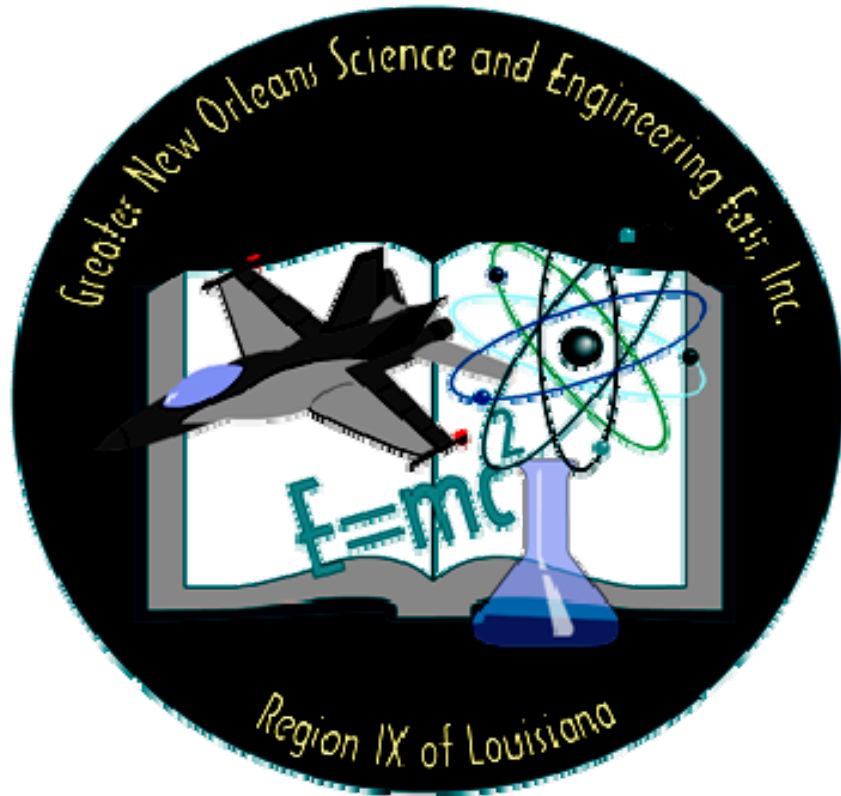


2012-2013 GNOSEF Guidelines



Greater New Orleans Science and Engineering Fair, Inc.

2013 GNOSEF Guidelines in modification to:
International Rules: Guidelines for Science and Engineering Fairs 2012–2013, www.societyforscience.org/isef

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2012-2013 GNOSEF Timeline

Important Deadlines

October 1, 2012	DEADLINE TO SUBMIT SCHOOL AFFILIATION FORMS. Schools indicate intent to participate via registration.
October 19, 2012	DEADLINE TO SUBMIT FORMS FOR PROJECT PRE-APPROVAL TO SRC. All forms requiring GNOEF SRC review or approval are due.
November 16, 2012	DEADLINE TO SUBMIT SRC REQUESTED REVISIONS TO PRE-APPROVAL FORMS. FINAL DEADLINE: All revised or additional forms SRC requested for prior submissions for GNOEF SRC approval. (CORRECTIONS OR COMPLETION OF OCTOBER 19 SUBMITTED PACKETS.) Forms will not be accepted for projects that REQUIRE pre-approval that did not submit forms on October 19.
January 22, 2013	DEADLINE TO SUBMIT SCHOOL REGISTRATION PACKETS. FINAL DEADLINE: ALL forms due to GNOSEF SRC for all students participating in the GNOSEF. <i>Submitting incomplete or incorrectly completed forms may result in the disqualification of a project.</i>
February 8, 2013	Final date to submit SRC requested revisions for participation in GNOSEF.
March 8, 2013	Deadline for LSEF Registration for projects eligible for state competition.

GNOSEF Dates

February 26- 28, 2013

February 26	Set Up Fair Date
February 27	Fair Judging Date
February 28	Fair Public Viewing Date
February 28	Awards Ceremony Date

GNOSEF CATEGORIES

JUNIOR DIVISION CATEGORIES

Biological Science
Chemistry
Earth Science
Environmental Science
Math & Computers
Physics
Engineering

SENIOR DIVISION CATEGORIES

ANIMAL SCIENCES

Development, Ecology, Animal Husbandry, Pathology, Physiology, Population Genetics, Systematics
Other

BEHAVIORAL AND SOCIAL SCIENCES

Clinical & Developmental, Psychology, Cognitive Psychology
Physiological Psychology, Sociology
Other

BIOCHEMISTRY

General Biochemistry, Metabolism, Structural Biochemistry
Other

CELLULAR AND MOLECULAR BIOLOGY

Cellular Biology, Cellular and Molecular Genetics, Immunology, Molecular Biology
Other

CHEMISTRY

Analytical Chemistry, General Chemistry, Inorganic Chemistry
Organic Chemistry, Physical Chemistry
Other

COMPUTER SCIENCE

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

EARTH AND PLANETARY SCIENCE

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

ENGINEERING: Electrical and Mechanical

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

ENGINEERING: Materials and Bioengineering

Bioengineering
Civil Engineering, Construction Engineering
Chemical Engineering
Industrial Engineering, Processing
Material Science
Other

ENERGY & TRANSPORTATION

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

ENVIRONMENTAL MANAGEMENT

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

ENVIRONMENTAL SCIENCES

Air or Water Pollution and Quality
Soil Contamination and Soil Quality
Other

MATHEMATICAL SCIENCES

Algebra, Analysis
Applied Mathematics
Geometry. Probability and Statistics
Other

MEDICINE & HEALTH SCIENCES

Disease Diagnosis and Treatment
Epidemiology, Genetics
Molecular Biology of Diseases
Physiology and Pathology
Other

MICROBIOLOGY

Antibiotics, Antimicrobials
Bacteriology, Microbial Genetics, Virology
Other

PHYSICS AND ASTRONOMY

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

PLANT SCIENCES

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

GNOSEF REQUIREMENTS FOR 2013

Please read the following guidelines carefully as they represent 2013 GNOSEF requirements for project review and approval by the *GNOSEF Scientific Review Committee (GNOEF SRC)* that will **supersede the ISEF approval guidelines.**

THE DEADLINE TO SUBMIT PRE-APPROVAL FORMS TO THE SRC IS OCTOBER 19, 2012.

THE NOVEMBER 16, 2012 DEADLINE IS FOR CORRECTIONS TO PRE-APPROVAL FORMS THAT HAVE BEEN PREVIOUSLY SUBMITTED.

ALL projects which deal with the following conditions or test subjects **MUST** be submitted for *PRIOR GNOSEF SRC* review and approval before students initiate projects.

- All microorganisms whether known or unknown, or any potential pathogens,
- Non-human vertebrate organisms including all cells, tissue, body fluids, embryos or fetuses, and eggs (indicate gestational age),
- All human subjects (including all human cells, tissue, body fluids and all behavioral science projects),
 - Include school completed IRB information (form 4) and any needed consent form templates,
- Prescription drugs, alcohol, tobacco product and any other restricted or controlled substances,
- Potentially hazardous biological or chemical materials/substances,
- Recombinant DNA technologies,
- Potentially hazardous equipment, devices or practices such as those dealing with firearms, explosive materials, radiation.

All projects submitted for review should have appropriate risk assessment, consent, and safety information. Projects that require school-level Institutional Review Board or Institutional Reviews should have properly signed and dated forms indicating review and approval *BEFORE* submitting for GNOSEF SRC approval and before students initiate projects. **All projects reviewed should include a thoroughly detailed Research Plan as described in the ISEF Guidelines, p. 33.**

1. **Students should retain all original documents and forms and submit digital copies (fax or scanned email attachments) of all materials to be reviewed by the SRC for prior approval.** If the SRC needs additional information or corrections, School Coordinators will be notified and students then will correct or complete the ORIGINAL documents and submit **another digital copy** for PRIOR REVIEW. School Coordinators will receive a list of student projects approved by the SRC. Students who participate at the 2012 GNOSEF will submit completed and corrected original documents with GNOSEF registration materials.
2. When all packets are submitted for fair competition, teachers must submit with school registration materials, a packet containing abstracts for ALL projects being entered. The deadline for submission of all packets is **January 22, 2013**. These abstracts may be used for review by the judges prior to judging.
3. In the event of ties at school level fairs, it is the responsibility of the school to choose the three GNOSEF submissions. Each school may submit *only three entries per category*. In the event that there are more submissions, the first three electronically submitted will be accepted.
4. No additional forms, no completion of incomplete forms, or submission of SCHOOL REGISTRATION PACKETS will be accepted after the DEADLINE TO SUBMIT FORMS (See page 3 for dates.) Students are expected to have completed any additional requests by the SRC by the deadline for corrections (See page 3 for dates.)

Students must submit their initial forms and complete, detailed research plan by the appropriate DEADLINE TO SUBMIT FORMS (See page 3 for specific dates) for projects requiring SRC approval prior to beginning the project. Projects will not be eligible for competition or display at the GNOSEF if any form deadlines are missed. Incomplete or incorrect forms submitted by the final forms submission deadline will be disqualified. (See page 3 for details.)

ABSOLUTELY NO RESEARCH PLANS WILL BE ACCEPTED FOR EVALUATION OF PRIOR APPROVAL BY THE SRC AFTER the DEADLINE TO SUBMIT FORMS (See page 3 for dates).

ALL PROJECTS

ETHICS STATEMENT

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs and the Intel ISEF. Society for Science & the Public reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

ELIGIBILITY/LIMITATIONS

1. Each student may enter only one project. That project may include no more than 12 months of continuous research and may not include research performed before January 2012.
2. Team projects may have two or three members. Teams may not have had more than three members at a local fair. Teams may not substitute members in a given research year.
3. Students may compete in only one Intel ISEF affiliated fair, except when proceeding to a state/national fair affiliated with the Intel ISEF from an affiliated regional fair.
4. Projects that are demonstrations, 'library' research, informational projects, 'explanation' models or kit- building are not appropriate for GNOSEF or the Intel ISEF.
5. A research project may be a part of a larger study performed by professional scientists, **but the project presented by the student must be only their own portion of the complete study.**

REQUIREMENTS

GENERAL

1. All students competing at GNOSEF must adhere to all rules as set forth in this document.
2. All projects must adhere to the Ethics Statement above.
3. All projects must adhere to the requirements of the affiliated fair in which it competes to qualify for participation in the Intel ISEF. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.
4. Projects must adhere to local, state and U.S. Federal laws, regulations and permitting conditions. In addition, projects conducted outside the U.S. must also adhere to the laws of the country and jurisdiction in which the project was performed.
5. The use of non-animal research methods and the use of alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project.
6. Introduction or disposal of non-native species, pathogens, toxic chemicals or foreign substances into the environment is prohibited.
7. GNOSEF exhibits must adhere to GNOSEF and Intel ISEF display and safety requirements.

APPROVAL AND DOCUMENTATION

1. Before experimentation begins, the GNOSEF must review and approve most projects involving human participants, vertebrate animals, potentially hazardous biological agents, hazardous chemicals or hazardous activities.
2. Every student must complete the Student Checklist (1A), a Research Plan and Approval Form (1B) and review the project with the Adult Sponsor in coordination with completion by the Adult Sponsor of the Checklist for Adult Sponsor (1).
3. A Qualified Scientist is required for all studies involving BSL-2 potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.

4. After initial IRB/SRC approval (if required), any proposed changes in the Student Checklist (1A) and Research Plan must be re-approved before laboratory experimentation/data collection resumes.
5. Projects which are continuations of a previous year's work and which require IRB/SRC approval must undergo the review process with the current year proposal prior to experimentation/data collection for the current year.
6. Any continuing project must document that the additional research is new and different (see Continuation Projects Form (7)).
7. If work was conducted in a Regulated Research Institution, industrial setting or any work site other than home, school or field, at any time during the current Intel ISEF project year, the Regulated Research Institutional/Industrial Setting Form (1C) must be completed and displayed at the project booth.
8. 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 the supervising adult(s).
9. A project data book and research paper are not required, but are recommended. Regional or local fairs may require a project data book and/or a research paper.
10. All signed forms, certifications, and permits must be available for review by all regional, state, national and international affiliated fair SRCs in which the student(s) participate. This review must occur after experimentation and before competition.

CONTINUATION OF PROJECTS

1. As in the professional world, research projects may build on work performed previously. A valid continuation project is a sound scientific endeavor. Students will be judged only on laboratory experiment/data collection performed over 12 continuous months beginning no earlier than January 2012 and ending May 2013.
2. Any project based on the student's prior research could be considered a continuation project. If the current year's project could not have been performed without the outcome of a past year's research project, then it is considered a continuation for competition. These projects must document that the additional research is a substantive expansion from prior work (e.g. testing a new variable or new line of investigation.) Repetition of previous experimentation with the same methodology and research question, even with an increased sample size, is an example of an unacceptable continuation.
3. Display board and abstract must reflect the current year's work only. The project title displayed in the Finalist's booth may mention years (for example, "Year Two of an Ongoing Study"). Supporting data books (not research papers) from previous related research may be exhibited if properly labeled as such.
4. Longitudinal studies are permitted as an acceptable continuation under the following conditions:
 - a. The study is a multi-year study testing or documenting the same variables in which time is a critical variable. (Examples: effect of high rain or drought on soil in a given basin, return of flora and fauna in a burned area over time.)
 - b. Each consecutive year demonstrates time-based change.
 - c. The display board is based on collective past definitive data and its comparison to the current year data set. No raw data from previous years may be displayed.
5. All continuation projects must be reviewed and approved each year and forms must again be completed for the new year.

NOTE: For competition in the Intel ISEF, documentation must include the Continuation Project Form (7), the previous year's abstract and research plan and the abstract for all other prior years. Documentation must be labeled clearly with the year (ex: 2011-2012). Retention of all prior years' paperwork is required and must be presented to the Intel ISEF SRC upon request.

TEAM PROJECTS

1. Team projects compete and are judged in the scientific category of their research.
2. Teams may have two or three members. Teams may not have had more than three members at any level of affiliated fair. Teams may not substitute members in a given research year.
3. **Team membership cannot be changed during a given research year, including converting from an individual project to a team project, or vice versa. In future years, the project may be converted from an individual to a team project, from a team to an individual project and/or change team members.**
4. Each team is encouraged to 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). Team members must jointly submit the Checklist for Adult Sponsor (1), one abstract, a Student Checklist (1A), a Research Plan and other required forms.
6. Full names of all team members must appear on forms.

RESEARCH PLAN INSTRUCTIONS (ISEF, P.33)

A complete and detailed research plan is required for all projects and must accompany required forms for GNOSEF registration and for SRC approval. All students must provide an additional copy of the typed research plan to be displayed with project.

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

A. Question or Problem being addressed

B. Goals/Expected Outcomes/Hypotheses

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

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

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

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

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

1. Human participants research:

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

2. Vertebrate animal research:

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

3. Potentially Hazardous Biological Agents:

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

4. Hazardous Chemicals, Activities & Devices:

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

ISEF 2013 RULES & GUIDELINES

CHANGES AND MODIFICATIONS FOR 2012-2013

ELIGIBILITY/LIMITATIONS

- Student must not have reached age 20 on or before May 1 preceding the Intel ISEF in order to be eligible to compete at ISEF.

VERTEBRATE ANIMALS

- No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup. Such a project will fail to qualify for competition.
- Any death which occurs must be investigated by an individual qualified to determine the cause of death. The results of the investigation must be documented in writing.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

- Studies involving the decomposition of vertebrate organisms (such as in forensic projects) require a Risk Assessment Form 3.
- Human and other primate established cell lines and tissue cultures are to be treated as potentially hazardous biological agents. Plant and non-primate established cell lines and tissue culture collections do not need to be treated as potentially hazardous biological agents.

FORM CHANGES

- Vertebrate Animal Form 5A
 - Added question regarding weight loss or death of any animal.
 - If weight loss or death occurred, the student needs to attach documentation from qualified individual*.
- Vertebrate Animal Form 5B
 - Added question regarding weight loss or death of any animal.
 - If weight loss or death occurred, the student needs to attach documentation from qualified individual.
- Removed the certification/documentation of student researcher training.

***“The Intel ISEF Vertebrate Animal Rules require that any death, illness or unexpected weight loss be investigated and documented by a letter from the qualified scientist, designated supervisor or a veterinarian. If applicable, attach this letter with this form when submitting your paperwork to the SRC prior to competition.”**

GNOSEF DISPLAY AND SAFETY REGULATIONS

The Greater New Orleans Science and Engineering Fair Guidelines developed by the GNOSEF Scientific Review Committee and Display Safety Committee contain some provisions that are in addition to the ISEF guidelines. GNOSEF Guidelines were developed to insure adherence to safety practices.

Where GNOSEF and ISEF guidelines or requirements differ, GNOSEF guidelines and restrictions will apply for the GNOSEF Region IX fair. The GNOSEF *Display and Safety Committee* may require students to make revisions in their display to conform to GNOSEF display and safety regulations. Failure to do so will result in the disqualification of the project.

GENERAL REQUIREMENTS

The GNOSEF *Display and Safety Committee* (DSC) is the final authority on display and safety issues for projects approved by the *Scientific Review Committee* (SRC) to compete in the GNOSEF.

DISPLAY CONTENT FOR RESEARCH INSTITUTION AND/OR CONTINUATION PROJECTS

The project display summarizes the research project and must focus on the student(s) work for this year's study with only minimal reference to previous research. Longitudinal studies may present only conclusionary data from prior years.

[Exception: the project title of the display board 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.

In addition, the project display must be limited to the work conducted by the student(s) for the project. The mentor's research, even if it was a precursor to student experimentation (e.g. animal research from which tissue was obtained for the project) is not a part of the student research project and must not be included in the display. Very minimal reference to work done by a mentor or others may be included only for background information or clarification of what the student's research covered and must clearly indicate that it was not part of the student's work.

MAXIMUM SIZE OF PROJECT

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

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

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

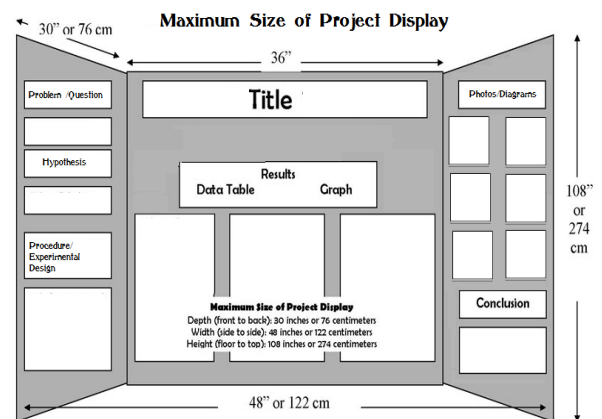
At the GNOSEF, fair-provided tables will not exceed a height of 36 inches (91 centimeters). Maximum project sizes include all project materials, supports, and demonstrations for public and judges.

If a table is used, it becomes part of the project and must not itself exceed the allowed dimensions *nor may the table plus any part of the project exceed the allowed dimensions.*

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

REQUIRED TO BE VISIBLY DISPLAYED AT THE GNOSEF

- Original of official Abstract without student or school identifiers



- Completed GNOSEF Project Safety Set-up Approval Form signed by the GNOSEF Safety Review Committee
- Photograph / image credits

REQUIRED TO BE PREVIOUSLY SUBMITTED BUT NOT DISPLAYED AT THE GNOSEF

All forms required for Scientific Review Committee review and approval including, but not limited to:

- | | |
|-----------------------------------|------------------------------------|
| ▪ Checklist for Adult Sponsor (1) | ▪ Approval Form (1B) |
| ▪ Student Checklist (1A) | ▪ Human Subjects (4) |
| ▪ Research Plan | ▪ Informed Consent, Photo Consents |

These forms are not displayed as part of the project, but must be submitted to the GNOSEF on or before the date indicated in the GNOSEF timeline for review by the Safety and Scientific Review Committees.

Students must submit their initial forms by the first form deadline required for the specific project. (See page 3 for dates and requirements.) Projects will not be eligible for competition or display at the GNOSEF if any form deadlines are missed. Projects with incomplete or incorrect forms submitted by the final forms deadline will be disqualified.

PHOTOGRAPH/IMAGE DISPLAY REQUIREMENTS

The GNOSEF Display and Safety Committee require a photograph/ video release form signed by the human subject for visual images of humans (other than the student) displayed as part of the project. These forms and any informed consents forms should not be displayed.

Photographs used must be credited on the display. To retain non-disclosure, if the student is the photographer, the credit might indicate “Photograph taken by submitting student” or another statement which does not indicate student name.

Display of photographs other than that of the finalist must have a photo release signed by the subject, and if under 18 years of age, also by the guardian of the subject. Sample consent text: *“I consent to the use of visual images (photos, videos, etc.) involving my participation/my child’s participation in this research.”*

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.

Any photograph/visual image/chart/table and/or graph is allowed if:

- It is not deemed offensive or inappropriate (*which includes images/photographs showing invertebrate or vertebrate animals/humans in surgical, necrotizing or dissection situations*) by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public. The decision made by any one of the groups mentioned above is final.
- It has a credit line of origin (“Photograph taken by...,” or “Image taken from...,” or “Graph/Chart/Table taken from. . .”). (If all images, etc. being displayed were taken or created by the finalist or are from the same source, one credit line prominently and vertically displayed on the backboard/poster or tabletop is sufficient.)
- It is from the Internet, magazine, newspaper, journal, etc., and a credit line is attached. (If all photographs, etc. are from the same source, one credit prominently and vertically displayed is sufficient.)
- It is a photograph or visual depiction of the finalist.
- It is a photograph or visual depiction for which a signed consent form is at the project or in the booth.

Note: Images used as backgrounds must also be credited.

HANDOUTS/OFFICIAL ABSTRACT AND CERTIFICATION AT THE GNOSEF

The GNOSEF Scientific Review Committee requires the official ISEF abstract to be displayed with the project without the name of the submitting student or any other information that identifies the student or school. **The term “abstract” may not be used as a title or reference for any information on a student’s display or in a student’s materials at the project except as part of displaying the official abstract.** An official abstract must be available for the judges and must be located on the table at the project. Handouts to judges and to the public must be limited to *UNALTERED PHOTOCOPIES* of the official abstract.

NOT ALLOWED TO BE DISPLAYED WITH PROJECT

1. The name of the student or their school will not be displayed on the project board, paper, abstract or any other part of the project.
2. Brand names of products/items tested.
3. Soil, sand, rock and/or waste samples even if permanently encased in a slab of plastic.
4. Living organisms, including plants
5. Taxidermy specimens or parts
6. Preserved vertebrate or invertebrate animals
7. Human or animal food (Note: This includes any edible item that might be attached to the board as decoration. Students will be required to remove all food items which if attached to board might cause damage to the board.)
8. Human/animal parts or body fluids (for example, blood, urine)
9. 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) (Note: This includes any plant material that might be attached to the board as decoration. Students will be required to remove all plant material which if attached to board might cause damage to the board.)
10. All chemicals including water (Exceptions: water integral to an enclosed, sealed apparatus.)
11. All hazardous substances or devices [for example, poisons, drugs, firearms, weapons, ammunition, reloading devices, and lasers (as indicated in item 5 in the section of these rules entitled “Allowed at Project or in Booth BUT with the Restrictions Indicated”)]
12. Dry ice or other sublimating solids
13. Sharp items (for example, syringes, needles, pipettes, knives)
14. Flames or highly flammable materials
15. Batteries with open-top cells
16. Awards, medals, business cards, flags, logos, endorsements, and/or acknowledgments (graphic or written) unless the item(s) are an integral part of the project (Exception: GNOSEF medal(s) may be worn at all times.)
17. Photographs or other visual presentations depicting vertebrate animals in surgical techniques, dissections, necropsies, or other lab procedures
18. Product labels and/or other recognizable indications of brand names of products
19. Active Internet or e-mail connections as part of displaying or operating the project at the GNOSEF
20. Prior years’ written material or visual depictions on the vertical display board. [Exception: the project title displayed in the student’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.
21. 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)
22. Any apparatus deemed unsafe by the Scientific Review Committee, the Display and Safety Committee, or Society for Science & the Public (for example, large vacuum tubes or dangerous ray-

generating devices, empty tanks that previously contained combustible liquids or gases, pressurized tanks, etc.)

ALLOWED AT PROJECT OR IN BOOTH WITH THE RESTRICTIONS INDICATED

1. Photographs and/or visual depictions IF:
 - a. They are not deemed offensive or inappropriate by the Scientific Review Committee or the Display and Safety Committee. This includes, but is not limited to, visually offensive photographs or visual depictions of invertebrate or vertebrate animals, including humans. The decision by any one of the groups mentioned above is final.
 - b. They have credit lines of origin (“Photograph taken by...” or “Image taken from...”). (If all photographs being displayed were taken by the student or are from the same source, one credit line prominently and vertically displayed is sufficient.)
 - c. They are from the Internet, magazines, newspapers, journals, etc., and credit lines are attached. (If all photographs/images are from the same source, one credit prominently and vertically displayed is sufficient.)
 - d. They are photographs or visual depictions of the student.
 - e. They are photographs of human subjects for which signed consent forms with the registration officials.
2. Any apparatus with unshielded belts, pulleys, chains, or moving parts with tension or pinch points if for display only and not operated.
 - a. Any demonstration for judges or the public must be performed within the maximum size of the project permitted, an area 30”(Depth) by 48”(Width) by 108” (Height)
 - b. Class II lasers if:
 - i. The output energy is <1 mW and is operated only by the student
 - ii. Operated only during the Display and Safety inspection and during judging
 - iii. Labeled with a sign reading “Laser Radiation: Do Not Look into Beam”
 - iv. Enclosed in protective housing that prevents physical and visual access to beam
 - v. Disconnected when not operating
 - vi. **MUST BE REMOVED AFTER JUDGING COMPLETES.**
 - c. *Note: Class II lasers are found in laser pointers and in aiming and range-finding devices. They pose a risk if the beam is directly viewed over a long period of time.*
3. Class III and IV lasers if for display only and not operated (See the description of Class III and Class IV lasers in the Radiation section of the Hazardous Chemicals, Activities, or Devices, at
 - a. http://www.societyforscience.org/isef/about/rules_regulations.asp) **MUST BE REMOVED AFTER JUDGING COMPLETES.**
4. Any apparatus producing temperatures that will cause physical burns if adequately insulated
5. The only items that may be displayed on the front of the provided tables are the forms listed in the section of these rules entitled “Required to be Visible and Vertically Displayed at the GNOSEF”.

ELECTRICAL REGULATIONS AT THE GNOSEF

1. Students 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 GNOSEF 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 student. Exposed electrical equipment or metal that possibly may be energized must be shielded with a non-conducting material or with a grounded metal box to prevent accidental contact.
5. Wiring not part of a commercially available UL-listed appliance or piece of equipment must have a clearly visible fuse or circuit breaker on the supply side of the power source and prior to any project equipment.
6. There must be an accessible, clearly visible on/off switch or other means of disconnect from the 120 or 220 Volt power source.
7. Any lighting that generates considerable and excessive amounts of heat (high-intensity lamps, halogen lights, etc.) must be turned off when the student is not present.

OTHER GNOSEF INFORMATION AND REQUIREMENTS

1. *Students must be present at their projects for the Display and Safety inspection.* The inspection is a process that takes place between the student and inspector; therefore, no other persons should be present representing the student 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. Doing so may result in disqualification of the project.**
3. The Scientific Review Committee, and/or the Display and Safety Committee reserve the right to remove any project for safety reasons or to protect the integrity of the GNOSEF and its rules and regulations.
4. A project data book and research paper are not required but are *highly recommended*. There should be no identifying information of the student or their school.
5. Display of photographs other than that of the student must have a photo release signed by the subject, and if under 18 years of age, also by the guardian of the subject. Sample consent text: "I consent to the use of visual images (photos, videos, etc.) involving my participation/my child's participation in this research." These will be collected by the DSC and attached to the student's packet of submitting project information. They are not to be displayed with the project.
6. Students using audio-visual or multi-media presentations (for example, 35mm slides; videotapes; images, graphics, animations, etc., displayed on computer monitors; or other non-print presentation methods) must be prepared to show the entire presentation to the Display and Safety inspectors before the project is approved.
7. If a project fails to qualify and is not removed by the student the DSC or GNOEF SRC will remove the project in the safest manner possible but is not responsible for damage to the project.
8. Any disks, CDs, printed materials, etc. (including unofficial abstracts) designed to be distributed to judges or the public will be confiscated by the Display and Safety Committee and will be discarded immediately.
9. Project sounds, lights, odors, or any other display items must not be distracting.
10. No food or drinks, except small containers of bottled water for personal consumption, are allowed in the Exhibit Hall.

PROJECT REVIEW

SCHOOL LEVEL REVIEW

Institutional Review Board (IRB)

The IRB must evaluate the potential physical and/or psychological risk of ALL research involving human subjects. All proposed human research must be reviewed and approved by a school level IRB before SRC review and experimentation begins. (See specifics below.)

GNOSEF LEVEL REVIEW

GNOSEF SCIENTIFIC REVIEW COMMITTEE (SRC)

The GNOSEF Scientific Review Committee is established for review of student research, certifications, research plans and exhibits for compliance with the GNOSEF Rules, pertinent laws and regulations and to ensure that the appropriate forms have been completed.

Projects involving research risks or issues and special protocols must be reviewed by a Scientific Review Committee (SRC) **BEFORE THE START OF EXPERIMENTATION**. Any proposed research in the following areas must be reviewed and approved **BEFORE** experimentation:

- Known or unknown microorganisms, or potential pathogens
- Non-human vertebrate organisms including all tissue, body fluids, embryos or fetuses, and eggs (indicate gestational age)
- Human subjects (including all human tissue, body fluids)
- Prescription drugs, alcohol, tobacco product and any other restricted or controlled substances
- Potentially hazardous biological or chemical materials/substances
- Recombinant DNA technologies
- Potentially hazardous equipment, devices or practices such as those dealing with firearms, explosive materials, radiation.

The SRC gives special attention to the following items:

- evidence of proper supervision
- use of appropriate research techniques
- properly completed forms, including appropriate signatures and dates
- humane treatment of animals; proper care and housing of animals
- compliance with rules regarding potentially hazardous biological agents
- documentation of substantial expansion of continuing projects
- compliance with ISEF Ethics Statement
- evidence of evaluation of risk assessment.

UNIVERSITY/INSTITUTIONAL LABORATORY LEVEL REVIEW (IF REQUIRED)

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

- a. Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
- b. Institutional Review Board (IRB)
- c. Human Subjects Research Board (HSRB)
- d. Institutional Biosafety Committee (IBC)
- e. Embryonic Stem Cell Research Oversight Committee (ESCRO)

Research determined to be a Biosafety Level 2 (BSL-2) MUST be conducted in a laboratory rated BSL-2 or above (commonly found in a regulated research institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter obtained from an institutional representative that the research does not require review. The research must be supervised by a Qualified Scientist. The student researcher must receive extensive training, demonstrate competency and be directly supervised while conducting microbiological procedures.

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.)

No Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Designated Supervisor who oversee the project may serve on the IRB reviewing that project. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

INSTITUTIONAL REVIEW BOARD (IRB)

1. An Institutional Review Board (IRB) is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving human subjects. All proposed human research must be reviewed and approved by an IRB *BEFORE EXPERIMENTATION BEGINS*. This *includes review of any surveys or questionnaires* to be used in a project.
2. An IRB at the school 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 MAY 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. **one of the following who is knowledgeable and capable of evaluating the physical and/or psychological risk involved in a given study: a medical doctor, physician's assistant, registered nurse, a psychiatrist, psychologist, licensed professional counselor or licensed social worker.**
3. 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.
4. The Adult Sponsor is responsible for ensuring that the project is appropriate for a pre-college student and adheres to the GNOSEF rules.
5. All human subject research must be reviewed by the GNOSEF SRC *PRIOR TO EXPERIMENTATION*. An IRB generally makes the final determination of risk. However, in reviewing projects, if the GNOSEF SRC determines that the research places human subjects at risk, the GNOSEF SRC may override the IRB's decision and the project may fail to qualify for competition.

ROLES AND RESPONSIBILITIES OF STUDENTS & ADULTS

STUDENT

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

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.

ADULT SPONSOR

An Adult Sponsor may be a teacher, parent, university professor, or scientist in whose lab the student is working. This individual must *have a solid background in science and should have close contact with the student during the course of the project*. The Adult Sponsor is responsible for working with the student to *evaluate any possible risks* involved in order to ensure the health and safety of the student conducting the research and the humans or animals involved in the study. The Adult Sponsor must review the completed 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.

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 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.

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.

COMMON REASONS FOR FAILURE TO QUALIFY OR RETURN OF STUDENT FORMS:

1. Paperwork
 - Failure to obtain prior SRC approval
 - Not getting paperwork in on time
 - Incomplete paperwork, missing forms or signatures
 - Missing FORM (1C) for projects completed in research facilities.
 - Not differentiating between a qualified scientist and a designated supervisor or forms missing
 - Risk Assessment form needed but not included or is incomplete
 - Incorrect or incomplete Abstract
2. Human, vertebrate animal, or PHBA studies that did not have preapproval
 - Need IRB preapproval for human subjects studies
 - Need SRC or IACUC preapproval for vertebrate animal studies
 - Need SRC or IBC preapproval for PHBA studies
1. Prohibited Vertebrate Animal Studies
 - Studies done at home/school/field that should have been done at a regulated research institution
 - Studies that caused more than momentary pain or suffering or that were designed to kill
 - Induced toxicity studies
 - Predator/vertebrate prey experiments
 - Studies where student performed euthanasia on a vertebrate animal
 - Studies with an animal death in any group or subgroup due to the experimental procedures
 - Studies where animals have a weight loss greater than or equal to 15%
 - Studies where there was an inappropriate restriction of water or food
 - Studies treated as embryonic studies that were actually vertebrate studies
2. Prohibited Studies using Potentially Hazardous Biological Agents (PHBA's)
 - Inappropriate or insufficient handling and safety precautions for the use of bacteria and molds (potentially-pathogenic agents) indicated in plan or Risk Assessment
 - Microorganisms were cultured at home
 - BSL-2 studies (including opening plates or containers of unknown microorganisms) done in a BSL-1 lab
 - Studies using human and other primate established cell lines without SRC pre-review and approval
3. Prohibited Human Subjects Studies
 - Studies where the IRB required written documentation of consents which were not obtained
 - Studies where the student used surveys/questionnaires without IRB pre-review and approval
4. Eligibility Problems
 - Student worked with a partner or team but competed as an individual, or vice versa
 - Project was more than 1 year in length or was too old
 - More than three students on a team
5. Scientific Misconduct
 - Plagiarism
 - Student presented mentor's research as his/her own
 - Falsification of data
6. Other problems that may result in an FTQ
 - Continuation study which was merely a repeat of a previous project conducted by the student
 - Student removed or added items to the project display which he/she had been previously told to change

GUIDELINES FOR PROJECTS REQUIRING SPECIAL DOCUMENTATION AND REVIEW

Human Participants

ALL HUMAN PARTICIPANT PROJECTS MUST BE REVIEWED BY THE GNOSEF SRC PRIOR TO START OF EXPERIMENTATION. ALL IRB INFORMATION MUST BE SUBMITTED WITH FORMS FOR PRE-APPROVAL.

Student researchers must follow federal guidelines (Code of Federal Regulations 45 CFR 46) to protect the human research participant and the student researcher. When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB) and informed consent/assent from the research participant.

RULES

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

5. Research conducted by a pre-college student at a federally Regulated Research Institution (e.g., university, medical center, government lab, correctional institution) 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) and/or an official letter from the IRB attesting to approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.
6. Research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants may give their own consent. Research participants under 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing permission. The IRB will determine whether the consent/assent/parental permission may be verbal or must be written depending on the level of risk and the type of study, and will determine if a Qualified Scientist is required to oversee the project. See Risk Assessment below and the Risk Assessment Guide for further explanation of informed consent.
 - Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
 - Participants must be informed that their participation is voluntary (i.e., they may participate or decline to participate, with no adverse consequences of nonparticipation or aborted participation) and that they are free to stop participating at any time.
 - Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature.
 - When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
7. A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a medical professional. This medical professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medication and/or performing invasive medical procedures on human participants. The IRB must also confirm that the student is not violating the medical practice act of the state or country in which he/she is conducting the research.
8. Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).
9. All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.
10. Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in a) collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the Risk Assessment Guide and the Online Survey Consent Procedures.
11. After experimentation and before Intel ISEF competition, the Intel ISEF SRC reviews and approves previously-approved projects to ensure that students followed the approved Research Plan and all of the Intel ISEF rules.

12. The following forms are required:
- a) Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b) Human Participants Form (4) with applicable consents and survey(s)
 - c) Regulated Research Institution Form (1C), when applicable
 - d) Qualified Scientist Form (2), when applicable.

13) Sources of Information are available at www.societyforscience.org/isef/rulesandguidelines.

IRB WAIVER OF WRITTEN INFORMED CONSENT

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

- a. Research involving normal educational practices.
- b. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.
- c. Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
- d. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.
- e. If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

RISK ASSESSMENT

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

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

1. Examples of Greater than Minimal Physical Risk

- a) Exercise other than ordinarily encountered in everyday life
- b) Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
- c) Exposure to any potentially hazardous material.

2. Examples of Greater than Minimal Psychological Risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing video images.

3. Privacy Concerns

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

Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4. Risk Groups

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

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

See the online Risk Assessment Guide and Online Survey Consent Procedures for more detailed information on risk assessment.

INFORMED CONSENT

Research subjects, or their parents, need to give informed consent before participating in a research project. Many cases will require written documentation of the consent.

For informed consent to occur the human subjects are told:

- what they will be asked to do in the study
- risks and benefits (if any) associated with participation,
- the voluntary nature of the study
- their right to withdraw from the study at any time

Informed consent should be documented through the use of Form 4 for most, if not all projects. *IRBs should make conservative decisions and require documentation of informed consent if there is any doubt if a study involves more than minimal risk.*

Individuals under the age of 18 years are members of a risk group and therefore should have documentation of informed consent. A parent or legal guardian should give informed consent for his/her child to be a human subject in a science fair project. However, many students choose to use their peers as research subjects and some of these projects are truly minimal risk with anonymous data collection. The ISEF Rules and Guidelines permit some of these projects to be conducted without documentation of informed consent. Written documentation of Informed consent can be waived if the study involves:

- minimal risk and,
- anonymous data collection and,
- one of the following

- observation of legal public behavior
- study of existing data
- study of normal educational practices
- study of behavior where no manipulation
- surveys of perception, cognition, game theory
- physical activity with no more than minimal risk

While documentation of parental informed consent may not be required, it is still necessary to inform the student research subjects

- what they will be asked to do in the study
- the voluntary nature of the study
- their right to withdrawal from or stop participating in the study at any time
- the risks and benefits (if any) associated with participation

The typical high school student can understand the above information and can advocate for him/herself if the research procedures become aversive in any way (i.e., the student gets a headache and wants to leave the room). On the other hand, a younger child may not understand that he/she is even participating in a research project. We recommend that IRBs be very cautious in waiving the need for parental consent for research involving children below high school age. Members of the IRB may want to consider how the most conservative parents would react if their child had participated in a “research project” without the parents’ approval.

WAYS THAT THE STUDENT RESEARCHER MAY MINIMIZE RISK

The student researcher must develop recruiting procedures that highlight that participation in the study is voluntary and that students can withdraw from the study at any time. Efforts must also be taken to ensure that students that do not want to participate must be able to decline participation inconspicuously.

Anonymous data collection should be used. This means that the surveys/questionnaires do not ask for any identifying information. For example, subjects are not asked to write down their names, birthdates, phone numbers, email addresses or other pieces of information that would allow the researcher or another person looking at the survey to determine who provided the information. In some instances, collecting information such as racial or ethnic group or neighborhood could be identifying information if only a few students identify themselves as being from a specific ethnic group or living in a specific neighborhood. That is, if there are only two Asian students in the class, it will be relatively obvious who provided the information on a survey that has “Asian” checked. The student researcher, mentor and IRB must carefully consider whether some variables may identify a specific person or very small group of people.

Students may want to print on the survey a statement such as *“Participation in my science fair project is completely voluntary. This study is anonymous. Please do not put your name on the survey. If you want to participate, please complete the following survey. When you are finished fold your paper in half and wait for someone to collect it. If you DO NOT want to participate, do not complete the survey. You may simply fold this paper in half and wait for someone to collect it. You may change your mind at any time and decide not to participate.”*

If a student researcher was recruiting other students in a hallway to participate in his/her study, he could post a sign such as *“Participation in my science fair project is voluntary. If you would like to participate by filling out my questionnaire, please take one and fill it out. You can change your mind and decide not to participate at any time. This study is anonymous. Please do not put your name on the questionnaire.”*

NON-HUMAN VERTEBRATE ANIMALS

The following rules were developed to help pre-college student researchers adhere to the federal regulations governing professional scientists and to protect the welfare of both animal subjects and the student researcher. When students conduct research with animal subjects, health and well-being is of high priority. SSP strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research. If the use of vertebrate animals is necessary, students must consider additional alternatives to reduce and refine the use of animals.

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.

A project is considered a tissue study and not a vertebrate animal study if tissue is obtained from an animal that was euthanized for a purpose other than the student's project. (Documentation is required of the IACUC approval for the original animal study from which tissues are obtained.) In tissue studies, a student may observe the vertebrate study, but may not manipulate or have any direct involvement in the vertebrate animal experimental procedures.

RULES FOR ALL VERTEBRATE ANIMAL STUDIES

1. The use of vertebrate animals in science projects is allowable under the conditions and rules in the following sections. Vertebrate animals, as covered by these rules, are defined as:
 - Live, nonhuman vertebrate mammalian embryos or fetuses
 - Tadpoles
 - Bird and reptile eggs within three days (72 hours) of hatching
 - All other nonhuman vertebrates (including fish) at hatching or birth.

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

2. Alternatives to the use of vertebrate animals for research must be explored and discussed in the research plan. Alternatives include the following "Four R's":
 - **Replace** vertebrate animals with invertebrates, lower life forms, tissue/cell cultures and/or computer simulations where possible.
 - **Reduce** the number of animals without compromising statistical validity.
 - **Refine** the experimental protocol to minimize pain or distress to the animals.
 - **Respect** animals and their contribution to research.
3. All vertebrate animal studies must be reviewed and approved before experimentation begins. An Institutional Animal Care and Use Committee, known as an IACUC, is the institutional animal oversight review and approval body for all animal studies at a Regulated Research Institution. The affiliated fair SRC serves in this capacity for vertebrate animals studies performed in a school, home or field. Any affiliated fair SRC serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.
4. All vertebrate animal studies must have a research plan that includes:
 - A. Justification why animals must be used, including the reasons for the choice of species, the source of animals and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.

- B. Description of how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Describe the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation. Identify the species, strain, sex, age, weight, source and number of animals proposed for use.
5. Studies involving behavioral observations of animals are exempt from advance SRC review if ALL of the following apply:
- There is no interaction with the animals being observed,
 - There is no manipulation of the animal environment in any way, and
 - The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.
6. Students performing vertebrate animal research must satisfy local, state, country laws and regulations of the jurisdiction in which research is performed as well as U.S. federal law.
7. Research projects which cause more than momentary or slight pain or distress are prohibited. If there is illness or unexpected weight loss this must be investigated and a veterinarian must be consulted to oversee any indicated medical care. This investigation must be documented by the Qualified Scientist, Designated Supervisor who is qualified to determine the illness or a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.
8. No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup. Such a project will fail to qualify for competition.
- A. Studies that are designed or anticipated to cause vertebrate animal death are prohibited.
- B. Any death that occurs must be investigated by a veterinarian, the Qualified Scientist or the Designated Supervisor who is qualified to determine the cause of death. The project must be suspended until such investigation occurs and the results must be documented in writing.
- C. If death was the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.
9. All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal is 15%.
- 10. Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:**
- **Induced toxicity studies with known toxic substances that could impair health or end life, including, but not limited to, alcohol, acid rain, pesticides, or heavy metals.**
 - **Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.**
 - **Studies of pain.**
 - **Predator/vertebrate prey experiments.**
11. Justification is required for an experimental design that involves food or fluid restriction and must be appropriate to the species. If the restriction exceeds 18 hours, the project must be reviewed and approved by an IACUC and conducted at a regulated research institution.
12. 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, local and national fishing laws and regulations. Students are prohibited from performing electrofishing.

13. A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.
14. After initial SRC approval, a student with any proposed changes in the Research Plan of the project must repeat the approval process before laboratory experimentation/data collection resumes.

ADDITIONAL RULES FOR PROJECTS CONDUCTED AT SCHOOL/HOME/FIELD

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

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

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

1. These projects must adhere to BOTH of the following guidelines:
 - A. The research involves only agricultural, behavioral, observational or supplemental nutritional studies on animals.

AND

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

All studies meeting the general guidelines but not meeting the above criteria specifically for home, school or field must be conducted at a Regulated Research Institution. See Section B.

2. Animals must be treated kindly and cared for properly. Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species. 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. Any of the following U.S. documents provide further guidance for animal husbandry:
 - *Federal Animal Welfare Regulation*
 - *Guide for the Care and Use of Laboratory Animals*
 - *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Ag-Guide)*
3. The affiliated fair Scientific Review Committee must determine if a veterinarian's certification of the research plan and animal husbandry plans is required. This certification is required before experimentation and SRC approval and is documented on Vertebrate Animal Form 5A. A veterinarian must certify experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.
4. If an illness or emergency occurs, the affected animal(s) must receive proper medical or nursing care that is directed by a veterinarian. A student researcher must stop experimentation if there is unexpected weight loss or death in the experimental subjects. The experiment can only be resumed if the cause of illness or death is not related to the experimental procedures and if appropriate steps are taken to eliminate the causal factors. If death is the result of the experimental procedure, the study must be terminated, and the study will not qualify for competition.

5. The final disposition of the animals must be described on Vertebrate Animal Form 5A. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site.
6. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b. Vertebrate Animal Form (5A)
 - c. Qualified Scientist Form (2), when applicable

ADDITIONAL RULES FOR PROJECTS CONDUCTED IN A REGULATED RESEARCH INSTITUTION

All studies not meeting the criteria in Section A. but are otherwise permissible under Intel ISEF rules must be conducted in a Regulated Research Institution (RRI). A Regulated Research Institution within the U.S. is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to U.S. Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Welfare Act but have an operational Institutional Animal Care and Use Committee and are in compliance with U.S. federal laws are included in this definition. For project conducted outside of the United States, a Regulated Research Institution would be a comparable research institution that adheres to country laws governing the care and use of vertebrate animals.

Some protocols permitted in a Registered Research Institution are not permitted for participation in the Intel ISEF; adherence to RRI rules is necessary but may not be sufficient.

1. The Institutional Animal Care and Use Committee (IACUC) or the comparable animal oversight committee must approve all student research projects before experimentation begins. Such research projects must be conducted under the responsibility of a principal investigator. The local and regional SRC must also review the project to certify that the research project complies with Intel ISEF Rules. This local and regional SRC review should occur before experimentation begins, if possible.
2. Student researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted. All methods of euthanasia must adhere to current American Veterinarian Medical Association (AVMA) Guidelines.
3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used.
4. Research in nutritional deficiency or research involving substances or drugs of unknown effect is permitted to the point that any clinical sign of distress is noted. In the case that distress is observed, the project must be suspended and measures must be taken to correct the deficiency or drug effect. A project can only be resumed if appropriate steps are taken to correct the causal factors.
5. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - b. Regulated Research Institution Form (1C)
 - c. Vertebrate Animal Form (5B)
 - d. Qualified Scientist Form (2)

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

Research using microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids may involve potentially hazardous biological agents. Students are permitted to do some research projects with potentially hazardous biological agents meeting the conditions and rules described below which were designed to protect students and to ensure adherence to federal and international biosafety regulations and guidelines.

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

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

RULES FOR ALL STUDIES WITH POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

1. The following types of studies are exempt from prior SRC review and require no additional forms:
 - A. Studies involving baker's yeast and brewer's yeast, except when used with rDNA studies.
 - B. Studies involving *Lactobacillus*, *Bacillus thurgensis*, nitrogen-fixing, oil-eating bacteria, and algae-eating bacteria introduced into their natural environment. (Not exempt if cultured in a petri dish environment.)
 - C. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold.
2. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
 - A. Studies involving protists, archaea and similar microorganisms.
 - B. Research using manure for composting, fuel production, or other non-culturing experiments.
 - C. Commercially-available color change coliform water test kits. These kits must remain sealed and must be properly disposed.
 - D. Studies involving decomposition of vertebrate organisms (such as in forensic projects).
3. The use of potentially hazardous microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, and parasites), recombinant DNA (rDNA) technologies or human or animal fresh/frozen tissues, blood, or body fluids, is allowable as follows:
 - A. An affiliated fair SRC, an IBC or an 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, IBC or IACUC.
 - B. Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment. However, specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment determined by the affiliated fair SRC.
 - C. Research determined to be at Biosafety Level 1 (BSL-1) must be conducted in a BSL-1 or higher laboratory. The research must be supervised by a trained Designated Supervisor or a Qualified Scientist. The student must be properly trained in standard microbiological practices.
 - D. Research determined to be a Biosafety Level 2 (BSL-2) must be conducted in a laboratory rated BSL-2 or above (commonly limited to a Regulated Research Institution). The research must be reviewed and approved by the Institutional Biosafety Committee (IBC) or a letter or document

from the Regulated Research Institution that the research does not require review. The research must be supervised by a Qualified Scientist.

- E. BSL-3 or -4 research is prohibited.
 - F. Laboratory studies culturing known MRSA (Methicillin-resistant Staphylococcus aureus), VRE (Vancomycin-resistant enterococci) and KPC (Klebsiella pneumonia) must be conducted in a BSL-2 laboratory in a Regulated Research Institution with documented IBC Committee review and approval.
 - G. Studies that genetically engineer bacteria with multiple antibiotic resistance are prohibited.
 - H. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms require at least BSL-2 containment.
 - I. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
 - J. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
 - K. All potentially hazardous biological agents must be properly disposed at the end of experimentation in accordance with their biosafety level. For BSL 1 or BSL 2 organisms: Autoclave at 121 degrees Celsius for 20 minutes, use of a 10% bleach solution (1:10 dilution of domestic bleach), incineration, alkaline hydrolysis, biosafety pick-up and other manufacturer recommendations are acceptable.
 - L. Any proposed changes in the Research Plan by the student after initial local or affiliated fair SRC approval must undergo subsequent SRC or IBC review and approval before such changes are made and before experimentation resumes.
4. The following forms are required:
- A. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, and Approval Form (1B)
 - B. Regulated Research Institution Form (1C) - when applicable.
 - C. Qualified Scientist (2), when applicable
 - D. Risk Assessment (3), when applicable
 - E. PHBA Risk Assessment Form (6A), when applicable
 - F. Human and Vertebrate Animal Tissue Form (6B) – for all studies involving tissues and body fluids.

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.)

- 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 includes two heavy-duty (2-ply) sealed bags.
 - B. Experiment involves only procedures in which the Petri dish remains sealed throughout the experiment (e.g., counting presence of organisms or colonies).
 - C. The sealed Petri dish is disposed of via autoclaving or disinfection under the supervision of the Designated Supervisor.
- 2. If a culture container with unknown microorganisms is opened for any purpose, (except for disinfection for disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory procedures.

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 the risk level assignment. Some rDNA studies 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 must be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or Designated Supervisor and must be approved by the SRC prior to experimentation. Examples include cloning of DNA in *E. coli* K12, *S. cerevisiae*, and *B. subtilis* host-vector systems.
2. Commercially available rDNA kits using BSL-1 organisms may be conducted in a BSL-1 laboratory under the supervision of a Qualified Scientist or trained Designated Supervisor and must be approved by the SRC prior to experimentation.
3. An rDNA technology study using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation must be conducted entirely in a BSL-2 facility.
4. All rDNA technology studies involving BSL-2 organisms and/or BSL-2 host vector systems must be conducted in a Regulated Research Institution and approved by the IBC prior to experimentation.
5. Propagation of recombinants containing DNA coding for oncogenes or other human, plant or animal toxins (including viruses) is prohibited.

ADDITIONAL RULES FOR PROJECTS WITH TISSUES AND BODY FLUIDS, INCLUDING BLOOD AND BLOOD PRODUCTS

Studies involving fresh/frozen tissue, blood or body fluids obtained from humans and/or vertebrates may contain microorganisms and have the potential of causing disease. Therefore, a proper risk assessment is required.

1. The following types of tissue do not need to be treated as potentially hazardous biological agents but should be submitted for SRC approval with proper safety and risk assessment documentation:
 - A. Plant tissue
 - B. Plant and non-primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection). The source and/or catalog number of the cultures must be identified in the Research Plan.
 - C. Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants, or packing houses.
 - D. Hair.
 - E. Teeth that have been sterilized to kill any blood-borne pathogen that may be present. Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended.
 - F. Fossilized tissue or archeological specimens.
 - G. Prepared fixed tissue.
2. Research involving human and/or non-human primate established cell lines and tissue culture collections (e.g., obtained from the American Type Culture Collection) must be considered a BSL-1 or BSL-2 level organism as indicated by source information and treated accordingly. The source and/or catalog number of the cultures must be identified in the Research Plan.
3. If tissues are obtained from an animal that was euthanized for a purpose other than the student's project, it may be considered a tissue study. Documentation of the IACUC approval for the original animal study from which tissues are obtained is required.
4. If the animal was euthanized solely for the student's project, the study must be considered a vertebrate animal project and is subject to the vertebrate animal rules for studies conducted at a Regulated Research Institution. (See vertebrate animal rules.)
5. Biosafety level 1 tissue studies involve the collection and examination of fresh/frozen tissue and/or body fluids, (not including blood or blood products; see rule 7) from a non-infectious source with little likelihood of microorganisms present. Biosafety level 1 studies must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.
6. Biosafety level 2 tissue studies involve the collection and examination of fresh/frozen tissues or body fluids that may contain microorganisms belonging to BSL-1 or -2. These studies must be conducted in a Regulated Research Institution in a BSL-2 laboratory under the supervision of a Qualified Scientist.

7. 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. 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 blood-borne pathogens (e.g. blood, blood products, tissues that release blood when compressed, blood contaminated instruments) must be properly disposed after experimentation.
8. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk are considered BSL-2.
9. Any study involving the collection and examination of body fluids which may contain biological agents belonging to BSL-3 or -4 is prohibited.
10. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent. Student researchers using their own body fluids are exempt from this requirement.
11. Self-sampling of capillary blood for analysis (e.g. glucometer reading) may be conducted in a home setting.
12. Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

RISK ASSESSMENT

(USE THIS INFORMATION TO COMPLETE PHBA RISK ASSESSMENT FORM 6A)

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

Risk assessment involves:

- Assignment of the biological agent to a risk group
 - Studies involving a known microorganism should begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
 - The study of unknown microorganisms and the use of fresh tissues should rely on the expertise of qualified adults supervising the project.
- Determination of the level of biological containment available to the student researcher to conduct the experimentation. (Please see Levels of Biological Containment below for more details.)
- Assessment of the experience and expertise of the adult(s) supervising the student.
- Assignment of a final biosafety level for the study based on risk group of biological agent, level of biological containment available and the expertise of the Qualified Scientist or Designated Supervisor who will be supervising the project.

If a study is conducted at a non-regulated site (e.g. school), the final biosafety level must be confirmed by the SRC. If the research is conducted at a regulated site, the final biosafety level must be assigned by an Institutional Biosafety Committee (IBC) or equivalent approval body or a letter obtained from an institutional representative that the research does not require review. If no approval body exists at the regulated site, the SRC should review the project and assign a final biosafety level.

CLASSIFICATION OF BIOLOGICAL AGENTS RISK GROUPS

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

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

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

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

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

LEVELS OF BIOLOGICAL CONTAINMENT

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

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

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

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

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

HAZARDOUS CHEMICALS, ACTIVITIES AND DEVICES

The following rules apply to research using hazardous chemicals, devices and activities. These 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, tobacco, 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 proper supervision and the consideration of all potential risks so that the appropriate safety precautions are taken. Students are required to meet all standards imposed by Intel ISEF, school, local, and/or regional fair(s).

RULES FOR ALL PROJECTS INVOLVING HAZARDOUS CHEMICALS, ACTIVITIES AND DEVICES

1. The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Designated Supervisor, except those involving DEA-controlled substances, which require supervision by a Qualified Scientist.
2. The student researcher must conduct a risk assessment in collaboration with a Designated Supervisor or Qualified Scientist prior to experimentation. This risk assessment is documented on the Risk Assessment Form 3.
3. Student researchers must acquire and use regulated substances in accordance with all local, state, U.S. federal and country laws. For further information or classification for these laws and regulations, contact the appropriate regulatory agencies.
4. For all chemicals, devices or activities requiring a Federal and/or State Permit, the student/supervisor must obtain the permit prior to the onset of experimentation. A copy of the permit must be available for review by adults supervising the project and the local and affiliated and the ISEF Scientific Review Committee in their review prior to competition.
5. The student researcher must minimize the impact of an experiment on the environment. Examples include using minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner and in accordance with good laboratory practices.
6. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan and Approval Form (1B)
 - b. Regulated Research Institution Form (1C), when applicable
 - c. Qualified Scientist Form (2), when applicable
 - d. 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 chemicals that can be diverted from their intended use to make illegal drugs. Other countries may have similar regulatory bodies; students outside of the U.S. must adhere to their own country's drug regulatory agency requirements in addition to U.S. DEA regulations. DEA-controlled substances and their schedule number are at the DEA website under Sources of Information. It

is the responsibility of the student to consult this list if there is a possibility that substances used in experimentation could be regulated.

- 1) All studies using DEA-controlled substances must be supervised by a Qualified Scientist who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.
- 2) All studies using DEA Schedule 1 substances must have the research protocol approved by DEA before research begins. Schedule 2, 3 and 4 substances do not require protocol approval by DEA.

B. Prescription Drugs

Prescription drugs are drugs regulated by federal or country laws and are available only through a pharmacy to protect against inappropriate or unsafe use. Special precautions must be taken in their use for a science project as follows:

- 1) Students are prohibited from administering prescription drugs to human participants.
- 2) A veterinarian must supervise student administration of any prescription drugs to vertebrate animals.

C. Alcohol and Tobacco

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulate the production of alcohol and distribution of alcohol and tobacco products. Many such products are restricted by age for purchase, possession and consumption. Students outside of the U.S. must adhere to U.S. regulations and to their local and country laws and regulations.

1. The Designated Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
2. Production of ethyl alcohol (wine or beer) is allowable in the home under parental supervision and must meet the TTB home production regulations.
3. Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
4. Students are allowed to distill alcohol for fuel or other non-consumable products. To do so, the work must be conducted at school and a TTB permit must be obtained by school authorities. Details regarding this process are available from the Alcohol and Tobacco Tax and Trade Bureau (TTB) website.

D. Firearms and Explosives

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

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

1. Projects involving firearms and explosives are allowable when conducted with the direct supervision of a Designated Supervisor and when in compliance with all federal, state and local laws.
2. A fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.
3. Potato guns and paintball guns are not firearms unless they are intended to be used as weapons. They must be treated as hazardous devices.

GUIDANCE FOR RISK ASSESSMENT

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

- A. Hazardous Chemicals

- B. Hazardous Devices
- C. Radiation

A. Hazardous Chemicals

A proper risk assessment of chemicals must include review of the following factors:

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 assessing risk, 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 of the chemical. The student researcher must refer to Material Safety Data Sheets provided by the vendor (MSDS) to ensure that proper safety precautions are taken. Some MSDS sheets (e.g., Flinn) rank the degree of hazard associated with a chemical. This rating may assist students and adult sponsors in determining risk associated with the use of a chemical.

A risk assessment must include proper disposal methods for the chemicals used in an experiment. The Flinn Catalog (referenced in the Sources of Information section) provides 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.

B. Hazardous Devices

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

C. Radiation

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

- Class I lasers are those found in CD players, laser printers, geological survey equipment and some laboratory equipment. There are no known risks associated with using a Class I laser.
- Class II lasers are found in laser pointers, aiming and range finding devices and pose a risk if the beam is directly viewed over a long period of time.
- Class III lasers are found in higher-powered laser pointers, printers and spectrometers. They are to be considered hazardous devices which can cause eye damage when the beam is directly viewed even for a short period of time.

- Class IV lasers are high-powered lasers used in surgery, research, and industrial settings. They are extremely hazardous and can cause eye and skin damage from both direct and indirect exposure. The beam is also a fire hazard.

Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study. Depending upon the level of exposure, radiation released from these sources can be a health hazard. Most research institutions have a Radiation Safety Office which oversees the use of ionizing radiation and ensures compliance with state and federal regulations.

Additional Sources of Information are available at www.societyforscience.org/isef/rulesandguidelines .

SOURCES FOR INFORMATION

Hazardous Materials/Biological Agents

1. General Lab/Chemical Safety in *Academic Chemistry Laboratories, Volumes 1 and 2, 2003*. Washington, DC: American Chemical Society. website: <http://www.acs.org/publications>
2. *Safety in the Research Laboratory* A free DVD from Howard Hughes Medical Institute that includes sections on working with cell cultures, radioactive materials and other laboratory materials. Other free safety DVD's are also available. <http://catalog.hhmi.org/index.jsp>
3. Environmental Protection Agency (EPA) website for green chemistry: <http://www.epa.gov/greenchemistry>
4. Material Safety and Data Sheets (MSDS) MSDS should be collected by your laboratory or available from the manufacturer. The internet also has a range of free resources:
 - a. <http://www.flinnsci.com/sections/safety/safety.asp>
 - b. <http://www.ilpi.com/msds/index.html>
5. DEA Controlled Substances <http://www.usdoj.gov/dea>
6. Controlled Substance Schedules <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>
7. Alcohol, Tobacco Firearms and Explosives Alcohol and Tobacco Tax and Trade Bureau <http://www.ttb.gov/>
8. Bureau of Alcohol, Tobacco, Firearms and Explosives <http://www.atf.gov>
9. Radiation Studies Information (CDC) <http://www.cdc.gov/nceh/radiation/default.htm>
10. CDC Laboratory Safety Manuals <http://www.cdc.gov/od/ohs/safety/SUPSAFE.PDF>
<http://www.cdc.gov/od/ohs/safety/S2.pdf>
11. Occupational Safety and Health Administration Documents available from: OSHA Publications <http://www.osha.gov>
 - a. *PUB 8-1.7 - Guidelines for Laser Safety and Hazard Assessment*
 - b. *STD 1-4.1 - OSHA Coverage of Ionizing Radiation Sources Not Covered by Atomic Energy Act of 1954*
12. U.S. Nuclear Regulatory Commission Material Safety and Inspection Branch <http://www.nrc.gov>
13. American Biological Safety Association: ABSA Risk Group <http://www.atcc.org>
14. Bergey's Manual of Systematic Bacteriology website – <http://www.bergeys.org>
15. Biosafety in Microbiological and Biomedical Laboratories- 4th Edition
<http://www.cdc.gov/od/ohs/biosfty/biosfty.htm>
16. World Health Organization Laboratory Safety Manual-3rd Edition <http://www.who.int/csr/bioriskreduction/>
17. Canada – Agency of Public Health – list of non-pathogenic organisms http://www.phac-aspc.gc.ca/ols-bsl/pathogen/organism_e.html
18. Microorganisms for Education Website – list of organisms <http://www.science-projects.com/safemicrobes.htm>
19. NIH Guidelines for Research Involving Recombinant DNA Molecules. Published by National Institutes of Health.
<http://oba.od.nih.gov/oba/index.html>
20. OSHA – Occupational Health and Safety Administration <http://www.osha.gov>

Human Subjects

1. *Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*
<http://ohsr.od.nih.gov/guidelines/45cfr46.html>
2. Dunn, C. M. and Chadwick, G. L., *Protecting Study Volunteers in Research: A Manual for Investigative Sites* ISBN 1-930624-36-0. NIH tutorial also provides similar information: <http://www.cancer.gov/clinicaltrials/learning/page2>
3. Penslar, R.L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
4. *Belmont Report*, April 18, 1979 <http://ohsr.od.nih.gov/guidelines/belmont.html>
5. *Standards for Educational and Psychological Testing*. (1999). Washington, DC: AERA, APA, NCME.
<http://www.apa.org/science/standards.html>
6. American Psychological Association Information for students: <http://www.apa.org/science/infostu.html>
7. Information regarding publications: <http://www.apa.org/publications/>
8. Educational and Psychological Testing, Testing Office for the APA Science Directorate
<http://www.apa.org/science/testing.html>

Animal Care and Use

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

2. *Principles and Guidelines for the Use of Animals in Precollege Education* (a free pamphlet from ILAR) Can be found online: http://dels.nas.edu/ilar_n/ilarhome/reports.shtml
3. *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research* (2003), Institute for Laboratory Animal Research (ILAR). <http://www.nap.edu>
4. Federal Animal Welfare Act (AWA) 7 U.S.C. 2131-2157 Subchapter A - Animal Welfare (Parts I, II, III) <http://www.nal.usda.gov/awic/legislat/awicregs.htm>
5. *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)* Federation of Animal Science Societies (FASS) <http://www.fass.org>
6. *Guidelines for the Use of Fish in Research* (2004), American Fisheries Society. <http://www.fisheries.org/afs/publicpolicy.html>
7. Euthanasia Guidelines *AVMA Guidelines on Euthanasia* (June 2007) American Veterinary Medical Association. http://www.avma.org/issues/animal_welfare/euthanasia.pdf

Alternative Research and Animal Welfare

1. The National Library of Medicine computer searches through MEDLINE: <http://www.nlm.nih.gov>
<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>
2. National Agriculture Library (NAL) reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare. <http://www.nal.usda.gov/awic>
3. John's Hopkins Center for Alternatives to Animal Testing <http://caat.jhsph.edu/>
4. Institute of Laboratory Animal Resources (ILAR) <http://dels.nas.edu/ilar/>
5. Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing <http://toxnet.nlm.nih.gov/altbib.html>

This document was created from the 2013 Intel International Science and Engineering Fair (ISEF) Rules and Regulations and modified to contain rules, regulations and expectations specific to the ISEF-affiliated Greater New Orleans Science and Engineering Fair.

Full documentation of ISEF forms and guidelines can be found at:
http://www.societyforscience.org/ISEF/about/rules_regulations.asp .