are directly responsible for protecting the rights and welfare of the participating human subjects.

Rules

1) **All human research projects (including surveys, professional tests, questionnaires, and studies in which the researcher is the subject of his/her own research) are subject to a complete review before experimentation begins.** Copies of standardized tests and student-prepared tests, surveys, etc. must be attached to the **Research Plan (1A)**. Observational studies and related data collection are exempt from use of **Informed Consent Form (4B)**, but **Form (4A)**, including IRB review is still required.

   Research of students under 18 does not need an **Informed Consent Form (4B)** or a **Qualified Scientist Form (2)** for the following:

   a) Research conducted in established settings:
      (1) involving normal educational practices
      (2) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. (see p.12, point 2 of *Possible Risk Activities* for clarification)

   b) Research involving observation of legal public behavior.

   c) Research involving collection or study of existing publicly available data.

2) Student researchers must assess the risks to their human subjects when developing the **Research Plan (1A).** Any possible risks must be described in **Human Subjects Form (4A)** and a sample of 4A and **Informed Consent Form (4B)** must be submitted for review and approval by an IRB before experimentation begins. Upon assessment of risks by the IRB, changes in the research plan may be required and IRB approval obtained prior to experimentation.

3) If the IRB requires any **Research Plan (1A)** changes, the student must incorporate those changes into the **Research Plan (1A)** before the IRB signs for approval.

4) After an IRB has approved the **Research Plan (1A)** and related forms, the student may begin experimentation. Additional review by a local SRC is not required before experimentation.

5) Research conducted by a precollege student at federally registered research institutions (*e.g.*, university labs, medical centers, NIH, etc.) must be reviewed and approved by that institution's IRB. Documentation must be provided that certifies the student was approved by the IRB to perform specific experimental procedures and the project identified in the research plan. A letter from the mentor attesting to this approval is not sufficient.

6) A student may observe and collect data for analysis of new procedures and medications only under the direct supervision of a licensed professional. Students are prohibited from administering medications to human subjects. The IRB must ascertain that the student is not violating the medical practice act of that particular state or nation.

7) It is illegal to publish or display information in a report that identifies the human subjects directly or through identifiers linked to the subjects, including photographs without written informed consent. (Public Health Service Act, 42 U.S.C., 241(d).) Use **Informed Consent Form (4B).**

8) A **Qualified Scientist Form (2)** will be required if the IRB determines there is more than minimal risk. If the Qualified Scientist is unable to supervise the experiment, a trained Designated Supervisor is required.

9) Any proposed changes in the **Research Plan (1A)** by the student after initial IRB approval **must have subsequent IRB approval before such changes are made and before experimentation begins/resumes.**

Assessing Risks and Choosing a Study Group

When choosing a study group, the criteria for selecting the subjects should be clearly defined. In other words, students should ask questions that will define the exact study population. For example, if students want to study nondiabetic males, they should make sure to ask the appropriate questions that would eliminate diabetic individuals. Similarly, in studies where exercise is involved in the project, the student researcher should determine that the research subject is not at risk by exercising, e.g., the subject has no cardiac or respiratory disease/disorder.

Once a population is chosen, the International Rules require students to assess any potential risks when developing the **Research Plan (1A).** Any possible risks must be explained on **Human Subjects Form (4A)** and a sample **Informed Consent Form (4B).** The student must submit **Human Subjects Form (4A)** and a sample **Informed Consent Form (4B)** with the **Checklist for Adult Sponsor**, **Research Plan (1A)/Approval Form (1B)** to an IRB for review and approval before the beginning of experimentation.

Parents have the right to deny participation in any study including those involving tests or questionnaires. The IRB may judge certain tests or questionnaires to involve more than minimal risks and **Informed Consent (4B)** will be required for all subjects. Such tests or questionnaires must be provided to parents with **Informed Consent Form (4B).**

Informed Consent Form (4B) is required for subjects under 18 years of age (except as noted in Rule 1), required for all subjects when more than minimal risk is determined by the IRB, and is strongly recommended for all projects involving human subjects. A sample of this form must be submitted to the IRB before experimentation begins. The only acceptable alternative forms to **Informed Consent Form (4B)** are those provided by a registered research institution.

Risk Evaluation:

In evaluating risk, students and IRBs should 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.

The following are examples of activities or groups that contain more than minimal risks:

Possible Risk Activities:

1) **Exercise**
2) **Emotional stress** resulting from invasion of privacy (See Privacy Act of 1974 45CFR5B). Questions on sexual activities or preferences, AIDS testing and results, suicide attitudes, divorce and its effects on psychological well-being all may be judged as overtly invasive or high-risk. Student researchers should always carefully evaluate controversial questions for compliance with federal regulations.
3) **Ingestion of any substance** or physical contact with any potentially hazardous materials. This rule applies to the student researcher as well as the human subject(s).

Risk Groups:

1) Any member of a group that is naturally at-risk (*e.g*., pregnant women, individuals with diseases such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, dyslexia, AIDS, etc.).
2) Special vulnerable groups covered by federal regulations (*e.g*., children, prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons). Additional safeguards are applied to these subjects because they have been judged as vulnerable to coercion or undue influence.

Notes on the Institutional Review Board (IRB)

1) Institutional Review Boards (IRBs) exist at federally registered research institutions. For research not performed at one of these facilities, the sponsoring research organization (high school, local or affiliated fair, etc.) must appoint an IRB to review and approve any proposed research involving human subjects.
2) A minimum of three members are required for a school or ISEF-Affiliated Fair IRB. An IRB must include a science teacher, a school administrator, and one of the following: a psychologist, psychiatrist, medical doctor, physician's assistant, registered nurse or individual with human behavioral training. When the project concerns behavioral research, the IRB must include a psychologist, or psychiatrist (Federal law 25-CFR-46).
3) An IRB generally makes the final determination of risk. However, 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.

■ Required Forms for Human Subjects

A) Checklist for Adult Sponsor
Research Plan (1A)
Approval Form (1B)

Must be submitted to an Institutional Review Board (IRB) for review and approval before student begins experimentation. A copy of any tests or questionnaires must be included with the **Research Plan (1A).**

CAUTION: Any proposed changes in the Research Plan (1A) by the student after initial IRB approval must have subsequent IRB re-approval before such changes are made and before experimentation begins or resumes.

B) If research was conducted or equipment used in an institutional or industrial setting any time during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) Human Subjects Form (4A)
Must be submitted to an IRB for review and approval before experimentation is started.

D) Informed Consent Form (4B)
This form is strongly recommended for all projects using human subjects and is required for subjects under 18 years of age (except as noted in Rule 1), required for all subjects when more than minimal risk is determined by the IRB, and strongly recommended for all projects. A sample of this form must be submitted to the IRB before experimentation begins. The only acceptable alternative form to **Informed Consent Form (4B)** is that provided by a registered research institution.

If the IRB determines that more than minimal risk is present the following additional forms are required:

E) Qualified Scientist Form (2)
Required if more than minimal risk to the subjects is determined. Should the student anticipate that risk might be involved, this form must be provided to the IRB together with the **Checklist, Form (1A)/(1B)** and **Form (4A)** above at the time of original review by an IRB.

F) Designated Supervisor Form (3)
If the Qualified Scientist is unable to supervise the experiment, a Designated Supervisor who is knowledgeable about the project and its risks must supervise. This individual must have training in the procedures and methods used by the student to achieve the specific aims of the project.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be re-approved prior to experimentation for the current year.

Sources of Information

1) *CFR, Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*

2) Penslar, R. L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH

3) *Bellmont Report*, April 18, 1979

Above documents available from:
Office for Protection From Research Risks (OPRR)
National Institutes of Health
6100 Executive Blvd., Suite 3B01, MSC-7507
Rockville, MD 20892-7507
phone: 301-496-7005, fax: 301-402-2071
email: oprr@od.nih.gov
website: http://grants.nih.gov/grants/oprr/library_human.htm

Division of Human Subject Protections
phone: 301-402-0527

To have documents faxed call: 301-594-0464

American Psychological Association

750 First Street, NE
Washington, DC 20002
phone: 202-336-5500
website: http://www.apa.org
Information for students:
http://www.apa.org/science/infostu.html
Information regarding publications:
http://www.apa.org/science/pubs.html

Educational and Psychological Testing
Testing Office for the APA Science Directorate
phone: 202-336-6000

Standards for educational and psychological testing. (1999).
Washington, DC: AERA, APA, NCME.

To order call: (800) 628-4094.
http://www.apa.org/science/standards.html

❖ Nonhuman Vertebrate Animals ❖

Students proposing research on nonhuman vertebrate animals should explore all possible alternatives. If vertebrates are used for research and testing, the student researchers and Adult Sponsors are responsible for granting the animals every humane consideration for their comfort and well being before, during, and after the research.

Studies involving animals in their natural environment as well as animals in zoological parks with no interaction between the experimenter and the subject animal(s) do not require Qualified Scientist Form (2) or Nonhuman Vertebrate Animal Form (5).

Although certain research is permissible for professionals in research institutions, it may not be appropriate for high school students. All research involving nonhuman vertebrate animals must be approved by a Scientific Review Committee (SRC) before experimentation begins. Please review the rules and limitations below.

Rules

1) **Alternatives:** Alternatives to the use of nonhuman vertebrate animals for research **MUST BE** explored and discussed in **Research Plan (1A), 9c**. Alternatives may include replacement, reduction or refinement.

The three Rs of animal experimentation:

Replace vertebrate animals with invertebrates or lower life forms whenever possible.

Reduce the number of animals whenever possible.

(Do not reduce numbers beyond statistical validity.)

Refine experimental protocols to lessen pain or distress to the animals.

We encourage any non-invasive and non-intrusive studies (*i.e.*, observational, behavioral, and natural history studies) that do not affect an animal's health or well-being by causing stress, discomfort, pain or death. The International Rules allow intrusive studies on vertebrate animals and invertebrate animals that have advanced nervous systems ONLY when lower vertebrates or other alternatives are not suitable.

Examples of possible alternatives are listed below:

a) Cells and tissue cultures
b) Plants, yeast and fungi
c) Mathematical or computer models
d) Invertebrates with more primitive nervous systems (*i.e.*, protozoa, planaria, insects)
e) Primary tissue or cell explants from humanely euthanatized animals
f) Chicken embryos prior to three days before hatching

2) The International Rules define an animal as any live, nonhuman vertebrate, mammalian embryo or fetus, bird eggs within three days of hatching, and all other vertebrates at hatching or birth.

3) Students performing animal research must follow local, state, and federal regulations. Research conducted at registered research institutions (*e.g.*, university lab, medical center, NIH, etc.) must be reviewed and approved by that institution's Animal Care and Use Committee. **Research conducted at all other sites must have prior SRC review and approval. Invasive studies which duplicate previous research by others should be avoided.**

4) **Procurement:** All animals must be legally acquired from reputable animal breeders.

a) Common laboratory animals must be obtained from licensed laboratory animal breeders. Pet store animals, except fish, are inappropriate because their genetic and nutritional background, as well as disease potential, are unknown. Fish may be obtained locally.

b) Animals should be healthy and free of diseases that can be transmitted to humans or other animals.

c) Animals may not be captured from or released into the wild without approval of authorized wildlife and public health officials. This authorization should include student identity, species involved, site and method of capture, name of collector and disposition of animals (e.g. released, maintained, euthanized.)

d) All animals are classified as laboratory animals on the first day of study. Proper forms, including the **Research Plan (1A)**, must be completed and submitted for review and approval by the SRC before experimentation begins.

5) **Housing:** The Intel ISEF accepts two basic animal care guides on the care and use of laboratory animals: *Federal Animal Welfare Act*, and the *Guide for the Care and Use of Laboratory Animals*. For farm animals, use the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*. Any deviations from these guides must be approved by an Animal Care Supervisor and the governing SRC.

a) Animals must be housed in clean, ventilated, comfortable environments compatible with the standards and requirements appropriate for the species used. Animals must have adequate lighting, humidity and controlled temperature (with as little variation as possible), and have sanitizable cages of adequate sizes for the typical activities and social interactions of the species (unless individual housing is dictated by experimental protocol) and has been pre-approved by SRC. Lighting must be adequately controlled to support proper circadian rhythms.

b) Because the conditions above are critical, experiments involving small common laboratory animals (*e.g.*, mice, rats, hamsters, guinea pigs, gerbils, rabbits) are ONLY allowed in an **institutional setting** or **school setting** (if environment, housing and husbandry standards are maintained) and **not** in a student's home environment. Home environments are not as tightly controlled as institutional settings and therefore are not appropriate for experimentation.

However, non-invasive and behavioral studies involving pets, including fish, and livestock may be done at home. Exceptions for behavioral and agricultural research may be granted only by the governing SRC.

6) **Husbandry:** Animals must be treated kindly and cared for properly.

   a) Animals must be given a continuous, clean (uncontaminated) water and food supply. Food should meet the nutritional requirements of the particular species. Standard laboratory formulations should always be used for common laboratory animals (unless prevented by experimental protocol). Watering and feeding devices should be cleaned frequently.

   b) 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.

   c) Cages, pens, and fish tanks must be cleaned frequently. A highly absorbent bedding should be used in cages and pens. Hardwood chips are recommended (do not use cedar) and can be obtained from local pet or feed stores. Do not use newspaper or paper towels because inks may be carcinogens and adversely affect liver enzyme function.

   d) If an unexpected illness or emergency occurs, animals must have proper veterinary medical and nursing care under the direction of a veterinarian.

7) Research involving stress factors is permitted only when it causes no permanent alteration in the psychological or physical well-being of the animals.

8) Research on animals involving anesthetics, drugs, thermal procedures, physical stress, organisms pathogenic for humans or other vertebrates, ionizing radiation, carcinogens, mutagens, tumors, or surgical procedures must be directly supervised by a Qualified Scientist or Designated Supervisor within a hospital, school, or clinical/research institution approved by the governing SRC.

   Projects involving any of the above must be reviewed by the Institutional Animal Care and Use Committee (IACUC) or regional SRC. IACUC documentation of this approval must be attached to the research plan. A letter from the mentor attesting to this approval is not sufficient.

   Students are prohibited from doing such research in a home environment, even if institutional housing is not available.

9) Experimental procedures that cause unnecessary pain or unnecessary discomfort on any vertebrate animals, including operant predator/prey experiments, **are prohibited** (*e.g.*, mammals, birds, reptiles, amphibians, fish).

10) The **use of alcohol**, acid rain, insecticide, herbicide, and heavy metal in toxicity or behavioral studies on live vertebrates is prohibited. Tissue culture, chicken embryos up to three days before hatching, and invertebrate studies are recommended as alternative models for testing.

11) Weight loss is one significant sign of stress or toxicity. Maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal(s) is 15 percent.

12) **LD50**: LD means lethal dose or death rate. **A death rate of 50 percent or greater in any group or subgroup, by design or as an unexpected result of experimental procedure is not permitted and the project will fail to qualify for competition.**

13) Research in nutritional deficiency, ingestion, inoculation or exposure to hazardous or reputedly toxic materials or drugs is permitted to proceed only to the point where signs or lesions of the deficiency or toxicity first appear. Appropriate measures must then be taken to correct the deficiency, toxicity, or drug effect, if such action is feasible. If not, the animal(s) must be euthanatized. **Experiments designed to kill vertebrate animals are not permitted. However, experimental designs incorporating humane euthanasia are permitted.**

14) **Euthanasia**: Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted.

   a. Only the Animal Care Supervisor, Qualified Scientist, or the Designated Supervisor may perform euthanasia. **Student researchers may perform euthanasia only in an emergency.**

   b. Methods of Euthansia

   1. **Acceptable** Methods of Euthanasia: administration of barbituric acid derivatives in conformance with applicable laws; inhalation of gas anesthetic in a well ventilated area; induced narcosis with carbon dioxide or nitrogen for common laboratory animals; use of MS-222 and hypothermia with subsequent cervical dislocation for cold-blooded aquatic species.

   2. **Unacceptable** Methods of Euthanasia: injection of air, or any product containing strychnine, curare, succinylcholine or other neuromuscular blocking agents; guillotine, decapitation and cervical dislocation without prior anesthesia; exhaust fumes; chloroform or ether; stunning blows to the head; microwaves. These methods are unacceptable for student research projects regardless of who conducts the procedure.

15) **Any proposed changes in the Research Plan (1A) by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.**

■ Required Forms for Nonhuman Vertebrate Animals

A) **Checklist for Adult Sponsor**
Research Plan (1A)
Approval Form (1B)

Must be submitted along with the following forms to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) If research was conducted or equipment used in an institutional or industrial setting anytime during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Qualified Scientist Form (2)**
Required for any project involving nonhuman vertebrate animals.

D) **Designated Supervisor Form (3)**
Required if the Qualified Scientist is unable to directly supervise the experiment, a Designated Supervisor who has thorough knowledge of the student's research project must supervise. The Designated Supervisor need not have an advanced degree, but must have training in the standards of nonhuman vertebrate animal research.

E) **Nonhuman Vertebrate Animal Form (5)**
Students must enlist an adult who is knowledgeable about animal care to oversee the care and handling of animals. The Animal Care Supervisor must sign this form. If multiple vertebrate animal species are used in a project, a separate Nonhuman Vertebrate Animal Form must be completed for each species.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

■ Instructions for the Research Plan (1A)

Question #9 on the **Research Plan (1A)** asks for a description of methods and procedures. Projects that involve vertebrate animals require an extremely detailed **Research Plan (1A)** for SRC review purposes. Although most of the following information is requested on **Nonhuman Vertebrate Animal Form (5)**, the SRC requires a comprehensive **Research Plan (1A)** detailing the specifics listed below:

1) Describe in detail, how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.

2) 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.

3) Provide detailed information on the animal's housing, husbandry, and environment. Also, provide information on the veterinary medical/nursing care, to be obtained in the case of illness or emergency.

4) Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Invasive studies which duplicate previous research by others should be avoided. ***The Intel ISEF discourages any procedures that will cause discomfort to animals.***

5) Describe any analgesic, anesthetic or tranquilizing drugs (show dosage in **mg/kg of body weight**) and comfortable restraining devices used to minimize discomfort, distress, pain, and injury. Also indicate dosage of any drugs or substances used in the animals in mg/kg of body weight (see example below).

6) Explain what will happen to the animal(s) after the project is finished. If euthanasia will be performed by a Qualified Scientist **(students are not permitted to perform euthanasia except in an emergency)**, describe the method and reasons for selection. Methods should comply with the Euthanasia Guidelines in the 1993 AVMA report.

Example

Calculation of Dosage: If one doses a 20 gram organism with 40 mg of test substance, how many mg/kg (of bodyweight) is this dosage? **Note: In this example, a one-gram (1,000 mg) packet of test substance contains only 40 mg of active ingredient.** The rest of the packet contains inert ingredient(s). This condition is true for many foods and pharmaceutical products.

Step 1: Establish the weight of the variables. In this example, the organism weighs 20 g and the test substance is 40 mg.

Step 2: Convert the weight of the organism into kg.

$$1\text{ kg} = 1{,}000\text{g}\ ; \quad \frac{20\text{ g}}{1{,}000\text{g}} = 00.02\text{kg}$$

Step 3: Compute the ratio between the weight of the test substance to the weight of the organism using the following formula:

$$\text{dosage} = \frac{\text{weight of test substance (mg)}}{\text{weight of organism (kg)}}$$

$$\textbf{Thus, dosage} = \frac{40\text{ mg}}{0.02\text{ kg}} = 2{,}000\text{ mg/kg}$$

Sources of Information for Animal Care and Use

1) *Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources (IlAR),* National Research Council, 1996.

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

To order contact:
National Academy Press
2101 Constitution Avenue, NW
Lockbox 285
Washington, DC 20055
phone: 888-624-8373 or 202-334-3313
http://www.nap.edu

or visit the ILAR website at:
http://www4.nas.edu/cls/ilarhome.nsf

2) Federal Animal Welfare Act (AWA)
7 U.S.C. 2131-2157
Subchapter A - Animal Welfare (Parts I, II, III)

Above document is available from:
Animal Care
Animal and Plant Health Inspection Service (APHIS)
U.S. Department of Agriculture
12th & Independence Avenue, SW
Washington, DC 20250
http://www.aphis.usda.gov/ac/awainfo.html

3) *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*
American Dairy Science Association
1111 N. Dunlap Avenue
Savoy, IL 61874
(217) 356-3182
http://www.adsa.uiuc.edu

Sources of Information for Alternative Research and Animal Welfare

1) The National Library of Medicine provides computer searches through MEDLINE under the key phrase Animal Welfare.

Reference Librarian
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
1-888-FIND-NLM or 1-888-346-3656
(301) 496-6308
http://www.nlm.nih.gov

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
5th Floor, 10301 Baltimore Blvd.
Beltsville, MD 20705-2351
(301) 504-6212
http://www.nal.udsa.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.

Institute for Laboratory Animal Research (ILAR)
NAS 347
2101 Constitution Avenue, NW
Washington, DC 20418
phone: (202) 334-2590, fax: 202-334-1687
email: ILAR@nas.edu
http://www4.nas.edu/cls/ilarhome.nsf

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

National Library of Medicine
Special Information Services
8600 Rockville Pike
Bethesda, MD 20894
1-888-FIND-NLM or 1-888-346-3656
http://www.sis.nlm.nih.gov

4) Euthanasia Guidelines

1993 Report of the AVMA Panel on Euthanasia published in the Journal of the American Veterinary Medical Association (JAVMA), Vol. 203, No. 2: 229-249, 1993.

Other Federal Laws That May Apply

Endangered Species Acts (16 U.S.C. 1531)

U.S. Fish & Wildlife Service
Division of Endangered Species
Department of the Interior
1849 C Street, NW
Washington, DC 20240
http://endangered.fws.gov/esa.html

Other Guidelines and Regulations that May Apply to Animal Research Projects or Laboratory Safety

1) Carcinogens, Chemicals and rDNA
   National Institutes of Health
   Occupational Safety & Health Branch (OSHB)
   Building 31, Room 1C02
   Bethesda, MD 20892
   (301) 496-2960
   http://www.nih.gov/od/ors/ds

2) Infectious Agents
   Centers for Disease Control
   Office of Health and Safety
   1600 Clifton Road F-05
   Atlanta, GA 30333
   (404) 639-3235
   http://www.cdc.gov

3) Radioisotopes and Radioactive Substances
   John Hickey
   U.S. Nuclear Regulatory Commission
   Material Safety and Inspection Branch
   11555 Rockville Pike
   Rockville, MD 20852
   phone: (301) 415-7231
   http://www.nrc.gov

4) Radiation and Medical Devices
   Department of Labor
   Occupational Safety and Health Administration (OSHA)
   Publications Office
   200 Constitution Avenue, N.W.
   Washington, DC 20210
   phone: (202) 219-4667
   http://www.osha.gov

   STD 1-4.1 - OSHA Coverage of Ionizing Radiation Sources Not Covered by Atomic Energy Act of 1954

5) Safety and Health
   U.S. Department of Labor
   Occupational Safety and Health Administration
   Publications Office
   200 Constitution Avenue, N.W.
   Washington, DC 20210
   phone: (202) 219-4667
   http://www.osha.gov

Education and Training in the Care & Use of Laboratory Animals: A Guide for Developing Institutional Programs, 1991.

To order contact:
Institute for Laboratory Animal Research
NAS 347
2101 Constitution Avenue, NW
Washington, DC 20418
phone: (202) 334-2590, fax: 202-334-1687
email: ILAR@nas.edu
http://www4.nas.edu/cls/ilarhome.nsf

❖ Pathogenic Agents ❖

(applies to all pathogens — human, nonhuman and plants)

The ISEF Affiliated Fair/Intel ISEF allows students to experiment with pathogenic agents as long as the students adhere to federal regulations and guidelines, which are designed to protect the safety of researchers. Carelessness and improper techniques in working with pathogenic and non-pathogenic agents can lead to laboratory- and/or field-contracted infections.

Rules

1) Research involving pathogenic agents must be approved by a Scientific Review Committee (SRC) before experimentation begins.

2) Pathogenic agents are disease-causing or potentially disease-causing agents such as bacteria, viruses, viroids, prions, rickettsia, fungi, or parasites. When using pathogenic agents, student researchers and their Adult Sponsors are required to follow standard microbiological practices, as defined in *Biosafety in Microbiological and Biomedical Laboratories*. Organisms collected, isolated, and/or cultured from any environment during student research projects, should be considered potentially pathogenic. Raw or partially-processed human or animal waste is considered to contain potentially-pathogenic agents (Agricultural use of animal waste as fertilizer is exempt). *E. coli* strain K12 and Baker's and brewer's yeasts are not considered to be pathogens. **Purchased cultures certified by the supplier as being non-pathogenic must be identified with full name, source and catalog number in Research Plan (1A).**

3) Student research with pathogenic agents may be performed **only** under the direct supervision of an experienced Qualified Scientist or Designated Supervisor in an institutional laboratory, including a school if facilities are adequate and appropriate. **Studies involving pathogenic agents or potential pathogens are prohibited in a home environment, but specimens may be collected at home.**

4) **Any proposed changes in the Research Plan (1A) by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.**

■ Required Forms

A) Checklist for Adult Sponsor
Research Plan (1A)
Approval Form (1B)
Must be submitted along with the form(s) listed below to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) If research was conducted or equipment used in an institutional or industrial setting anytime during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Qualified Scientist Form (2)**
Students using pathogens must enlist the expertise of a Qualified Scientist with microbiology specialty to oversee their projects.

D) **Designated Supervisor Form (3)**
If a Qualified Scientist is unable to supervise the student's experiment, a Designated Supervisor who is trained and thoroughly knowledgeable about the student's research project must supervise. The Designated Supervisor need not have an advanced degree, but must have training in the standards of proper microbiological practices and a working knowledge of the organisms.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Sources of Information

Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 4th Edition. Published by CDC-NIH
To order contact:
Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Road, NE Mailstop F05
Atlanta, GA 30333
website: http://www.cdc.gov/od/ohs/biosfty/biosfty.htm

Bergey's Manual of Systematic Bacteriology (four volumes). (1984, 1986, 1989), Baltimore: Williams & Wilkens.
To order contact:
Lippincott Williams and Wilkins
P.O. Box 1600
Hagerstown, MD 21741
phone: (301) 714-2300 or (800) 638-3030
http://www.lww.com or
http://www.cme.msu.edu/bergeys/bmsb.html

❖ Controlled Substances ❖

Controlled substances, including DEA classed substances, prescription drugs, alcohol, and tobacco, must be acquired and used according to existing local, state and federal laws.

Rules

1) Research involving controlled substances must be approved by a Scientific Review Committee (SRC) before experimentation begins.
2) Student researchers must adhere to all federal regulations governing controlled substances. For further information, contact the regulatory agencies listed below.
3) Production of alcohol is federally regulated and students must contact the Bureau of Alcohol, Tobacco and Firearms for regulations and permission (see below).
4) Only under the direct supervision of a Qualified Scientist or Designated Supervisor may a student use any federally-controlled or experimental substances for therapy or experimentation.
5) Students under 21 are prohibited by federal and most state laws from purchasing and/or handling smokeless powder or black powder for science projects. For further regulations, contact the Firearms & Explosives Division of the Bureau of Alcohol, Tobacco, and Firearms listed below.
6) **Any proposed changes in the Research Plan (1A) by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.**

■ Required Forms

A) **Checklist for Adult Sponsor**
Research Plan (1A)
Approval Form (1B)
Must be submitted with the form(s) listed below to an ISEF-Affiliated Fair SRC for review and approval before experimentation is started.

B) If research was conducted or equipment used in an institutional or industrial setting anytime during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Qualified Scientist Form (2)**
Students using controlled substances must enlist the expertise of a Qualified Scientist to oversee their projects. The Qualified Scientist should have a thorough knowledge of the student's area of research.

D) **Designated Supervisor Form (3)**
If a Qualified Scientist is unable to supervise the student's experiment, a Designated Supervisor who is thoroughly knowledgeable about the student's research project may do so. The Designated Supervisor need not have an advanced degree, but must have training in working with controlled substances.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Sources of Information

Prescription Drugs
Superintendent of Documents
U.S. GPO
Washington, DC 20402
(202) 512-1800
http://www.access.gpo.gov/su_docs

Alcohol, Tobacco and Firearms
The Bureau of Alcohol, Tobacco and Firearms
650 Massachusetts Ave., N.W.
Washington, DC 20226
http://www.atf.treas.gov

Distilled Spirits and Tobacco Branch - (202) 927-8210

Firearms & Explosives Division - (202) 927-8300

Narcotics and Addictive Drugs
The Drug Enforcement Administration*
Registration Department
Washington, DC 20537
(202) 307-7255
http://www.usdoj.gov/dea

*Contact appropriate state agencies concerning additional regulations.

❖ Recombinant DNA (rDNA) ❖

(Applies to all recombinant studies regardless of host)

The ISEF-Affiliated Fair/Intel ISEF, following federal regulations, allows students to conduct recombinant DNA (rDNA) research. When using rDNA and host organisms, students and supervising adults are urged to proceed in a safe and responsible manner in the laboratory.

Rules

1) All student research proposals involving rDNA must be reviewed and approved by a Scientific Review Committee (SRC) before experimentation begins.

2) Student researchers working with any microorganisms must always follow standard microbiological practices.

3) The Intel ISEF adheres to NIH Guidelines and accepts the following definitions as recombinant DNA molecules:

   a) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.

   b) Molecules that result from the replication of those described above.

4) Students may conduct studies on both exempt and non-exempt rDNA and host organisms. (The International Rules generally follow the NABT guidelines.)

   a) Nonexempt rDNA studies must be conducted in a federally registered research institution (e.g., university lab, medical center, NIH, etc.) under the direct supervision of a Qualified Scientist. Copies of the institution's review and approval forms must accompany the required ISEF forms to the ISEF-Affiliated Fair for the SRC to review after experimentation but before competition.

   b) Exempt rDNA studies may be conducted in non-federally registered laboratories, including school laboratories, under the direct supervision of a trained teacher, Qualified Scientist and/or Designated Supervisor and must follow federal regulations.

      (1) Exempt host organisms include the following: bacterium *Escherichia*, bacterium *Bacillus subtilus*, and yeast *Saccharomyces cerevesiae*.

      (2) Exempt DNA insert molecules include the following: (a) DNA molecules that are not in the DNA of organisms or viruses, (b) DNA from single non-chromosomal or 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) The following DNA molecules and host organisms are recommended: (a) DNA molecules: vectors (pAMP, pKAN, pUC, pBR322, M13), (b) host organisms: *E. coli* K-12 strains: MM 294, HB 101, JM 101, and (c) DNA inserts; *Bacteriophage lambda*, *Bacteriophage T4*, *E. coli* sequences, recombinants of any of the above listed plasmids.

   c) Important Restrictions:

      (1) Recombinants containing DNA coding for oncogens or other human, plant or animal toxins (including viruses) cannot be made and/or propagated.

      (2) **Students must not handle ethidium bromide or gels stained with ethidium bromide**. Any handling of ethidium bromide must be done by qualified laboratory personnel, not the student.

5) Any proposed changes in the Research Plan (1A) by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.

■ Required Forms

A) **Checklist for Adult Sponsor**
Research Plan (1A)
Approval Form (1B)
Must be submitted along with the forms listed below to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) If research was conducted or equipment used in an institutional or industrial setting any time during the current ISEF project year**, Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Qualified Scientist Form (2)**
Students using nonexempt rDNA must enlist the expertise of a Qualified Scientist to oversee their projects.

D) **Designated Supervisor Form (3)**
If a Qualified Scientist is unable to supervise a student's nonexempt rDNA experiment, a Designated Supervisor who is thoroughly knowledgeable about the student's research project may supervise. A trained teacher (Designated Supervisor) can directly supervise exempt rDNA experiments. The Designated Supervisor need not have an advanced degree, but must have training in the standards of good microbiological practices and a working knowledge of the organisms.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Sources of Information

NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health.

To order contact:

Office of BioTechnology Activities
National Institutes of Health, MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda, MD 20892-7010
phone: (301) 496-9838
http://www.nih.gov/od/oba

Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 4th Edition. Published by CDC-NIH

To order contact:

Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Road, NE Mailstop F05
Atlanta, GA 30333
website: http://www.cdc.gov/od/ohs/biosfty/biosfty.htm

Working With DNA & Bacteria in Pre-College Science Classrooms. Reston, VA: National Association of Biology Teachers.

To order contact:

National Association of Biology Teachers
12030 Sunrise Valley Drive, Suite 110
Reston, VA 20191-3409
phone: (703) 264-9696 or (800) 406-0775
email: nabter@aol.com
http://www.nabt.org/publications_hypertext.html

❖ Human and Nonhuman Animal Tissue ❖

For the purpose of student research, all body fluids, including saliva and urine, are to be considered tissue.

Rules

1) Research involving human or nonhuman vertebrate animal tissue must be approved by a Scientific Review Committee (SRC) before experimentation begins.

2) A **Human and Animal Tissue Form (6)** is required for all research projects using human or nonhuman vertebrate animal tissue when such tissue is obtained by the student from any research institution, biological supply house, or biomedical scientist.

3) Students may conduct research on human blood, blood products or other body fluids under either one of the following conditions: a) tissue fluids are documented free of HIV and hepatitis B and C before the student receives them; b) tissues are handled in accordance with standards and guidelines set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 – Blood Borne Pathogens. A Qualified Scientist is required for condition 3b.

4) Students using their own blood do not need the HIV or hepatitis certifications (see #3).

5) Several types of tissue are exempt, and do not require a **Human and Animal Tissue Form (6)** or prior SRC approval.
   a) Plant tissue
   b) Established cell and tissue cultures (*e.g.,* those obtained from the American Type Culture Collection). Identify culture source and catalog number in **Research Plan (1A).**
   c) Meat or meat by-products obtained from food stores, restaurants, or packing houses
   d) Hair
   e) Teeth that have been sterilized.*

   *A student who is using teeth in a research project must use those which are not capable of causing disease, regardless of the source (human, primate, shark, etc.), i.e. they must be sterilized. The method of decontamination should be determined by the mentor, but autoclaving is recommended (121 degrees celsius for 30 minutes.)

6) **Any proposed changes in the Research Plan (1A) by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes**.

■ Required Forms for Human and Nonhuman Animal Tissue

A) **Checklist for Adult Sponsor**
Research Plan (1A)
Approval Form (1B)
Must be submitted to an SRC for review and approval before student begins.

B) If research was conducted or equipment used in an institutional or industrial setting anytime during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Human and Animal Tissue Form (6)**
Must be submitted to an SRC for review and approval before student begins experimentation.

D) **Qualified Scientist Form (2)**
If non-certified tissues or fluids are to be handled by the student. (see 3b)

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Sources of Cultures

American Type Culture Collection
1081 University Boulevard
Manassas, VA 20110-2209
(703) 365-2700
(800) 638-6597 (US, Canada, & Puerto Rico)
http://www.atcc.org

Carolina Biological Supply Company
Main Office and Laboratories
2700 York Rd.
Burlington, NC 27215
336-584-0381
(800) 334-5551 (US, Canada, & Puerto Rico)
http://www.carolina.com

❖ Hazardous Substances or Devices ❖

The ISEF Affiliated Fair/Intel ISEF allows students to conduct research involving hazardous substances or devices as long as students adhere to federal and state regulations and guidelines which are designed to protect the safety of researchers.

Rules

1) The use of hazardous chemicals and equipment, firearms, radioactive substances and radiation require proper supervision by a Designated Supervisor. The Designated Supervisor must be directly responsible for overseeing student experimentation.
2) Student researchers working with hazardous substances or devices must follow proper safety procedures for each chemical or device used in the research. Flammable, explosive or highly toxic chemicals are of particular concern. Also included are mutagens and carcinogens as well as chemical mixtures found in pesticides.
3) For all research 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 must be submitted for review to the ISEF-Affiliated Fair SRC along with the other appropriate forms after experimentation but prior to competition.
4) Use of radiation and radioactive substances are tightly regulated. Students should strictly adhere to safety standards of the authorized institution where such substances/devices are used in the research.
5) Differentiation between hazardous and non-hazardous chemicals can best be determined by utilizing the Materials Safety Data Sheets (MSDS).

■ Required Forms for Hazardous Substances or Devices

A) **Checklist for Adult Sponsor**
Research Plan (1A)
Approval Form (1B)
Must be submitted with the form listed below to the ISEF-Affiliated Fair SRC for review and approval after experimentation but prior to competition.

B) If research was conducted or equipment used in an institutional or industrial setting anytime during the current ISEF project year, **Registered Research Institutional/Industrial Setting Form (1C)** must be completed.

C) **Designated Supervisor Form (3)**
A Designated Supervisor who is thoroughly knowledgeable regarding the student's research project, must be directly responsible for overseeing student experimentation. The Designated Supervisor need not have an advanced degree, but must have training and experience in working with the hazardous substances and/or devices used.

NOTE

Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Sources of Information

Chemical

Safety in Academic Chemistry Laboratories, 1995. Washington, DC: American Chemical Society.

Order from (first copy free of charge):
American Chemical Society
Office of Society Services
1155 16th Street, NW
Washington, DC 20036
phone: 1-800-227-5558

Material Safety 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.ilpi.com/msds/index.html

Lasers and Radiation/Radioactive Substances

U.S. Department of Labor
Occupational Safety and Health Administration (OSHA)
Publications Office
200 Constitution Avenue, N.W.
Washington, DC 20210
phone: (202) 219-4667
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

Radioisotopes and Radioactive Substances

John Hickey
U.S. Nuclear Regulatory Commission
Material Safety and Inspection Branch
11555 Rockville Pike
Rockville, MD 20852
phone: (301) 415-7231
http://www.nrc.gov

Firearms

Local Police Department or State Police
The Bureau of Alcohol, Tobacco and Firearms
650 Massachusetts Ave., NW
Washington, DC 20226
Firearms & Explosives Division:
phone: (202) 927-8300
http://www.atf.treas.gov