

REGENERON

ISEE

A PROGRAM OF _____
SOCIETY FOR SCIENCE

**INTERNATIONAL RULES
FOR PRE-COLLEGE SCIENCE RESEARCH
GUIDELINES FOR SCIENCE AND ENGINEERING FAIRS 2022–2023**

INTERNATIONAL RULES FOR PRE-COLLEGE SCIENCE RESEARCH: GUIDELINES FOR SCIENCE AND ENGINEERING FAIRS 2022–2023

TABLE OF CONTENTS

General Requirements for All Projects

1. ISEF Ethics Statement	3
2. ISEF Eligibility/Limitations	3
3. ISEF Requirements.....	3
4. Continuation/Research Progression of Projects.....	4
5. Team Projects.....	4

Roles and Responsibilities of Students and Adults

6. The Student Researcher(s).....	5
7. The Adult Sponsor	5
8. The Qualified Scientist	5
9. The Designated Supervisor.....	5
10. The Institutional Review Board (IRB).....	6
11. The Affiliated Fair Scientific Review Committees (SRC)	6
12. Regulated Research Institution/Industrial Settings Review Committees	7
13. ISEF Scientific Review Committee	7

Human Participants Rules

1. Rules	8
2. Exempt Studies.....	9
3. Human Participant & IRB Resources.....	11

Vertebrate Animals Rules

1. Rules for ALL Vertebrate Animal Studies	12
2. Additional Rules for Projects Conducted at School/Home/Field	13
3. Additional Rules for Projects Conducted in a Regulated Research Institution	14

Potentially Hazardous Biological Agents Rules

1. Rules for ALL Projects Involving Potentially Hazardous Biological Agents.....	15
2. Additional Rules for Projects Involving Unknown Microorganisms.....	16
3. Additional Rules for Projects Involving Recombinant DNA (rDNA) Technologies	16
4. Additional Rules for Projects Involving Tissues and Body Fluids Including Blood and Blood Products	17
5. Potentially Hazardous Biological Agents Risk Assessment	18

Hazardous Chemicals, Activities or Devices Rules

1. Rules for ALL Projects Involving Hazardous Chemicals, Activities or Devices	19
2. Additional Rules for Specific Regulated Areas	19
3. Hazardous Chemicals, Activities or Devices Risk Assessment.....	21

Engineering & Inventions Projects Guide	22
--	-----------

Sources of Information	23
-------------------------------------	-----------

Display & Safety Regulations	26
---	-----------

Categories & Sub-Categories	29
--	-----------

Information on Required Abstract	30
---	-----------

Forms	31
--------------------	-----------

INTERNATIONAL RULES AND GUIDELINES

The full text of the International Rules and forms in html and as a downloadable pdf.

ISEF RULES WIZARD

An interactive tool which asks questions about your intended project and provides a list of forms required.

ISEF RULES FAQs

Answers to questions that are commonly received in the email account src@societyforscience.org. We encourage you to submit suggestions.

THESE RULES ARE APPLICABLE FOR

Society for Science affiliated science fairs and the Regeneron International Science & Engineering Fair 2023.

The purpose of these rules is to:

- protect the rights and welfare of the student researcher
- protect the rights and welfare of human participants
- protect the health and welfare of vertebrate animal subjects
- protect and promote good stewardship of the environment
- ensure adherence to federal regulations
- ensure use of safe laboratory practices
- determine eligibility for competition in ISEF

For pre-review and approval of your project, find your fair at:

<https://findafair.societyforscience.org>

For rules questions, contact the ISEF Scientific Review Committee:

SRC@societyforscience.org

For general questions, contact:

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

The International Rules and Guidelines for Science Fairs is available at societyforscience.org/ISEF in multiple formats. Familiarity with the rules is critical for students, parents, teachers, mentors, fair directors and local and affiliated fair Scientific Review Committees (SRC) and Institutional Review Boards (IRB).

ETHICS STATEMENT

Student researchers, as well as adults who have a role in their projects, are expected to maintain the highest ethical standards. These standards include, but are not limited to:

- **Integrity.** Honesty, objectivity, and avoidance of conflicts of interest are expected during every phase of the project. The project should reflect independent research done by the student(s) and be free of fraudulent data and/or plagiarism and represent only one year's work.
- **Legality.** Compliance with all federal, state and local laws and regulations is essential. 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. All projects must be approved by a Scientific Review Committee (SRC), and when necessary must also be approved by an Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and/or Institutional Biosafety Committee (IBC). Native, genetically-altered, and/or invasive species, (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances reintroduced into the environment is prohibited. It is recommended that students reference their local, state or national laws and regulations.
- **Respect for Confidentiality and Intellectual Property.** Confidential communications, as well as patents, copyrights, and other forms of intellectual property must be honored. Unpublished data, methods, or results may not be used without permission, and credit must be given for all contributions to the research.
- **Stewardship of the Environment.** It is the responsibility of the researcher and the adults involved to protect the environment from harm. Introduction or disposal of native, genetically-altered, and/or invasive species, (e.g. insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. It is recommended that students reference their local, state or national regulations and quarantine lists.
- **Acknowledgment of Risks.** All projects involve some amount of risk. Everyone is expected to recognize the hazards, assess the risks, minimize the risks, and prepare for emergencies.
- **Animal Care.** Proper care and respect must be given to vertebrate animals. The use of non-animal research methods and alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project. The guiding principles for the use of animals in research includes the following "Four R's": Replace, Reduce, Refine, Respect.
- **Human Participant Protection.** The highest priority is the health and well-being of the student researcher(s) and human participants.
- **Potentially Hazardous Biological Agents (PHBAs).** It is the responsibility of the student and adults involved in the project to conduct and document a risk assessment, and to safely handle and dispose of organisms and materials.

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 ISEF. Society for Science reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

ELIGIBILITY/LIMITATIONS

1. Each ISEF-affiliated fair may send to ISEF the number of projects allocated and committed to within their affiliation agreement.
2. A student must be selected by an ISEF-affiliated fair, and meet both of the following:
 - a. be in grades 9–12 or equivalent; and
 - b. not have reached age 20 on or before May 1 preceding ISEF.
3. English is the official language of ISEF. Student project boards and abstracts must be in English.
4. Each student is only allowed to enter one project. That project may include no more than 12 months of continuous research and may not include research performed before January 2022.
5. Team projects must have no more than three members. Teams competing at ISEF must be composed of the original members who competed at the ISEF-affiliated fair and must all meet ISEF eligibility.
6. Students may compete in only one ISEF affiliated fair, except when proceeding to a state/national fair affiliated with ISEF from an affiliated regional fair.
7. Projects that are demonstrations, 'library' research or informational projects, and/or 'explanation' models are not recommended or appropriate for ISEF.
8. All sciences and engineering disciplines are represented at ISEF and projects compete in one of the 21 categories. Review a [complete list of categories and sub-categories with definitions](#).
9. 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 domestic and international students competing in an ISEF-affiliated fair must adhere to all rules as set forth in this document.
2. All projects must adhere to all of the tenets of the Ethics Statement.
3. It is the responsibility of the student and the Adult Sponsor to evaluate the study to determine which forms are required and whether approval by a committee must be obtained prior to experimentation.
4. Projects competing at ISEF must have an exhibit that adheres to ISEF Display & Safety requirements and is visible during all operable hours of the exhibit hall without reliance on electricity or internet connections.

- All projects must adhere to the requirements of the affiliated fair(s) in which it competes to qualify for participation in ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the student and Adult Sponsor.

APPROVAL AND DOCUMENTATION

- Project documentation should begin before experimentation with the current forms available. Projects involving human participants, vertebrate animals, and potentially hazardous biological agents must be reviewed and approved by a local or regional Institutional Review Board (IRB) or Scientific Review Committee (SRC) prior to the start of experimentation. **Note: If a project involves the testing of a student designed invention, prototype or concept by a human, an IRB review and approval may be required prior to experimentation. See Human Participants Rules for details.**
- Every student must complete the [Student Checklist \(1A\)](#), a [Research Plan/Project Summary](#) 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 \(1\)](#).
- A [Qualified Scientist](#) is required for all studies involving Biosafety Level 2 (BSL-2) potentially hazardous biological agents and DEA-controlled substances and is also required for many human participant studies and many vertebrate animal studies.
- After initial IRB/SRC approval (if required), any proposed changes in the [Student Checklist \(1A\)](#) and Research Plan/Project Summary must be re-approved before laboratory experimentation/data collection resumes.
- 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 Research Plan/Project Summary prior to experimentation/data collection for the current year.
- Any continuing project must document that the additional research is new and different by completing [Continuation/Research Progression Projects Form \(7\)](#). This form must be displayed at the project booth.
- If work was conducted either virtually or on site at a regulated research institution, industrial setting, or any work site other than home, school or field at any time during the current ISEF project year, the [Regulated Research Institutional/Industrial Setting Form \(1C\)](#) must be completed and displayed at the project booth.
- 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).
- A project data book and research paper are not required, but are strongly recommended for judging purposes. Regional or local fairs may require a project data book and/or a research paper.
- 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.

DIGITAL PAPERWORK AND SIGNATURES

Submission of forms generated by a digital system are allowable under the following conditions:

- The forms must have the same content and order as ISEF forms.
- Digital signatures must have a verification system via login and have a time and date stamp to indicate this authentication.
- Paperwork submitted to Society for Science for ISEF must be scanned and submitted via the online portal.

CONTINUATION/RESEARCH PROGRESSION OF PROJECTS

- 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 2022 and ending May 2023.
- Any project based on the student's prior research could be considered a continuation/research progression project. 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.
- The 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"). Previous year's databooks, research papers and supporting documents may be at the booth if properly labeled as such.
- Longitudinal studies are permitted as acceptable continuations under the following conditions:
 - 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.)
 - Each consecutive year must demonstrate time-based change.
 - The display board must be based on collective past conclusionary data and its comparison to the current year data set. No raw data from previous years may be displayed.
- All projects must be reviewed and approved each year and forms must be completed for the new year.

TEAM PROJECTS

- Team projects compete and are judged in the category of their research at ISEF. All team members must meet the eligibility requirements for ISEF.
- Teams must have no more than three members. A team with members from different geographic regions may compete at an affiliated fair of one of its members, but not at multiple fairs. However, each affiliated fair holds the authority to determine whether teams with members outside of a fair's geographic territory are eligible to compete, understanding that if the team wins the right to attend ISEF, all team members' expenses must be supported by the fair.
 - Team membership cannot be changed during a given research year unless there are extenuating circumstances and the local SRC reviews and approves the change,

- including converting a team project to an individual project or vice versa. Such conversions must address rationale for the change and include a clear delineation between research preceding the change and that which will follow. A memorandum documenting this review and approval should be attached to Form 1A.
- Once a project has competed in a science fair at any level, team membership cannot change and the project cannot be converted from an individual project to a team project or vice versa.
- In a future research year, any project may be converted from an individual to a team project, from a team to an individual project and/or have a change in team membership.

- 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 the same judging criteria as individual projects.
- 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/Project Summary and other required forms.
- Full names of all team members must appear on the abstract and forms.

ROLES AND RESPONSIBILITIES OF STUDENTS AND ADULTS

THE STUDENT RESEARCHER(S)

The student researcher is responsible for all aspects of the research project:

- Enlisting the aid of any required supervisory adults (Adult Sponsor, Qualified Scientist, etc.)
- Following the International Rules & Guidelines, obtaining all necessary approvals (SRC, IRB, etc.) and completing all appropriate documentation
- Performing the project (which may include, but is not limited to) experimentation, data collection, engineering, data analysis, and any other process or procedures related to the project
- Understanding and abiding by the Ethics Statement and attesting to this understanding on Approval Form 1B.

To avoid conflict of interest, no Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Designated Supervisor who oversees the project, may serve on the SRC or IRB reviewing that project.

The Adult Sponsor

Qualifications:

- An Adult Sponsor may be a teacher, parent, professor, and/or other professional scientist
- Should be knowledgeable in the area of student research, be familiar with the regulations around procedures and materials that apply to the student project, particularly when involving human participants, vertebrate animals, potentially hazardous biological agents or hazardous chemicals, devices or activities.

- Should have close contact with the student throughout the timeline of the project.

Responsibilities:

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 and/or animals involved in the study.
- Reviewing the student's Student Checklist (1A) and Research Plan/Project Summary to ensure that:
 - experimentation follows local, state, and federal laws and ISEF rules
 - forms are completed by other required adults
 - any required Qualified Scientist meets the criteria as set forth in the ISEF Rules and Guidelines
 - the student's research is eligible for entry in ISEF

THE QUALIFIED SCIENTIST (QS)

Qualifications:

- Earned a doctoral/professional degree in a scientific discipline related to student's area of research

AND/OR

- Individual with extensive experience and expertise in the student's area of research
- Must be thoroughly familiar with the following regulations that govern the student's area of research including all local, state, Federal and if applicable, non-U.S. national regulations and laws.
- Can also serve as the Adult Sponsor, if that person meets both sets of qualifications
- May live elsewhere and not be local to the student, in which case, a Designated Supervisor must be appointed and trained to serve as the onsite supervision as necessary for the specific student project.

Responsibilities:

The Qualified Scientist is responsible for:

- Reviewing the ISEF rules relevant to the project and approving the student's research plan or engineering design prior to the start of experimentation
- Providing direct supervision throughout the timeline of the project or coordinating with a Designated Supervisor to serve in this capacity
- Ensuring the proper training of the Student Researcher and/or Designated Supervisor in the necessary procedures
- Completing the required documentation which may include the Regulated Research Institutional Setting Form (1C), the Qualified Scientist Form (2) and the Risk Assessment Form (3), when applicable.

THE DESIGNATED SUPERVISOR (DS)

Qualifications:

- Does not need an advanced degree
- Must be familiar with the student's project and agree to any training necessary
- May also serve as the Adult Sponsor for the project
- If the project involves the use of Vertebrate Animals (where behavior/habitat is influenced by humans), must be

knowledgeable about the humane care and handling of the animals

Responsibilities:

- Providing direct supervision of the student experimentation
- Completing the required documentation—the Designated Supervisor box on the Qualified Scientist Form (2) when applicable
- Reviewing and completing the Risk Assessment Form (3) when needed

REVIEW COMMITTEES

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

AFFILIATED FAIR SCIENTIFIC REVIEW COMMITTEE (SRC)

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, certifications, research plans and exhibits for compliance with the rules, applicable laws and regulations at each level of science fair competition. Affiliated Fairs may authorize local SRCs to serve in this prior review capacity. The operation and composition of the local and Affiliated Fair SRCs must fully comply with the International Rules. Directions for obtaining preapproval are available from the affiliated fair. A list of fairs can be found at <https://findafair.societyforscience.org>.

Most proposed research projects involving vertebrate animals and/or potentially hazardous biological agents must be reviewed and approved BEFORE experimentation. Local or regional SRC prior review is not required for human studies previously reviewed and approved by a properly constituted IRB.

ALL projects, including those previously reviewed and approved by an IRB must be reviewed and approved by the SRC after experimentation and before competition in an Affiliated Fair. Projects which were conducted at a Regulated Research Institution, industrial setting or any work site other than home, school or field and which were reviewed and approved by the proper institutional board before experimentation, must also be approved by the Affiliated Fair SRC.

An SRC must consist of a minimum of three persons, including the following:

- a biomedical scientist with an earned graduate degree
- an educator
- at least one additional member

Additional expertise: Many project evaluations require additional expertise (e.g., on biosafety and/or of human risk groups). If the SRC needs an expert as one of its members and one is not in the immediate area, all documented contact with an external expert must be submitted. If animal research is involved, at least one member must be familiar with proper animal care procedures. Depending on the nature of the study, this person can be a veterinarian or animal care provider with training and/or experience in the species being studied.

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

- Evidence of proper supervision

- Completed forms, signatures, research dates, and preapproval dates (when required)
- Evidence of proper team composition
- Compliance with rules and laws governing human and/or animal research and research involving potentially hazardous biological agents and/or hazardous chemicals, activities or devices
- Compliance with ISEF ethics statement
- Use of accepted and appropriate research techniques
- Evidence that risks have been properly assessed
- Evidence of search for alternatives to animal use
- Humane treatment of animals
- Documentation of substantial expansion for continuation projects
- Evidence of appropriate literature search and attribution

FOR HUMAN PARTICIPANT PROJECTS REVIEW — THE INSTITUTIONAL REVIEWBOARD (IRB)

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

Federal regulations require local community involvement. Therefore, it is advisable that an IRB be established at the school level to evaluate human research projects. If necessary, the local or ISEF-affiliated SRC can serve as an IRB as long as it has the required membership. An IRB must consist of a minimum of **three** members including the following:

- An educator
- A school administrator (preferably principal or vice principal)
- A medical or mental health professional. The medical or mental health professional may be a medical doctor, nurse practitioner, physician's assistant, doctor of pharmacy, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor. The medical or mental health professional on the IRB may change depending on the nature of the study. This person must be knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study.

Additional Expertise: If an expert is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of that expert.

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

It is the responsibility of the members of the IRB to thoroughly review the Research Plan and collectively decide whether to approve the project, request revisions to the methodology/require

more oversight (e.g., QS) to reduce risk to participants, or to determine that the project is not appropriate for student research. An IRB documents the determination of risk level on Human Participant Form 4.

In reviewing projects just prior to a fair, if the SRC serving at that level of competition judges an IRB's decision as inappropriate, thereby placing human participants in jeopardy, they may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with ISEF SRC in questionable cases.

COMBINED SRC/IRB COMMITTEE

A combined committee is allowed as long as the membership meets both the SRC and IRB requirements listed previously.

REGULATED RESEARCH INSTITUTIONS/ (RRI) REVIEW COMMITTEES

Regulated Research Institution: 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 projects 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.

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

- Institutional Animal Care and Use Committee (IACUC); Animal Care and Use Committee (ACUC); Animal Ethics Committee
- Institutional Review Board (IRB); Human Subjects Participant Program (HSPP)
- Institutional Biosafety Committee (IBC)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)
- Safety Review Committee

Independent or private laboratories, such as those established to support student researchers do not meet the requirements of oversight or committee infrastructure to be considered Regulated Research Institutions (RRI). Therefore, such laboratories should be considered the same as high school laboratories as it pertains to the International Rules and the types of projects able to be conducted in this setting. For purposes of documentation, such facilities may complete the Regulated Research Institution/Industrial Setting Form 1C to address the adult supervision and conditions of research.

THE ISEF SCIENTIFIC REVIEW COMMITTEE (ISEF SRC)

All projects are reviewed by ISEF Scientific Review Committee prior to competition. ISEF SRC is the final arbiter of the qualification of students to participate in ISEF. Before the fair, committee members review research plans and all required forms to confirm that applicable ISEF rules have been followed. ISEF SRC may request additional information from students prior to ISEF or may interview potential ISEF participants at the fair to ensure that they qualify to compete.

ISEF SRC, like an Affiliated Fair SRC, is made up of adults knowledgeable about research regulations. In addition to the review of all projects at ISEF, committee members answer questions about the rules throughout the year from students and teachers. The ISEF SRC can be contacted at SRC@societyforscience.org.

Members of ISEF Scientific Review Committee 2023

Ms. Susan Appel
Mr. Henry Disston
Dr. Jennifer Green
Dr. Paula Johnson
Dr. Timothy Martin
Mrs. Evelyn Montalvo
Mr. Joseph Scott
Dr. Jason Shuffitt
Mrs. Andrea Spencer

HUMAN PARTICIPANTS RULES

Rules involving human participants

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 human participants and the student researcher. Health and well-being is of the highest priority when students conduct research with human participants.

According to Code of Federal Regulation 45, CFR 46, a human participant is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individuals(s) or (2) identifiable private information.

Examples of projects that are considered “human participant research” include:

- Participants 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
- Testing of student designed invention, prototype or computer application by human participants other than student researcher
- Data/record review projects that include data that are not de-identified/anonymized (e.g., data set that includes name, birth date, phone number or other identifying variables)
- Behavioral observations that
 - a. involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
 - b. occur in non-public or restricted access settings (e.g., day care setting, doctor’s office)
 - c. involve the recording of personally identifiable information.

RULES

1. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan/Project Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment information on page 11 and the online Risk Assessment Guide (<https://student.societyforscience.org/human-participants/#riskassess>) for additional guidance.
2. Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) (See page 6) before any interaction (e.g., recruitment, data collection) with human participants may begin. It is the responsibility of the IRB to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for the student researcher and participants.
 - a. Projects that are conducted at school, at home or in the community that are not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the School IRB before the student may begin recruiting and/or interacting with human participants. The School IRB must assess the risk and document its determination of risk on Form 4.

- b. Projects that are conducted at a Regulated Research Institution (RRI) (e.g., university, hospital, medical center, government lab) must have IRB approval from the RRI. A copy of the IRB approval for the project must be obtained. A letter from an adult mentor and/or Qualified Scientist is not sufficient documentation of the RRI IRB review and approval process.
3. The student must comply with all determinations made by the School or RRI IRB before beginning any interaction with human participants (e.g., recruitment, data collection).
 - a. If the IRB requires a Qualified Scientist (QS), Form 2 must be completed by the QS before any interaction with human participants. The School IRB will review this completed form before approving the project.
 - b. If the IRB requires a Designated Supervisor (DS), Form 3 must be completed before any interaction with human participants. The School IRB will review this completed form before approving the project.
 - c. See rule #4 below regarding required procedures for obtaining informed consent/assent and/or parental permission.
 4. Participation in research may begin only after research participants have voluntarily given informed consent/assent (in some cases with parental permission). 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 School IRB will determine whether the consent/assent/parental permission may be a) verbal or implicit or b) must be written. See the Risk Assessment information on page 11 and the online [Risk Assessment Guide](#) for further explanation of informed consent.

- a. 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.
- b. Participants must be informed that their participation is voluntary and that they are free to stop participating at any time (i.e., they may participate or decline to participate, with no adverse consequences of non-participation or aborted participation).
- c. Informed consent may not involve coercion.
- d. When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
- e. The student researcher may request that the IRB waive the requirement for written informed consent/parental permission in his/her research plan if the project meets specific requirements. See section on IRB waivers for more information about situations in which written parental permission and/or written informed consent can be waived by the IRB.

5. The research study must be in compliance with all privacy laws (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and the U.S. Health Insurance Portability and Accountability Act (HIPAA)) when they apply to the project (e.g. the project involves medical information).
6. Students are prohibited from independently diagnosing disease, administering medication, and/or performing medical procedures on human participants.
 - a. A student may observe and collect data for analysis of medical procedures, medication/treatment efficacy, and diagnosis of illness, only under the direct supervision of a licensed health care provider/professional.
 - b. This Healthcare provider/professional must be named in the research plan/ protocol approved by the IRB. The IRB must also confirm that the student is not violating the appropriate practice act (medical, nursing, pharmacy, etc) of the state or country in which he/she is conducting the research.
 - c. Students are prohibited from providing diagnostic or medical information to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.
7. 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)).
8. 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.
9. 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 collecting anonymous data, obtaining informed consent, and ensuring that participants are of the appropriate age to give informed consent.
 - a. Studies that involve the use of minors in conducting online surveys must have Informed Consent and the parent/guardian of the minor must provide written parental permission before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.
 - b. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be delineated in the Research Plan.

For suggestions as to how to comply with 9a and 9b above please see the [Online Survey Consent Procedures](#).

10. After initial IRB approval, a student with any proposed changes in the Research Plan must repeat the approval process and regain approval before resuming interaction (recruitment, data collection) with human participants.
11. After experimentation and before competition, the Affiliated Fair SRC will review for compliance with all rules.

12. The following forms are required for studies involving human participants:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
 - b. Human Participants Form (4) for projects reviewed by school IRB or IRB approval documentation from an RRI and all applicable informed consents and survey(s)
 - c. Regulated Research Institution Form (1C), when applicable
 - d. Qualified Scientist Form (2), when applicable
 - e. Risk Assessment (3) when applicable

IRB WAIVER OF WRITTEN INFORMED CONSENT/PARENTAL PERMISSION

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:

1. Research involving normal educational practices
2. 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.
3. Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
4. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

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

HUMAN PARTICIPANT INVOLVEMENT IN STUDENT-DESIGNED INVENTION, PROTOTYPE, COMPUTER APPLICATION, ENGINEERING/DESIGN CONSUMER PROJECTS & PRODUCT TESTING

Student-designed invention, prototype, computer application, engineering/design projects and product testing that involve testing of the invention or consumer product by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype.

1. IRB review and pre-approval is required when the student-designed invention, prototype, application, etc. is tested by human participants other than the student researcher(s) or single adult guardian/adult sponsor/QS/DS when the testing requires an adult tester. This includes surveys conducted regarding potential use, review of the invention or consumer product and/or opinions regarding the project/product.
2. Human participants testing of an invention, prototype or project that involves a medical diagnosis or intervention (as defined by the FDA or Medical Practices Act) must adhere to Rule 6 of the Human Participant Rules regarding prohibition of medical procedures and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention being studied.
3. A Risk Assessment Form 3 is required for all projects that involve human participant testing of any project involving student- designed inventions, prototypes or consumer products.

EXEMPT STUDIES (DO NOT REQUIRE IRB PREAPPROVAL OR HUMAN PARTICIPANTS PAPERWORK)

Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for ISEF and affiliated fairs are:

1. Student-designed Invention, Prototype, Computer Applications, Engineering/Design Project or Consumer Product Testing in which the student researcher is the only person testing the invention, prototype, computer application or consumer product and the testing does not pose a health or safety hazard.
 - a. The exemption can also apply when the human participant testing is a single adult guardian or Adult Sponsor/QS/DS when the testing requires an adult tester.
 - b. It is required that a Risk Assessment Form (3) be completed for all such projects.
 - c. IRB review and pre-approval is required if the project involves more than the student researcher or any introduction of a human variable or factor in the testing of a consumer product/invention/prototype/application (e.g., amount of sleep, strength or endurance of tester, etc.).
2. Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.
3. Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
 - a. the researcher has no interaction with the individuals being observed
 - b. the researcher does not manipulate the environment in any way and
 - c. the researcher does not record any personally identifiable data.
4. Projects in which the student receives pre-existing/retrospective data in a **de-identified/anonymous** format which complies with both of the following conditions:
 - a. the professional providing the data certifies in writing that the data have been appropriately de-identified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
 - b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

HUMAN PARTICIPANT & IRB RESOURCES

Use this information to help determine the level of risk involved in a study involving human participants.

All human participant projects are considered to have some level of risk.

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 by a potential participant 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 visual images.

3. Privacy Concerns

- a. 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.
- b. 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.

VERTEBRATE ANIMALS RULES

Rules involving 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. Health and well-being is of high priority when students conduct research with animal subjects.

The Society for Science strongly endorses the use of non-animal research methods and encourages students to use alternatives to animal research, which must be explored and discussed in the research plan. The guiding principles for the use of animals in research 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.

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 for all vertebrate animal studies 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. (Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of an IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.) 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.

Vertebrate animals, as covered by these rules, are defined as:

1. Live, nonhuman vertebrate mammalian embryos or fetuses
2. Tadpoles
3. Bird and reptile eggs starting three days (72 hours) prior to hatching
4. All other nonhuman vertebrates (including fish) at hatching or birth.

Exception: Because of their delayed cognitive neural development, zebrafish embryos may be used up to seven days (168 hours) post-fertilization and not be considered a vertebrate. However, regardless of time of treatment, survival past the 7 days must be considered a vertebrate animal and the entire study is subject to all of the rules below.

RULES FOR ALL VERTEBRATE ANIMAL STUDIES

1. 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; description,

explanation, or identification of alternatives to animal use that were considered, and the reasons these alternatives were unacceptable; explanation of 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; description of the procedures that will minimize the potential for discomfort, distress, pain and injury to the animals during the course of experimentation; identification of the species, strain, sex, age, weight, source and number of animals proposed for use.
2. 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 local or affiliated fair SRC serves in this capacity for vertebrate animal studies performed in a school, home or field. Any SRC serving in this capacity must include a veterinarian or an animal care provider with training and/or experience in the species being studied.
3. Students performing vertebrate animal research must satisfy US federal law as well as local, state, and country laws and regulations of the jurisdiction in which research is performed.
4. Research projects which cause more than momentary or slight pain or distress are prohibited. Any illness or unexpected weight loss must be investigated and a veterinarian consulted to receive required medical care. This investigation must be documented by the Qualified Scientist or Designated Supervisor, who is qualified to determine the illness, or by a veterinarian. If the illness or distress is caused by the study, the experiment must be terminated immediately.
5. No vertebrate animal deaths due to the experimental procedures are permitted in any group or subgroup.
 - 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 if the cause of death was incidental or due to the experimental procedures. The project must be suspended until the cause is determined and then 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.
6. All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, weight must be recorded at least weekly with 15% being the maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal. If weighing of animals cannot be done in a fashion that is safe for both the researcher and the animal, then an explanation and approval by an SRC or IACUC needs to be included in the research plan, as well as an alternative method(s) to address signs of distress. Additionally, body conditioning scoring (BCS) systems are

available for most species of animals utilized in research and agriculture and are an objective method for assessing the overall health status of the research subject, with or without weight loss. A BCS system should be included in the design of any study utilizing live vertebrate animals and results regularly recorded.

7. Students are prohibited from designing or participating in an experiment associated with the following types of studies on vertebrate animals:
 - a. Induced toxicity studies with known toxic substances that could cause pain, distress, or death, including but not limited to alcohol, acid rain, pesticides, or heavy metals or studies with the intent to study toxic effects of a substance on a vertebrate animal.
 - b. Behavioral experiments using conditioning with aversive stimuli, mother/infant separation or induced helplessness.
 - c. Studies of pain.
 - d. Predator/vertebrate prey experiments.
8. 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 (RRI).
9. Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. All appropriate methods and precautions must be used to decrease stress. 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. The use of electrofishing is permissible only if conducted by a trained supervisor; students are prohibited from performing electrofishing.
10. A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies.
11. After initial SRC approval, a student with any proposed changes in the Research Plan/Project Summary of the project must repeat the approval process before laboratory experimentation/data collection resumes.

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

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

1. Studies of animals in their natural environment.
2. Studies of animals in zoological parks.
3. Studies of livestock that use standard agricultural practices.
4. Studies of fish that use standard aquaculture 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 vertebrate animal studies that do not meet the criteria in Section A. must be conducted in 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)
 - Quality Assurance Manuals (for the appropriate species)
3. The local or affiliated fair Scientific Review Committee must determine if a veterinarian’s certification of the research and animal husbandry plan is required. This certification, as well as SRC approval, is required before experimentation 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 conducted in a responsible and ethical manner, and must be described on Vertebrate Animal Form 5A.
6. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school/home/field site.
7. Livestock or fish raised for food using standard agricultural/aquacultural production practices may be euthanized by a qualified adult for carcass evaluation.
8. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
 - b. Vertebrate Animal Form (5A)
 - c. Qualified Scientist Form (2), when applicable

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

All studies not meeting the criteria in Section A that are otherwise permissible under 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 (IACUC) and are in compliance with U.S. federal laws are included in this definition. For projects 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 Regulated Research Institution are not permitted for participation in 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 affiliated fair SRCs must also review the project to certify that the research project complies with 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 Veterinary Medical Association (AVMA) Guidelines.
3. Research projects that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless mitigated by IACUC-approved anesthetics, analgesics and/or tranquilizers.

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/Project Summary, and Approval Form (1B)
 - b. Regulated Research Institution Form (1C)
 - c. Qualified Scientist Form (2)
 - d. Vertebrate Animal Form (5B)
 - e. PHBA Risk Assessment Form (6A) –for all studies involving tissues and body fluids.
 - f. Human and Vertebrate Animal Tissue Form (6B) – for all studies involving tissues and body fluids.

Sources of Information are available as a separate section at the end of the document.

EXEMPT STUDIES (DO NOT REQUIRE SRC PREAPPROVAL)

1. Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:
 - a. There is no interaction with the animals being observed,
 - b. There is no manipulation of the animal environment in any way, and
 - c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS (PHBA) RULES

Potentially Hazardous Biological Agents Rules for use of microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi and parasites), recombinant DNA technologies or human or animal fresh/frozen tissues, blood, or body fluids.

Students are permitted to do 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 on 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 proposed laboratory facility is properly equipped and all personnel are trained and appropriate supervision is planned.

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 (PHBA)

1. Prior review and approval is required for 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.
2. 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.
3. 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.
4. 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.
5. 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) if the Regulated Research Institution requires the review. For a high school BSL-2 laboratory, the SRC must review and approve. The research must be supervised by a Qualified Scientist.
6. Students are prohibited from designing or participating in BSL-3 or BSL-4 Research.
7. Laboratory studies designed to culture known clinically significant multidrug resistant organisms (MDROs) must have a written justification for usage and be conducted at a

Regulated Research Institution laboratory with a minimum of BSL-2 containment and documented IBC review and approval. Representative examples include, but are not limited to the following known agents: MRSA (Methicillin-Resistant *Staphylococcus aureus*), VISA/VRSA (Vancomycin Intermediate or Resistant *Staphylococcus aureus*), VRE (Vancomycin-Resistant *Enterococci*), CRE (Carbapenem Resistant *Enterobacteriaceae*), ESBLs (Extended Spectrum Beta-Lactamase producing gram negative organisms), and fungi (yeasts or molds) with known resistance to antifungal agents.

8. Insertion of antibiotic resistance markers for the clonal selection of bioengineered organisms is permitted, with the following exceptions:
 - a. Students are prohibited from the insertion of antibiotic-resistance traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals, or plants.
 - b. Students are prohibited from designing or selecting for multiple drug resistant organisms (MDROs) to investigate the pathology, development, or treatment of antibiotic-resistant infections.
9. Extreme caution must be exercised when selecting and sub-culturing antibiotic-resistant organisms. Studies using such organisms, including BSL-1 organisms that may have originally been exempt from prior SRC approval, require at least BSL-2 containment.
10. The culturing of human or animal waste, including sewage sludge, is considered a BSL-2 study.
11. Naturally-occurring plant pathogens may be studied (not cultured) at home, but may not be introduced into a home/garden environment.
12. 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.
13. Any proposed changes in the Research Plan/Project Summary 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.
14. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, 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.

A. Additional Rules for Projects Involving Unknown Microorganisms

Studies involving unknown microorganisms present a challenge because the presence, concentration and pathogenicity of possible agents are unknown. In science fair projects, these studies typically involve the collection and culturing of microorganisms from the environment (e.g. soil, household surfaces, skin.)

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 sterile non-breakable container) and sealed.
 - 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/disposal), it must be treated as a BSL-2 study and involve BSL-2 laboratory precautions.

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

Studies involving rDNA technologies in which microorganisms, plants and/or animals 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 SRC.

1. All rDNA technology studies involving BSL-1 organisms and BSL-1 host vector systems, including commercially available kits, must be conducted in at least 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* K-12, *S. cerevisiae*, and *B. subtilis* host-vector systems.
2. 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.
3. 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, where applicable.
4. Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses) is prohibited. All genome editing studies that include alteration of germline cells, insertion of gene drives, use of rapid trait development systems (RTDS®), etc., should be categorized as a BSL-2 study and must be conducted at an RRI and approved by the IBC from the institution. Qualified scientists are expected to ensure that student research protocols address appropriate intrinsic and extrinsic containment precautions.
5. Introduction or disposal of non-native, genetically-altered, and/or invasive species (e.g. insects or other invertebrates, plants, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. Students and adult sponsors should reference their local, state and national regulations and quarantine lists.

C. 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. 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/Project Summary.
2. 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.
 - a. Use of tissues obtained from research conducted at a Regulated Research Institution requires a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.
 - b. Use of tissues obtained from agricultural/aquacultural studies require prior SRC approval.
3. 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. (See vertebrate animal rules.)
4. 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 must be considered biosafety Level 1 studies and must be conducted in a BSL-1 laboratory or higher and must be supervised by a Qualified Scientist or trained Designated Supervisor.
5. The collection and examination of fresh/frozen tissues or body fluids or meat and meat by-products NOT obtained from food stores, restaurants, or packing houses may contain microorganisms. Because of the increased risk from unknown potentially hazardous agents, these studies must be considered biosafety level 2 studies conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist.
6. Human breast milk of unknown origin, unless certified free of HIV and Hepatitis C, and domestic unpasteurized animal milk are considered BSL-2.
7. All studies involving human or wild animal blood or blood products should be considered at a minimum a biosafety level 2 study and must be conducted in a BSL-2 laboratory under the supervision of a Qualified Scientist. Known BSL-3 or BSL-4 blood is prohibited. 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. Studies of human body fluids, where the sample can be identified with a specific person, must have IRB review and approval, and informed consent.

9. Any study involving the collection and examination of body fluids that may contain biological agents belonging to BSL-3 or BSL-4 is prohibited.
10. A project involving a student researcher using their own body fluids (if not cultured)
 - a. can be considered a BSL-1 study
 - b. may be conducted in a home setting
 - c. must have IRB review if the body fluid is serving as a measure of an effect of an experimental procedure on the student researcher (e.g. student manipulates diet and takes a blood or urine sample). An example of a project not needing IRB review would be collecting urine to serve as a deer repellent.
 - d. must receive prior SRC review and approval prior to experimentation
11. Studies involving embryonic human stem cells must be conducted in a Registered Research Institution and reviewed and approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee.

EXEMPT STUDIES (NO SRC PRE-APPROVAL REQUIRED)

The following types of studies are exempt from requiring SRC pre-approval as listed below, but may be subject to additional rules dependent upon the design of the project. Student researchers and adult sponsors are required to refer to sections A, B, and C of this section to review additional rules for projects that involve unknown organisms, recombinant DNA (rDNA) technologies, tissues, fluids, blood, or blood products before deciding upon a final biosafety level (BSL) designation for projects.

1. The following types of studies are exempt from prior SRC review, but require a Risk Assessment Form 3:
 - a. Studies involving protists and archaea
 - b. Research using manure for composting, fuel production, or other non-culturing experiment
 - c. Commercially available color change coliform detection test kits; these kits must remain sealed and must be properly disposed
 - d. Studies involving decomposition of vertebrate organisms (such as in forensic projects)
 - e. Studies with microbial fuel cells in which the device is sealed during experimentation and disposed of properly at the conclusion of the study
2. The following types of studies involve BSL-1 organisms and are exempt from prior SRC review and require no additional forms:
 - a. Studies involving fermentation of baker's yeast and brewer's yeast, except in rDNA studies
 - b. Studies involving *Lactobacillus*, *Bacillus thuringiensis*, nitrogen-fixing, oil-eating, and algae-eating bacteria introduced into their natural environment (not exempt if cultured in a petri dish environment)
 - c. Studies involving water or soil microbes not concentrated in media conducive to their microbial growth
 - d. Studies of mold growth on food items if the experiment is terminated at the first evidence of mold
 - e. Studies of slime molds and edible mushrooms
 - f. Studies involving *E. coli* k-12 (and other strains of *E. coli* used solely as a food source for *C. elegans*) that are performed at school and are not subject to additional rules for recombinant DNA studies or use of antibiotic resistant organisms

EXEMPT TISSUES (NO SRC PRE-APPROVAL REQUIRED)

1. The following types of tissue do not need to be treated as potentially hazardous biological agents:
 - a. Plant tissue (except those known to be toxic or hazardous)
 - 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/Project Summary
 - c. Human capillary/blood collection (i.e. finger stick) of the student researcher to themselves; blood collection from any other human participants must be reviewed and approved by an IRB
 - d. Fresh or frozen meat, meat by-products obtained from food stores, restaurants, or packing houses and eggs or pasteurized milk
 - e. Hair, hooves, nails and feathers
 - f. Teeth that have been sterilized to kill any blood-borne pathogen that may be present
 - g. Fossilized tissue or archeological specimens.
 - h. Prepared fixed tissue

Sources of Information are available as a separate section at the end of the document.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS 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 biosafety level which then determines the laboratory facilities, equipment, training, and supervision required.

Risk assessment involves:

1. Assignment of the biological agent to a risk group.
2. Studies involving a known microorganism must begin with an initial assignment of the microorganism to a biosafety level risk group based on information available through a literature search.
3. The study of unknown microorganisms and the use of fresh tissues relies on the expertise of the supervising adult(s).
4. Determination of the level of biological containment available to the student researcher to conduct the experimentation. (See "Levels of Biological Containment" for details.)
5. Assessment of the experience and expertise of the adult(s) supervising the student.
6. Assignment of a 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.
7. Documentation of review and approval of study prior to experimentation:
 - a. If a study is conducted at a non-regulated site (e.g. school), the SRC reviews the Research Plan/Project Summary.
 - b. If the study was conducted at a Regulated Research Institution, and was approved by the appropriate institutional board (e.g. IBC, IACUC), the SRC reviews the institutional forms provided and documents SRC approval (Form(6A)).
 - c. If a PHBA study was conducted at a Regulated Research Institution but the institution does not require review for this type of study, the SRC must review the study and document approval on Form 6A that the student received appropriate training and the project complies with ISEF rules.

Classification of Biological Agents

Risk Groups

Biological agents 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: *Agrobacterium tumefaciens*, *Micrococcus leuteus*, *Neurospora crassa*, *Bacillus subtilis*.

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

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

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. Projects in the BSL-4 group are 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 an appropriate biosafety 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 and gloves are required. 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 and gloves are required; eye protection and face shields must also be worn as needed. The laboratory work must be supervised by a 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. Projects in the BSL-3 group are prohibited.

BSL-4 containment is required for dangerous/exotic agents that pose high risk of life-threatening disease. Projects in the BSL-4 group are prohibited.

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES RULES

Includes DEA-controlled substances, prescription drugs, alcohol & tobacco, firearms and explosives, radiation, lasers, etc.

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 ISEF, school, local, and/or regional fair(s).

RULES FOR ALL PROJECTS INVOLVING HAZARDOUS CHEMICALS, ACTIVITIES AND DEVICES

1. The student researcher must conduct a risk assessment in collaboration with a Designated Supervisor or Qualified Scientist prior to experimentation. This risk assessment should be documented in the research plan to include the risk assessment process, supervision, safety precautions and appropriate methods of disposal. This risk assessment is also documented on Risk Assessment Form 3.
2. 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.
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, affiliated, and ISEF SRCs 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. (Proper chemical, sharps and other hazardous materials disposal must follow local, state, federal guidelines.)
6. The following forms are required:
 - a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary 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 AREAS

There are additional rules for the following regulated areas:

- A. DEA-controlled Substances
- B. Prescription Drugs
- C. Alcohol & Tobacco
- D. Firearms and Explosives
- E. Regulated Drones
- F. Radiation

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.

- a. All studies using DEA-controlled substances must be supervised by a Qualified Scientist at a RRI (and must be conducted at a Regulated Research Institution) who is licensed by the DEA (or other international regulatory body) for use of the controlled substance.
- b. All studies using DEA Schedule 1 substances (including marijuana) 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

In the United States, the Food and Drug Administration tightly regulates the issuance of prescriptions and thus they are controlled substances. State laws further regulate the use of prescription drugs and it is unlawful for any person knowingly or intentionally to possess a controlled substance unless it was obtained directly from a valid prescription or order of a practitioner while acting in the course of their professional practice. It is also unlawful to use the prescription for persons or purposes outside of the original prescription. All applicable federal, state and country laws must be followed.

1. Students are prohibited from the use of prescription drugs in their study outside of the authority of a practitioner or researcher that has obtained the controlled substance with appropriate approvals and is using the substance for the purpose for which it was prescribed.
 - a. Such studies must be conducted with a Qualified Scientist and a Risk Assessment Form 3 is required documentation
 - b. Students are further prohibited from providing prescription drugs to human participants
2. In the case of prescription drugs administered to vertebrate animals, this may only be done under a veterinarian's supervision and with prescriptions provided for this specific purpose.

C. Alcohol and Tobacco

The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the production of alcohol and distribution of alcohol and tobacco products. Many such products are restricted by age for purchase, possession and consumption.

1. Fermentation studies in which minute quantities of ethyl alcohol are produced are permitted.
2. The Designated Supervisor is responsible for the acquisition, usage and appropriate disposal of the alcohol or tobacco used in the study.
3. Production of wine or beer by adults is allowable in the home and must meet TTB home production regulations. Students are allowed to design and conduct a research project, under direct parental supervision, involving the legal production of the wine or beer.
4. Students are prohibited from conducting experiments where consumable ethyl alcohol is produced by distillation. However, students are allowed to distill alcohol for fuel or other non-consumable products. To do so, the work must be conducted at school or a Regulated Research Institution and follow all local and country laws. See Alcohol and Tobacco Tax and Trade Bureau (TTB) website for details.

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 considered firearms unless they are intended to be used as weapons. However, they must be treated as hazardous devices.

E. Regulated Drones

Projects involving unmanned aircraft systems (UAS)/drones must follow all state, federal and country laws. See the Federal Aviation Administration (FAA) for more details (faa.gov/uas/).

Current U.S. law requires all forms of drones to be registered with the FAA.

F. Radiation

Projects involving radionuclides (radioisotopes) and X-rays must involve a careful examination of the risks associated with the study and appropriate safety precautions must be taken. Depending upon the level of exposure, radiation released from these sources can be a health hazard.

1. All studies may not exceed the dose limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
2. If the voltage needed in the study is <10 kvolts, a risk assessment must be conducted. The study may be done at home or school, and SRC preapproval is not required.
3. A study using 10–25 kvolts must have a risk assessment conducted and must be preapproved by the SRC to assess safety. Such a study must be conducted in a metal-lined chamber using a camera only, not direct view through glass. A dosimeter or radiation survey meter is required to measure radiation exposure.
4. All studies using > 25 kvolts must be conducted at an institution with a Licensed Radiation Program and must be preapproved by the Institutions' Radiation Safety Officer or the Committee which oversees the use of ionizing radiation to ensure compliance with state and federal regulations.

GUIDANCE FOR RISK ASSESSMENT

PLEASE FIND BELOW GUIDANCE ON CONDUCTING RISK ASSESSMENT WHEN USING THE FOLLOWING:
HAZARDOUS CHEMICALS, HAZARDOUS DEVICES, RADIATION

1. Hazardous Chemicals

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

- a. Toxicity—the tendency of a chemical to be hazardous to human or environmental health
 - Human health toxicity includes acute and chronic hazards when inhaled, swallowed, injected or in contact with the skin.
 - Environmental health includes aquatic toxicity (both acute and chronic), toxicity to mammals and birds, and impact on ecosystems.
- b. Reactivity—the tendency of a chemical to undergo chemical change, including instability and reactivity with other substances or conditions (i.e., reaction with water, air, temperature, pressure).
- c. Flammability—the tendency for a chemical substance

Environmentally Responsible Chemistry

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

- Waste prevention
- Use of the safest possible chemicals and products
- Design of the least possible hazardous chemical syntheses
- Use of renewable materials
- Use of catalysts in order to minimize chemical usage
- Use of solvents and reaction conditions that are safe as possible
- Maximization of energy efficiency
- Minimization of accident potential and avoiding the use of reactive substances

to be ignited at ambient temperatures. Combustible substances can include:

- Chemical solvents that produce vapors which readily ignite when used under normal working conditions.
- Combustible solids (small particles, powders, or substances easily ignited by fire or an ignition source)

- d. 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 Safety Data Sheets provided by the vendor (SDS) to ensure that proper safety precautions are taken. Some SDS 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 (documented on Form 3) 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.

2. Hazardous Devices

The documentation of 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.

3. Radiation

A risk assessment (documented on Form 3) must be conducted when a student's project involves 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).

ENGINEERING AND INVENTION PROJECTS GUIDE

USE THIS INFORMATION TO HELP DETERMINE THE REQUIREMENTS OF ENGINEERING PROJECTS AND POTENTIAL AREAS THAT WILL REQUIRE PRE-APPROVAL AND/OR EXTRA SAFETY PRECAUTIONS.

[A GUIDE TO ENGINEERING & INVENTION PROJECTS](#) HAS BEEN DEVELOPED AS AN ADDITIONAL RESOURCE AND PROVIDES A SERIES OF QUESTIONS TO CONSIDER AS YOU BEGIN AND DESIGN AN ENGINEERING OR INVENTION PROJECT.

ENGINEERING AND INVENTION PROJECT CHECKLIST

CONSIDER THE ANSWERS TO THE QUESTIONS BELOW. IF THE RESPONSE IS YES, THEN THE PROJECT MAY FALL UNDER MORE SPECIFIC RULES AND THOSE SECTIONS OF THE INTERNATIONAL RULES & GUIDELINES SHOULD BE CONSULTED.

Hazardous Chemicals, Activities and Devices

Will your project involve any of the following:

- DEA-controlled Substances
- Firearms and Explosives
- Prescription Drugs
- Alcohol & Tobacco
- Regulated Drones
- Radiation

If any are checked, see Hazardous Rules, page 19.

Device Testing with Human Participants

- Are you going to test your project (device, app, invention, prototype, etc.)? If yes, does it require persons to interact with it other than yourself or adult sponsor/supervisor?
- Do you intend to gather background knowledge through a survey or interviews to understand the potential use and needs for your project design?
- Are you going to ask for opinions or suggestions on your project design at any point of the project?
- Does your project intend to gather personal data/have a health benefit to the user?

If any are checked, see Human Participant Rules, page 8.

Vertebrate Animals

- Does your project include any interaction with vertebrate animals in any phase of the project?

If any are checked, see Vertebrate Animal Rules, page 12.

Potentially Hazardous Biological Agents

- Does your project include any collection, examination or handling of microorganisms, and/or fresh or frozen tissue, primary cell cultures, blood, blood products or body fluids?
- Are you going to culture or isolate any substance, known or unknown?

If any are checked, see Potentially Hazardous Biological Agents Rules, page 15.

SOURCES OF INFORMATION FOR ALL PROJECTS

1. United States Patent and Trade Office
Customer Service: 1-800-786-9199 (toll-free);
571-272-1000 (local); 571-272-9950 (TTY)
uspto.gov
uspto.gov/patents/process/index.jsp
Conducting a Patent Search:
 - <https://patents.google.com/>
 - <http://www.freepatentsonline.com/>
 - <https://worldwide.espacenet.com/>
 2. USPTO Resources
 - 7 Step Search Strategy Guide and Video Tutorial
<https://www.uspto.gov/learning-resources>
 - Pro Bono Program
<https://www.uspto.gov/patents-getting-started/using-legal-services/pro-bono/patent-pro-bono-program>
 - Law School Clinic Certification Program
[uspto.gov/learning-and-resources/ip-policy/public-information-about-practitioners/law-school-clinic-1](https://www.uspto.gov/learning-and-resources/ip-policy/public-information-about-practitioners/law-school-clinic-1)
 - USPTO Pro Se Assistance Program
<https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/pro-se-assistance-program>
 3. European Patent Office
www.epo.org
www.epo.org/applying/basics.html
 4. Aquatic Nuisance Species (ANS) Task Force
www.anstaskforce.gov
www.anstaskforce.gov/Documents/ISEF.pdf
 5. APHIS
https://www.aphis.usda.gov/aphis/ourfocus/wildlifedamage/operational-activities/SA_Invasive/CT_Invasive_species1
Animal and Plant Health Inspection Service
Invasive Species List
 6. Invasive Species Specialist Group
www.issg.org
The Global Invasive Species database contains invasive species information supplied by experts from around the world.
 7. Invasive Species Information
www.invasivespeciesinfo.gov/resources/lists.shtml
Provides information for species declared invasive, noxious, prohibited, or harmful or potentially harmful.
4. Standards for Educational and Psychological Testing. (1999). Washington, DC: AERA, APA, NCME.
<https://www.apa.org/science/programs/testing/standards>
 5. American Psychological Association
750 First Street, NE Washington, DC 20002-4242
phone: 202-336-5500; 800-374-2721
www.apa.org

Information for students:
<https://www.apa.org/about/students>

Information regarding publications:
www.apa.org/pubs/index.aspx
 6. Educational and Psychological Testing
Testing Office for the APA Science Directorate
phone: 202-336-6000
email: testing@apa.org
<https://www.apa.org/science/programs/testing/>
 7. The Children's Online Privacy Protection Act of 1998 (COPPA) (15 U.S.C. §§ 6501-6506)
<https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule>

VERTEBRATE ANIMALS

Animal Care and Use

1. Laboratory Animals, Institute of Laboratory Animal Research (ILAR), Commission on Life Sciences, National Research
<https://www.nationalacademies.org/ilar/institute-for-laboratory-animal-research>
2. Guide for the Care and Use of Laboratory Animals, 8th Edition (2011)
<http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>
3. Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003), Institute for Laboratory Animal Research (ILAR)
<https://www.nap.edu/catalog/10732/guidelines-for-the-care-and-use-of-mammals-in-neuroscience-and-behavioral-research>
To order these ILAR publications contact:
National Academies Press
500 Fifth Street, NW
Washington, DC 20055
phone: 888-624-8373 or 202-334-3313; fax: 202-334-2451
<https://www.nap.edu/content/help-with-ordering>
4. Federal Animal Welfare Act (AWA)
7 U.S.C. 2131-2157
Subchapter A - Animal Welfare (Parts I, II, III)
<https://www.nal.usda.gov/awic/animal-welfare-act>

Document is available from:
USDA/APHIS/AC
4700 River Road, Unit 84
Riverdale, MD 20737-1234
email: ace@aphis.usda.gov
phone: 301-734-7833; fax: 301-734-4978
<https://www.nal.usda.gov/awic>

HUMAN PARTICIPANTS

1. Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46>
2. NIH tutorial, "Protecting Human Research Participants"
<http://phrp.nihtraining.com/files/PHRP.pdf>
3. Belmont Report, April 18, 1979
https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

5. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide) Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International)
<https://www.aaalac.org/>
https://www.aaalac.org/about/Ag_Guide_3rd_ed.pdf
6. *Guidelines for the Use of Fish in Research* (2014), American Fisheries Society.
www.fisheries.org

<https://fisheries.org/policy-media/science-guidelines/guidelines-for-the-use-of-fishes-in-research/>
7. Euthanasia Guidelines
AVMA Guidelines on Euthanasia (2020)
American Veterinary Medical Association
<https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals>

ALTERNATIVE RESEARCH AND ANIMAL WELFARE

1. The National Library of Medicine provides computer searches through MEDLINE:
Reference & Customer Services
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
888-FIND-NLM or 888-346-3656; 301-594-5983;
email: info@ncbi.nlm.nih.gov
nlm.nih.gov
ncbi.nlm.nih.gov/pubmed
2. National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.
Animal Welfare Information Center
National Agriculture Library
10301 Baltimore Avenue, Room 410
Beltsville, MD 20705-2351
phone: 301-504-6212, fax: 301-504-7125
email: awic@ars.usda.gov
www.nal.usda.gov/awic
3. Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in *ILAR Journal*.
ILAR—The Keck Center of the National Academies
500 Fifth Street, NW, Keck 687
Washington, DC 20001
phone: 202-334-2590, fax: 202-334-1687
email: ILAR@nas.edu
<https://www.nationalacademies.org/ilar/institute-for-laboratory-animal-research>
4. Quarterly bibliographies of Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing may be obtained from:
Specialized Information Services
NLM/NIH
2 Democracy Plaza, Suite 510
6707 Democracy Blvd., MSC 5467
Bethesda, MD 20892-5467
phone: 301-496-1131; Fax: 301-480-3537
email: tehip@tehnlm.nih.gov
<https://toxnet.nlm.nih.gov/altbib.html>

5. Johns Hopkins Center for Alternatives to Animal Testing (CAAT) has worked with scientists since 1981 to find new methods to replace the use of laboratory animals in experiments, reduce the number of animals tested, and refine necessary tests to eliminate pain and distress.
email: caat@jhu.edu
<https://caat.jhsph.edu/>
6. Quality Assurance Manuals (for appropriate species)
Such as:
Poultry: <https://naldc.nal.usda.gov/download/CAT87798868/PDF>
Beef: <https://www.bqa.org/Media/BQA/Docs/nationalmanual.pdf>
Pork: <https://porkgateway.org/wp-content/uploads/2015/07/pork-quality-assurance1.pdf>

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

1. American Biological Safety Association: ABSA Risk Group Classification—list of organisms
www.absa.org
2. American Type Culture Collection (ATCC)
www.atcc.org
3. Bergey's Manual of Systematic Bacteriology website—follow the links for resources and microbial databases for a collection of international websites of microorganisms and cell cultures.
<https://www.bergeys.org>
4. Biosafety in Microbiological and Biomedical Laboratories (BMBL)—4th Edition. Published by CDC-NIH
<https://www.cdc.gov/labs/BMBL.html>
5. World Health Organization Laboratory Safety Manual
www.who.int/diagnostics_laboratory/guidance/en
6. Canada—Agency of Public Health—list of non-pathogenic organisms
<https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html>
 - American Society for Microbiology
<https://www.asm.org>
 - Microbiology Society
14-16 Meredith Street
London
EC1R 0AB
UK
info@microbiologysociety.org
microbiologysociety.org
7. *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Published by National Institutes of Health.
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
8. OSHA—Occupational Health and Safety Administration
osha.gov

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES

GENERAL LAB/CHEMICAL SAFETY

1. *Safety in Academic Chemistry Laboratories, Volumes 1 and 2, 2003*. Washington, DC: American Chemical Society.
Order from (first copy free of charge):
American Chemical Society
Publications Support Services
1155 16th Street, NW
Washington, DC 20036
phone: 202-872-4000 or 800-227-5558
email: help@acs.org
<https://www.acs.org/content/acs/en/education.html>
2. General
Howard Hughes Medical Institute has resources for working with cell cultures, radioactive materials and other laboratory materials.
<http://www.hhmi.org/developing-scientists/resources>
3. Environmental Protection Agency (EPA) website for green chemistry
www.epa.gov/greenchemistry
4. Safety and Data Sheets (SDS)
<https://www.flinnsci.com/safety/>
A directory of SDS sheets from Flinn Scientific Inc. that includes a ranking of hazard level and disposal methods.

www.ilpi.com/msds/index.html - A listing of numerous sites that have free downloads of SDS sheets.

NFPA (National Fire Protection Association) 704 Standard for guidance on Chemical Reactivity and Instability:
https://en.wikipedia.org/wiki/NFPA_704
5. Pesticides
National Pesticide Information Center
<http://npic.orst.edu/ingred/ptype/natbio.html>
Describes the various types of pesticides and the legal requirements for labelling. Provides links and phone numbers to get additional information.

Environmental Protection Agency
<http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1>
A database of product labels. Enter the product name or company name to view the approved label information of pesticides which are registered with the agency.
6. DEA Controlled Substances
Drug Enforcement Agency website:
<https://www.dea.gov>
Controlled Substance Schedules—a list of controlled substances:
www.deadiversion.usdoj.gov/schedules
7. Alcohol, Tobacco, Firearms, and Explosives
Alcohol and Tobacco Tax and Trade Bureau
<https://www.ttb.gov>
Bureau of Alcohol, Tobacco, Firearms and Explosives
<https://www.atf.gov/>
8. Radiation
Radiation Studies Information (CDC)
www.cdc.gov/nceh/radiation/default.htm
9. CDC Laboratory Safety Manuals
<https://www.cdc.gov/labs/BMBL.html>

10. Occupational Safety and Health Administration
www.osha.gov
Safety and Health Topics:
www.osha.gov/SLTC
www.osha.gov/SLTC/reactivechemicals/index.html
www.osha.gov/SLTC/laserhazards/index.html
www.osha.gov/SLTC/radiationionizing/index.html
11. U.S. Nuclear Regulatory Commission
Material Safety and Inspection Branch
One White Flint North
11555 Rockville Pike
Rockville, MD 20852
phone: 301-415-8200; 800-368-5642
www.nrc.gov

ISEF DISPLAY & SAFETY REGULATIONS

Please address any questions regarding ISEF Display & Safety Regulations to displayandsafety@societyscience.org

DISPLAY & SAFETY COMMITTEE MISSION

The mission of this committee is to ensure that all competitors qualify for competition according to the rules established in conjunction with the Scientific Review Committee and Society for Science.

The ISEF Display & Safety inspection process can be initiated only when all items are present at the display. The Display & Safety Committee will offer guidance on Display & Safety issues for projects approved by the SRC to compete in ISEF. Occasionally, the ISEF Display & Safety Committee may require students to make revisions to conform to Display & Safety regulations. Persistent issues will be directed to a committee of individuals which may include Society for Science (the Society) personnel, Display & Safety (D&S) and/or Scientific Review Committee (SRC) executive committee members.

The following regulations must be adhered to when a finalist exhibits a project at ISEF. All projects must adhere to the Display & Safety requirements of the affiliated fair(s) in which they compete to qualify for participation in ISEF. Affiliated fairs may have additional restrictions or requirements. Knowledge of these requirements is the responsibility of the Finalist, Adult Sponsor, and Fair Director.

DISPLAY REGULATIONS

Maximum Size of Project

- Depth (front to back): 30 inches or 76 centimeters**
- Width (side to side): 48 inches or 122 centimeters**
- Height (floor to top): 108 inches or 274 centimeters**

Please be aware when ordering posters that the mechanism that supports the poster should conform to the maximum size limitations stated above.

- All project materials and support mechanisms must fit within the project dimensions (including table covers).
- Fair-provided tables at ISEF will not exceed a height of 36 inches (91 centimeters).
- If a table is used it becomes part of the project and must not exceed the allowed dimensions.
- Nothing can be attached to the rear curtain.
- All demonstrations must be done within the confines of the finalist's booth space. When not being demonstrated, all project components must be returned to the project display and must fit within allowable dimensions as defined above.
- Projects can be continued under the table BUT this area is not to be used for storage.

Position of Project

The fair provided table or freestanding display must be parallel to, and positioned at, the back curtain of the booth. Projects may NOT lean against the back curtain.

Forms Required to be Visible and Vertically Displayed at the Project Booth

The placement of the required forms may include the front edge of the table, the display board, or in a free-standing acrylic frame placed on the table top.

Forms required at all projects:

- An original Official Abstract and Certification as approved (stamped/embossed) by the ISEF Scientific Review Committee.
 - Upon SRC approval, the stamped/embossed Official Abstract and Certification will be provided.
 - The abstract must be the official International Science and Engineering Fair Abstract and embossed/stamped by the ISEF Scientific Review Committee.
 - No other format or version of your approved Abstract & Certification will be allowed for any purpose at ISEF. Judges are provided the official Abstract and Certification digitally; no handouts are permitted.
 - The term "abstract" may NOT be used as a title or reference for any information on a finalist's display or materials at the project except as part of displaying the official stamped/embossed abstract.
 - It is the recommendation of the Display & Safety Committee to NOT include the word "abstract" nor the abstract itself when preparing backboards or posters prior to the fair. However, it is reasonable to leave a blank space (8½" x 11") on the backboard/poster so as to facilitate the addition of the official abstract. Keep in mind this document can also be displayed vertically on the front edge of the table or in a free-standing acrylic frame.
- ISEF Project Set-up Approval Form (received on-site at the Fair)
 - This form documents the project as approved by the Scientific Review Committee and is used to document the Display & Safety Committee's review process and final approval.
 - This form must be signed by the finalist and the Display & Safety Committee member at the time of inspection.

Additional Forms required (only when applicable):

- Regulated Research Institutional/Industrial Setting Form (1C)
 - If work was conducted in a regulated research institution, industrial setting or any work site other than home, school or field at any time during the current ISEF project year, the **Regulated Research Institutional/Industrial Setting Form (1C)** must be completed and vertically displayed at the project booth.

- The information provided by the mentor on Form 1C may be referenced to confirm that the information provided on the project board is that of the finalist. Only minimal reference to a mentor's or another researcher's work is allowable and must only reflect background information or be used to clarify differences between finalist's and others' work.
- Continuation/Research Progression Projects Form (7)
 - If a study is a continuation/research progression, the Continuation/Research Progression Projects Form (7) must be completed and vertically displayed at the project booth.
 - The display board and abstract must reflect only the current year's work. The project title displayed in the finalist's booth may mention years of continuing research (for example, "Year Two of an Ongoing Study").
 - Reference to past work on the display board must be limited to summative past conclusory data and its comparison to the current year data set. No raw data from previous years may be publicly displayed; however, it may be included in the student research notebooks and/or logbooks if properly labeled.

Forms Required at Project but not Displayed

- Forms, excluding those listed above, that were required for the Scientific Review Committee approval should not be vertically displayed, but must be available in the booth in case asked for by a judge or other ISEF official. These forms include, but are not limited to, Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, Approval Form (1B), and a photograph/video release form.
- A photograph/video release form signed by the subject is required for visual images of humans (other than the finalist) displayed as part of the project.

Forms NOT to be at the Project Display Booth or in the Exhibit Hall

Completed informed consent/assent forms for a human participant study are NOT to be displayed and should NOT be present at the project display. The Finalist may include a sample (incomplete) form in their logbook or research notebook but under NO CIRCUMSTANCE should the completed informed consent/assent forms for a human participant be in the Exhibit Hall.

Photograph/Image Display Requirements

- Any photograph/visual image/chart/table/student-created logo 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 & Safety Committee, or Society for Science
 - It has a credit line of origin ("Photograph taken by..." or "Image taken from..." or "Graph/Chart/Table taken from..."). If all images, etc. displayed were 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.
 - All images MUST BE properly cited. This includes student-created logos, background graphics, photographs and/or visual depictions of the finalist or photographs and/or visual depictions of others.

- All visual depictions of others require a signed photo/video release form in a notebook or logbook at the project booth. These signed release forms must be available upon request during the set-up and inspection process, but may not be displayed.
 - Sample release text: "I consent to the use of visual images (photos, videos, etc.) involving my participation/my child's participation in this research."
- Finalists using any presentation or demonstration outside of a project board must be prepared to show the entire presentation to the Display & Safety Inspectors before the project is approved. All aforementioned rules apply to this presentation and the presentation may not be altered in any way after the final Display & Safety inspection. Examples of presentations that require approval include, but are not limited to PowerPoint, Prezi, Keynote, software program/simulation and other images and/or graphics displayed on a computer screen or other non-print delivery method.

Items/Materials Not Allowed on Display or at Project Booth

- Any information on the project display or items that are self-promotions or external endorsements are not allowed in the project booth
 - The use of commercial logos including known brands, institutional crests or trademarks, flags unless integral to the project and approved by the SRC via inclusion in the Official Abstract and Certification.
 - Any reference to an institution or mentor that supported the finalist's research except as provided in an acknowledgement section of the poster and within official ISEF paperwork, most notably Form 1C.
 - Any reference to patent status of the project.
 - Any items intended for distribution such as disks, CDs, flash drives, brochures, booklets, endorsements, give-away items, business cards, printed materials or food items designed to be distributed to judges or the public.
- Any awards or medals, except for past or present ISEF medals that may be worn by the finalist.
- Postal addresses, World Wide Web, email and/or social media addresses, QR codes, telephone and/or fax numbers of a project or finalist. Note: The only personal information that is permissible to include on the display is the finalist name, school, city, state, country, age and grade.
- Active Internet or email connections as part of displaying or operating the project at ISEF.
- Any changes, modifications, or additions to projects including any attempt to uncover, replenish or return removed language or items after the approval by the Display & Safety Committee and the Scientific Review Committee has been received is prohibited.
 - Display & Safety inspections will include recording photographic evidence of the approved Project Display and Project booth.
 - Finalists who do not adhere to this signed agreement on the ISEF Project Set-up Approval Form regarding this regulation may fail to qualify for competition.

I/we understand that the initial Display & Safety Inspection has been completed, but that additional reviews occur and that I/we should check back regularly. I/we will vertically display this signed form at our project at all

times. I/we have not and will not store packing material under the booth. I/we further understand that returning items that have been removed by the SRC or D&S and/or adding items that are not permitted after final clearance are grounds for failing to qualify for competition and/or forfeiture of all awards received.

SAFETY REGULATIONS

Not Allowed at Project or Booth

Note: In the case in which a Finalist's Project includes an item that is prohibited from display, please consider taking photographs and/or documenting the significance of the prohibited item through video.

1. Living organisms, including plants
2. Glass
3. Soil, sand, rock, cement and/or waste samples, **even if permanently encased in a slab of acrylic**
4. Taxidermy specimens or parts
5. Preserved vertebrate or invertebrate animals
6. Human or animal food
7. Human/animal parts or body fluids (for example, blood, urine)
8. Plant materials (living, dead, or preserved) that are in their raw, unprocessed, or non-manufactured state
9. All chemicals including water. Absolutely no liquids can be utilized in the Project Display
10. All hazardous substances or devices (Example: poisons, drugs, firearms, weapons, ammunition, reloading devices, grease/oil and sublimating solids such as dry ice)
11. Items that may have contained or been in contact with hazardous chemicals (Exception: Item may be permitted if professionally cleaned and documentation for such cleaning is available). Filters (including microbial) may not be displayed unless the Display & Safety Committee can reasonably determine that the device was cleaned or was never used (please include receipts in your notebooks and/or logbooks)
12. Sharp items (for example, syringes, needles, pipettes, knives)
13. Flames and highly flammable materials
14. Batteries with open-top cells or wet cells
15. Drones or any flight-capable apparatus unless the propulsion power source removed
16. 3D Printers unless the power source is removed
17. Inadequately insulated apparatus capable of producing dangerous temperatures are not permitted
18. Any apparatus with belts, pulleys, chains, or moving parts with tension or pinch points that are not appropriately shielded
19. Any display items that are deemed distracting (i.e. sounds, lights, odors, etc.)
20. Personal items or packaging materials stored underneath the booth
21. Any apparatus or project material deemed unsafe by the Scientific Review Committee, the Display & Safety Committee, or the Society

Electrical Regulations

1. Electrical power supplied to the project is 120 or 220 Volt, AC, single phase, 60 Hz. No multi-phase will be available or shall be used. 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 & Safety Committee. For all electrical regulations, "120 Volt AC" or "220 Volt AC" is intended to encompass the corresponding range of voltage as supplied by the facility in which ISEF is being held.
2. Electrical devices must be protectively enclosed. Any enclosure must be non-combustible. All external non-current carrying metal parts must be grounded.
3. Energized wiring, switches, and metal parts must have adequate insulation and over-current safety devices (such as fuses) and must be inaccessible to anyone other than the finalist. Exposed electrical equipment or metal that may be energized must be shielded with a non-conducting material or with a grounded metal box to prevent accidental contact.
4. Decorative lighting or illumination is discouraged. If used, lighting must be as low a voltage as possible and must be LED lighting that does not generate heat. Incandescent and fluorescent light bulbs are prohibited. When student is not at the exhibit, all electrical power must be disconnected, or power bars must be switched off (Exception: during pre-judging audio visual displays may be available.)
5. An insulating grommet is required at the point where any wire or cable enters any enclosure.
6. No exposed live circuits over 36 volts are allowed.
7. There must be an accessible, clearly visible on/off switch or other means of quickly disconnecting from the 120 or 220 Volt power source.

Laser/Laser Pointer Regulations

Any Class 1, Class 2, Class 3A, or Class 3R lasers are allowed to be used responsibly. No other lasers may be used or displayed.

1. Laser beams may not pass through magnifying optics such as microscopes and telescopes.
2. Lasers must be labeled by the manufacturer so that power output can be inspected. Lasers without labels will NOT be permitted.
3. Handheld lasers are NOT permitted.
4. Lasers will be confiscated with no warning if not used in a safe manner.

ISEF CATEGORIES AND SUBCATEGORIES

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

Please visit our website at <https://www.societyforscience.org/isef/categories-and-subcategories> for a full description and definition of ISEF categories:

ANIMAL SCIENCES (ANIM)

Animal Behavior
Cellular Studies
Development
Ecology
Genetics
Nutrition and Growth
Physiology
Systematics and Evolution
Other

BEHAVIORAL AND SOCIAL SCIENCES (BEHA)

Clinical and Developmental Psychology
Cognitive Psychology
Neuroscience
Physiological Psychology
Sociology and Social Psychology
Other

BIOCHEMISTRY (BCHM)

Analytical Biochemistry
General Biochemistry
Medical Biochemistry
Structural Biochemistry
Other

BIOMEDICAL AND HEALTH SCIENCES (BMED)

Cell, Organ, and Systems Physiology
Genetics and Molecular Biology of Disease
Immunology
Nutrition and Natural Products
Pathophysiology
Other

BIOMEDICAL ENGINEERING (ENBM)

Biomaterials and Regen Medicine
Biomechanics
Biomedical Devices
Biomedical Imaging
Cell and Tissue Engineering
Synthetic Biology
Other

CELLULAR AND MOLECULAR BIOLOGY (CELL)

Cell Physiology
Cellular Immunology
Genetics
Molecular Biology
Neurobiology
Other

CHEMISTRY (CHEM)

Analytical Chemistry
Computational Chemistry
Environmental Chemistry
Inorganic Chemistry
Materials Chemistry
Organic Chemistry
Physical Chemistry
Other

COMPUTATIONAL BIOLOGY AND BIOINFORMATICS (CBIO)

Computational Biomodeling
Computational Epidemiology
Computational Evolutionary Biology
Computational Neuroscience
Computational Pharmacology
Genomics
Other

EARTH AND ENVIRONMENTAL SCIENCES (EAEV)

Atmospheric Science
Climate Science
Environmental Effects on Ecosystems
Geosciences
Water Science
Other

EMBEDDED SYSTEMS (EBED)

Circuits
Internet of Things
Microcontrollers
Networking and Data Communications
Optics
Sensors
Signal Processing
Other

ENERGY: SUSTAINABLE MATERIALS AND DESIGN (EGSD)

Biological Process and Design
Energy Storage
Hydrogen Generation and Storage
Other
Thermal Power
Solar Process, Materials, and Design
Thermal Generation and Design
Triboelectricity and Electrolysis
Wind
Wind and Water Movement Power
Generation
Other

ENGINEERING TECHNOLOGY: STATICS AND DYNAMICS (ETSD)

Aerospace and Aeronautical Engineering
Civil Engineering
Computational Mechanics
Control Theory
Ground Vehicle Systems
Industrial Engineering-Processing
Mechanical Engineering
Naval Systems
Other

ENVIRONMENTAL ENGINEERING (ENEV)

Bioremediation
Land Reclamation
Pollution Control
Recycling and Waste Management
Water Resources Management
Other

MATERIALS SCIENCE (MATS)

Biomaterials
Ceramic and Glasses
Composite Materials
Computation and Theory
Electronic, Optical and Magnetic Materials
Nanomaterials
Polymers
Other

MATHEMATICS (MATH)

Analysis
Combinatorics, Graph Theory, and Game Theory
Geometry and Topology
Number Theory
Probability and Statistics
Other

MICROBIOLOGY (MCRO)

Antimicrobials and Antibiotics
Applied Microbiology
Bacteriology
Environmental Microbiology
Microbial Genetics
Virology
Other

PHYSICS AND ASTRONOMY (PHYS)

Astronomy and Cosmology
Atomic, Molecular, and Optical Physics
Biological Physics
Condensed Matter and Materials
Mechanics
Nuclear and Particle Physics
Theoretical, Computational and Quantum Physics
Other

PLANT SCIENCES (PLNT)

Agriculture and Agronomy
Ecology
Genetics/Breeding
Growth and Development
Pathology
Plant Physiology
Systematics and Evolution
Other

ROBOTICS AND INTELLIGENT MACHINES (ROBO)

Biomechanics
Cognitive Systems
Control Theory
Machine Learning
Robot Kinematics
Other

SYSTEMS SOFTWARE (SOFT)

Algorithms
Cybersecurity
Databases
Human/Machine Interface
Languages and Operating Systems
Mobile Apps
Online Learning
Other

TRANSLATIONAL MEDICAL SCIENCES (TMED)

Disease Detection and Diagnosis
Disease Prevention
Disease Treatment and Therapies
Drug Identification and Testing
Pre-Clinical Studies
Other

INFORMATION ON REQUIRED ABSTRACT & CERTIFICATION FOR ALL PROJECTS AT ISEF

* This form may not be relevant for your regional or state fair; please refer to instructions from your affiliated fair.*

IN ADDITION TO THE BASIC FORM REQUIREMENTS FOR ALL PROJECTS AND ANY OTHER REQUIREMENTS DUE TO SPECIFIC AREAS OF RESEARCH, AN ABSTRACT & CERTIFICATION IS REQUIRED AT THE CONCLUSION OF RESEARCH. DETAILS ON THIS REQUIREMENT FOLLOW.

Completing the Abstract

After finishing research and experimentation, you are required to write a (maximum) 250 word, one-page abstract. For ISEF, this abstract is written in the online Finalist Questionnaire portal and submitted electronically.

It is recommended that it **include the following:**

- purpose of the experiment
- procedure
- data
- conclusions

It may also include any possible research applications. Only minimal reference to previous work may be included.

An abstract **must not include the following:**

- acknowledgments (including naming the research institution and/or mentor with which you were working), or self-promotions and external endorsements
- logos or proper names of commercial products
- work or procedures done by the mentor

Completing the Certification

At the bottom of the Abstract & Certification form there are six questions. Please read each carefully and answer appropriately. The ISEF Scientific Research Committee will review and approve the abstract and answers to the questions.

Revisions are permitted via the online portal through late April (please reference the system for current year deadlines.)

Once approved, two copies of the ISEF Abstract & Certification will be provided with a gold embossed seal; only this version of the abstract may be displayed or distributed.

NOTE: Your abstract must be on the International Science and Engineering Fair Abstract & Certification form and have the ISEF Scientific Review Committee approval seal before it is displayed or handed out. No other format or version of your approved Abstract will be allowed for any purpose at the ISEF.

ISEF Sample Abstract & Certification

PROJECT TITLE	PROJECT ID
FINALIST NAME(S)	Category
FINALIST SCHOOL, CITY, STATE/PROVINCE, COUNTRY	Pick one only—mark an "X" in box at right
ABSTRACT BODY	<input type="checkbox"/> Animal Sciences <input type="checkbox"/> Behavioral and Social Sciences <input type="checkbox"/> Biochemistry <input type="checkbox"/> Biomedical and Health Sciences <input type="checkbox"/> Biomedical Engineering <input type="checkbox"/> Cellular & Molecular Biology <input type="checkbox"/> Chemistry <input type="checkbox"/> Computational Biology and Bioinformatics <input type="checkbox"/> Earth & Environmental Sciences <input type="checkbox"/> Embedded Systems <input type="checkbox"/> Energy: Sustainable <input type="checkbox"/> Materials and Design <input type="checkbox"/> Engineering Technology: Statics and Dynamics <input type="checkbox"/> Environmental Engineering <input type="checkbox"/> Materials Science <input type="checkbox"/> Mathematics <input type="checkbox"/> Microbiology <input type="checkbox"/> Physics and Astronomy <input type="checkbox"/> Plant Sciences <input type="checkbox"/> Robotics & Intelligent Machines <input type="checkbox"/> Systems Software <input type="checkbox"/> Translational Medical Science

- As a part of this research project, the student directly handled, manipulated, or interacted with (check all that apply):

<input type="checkbox"/> human participants	<input type="checkbox"/> potentially hazardous biological agents
<input type="checkbox"/> vertebrate animals	<input type="checkbox"/> microorganisms <input type="checkbox"/> rDNA <input type="checkbox"/> tissue
- This abstract describes only procedures performed by me/us, reflects my/our own independent research, and represents one year's work only.
 yes no
- I/We worked or used equipment in a regulated research institution or industrial setting.
 yes no
- This project is a continuation of previous research.
 yes no
- My display board includes non-published photographs/visual depictions of humans (other than myself):
 yes no
- I/We hereby certify that the abstract and responses to the above statements are correct and properly reflect my/our own work.
 yes no



Checklist for Adult Sponsor (1)

This completed form is required for ALL projects.

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

Student's Name(s): _____

Project Title: _____

- I have reviewed the ISEF Rules and Guidelines, including the science fair ethics statement.
- I have reviewed the student's completed Student Checklist (1A) and Research Plan/Project Summary.
- I have worked with the student and we have discussed the possible risks involved in the project.
- The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC:

<input type="checkbox"/> Humans	<input type="checkbox"/> Potentially Hazardous Biological Agents
<input type="checkbox"/> Vertebrate Animals	<input type="checkbox"/> Microorganisms <input type="checkbox"/> rDNA <input type="checkbox"/> Tissues
- Items to be completed for **ALL PROJECTS**

<input type="checkbox"/> Adult Sponsor Checklist (1)	<input type="checkbox"/> Research Plan/Project Summary
<input type="checkbox"/> Student Checklist (1A)	<input type="checkbox"/> Approval Form (1B)
<input type="checkbox"/> Regulated Research Institutional/Industrial Setting Form (1C) (when applicable; after completed experiment)	
<input type="checkbox"/> Continuation/Research Progression Form (7) (when applicable)	

Additional forms required if the project includes the use of one or more of the following (check all that apply):

- Humans**, including student designed inventions/prototypes. (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.)
 - Human Participants Form (4) or appropriate Institutional IRB documentation
 - Sample of Informed Consent Form (when applicable and/or required by the IRB)
 - Qualified Scientist Form (2) (when applicable and/or required by the IRB)
- Vertebrate Animals** (Requires prior approval, see full text of the rules.)
 - Vertebrate Animal Form (5A) -for projects conducted in a school/home/field research site (SRC prior approval required)
 - Vertebrate Animal Form (5B) -for projects conducted at a Regulated Research Institution. (Institutional Animal Care and Use Committee (IACUC) approval required prior experimentation.)
 - Qualified Scientist Form (2) (Required for all vertebrate animal projects at a regulated research site or when applicable)
- Potentially Hazardous Biological Agents** (Requires prior approval by SRC, IACUC or IBC, see full text of the rules.)
 - Potentially Hazardous Biological Agents Risk Assessment Form (6A)
 - Human and Vertebrate Animal Tissue Form (6B) -to be completed in addition to Form 6A when project involves the use of fresh or frozen tissue, primary cell cultures, blood, blood products and body fluids.
 - Qualified Scientist Form (2) (when applicable)
 - The following are exempt from prior review but require a Risk Assessment Form 3: projects involving protists, archae and similar microorganisms, for projects using manure for composting, fuel production or other non-culturing experiments, projects using color change coliform water test kits, microbial fuel cells, and projects involving decomposing vertebrate organisms.
- Hazardous Chemicals, Activities and Devices** (No SRC prior approval required, see full text of the rules.)
 - Risk Assessment Form (3)
 - Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable)
- Other**
 - Risk Assessment Form (3)
- I attest to the information checked above and that I have read and agree to abide by the science fair ethics statement.**

Adult Sponsor's Printed Name

Signature

Date of Review (mm/dd/yy)

Phone

Email

Student Checklist (1A)

This form is required for ALL projects.

- Student/Team Leader: _____ Grade: _____
Email: _____ Phone: _____
 - Team Member: _____ c. Team Member: _____
- Title of Project: _____

- School: _____ School Phone: _____
School Address: _____

- Adult Sponsor: _____ Phone/Email: _____
- Does this project need SRC/IRB/IACUC or other pre-approval? Yes No Tentative start date: _____
- Is this a continuation/progression from a previous year? Yes No
If Yes:
 - Attach the previous year's Abstract **and** Research Plan/Project Summary
 - Explain how this project is new and different from previous years on Continuation/Research Progression Form (7)
- This year's experimentation/data collection:

Actual Start Date: (mm/dd/yy) _____ End Date: (mm/dd/yy) _____
- Where will you conduct your experimentation? (check all that apply)
 Research Institution School Field Home Other: _____
- Source of Data:
 Collected self/mentor Other Describe/url: _____
- List the name and address of all non-home and non-school work site(s), whether you worked there virtually or on-site:
Name _____
Address: _____

Phone/ email _____
- Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.**
- An abstract is required for all projects after experimentation.**

Research Plan/Project Summary Instructions

A complete Research Plan/Project Summary is required for ALL projects and must accompany Student Checklist (1A).

- All projects must have a Research Plan/Project Summary
 - The Research Plan is to be written prior to experimentation following the instructions below to detail the rationale, research question(s), methodology, and risk assessment of the proposed research.
 - If changes are made during the research, such changes can be added to the original research plan as an addendum, recognizing that some changes may require returning to the IRB or SRC for appropriate review and approvals. If no additional approvals are required, this addendum serves as a project summary to explain research that was conducted.
 - If no changes are made from the original research plan, no project summary is required.
 - Some studies, such as an engineering design or mathematics projects, will be less detailed in the initial project plan and will change through the course of research. If such changes occur, a project summary that explains what was done is required and can be appended to the original research plan.
 - The Research Plan/Project Summary should include the following:
 - RATIONALE:** Include a brief synopsis of the background that supports your research problem and explain why this research is important and if applicable, explain any societal impact of your research.
 - RESEARCH QUESTION(S), HYPOTHESIS(ES), ENGINEERING GOAL(S), EXPECTED OUTCOMES:** How is this based on the rationale described above?
 - Describe the following in detail:
 - Procedures:** Detail all procedures and experimental design including methods for data collection, and when applicable, the source of data used. Describe only your project. Do not include work done by mentor or others.
 - Risk and Safety:** Identify any potential risks and safety precautions needed.
 - Data Analysis:** Describe the procedures you will use to analyze the data/results.
 - BIBLIOGRAPHY:** List 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.

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

1. Human participants research:

- Participants:** Describe age range, gender, racial/ethnic composition of participants. Identify 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? If yes and not your own, how did you obtain? Did it require permissions? If so, explain. What is the frequency and length of time involved for each subject?
- Risk Assessment:** What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize risks? List any benefits to society or participants.
- Protection of Privacy:** Will identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential/anonymous? If anonymous, describe how the data will be collected. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will data be stored? Who will have access to the data? What will you do with the data after 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:

- Discuss potential ALTERNATIVES to vertebrate animal use and present justification for use of vertebrates.
- Explain potential impact or contribution of this research.
- Detail all procedures to be used, including methods used to minimize potential discomfort, distress, pain and injury to the animals and detailed chemical concentrations and drug dosages.
- Detail animal numbers, species, strain, sex, age, source, etc., include justification of the numbers planned.
- Describe housing and oversight of daily care.
- Discuss disposition of the animals at the end of the study.

• Potentially hazardous biological agents research:

- Give source of the organism and describe BSL assessment process and BSL determination.
- Detail safety precautions and discuss methods of disposal.

4. Hazardous chemicals, activities & devices:

- Describe Risk Assessment process, supervision, safety precautions and methods of disposal.
- Material Safety Data Sheets are not necessary to submit with paperwork.

Approval Form (1B)

A completed form is required for each student, including all team members.

1. To Be Completed by Student and Parent

a. Student Acknowledgment:

- I understand the risks and possible dangers to me of the proposed research plan.
- I have read the ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.
- I have read and will abide by the science fair ethics statement.

Student researchers are expected to maintain the highest standards of honesty and integrity. Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include but are not limited to 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 ISEF.

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

b. Parent/Guardian Approval: I have read and understand the risks and possible dangers involved in the Research Plan/Project Summary. I consent to my child participating in this research.

Parent/Guardian's Printed Name Signature Date Acknowledged (mm/dd/yy)
(Must be prior to experimentation.)

2. To be completed by the local or affiliated Fair SRC

(Required for projects requiring prior SRC/IRB APPROVAL. Sign 2a or 2b as appropriate.)

a. Required for projects that need prior SRC/IRB approval BEFORE experimentation (humans, vertebrates or potentially hazardous biological agents).

The SRC/IRB has carefully studied this project's **Research Plan/Project Summary** and all the required forms are included. My signature indicates approval of the **Research Plan/Project Summary** before the student begins experimentation.

SRC/IRB Chair's Printed Name

Signature Date of Approval (mm/dd/yy)
(Must be prior to experimentation.)

OR

b. Required for research conducted at all Regulated Research Institutions with no prior fair SRC/IRB approval.

This project was conducted at a regulated research institution (**not home or high school, etc.**), was reviewed and approved by the proper institutional board before experimentation and complies with the ISEF Rules. **Attach (1C) and any required institutional approvals (e.g. IACUC, IRB).**

SRC Chair's Printed Name

Signature Date of Signature (mm/dd/yy)
(May be after experimentation)

3. Final ISEF Affiliated Fair SRC Approval (Required for ALL Projects)

SRC Approval After Experimentation and Before Competition at Regional/State/National Fair

I certify that this project adheres to the approved **Research Plan/Project Summary** and complies with all ISEF Rules.

Regional SRC Chair's Printed Name Signature Date of Approval (mm/dd/yy)

State/National SRC Chair's Printed Name Signature Date of Approval (mm/dd/yy)
(where applicable)

Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed **AFTER** experimentation by the adult supervising the student research either **virtually or on site**, conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

Student's Name(s) _____

Title of Project _____

To be completed by the Supervising Adult in the Setting (NOT the Student(s)) after experimentation:

(Responses must be on the form as it is required to be displayed at student's project booth; please do not print double-sided.)

Research was supported at my work site:

1. Did you or your proxy (e.g. graduate student, postdoc, employee) mentor or provide substantial guidance to the student researcher? Yes No
- a. If no, describe your and/or your institution's role with the student researcher and his/her project (e.g. supervised use of equipment on site without ongoing mentorship and sign below.

- b. If yes, complete questions 2–5.

2. Is the student's research project a subset of your ongoing research or work? Yes No
Use questions 3, 4 and 5 to detail how the student's project was similar and/or different from ongoing research or work at your site. If this project is under a grant and needs to be acknowledged, please list the grant statement here.

3. Describe the independence and creativity with which the student:
- a. developed the hypotheses or engineering goals for the research project

- b. designed the methodology for his/her research project

- c. analyzed and interpreted data

(Continued on next page)

Regulated Research Institutional/Industrial Setting Form (1C) Continued

Student's Name(s) _____

4. Detail the student's role in conducting the research (e.g. data collection, specific procedures performed). Differentiate what the student observed and what the student actually did.

5. Did the student(s) work on the project as part of a group? Yes No
 If yes, how many individuals were in the group and who were they (e.g. high school students, graduate students, faculty, professional researchers)?

I attest that the student has conducted the work as indicated above and that any required review and approval by institutional regulatory board (IRB/IACUC/IBC) has been obtained. Copies are attached if applicable. I further acknowledge that the student will be presenting this work publicly in competition and I have communicated with the student research regarding any requirements for my review and/or restrictions of what is publicized.

Supervising Adult's Printed Name	Signature	Title
Institution	Date Signed (must be after experimentation) (mm/dd/yy)	
Address	Email/Phone	

Qualified Scientist Form (2)

May be required for research involving human participants, vertebrate animals, potentially hazardous biological agents, and hazardous substances and devices. Must be completed and signed before the start of student experimentation.

Student's Name(s) _____

Title of Project _____

To be completed by the Qualified Scientist:

Scientist Name: _____

Educational Background: _____ Degree(s): _____

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

Position/Institution: _____ Email/Phone: _____

1. Have you reviewed the ISEF rules relevant to this project and the science fair ethics statement relevant to this project? Yes No
2. Will any of the following be used?
 - a. Human participants Yes No
 - b. Vertebrate animals Yes No
 - c. Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products) Yes No
 - d. Hazardous substances and devices Yes No
3. Will this study be a sub-set of a larger study? Yes No
4. Will you directly supervise the student? Yes No
 - a. If no, who will directly supervise and serve as the Designated Supervisor?
 - b. Experience/Training of the Designated Supervisor: _____

To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the Research Plan/Project Summary prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the Research Plan/Project Summary. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my direct supervision.

Qualified Scientist's Printed Name	
Signature	Date of Approval (mm/dd/yy)

To be completed by the Designated Supervisor when the Qualified Scientist cannot directly supervise.

I certify that I have reviewed the Research Plan/Project Summary and have been trained in the techniques to be used by this student, and I will provide direct supervision.

Designated Supervisor's Printed Name	
Signature	Date of Approval (mm/dd/yy)
Phone	Email

Risk Assessment Form (3)

Must be completed before experimentation; recommended for all projects. May be required for projects involving Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents.

Student's Name(s) _____

Title of Project _____

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

1. Identify and assess the risks and hazards involved in this project.

2. a) List all hazardous chemicals, activities or devices to be used; b) identify and list all microorganisms to be used that are exempt from pre-approval (see Potentially Hazardous Biological Agent rules).

3. Describe the safety precautions and procedures that will be used to reduce the risks.

4. Describe the disposal procedures that will be used (when applicable).

5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):

I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan/Project Summary and the International Rules, including the science fair ethics statement and will provide direct supervision.

Designated Supervisor's Printed Name _____ Signature _____ Date of Review (mm/dd/yy) _____

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

Position/Institution _____ Phone or email contact information _____

Human Participants Form (4)

Required for all research involving human participants not at a Regulated Research Institution. If at a Regulated Research Institution, use institutional approval forms for documentation of prior review and approval. (IRB approval required before recruitment or data collection.)

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

Adult Sponsor _____ Phone/Email _____

MUST BE COMPLETED BY STUDENT RESEARCHER(S) IN COLLABORATION WITH THE ADULT SPONSOR/DESIGNATED SUPERVISOR/QUALIFIED SCIENTIST:

1. I have submitted my Research Plan/Project Summary which addresses ALL areas indicated in the Human Participants Section of the Research Plan/Project Summary Instructions.
2. I have attached any surveys or questionnaires I will be using in my project or other documents provided to human participants. Any published instrument(s) used was /were legally obtained.
3. I have attached an informed consent that I would use if required by the IRB.
4. Yes No Are you working with a Qualified Scientist? If yes, attach the Qualified Scientist Form 2.

BELOW – IRB USE ONLY

MUST BE COMPLETED BY INSTITUTIONAL REVIEW BOARD (IRB) AFTER REVIEW OF THE RESEARCH PLAN. ALL QUESTIONS MUST BE ANSWERED FOR THE APPROVAL TO BE VALID. (IF NOT APPROVED, RETURN PAPERWORK TO THE STUDENT WITH INSTRUCTIONS FOR MODIFICATIONS.)

- Approved with Full Committee Review (3 signatures required) and the following conditions: **(All 6 must be answered)**
1. Risk Level (check one) : Minimal Risk More than Minimal Risk
 2. Qualified Scientist (QS) Required (Form 2): Yes No
 3. Risk Assessment Required (Form 3): Yes No
 4. Written Minor Assent required for minor participants: Yes No Not applicable (No minors in this study)
 5. Written Parental Permission required for minor participants: Yes No Not applicable (No minors in this study)
 6. Written Informed Consent required for participants 18 years or older: Yes No Not applicable (No participants 18 yrs or older in this study)

IRB SIGNATURES (All 3 signatures required) None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest).

I attest that I have reviewed the student's project, that the checkboxes above have been completed to indicate the IRB determination and that I agree with the decisions above.

Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, doctor of pharmacy, or registered nurse) with expertise related to this project.

Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)

Educator

Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)

School Administrator

Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)

Human Informed Consent Form

Instructions to the Student Researcher(s): An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist.

This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form or may copy ALL elements of it into a new document.

If the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.

Student Researcher(s): _____

Title of Project: _____

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate area below.

Purpose of the project:

If you participate, you will be asked to:

Time required for participation:

Potential Risks of Study:

Benefits:

How confidentiality will be maintained:

If you have any questions about this study, feel free to contact:

Adult Sponsor/QS/DS: _____ Phone/email: _____

Voluntary Participation:

Participation in this study is completely voluntary. If you decide not to participate there will not be negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent or Minor Assent Date Reviewed & Signed: _____
(mm/dd/yy)

Research Participant Printed Name: _____ Signature: _____

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

Parent/Guardian Printed Name: _____ Signature: _____

Vertebrate Animal Form (5A)

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

Student's Name(s) _____

Title of Project _____

To be completed by Student Researcher:

1. Common name (or Genus, species) and number of animals used.
2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc. Add an additional page as necessary.
3. What will happen to the animals after experimentation?
4. Attach a copy of wildlife licenses or approval forms, as applicable
5. The 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.

To be completed by Local or Affiliate Fair Scientific Review Committee (SRC) BEFORE experimentation.

Level of Supervision Required for agricultural, behavioral or nutritional studies (select one):

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

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

Local or Affiliate Fair SRC Pre-Approval Signature:

SRC Chair Printed Name _____ Signature _____ Date of Approval (must be prior to experimentation) (mm/dd/yy)

To be completed by Veterinarian:

- I have reviewed this research and animal husbandry with the student before the start of experimentation.
- I have approved the use and dosages of prescription drugs and/or nutritional supplements.
- I will provide veterinary medical and nursing care in case of illness or emergency. (Fees may apply.)

Printed Name _____ Email/Phone _____
Signature _____ Date of Approval (mm/dd/yy) _____

To be completed by Designated Supervisor or Qualified Scientist when applicable:

- I have reviewed this research and animal husbandry with the student before the start of experimentation and I accept primary responsibility for the care and handling of the animals in this project.
- I will directly supervise the experiment.

Printed Name _____ Email/Phone _____
Signature _____ Date of Approval (mm/dd/yy) _____

Vertebrate Animal Form (5B)

Required for all research involving vertebrate animals that is conducted in at a Regulated Research Institution. (IACUC approval required before experimentation. Form must be completed and signed after experimentation.)

Student's Name(s) _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

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

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

3. Was there any weight loss or death of any animal? If yes, attach a letter obtained from the qualified scientist, designated supervisor or a veterinarian documenting the situation and the results of the investigation.

4. Did the student's project also involve the use of tissues?

- No
 Yes; complete Forms 6A and 6B

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

6. Attach a copy of the Regulated Research Institution IACUC Approval. A letter from the Qualified Scientist or Principal Investigator is not sufficient.

Qualified Scientist/Principal Investigator

Printed Name

Signature

Date (mm/dd/yy)

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA, fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids. SRC/IACUC/IBC approval required before experimentation.

Student's Name(s) _____

Title of Project _____

To be completed by the QUALIFIED SCIENTIST/DESIGNATED SUPERVISOR in collaboration with the student researcher(s). All questions are applicable and must be answered; additional page(s) may be attached.

SECTION 1: PROJECT ASSESSMENT

1. Identify potentially hazardous biological agents to be used in this experiment. Include the source, quantity and the biosafety level risk group of each microorganism.
2. Describe the site of experimentation including the level of biological containment.
3. Describe the procedures that will be used to minimize risk (personal protective equipment, hood type, etc.).
4. What final biosafety level do you recommend for this project given the risk assessment you conducted?
5. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents.

SECTION 2: TRAINING

1. What training will the student receive for this project?
2. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable).

SECTION 3: For ALL CELL LINES, MICROORGANISMS AND TISSUES – To be completed by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR - Check the appropriate box(es) below:

- Experimentation on the microorganisms/cell lines/tissues to be used in this study will NOT be conducted at a Regulated Research Institution, but will be conducted at a (check one) ___BSL-1 or ___BSL-2 laboratory (include a copy of the checklist for BSL-2). [This study has been reviewed by the local SRC and the procedures have been approved prior to experimentation.]
- Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution and was approved by the appropriate institutional board prior to experimentation; institutional approval forms are attached.
Origin of cell lines: _____ Date of IACUC/IBC approval _____
- Experimentation on the microorganisms/cell lines/tissues to be used in this study will be conducted at a Regulated Research Institution, which does not require pre-approval for this type of study. The SRC has seen and approved the research plan and supporting documentation and acknowledges the accuracy of the responses above.

CERTIFICATION – To be SIGNED by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR

The QS/DS has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above. This study has been approved as a (check one) BSL-1/ BSL-2 study, and will be conducted in an appropriate laboratory.

QS/DS Printed Name

Signature

Date of review (mm/dd/yy)

SECTION 4: CERTIFICATION – To be completed by the LOCAL or AFFILIATED FAIR SRC

The SRC has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided.

SRC Printed Name

Signature

Date of review (mm/dd/yy)

Human and Vertebrate Animal Tissue Form (6B)

Required for research involving fresh/frozen tissue (including primary cell lines, human and other primate established cell lines and tissue cultures), blood, blood products and body fluids. If the research involves living organisms please ensure that the proper human or animal forms are completed. **All projects using any tissue listed above must also complete Form 6A.**

Student's Name(s) _____

Title of Project _____

To be completed by Student Researcher(s):

1. What vertebrate animal tissue will be used in this study? Check all that apply.
 - Fresh or frozen tissue sample
 - Fresh organ or other body part
 - Blood
 - Body fluids
 - Primary cell/tissue cultures
 - Human or other primate established cell lines

2. Where will the above tissue(s) be obtained? If using an established cell line include source and catalog number.

3. If the tissue will be obtained from a vertebrate animal study conducted at a research institution attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and a copy of IACUC approval.

To be completed by the Qualified Scientist or Designated Supervisor:

I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.

AND/OR

I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in U.S. Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

Printed Name _____ Signature _____ Date of Approval (mm/dd/yy)
(Must be prior to experimentation.)

Title _____ Phone/Email _____

Institution _____

Continuation/Research Progression Projects Form (7)

Required for projects that are a continuation/progression in the same field of study as a previous project. This form must be accompanied by the previous year's abstract and Research Plan/Project Summary.

Student's Name(s) _____

To be completed by Student Researcher: List all components of the current project that make it new and different from previous research. The information must be on the form; use an additional form for previous year and earlier projects.

Components	Current Research Project	Previous Research Project: Year: _____
1. Title		
2. Change in goal/purpose/objective		
3. Changes in methodology		
4. Variable studied		
5. Additional changes		

Attached are:

- Abstract and Research Plan/Project Summary, Year _____

I hereby certify that the above information is correct and that the current year Abstract & Certification and project display board properly reflect work done only in the current year.

Student's Printed Name(s) Signature Date of Signature (mm/dd/yy)

The Regeneron International Science and Engineering Fair encourages students to tackle challenging scientific questions and develop the skills needed to solve the problems of tomorrow.

Society for Science

The Society for Science is a champion for science, dedicated to expanding scientific literacy, effective STEM education and scientific research. Founded in 1921, we are a nonprofit 501(c)(3) membership organization focused on promoting the understanding and appreciation of science and the vital role it plays in human advancement. Through its acclaimed science research competitions, including the Regeneron Science Talent Search, the Regeneron International Science and Engineering Fair and the Broadcom MASTERS, and its award-winning magazine, *Science News* and digital media properties, *Science News for Students*, the Society is committed to inform, educate and inspire.

Learn more at:

www.societyforscience.org

and follow us on

Facebook <https://www.facebook.com/societyforscience>

Twitter [@Society4Science](https://twitter.com/Society4Science)

Instagram [@Society4Science](https://www.instagram.com/Society4Science)

Snapchat [Society4Science](https://www.snapchat.com/add/Society4Science)

Society for Science

1719 N Street, NW

Washington, DC 20036-2801

202.785.2255

societyforscience.org/ISEF