Educator Guide to the 2025-2026 International Rules

A companion document to the
International Rules for Pre-College Science Research: Guidelines for Science and Engineering Fairs 2025-2026

EDUCATOR GUIDE TO THE INTERNATIONAL RULES

Table of Contents

INTRODUCTION

Welcome to the "Educator Guide to the International Rules and Guidelines for Pre-Collegiate Scientific Research." This guidebook is designed to be used in conjunction with the official International Rules. In an effort to streamline the International Rules, we removed much of the guidance scattered throughout the document. This Guide takes this information as well as other supporting documents that have been created over the years and brings them all together in one updated and organized resource.

Our students are curious, creative and are exploring an endless number of subjects in their science and engineering projects. Keeping up with the length and complexity of the International Rules and required approval processes and documentation can be difficult. It is our intent and goal that this Guide will support your comprehension of the rules and guide your students to successful, safe research.

The *International Rules for Pre-college Science Research: Guidelines for Science and Engineering Fairs* is published annually to support students doing independent research safely. The International Rules are the official rules of the Regeneron ISEF and students competing at Society-affiliated science fairs.

If you are not intimately familiar with the Rules, they can be intimidating. This Guide will hopefully make the path to enlightenment a little easier. While we call this an "Educator Guide," it is written for anyone involved in a student research project. If you are a high school freshman contemplating your first science fair project or a State Fair Director having been involved with hundreds, if not thousands of projects, it is our hope that you will find something in this document that makes your journey a little easier.

This Guide is crafted to be easily navigated; if there is an area of concern or question, you should be able to navigate directly to that area. The Guide is organized with the planning cycle of a research project in mind. At the end of the document, parallel with the organization of the International Rules, you will find a section per specialized area of research: Humans, Animals, PHBAs, Tissue & Body Fluids and Hazardous Chemicals, Materials and Devices.

Our number one priority is safety. The safety of the student, safety of the people around the student and the safety of the environment cannot be overstated. When working with chemicals, animals, PHBAs, etc., there is always the potential for unforeseen consequences. The Guidebook is a way to consider looking at some of those risk factors before experimentation. They will not define all potential risks but will provide an avenue to consider what the student is doing and the kinds of concerns the student should be mindful of before starting experimentation.

An area of focus in this Guide is to consider the risk of potential damage to the environment by students working in the field. We have included an environmental protection section that considers environmental concerns in the many areas of the International Rules. We also have included a new Field Study Plan that is intended to support management of the risks involved with field studies. After speaking to a field scientist with the EPA, there are many potential risks in field work, such as harmful PHBAs in the water, invasive species introduction, and many other considerations. We want to ensure students, and their mentors, consider these risks and take precautions prior to embarking on the experiment.

Another focus we have taken is to center the student research experience first and foremost on ethical conduct and practices. This Guide begins with a section on scientific integrity and the scientific ethics statement that ALL of those involved in a student research project – including mentors, teachers, parents and those serving on the SRC, IRB, IACUC – must fully understand and adhere to throughout the research and competition experience. Please take the time to read it and discuss the responsibilities it confers to students and all the adults in the process of supporting those students. This should be done early in the process and certainly prior to any experimental work beginning.

We are excited to share this resource with you; we are also aware that as a first version there may be errors, omissions or improvements that could be made. We encourage you to email us at src@societyforscience.org with suggestions as we collectively seek the best, ethical and safe research experiences for our students.

■ ISEF Scientific Review Committee, October 2025

SCIENTIFIC INTEGRITY

Scientific integrity is central to the credibility, reliability, and progress of science. It is important that researchers of any age adhere to principles of honesty, transparency, and objectivity in how they conduct, document, and present their research. This becomes even more critical as it pertains to competing with a project to ensure that all are meeting the requirements and standards equally for a fair and just judging process.

Participating in a Society for Science competition carries moral and ethical responsibilities for every young person. Society for Science expects students to act with honor and integrity when conducting scientific research and while interacting within their peer community.

- Scientific fraud and misconduct are prohibited at all levels of research and competition.
- Student scientists must not fabricate data or images, plagiarize or present someone else's work as their own.
- Student scientists must differentiate their own work from the work of others and cite all sources.
- Student scientists must respect confidentiality and intellectual property.

While pre-collegiate scientific research is an educational process that includes the potential for errors and omissions, it is essential that students' intentions remain honest and free from deceit.

ETHICS STATEMENT

(This is at the beginning of the International Rules and is provided here for emphasis and to provide some additional context and explanation.)

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 presented in their own words with proper citation. The presentation of fraudulent data, the evidence of plagiarism or the inappropriate use of AI are prohibited and grounds for the project to fail to qualify.
- **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). 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 researchers' 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.

INAPPROPRIATE USE OF AI

Artificial Intelligence applications are progressing quickly and setting policies and practices for its appropriate use in education will inevitably evolve in the next several years. The table below is adapted from an AHA Ad Hoc Committee on AI in History Education.[1] This is a preliminary model and is a suggested policy established by the ISEF SRC and Society staff to help define what is and isn't appropriate AI usage in conducting a science fair project. Affiliated fairs may adopt their own, more strict, policies.

The key to this table and to our philosophy is that AI may be used to ideate and to generate initial brainstorming and research but that it must be cited properly and reviewed thoroughly for accuracy and veracity. It is the responsibility of the student researcher to document where and how AI is used and to never attribute the results from an AI prompt as their own words.

As remains true in using the internet, students must be guided and gain AI literacy to understand how to use AI effectively while understanding its limitations. "*For all its capacities, generative AI regularly hallucinates content, references, sources, and quotations.* AI models are trained to identify and reproduce patterns, not to comprehend the world in all its complexity and contradictions. If a pattern leads to a false, biased, or imagined output, AI has no way to self-correct."[1]

Using AI responsibly requires a strict documentation process to allow a student (and the adults involved - adult sponsors, mentors, judges and fair officials) to be able to identify and trace where AI was used and how the student directed the prompts and then verified the information being provided.

This is most critical when it comes to a literature review and bibliography as it is a serious ethical violation to use an AI tool to generate your bibliography without ever having reviewed or consulted the articles and documents it identifies. "AI introduces new possibilities for fabricated sources; students must be trained to critically assess all outputs and to recognize that any information provided by a generative AI tool could be false unless properly verified."[1] Students are presenting scientific research as their own supported by their understanding from the existing literature. If the citations and references are fabricated it brings into question the validity and veracity of the student's research project.

Use of generative AI to support a research project

Task	Could this be acceptable use?	Under what conditions?
Ask generative AI to identify or summarize key points in an article before you read it. Use this as a starting point for your literature review.	Yes	Acceptable without explicit citation
Ask AI to summarize a book or article in your field. Reproduce that summary in your literature review without reading the book or article	No	Never acceptable, as there has been no engagement with the book or source itself
Use an AI chatbot as a writing tool to help generate and develop ideas	Yes	Acceptable, may require explicit citation depending on circumstances. Strongly encouraged to keep a log of your prompts as part of your research notebook.
Use generative AI to initially write the research plan, abstract, paper or poster.	No	Never acceptable. This must be the independent work of the student. Guidance or refinement after the initial document has been completed can be done with explicit citation and a log.
Ask generative AI to write an abstract or section of your research paper. Submit as your own work	No	Never acceptable
You write an abstract. Ask AI to sharpen the language but not modify, add to, or replace the main points	Yes	Acceptable use without explicit citation only if changes suggested by AI are limited to grammar and syntax

Task	Could this be acceptable use?	Under what conditions?
Use AI to write initial code for your project	Yes	Acceptable, only with explicit citation stating which portions of the code were AI generated and with a log of the prompts.
Ask generative AI to produce a flowchart, graphic, or image for a paper or presentation	Yes	Image should be clearly marked as AI-generated and with explicit citation as to how the image was created.
Write your research paper. Ask AI to add additional points to your research paper	No	Never acceptable.
Use AI to produce your conclusions, future steps, etc.	No	Never acceptable
Use AI to help identify appropriate statistical tests or software tools. (Interpretation of data must be done by the student researcher).	Yes	Acceptable, requires a log of your prompts as part of your research notebook
Ask generative AI to produce a starter bibliography	No	Never acceptable.
Use AI to collect data and write research plan. Use AI to provide citations that back up your claims	No	Never acceptable.
Ask generative AI to fix the structure or formatting of your bibliography	Yes	Acceptable without explicit citation. You must review and verify all citations as valid.

- Adapted from: Guiding Principles for Artificial Intelligence in History Education *Approved by AHA Council, July 29, 2025*

Download the table as a stand-alone document.

ACADEMIC INTEGRITY

It is of utmost importance that a student researcher works closely with the adults supporting their work to both provide appropriate acknowledgement of the support that they have received but to also gain all appropriate permissions and clearances to present their research in any circumstance in which the work is not solely their own. Working in a RRI laboratory, working with data that is not publicly available or working as a sub-set of any identifiable class or club project requires proper citations and crediting of others' work and may require formal Institutional review and approval from the RRI or RRI's appropriate review body before public presentation at a science fair. Seeking and receiving permissions should be done as you begin a project to make those involved aware of your intentions to produce an independent project, and compete at a future science fair. Student researchers need to obtain permission from their mentors before submitting their research to enter science fair. It is much better to have this discussion and agreement before the project has concluded and there are intellectual property or other proprietary concerns that the mentor has about publicly disclosing the research the student has done via science competition.

DISCLOSURE OF MENTORS & PAID SUPPORT

There is no rule that prohibits a student from working closely with a mentor – whether a family relative, friend or colleague or an individual sought for their expertise in the field of study. A student may participate in a paid or unpaid research program (with compensation to the mentor or not) and receive private lessons, tutoring or mentoring support.

What is important is full disclosure of the relationship, the nature of the mentorship and full acknowledgement of the support received in conducting the research. A student researcher must attest that they have done an independent project and what they are presenting is their own work. The documentation of their project – the research plan and the abstract – must present clearly what they have done and what support they received.

Society for Science does not endorse any particular research programs; in fact, we do not believe a student must participate in a research program to be successful as a scientist or in our programs. We do see the value in mentorship and learning research skills, and understand why some students may seek paid or unpaid options, but urge students and parents/guardians to be diligent in their selection of these types of programs.

For individuals seeking legitimate research programs, here are a few tips:

- A legitimate program will include the names and credentials of their staff and mentors on their website.
- A legitimate program shares transparent pricing on their website.
- Programs should not promise results. In addition, reciprocal payment based on student payment in competition is not permitted.
- Programs should not ask students for secrecy; this is inappropriate behavior when working with minors, and disclosure of additional support is required.

Society for Science is most concerned about safeguarding students and their parents against fraud and unfortunately there are many resources available that promise winning over supporting authentic student research. No research program should guarantee competition success. Any individual who is aware of fraudulent or suspicious research programs should email **isef@societyforscience.org.**

GRIEVANCES

Submitting a scientific integrity allegation is a serious action that should be done only with credible evidence and when you are willing to come forward as an identifiable source of that information. No adverse action or retaliation will be taken against a person who reports a violation or who participates in an investigation in good faith. Please note that the Society discourages anonymous allegations and may choose not to investigate them. Anonymous allegations — particularly those lacking context, evidence or full disclosure of relevant relationships — can hinder our ability to investigate thoroughly and fairly. False accusations can be a form of harassment, particularly when made publicly and can be actionable if knowingly charged without proper evidence. Individuals who come forward with concerns through our established reporting channels will not be retaliated against or punished in any way.

ROLES & RESPONSIBILITIES OF STUDENTS AND ADULTS

As a student researcher begins the planning for a research project, it is important to understand the different roles and responsibilities for the student(s) and the adults supporting
the project or the review of the project.
This information is also included in the International Rules.

INDEX

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.), obtaining necessary approvals (SRC, IRB, etc.)
- Following the International Rules & Guidelines and 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 Direct 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

Qualifications:

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

AND/OR

a. Individual with extensive experience and expertise in the student's area of research

b. 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.

c. Can also serve as the Adult Sponsor, if that person meets both sets of qualifications

d. May live elsewhere and not be local to the student, in which case, a Direct Supervisor has been 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 Direct Supervisor to serve in this capacity
- Ensuring the proper training of the Student Researcher and/or Direct 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 DIRECT SUPERVISOR

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 Direct Supervisor box on the Qualified Scientist Form (2) when applicable
- Reviewing and completing the Risk Assessment Form (3) when needed.

Documenting the Project

Writing a Research Plan and Risk Assessment

INDEX

INTRODUCTION

A research plan is the key to a successful project. It is a framework to plan a project -- to pose the question being asked or the problem being solved and the steps that will be taken to reach the goal. It is a clear and detailed accounting of the methodology or procedures intended. It is an opportunity to conduct a risk assessment that will in turn support decisions about the environment in which to conduct the project, the supervision necessary and if there are pre-approvals required before you begin experimentation.

A research plan does not need to have all of the answers; but it should be a clear roadmap for the student researcher to share the intended steps and to review and receive feedback before beginning. The research plan can be an iterative process and can be amended and appended with a project summary if changes are made along the way.

The International Rules provide clear guidance on the elements of your project that should be addressed in the plan. We strongly encourage educators, parents and mentors to be directly involved in reviewing and providing feedback as the research plan is developed. Consider potential constraints -- time, resources, research location, risks and expertise or supervision -- as well as the permissions that will be required for any given project. Time spent on developing a strong research plan will support student researcher safety and a close review of the rules with the research plan will lead to the successful completion of a student research project.

RESEARCH PLAN REQUIREMENTS

(from International Rules)

- 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 prior to competing in an affiliated fair, 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:
    a. 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.
    b. RESEARCH QUESTION(S), HYPOTHESIS(ES), ENGINEERING GOAL(S), EXPECTED OUTCOMES: How is this based on the rationale described above?
    c. Describe the following in detail:
- List of materials:
- Procedures: Detail all procedures and experimental design including list of materials, 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.

a. **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:**
   a. **Participants:** Describe age range, gender, racial/ethnic composition of participants. Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
   b. **Recruitment:** Where will you find your participants? How will they be invited to participate?
   c. **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?
   d. **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.
   e. **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?
   f. **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:**
   a. Discuss potential ALTERNATIVES to vertebrate animal use and present justification for use of vertebrates.
   b. Explain potential impact or contribution of this research.
   c. 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.
   d. Detail animal numbers, species, strain, sex, age, source, etc., include justification of the numbers planned.
   e. Describe housing and oversight of daily care.
   f. Discuss disposition of the animals at the end of the study.
3. **Potentially hazardous biological agents research:**
   a. Give source of the organism and describe BSL assessment process and BSL determination.
   b. Detail safety precautions and discuss methods of disposal.
4. **Hazardous chemicals, activities and devices:**
   a. Describe Risk Assessment process, supervision, safety precautions and methods of disposal.
   b. Safety Data Sheets are not necessary to submit with paperwork.

LITERATURE REVIEW/ RESOURCES/BIBLIOGRAPHY/ CITATIONS

An important element of planning a research project is to review the literature within the field of study and to establish a bibliography of the sources that were used in the development of the student researcher's plan. It is critical that the student researcher document and cite resources as they gather information so that they do not plagiarize or fail to acknowledge the work of others in the development of their project.

Ultimately, in the presentation of their project either in a research paper, powerpoint presentation or project board, citing the sources of background information, methodology, graphics, illustrations or other visuals used in the presentation of their research is vital. The citation requirements of Society for Science competitions have gotten stricter as materials are so easily accessible and transferable.

The intention of a bibliography is that it contains resources that were reviewed and used in the development of the project. Using AI to conduct a literature search and to develop the bibliography for a project is a tool that is readily available on the internet. It is not recommended that students use such tools, but if they do, it is imperative that a student recognizes its limitations and verifies every source that is generated. Many AI tools are not reliable and are liable to hallucinate and create sources that are not real. Having citations that are falsified by any means is a serious ethical concern and grounds for a project to fail to qualify.

LOGBOOK/RESEARCH NOTEBOOK

As you work with your students on the planning of their research, please also provide guidance on establishing a research laboratory notebook or logbook. Maintaining a laboratory notebook is an important documentation process to provide a written record of procedures, calculations, trials, explanations, etc. This can both be the legal documentation of a student's intellectual property and evidence of the work done over time as a reference for the student to refer to as they analyze their data. It is also the official record of the methodology of the project that would aid someone seeking to repeat the project. As referenced above, even recording the prompts used in generative AI inquiries are important to capture as a student begins their project.

A laboratory notebook can be a paper document or can be electronic. An RRI laboratory may have established documentation processes or you as an educator may have requirements that all students must follow. A student should consult with their Adult Sponsor or Qualified Scientist about the best template to use as they begin.

CONDUCTING A RISK ASSESSMENT

As students develop their research plan, all are asked to "identify any potential risks and safety precautions needed." There are some projects where the hazards are clear (to at least the adults supervising the project) and a risk assessment can be created that states clearly the required supervision, laboratory/research setting, the personal protective equipment (PPE), the proper disposal, etc.

And some projects appear to have no risks at all. Mathematics comes to mind. However, the process of considering risks is important for all projects and not just to avoid papercuts or eye strain (the popular answer on a mathematics project risk assessment.) It is a valuable exercise to consider unintended consequences and how to ensure that a student research project "does no harm." While the core of a risk assessment is the student researcher's safety, it is also important for a student to consider the potential risks in their data management and to any psychological or privacy concerns their project may involve (particularly those working with human participants.)

In the more 'classic" risk assessment, consider the formula:

Hazards x Exposure = Risk

A risk assessment is assessing the potential hazards involved in the materials or methodology of the project and the exposure to the student researcher. Wherever possible when assessing risk, the project should limit the hazard and the exposure to the hazard. In hazardous materials, this may mean using the least amount and the lowest concentration of hazardous materials as possible to achieve the goals of the project.

One example: A student project involves constructing an apparatus and power tools are going to be used.

- Is the student operating the equipment or will the direct supervisor be using?
- Where is the research being conducted (a laboratory, business workshop, or home basement)?
- Is the student trained to use the equipment?
- Is the student supervised during the usage of the equipment by a qualified individual?
- Does the student have the appropriate personal protective equipment (PPE)?
- How often/how frequently will the equipment need to be used?

In this example, you can imagine a fairly low-risk project to a highly risky project based on the answers to the questions.

The risk assessment is the process of asking those questions BEFORE experimentation and ensuring that all possible hazards and exposure to those hazards are reduced – through supervision, training, safety equipment or changing the methodology to use less dangerous materials or devices.

ONLINE SYSTEMS AND RESEARCH PLAN TEMPLATES

Student researchers can be aided in the development of their research plan using a template and/or an online system that is used by an affiliated fair to support the capture of the required elements of a plan. Check with your affiliated fair about any online portal requirements/help aids as you get started.

If your school or affiliated fair does not use an online system to capture this information, there is a research plan template on the Society for Science website.

EDITS/CORRECTIONS DURING THE REVIEW PROCESS

While the intent of creating a thorough research plan is to have a roadmap and to document the intended process, it is inevitable that research project changes are going to happen. It is important for the Adult Sponsor to monitor progress and to know when straying from the plan are minor adjustments or when a change introduces a significant difference that either now requires pre-approval to proceed or needs to return to the SRC or IRB that initially reviewed the project to receive additional/new review.

PROJECT SUMMARY

The International Rules labels the research plan the “Research Plan / Project Summary” to address modifications or adjustments that were made to the project after it began.
A project summary would be appended to the research plan to describe changes – in methodology, materials, processes – that occurred during the course of the project. This is especially useful for an engineering design project that is iterative. Documenting the changes that were made in the iterative process belong in the Project Summary.

ISEF Forms

Index

INTRODUCTION

In the planning of a research project, understanding what documentation is needed is a key element to ensure that all of the required questions related to the project are addressed and that the project receives the adult review (signified most often by a dated signature) signifying their approval and role in the project as appropriate.

RULES WIZARD

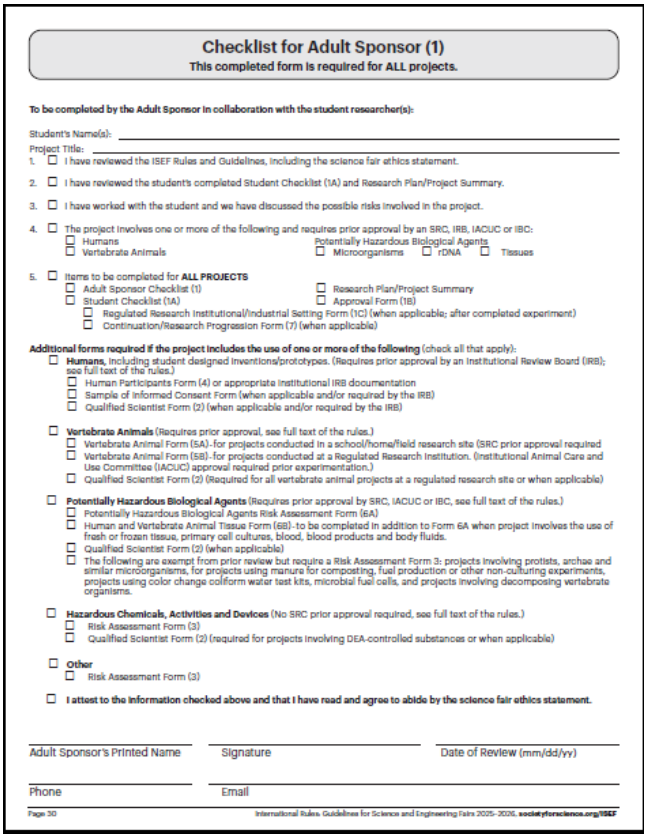
The Rules Wizard has been designed as a first step to help a student determine what forms and approvals are necessary before beginning a science fair project. It is a series of questions (that are intentionally repetitious). As a student selects a response, there are also pop-up messages with reminders relative to the selection (such as culturing microorganisms in a home environment is prohibited if “home” and “microorganisms” are both checked.). After completing the series of questions, a results page will list forms and links to the associated rules. Please review these results with your students to ensure that all of those involved understand the research being planned and the appropriate safety precautions and pre-approvals can be obtained.

This wizard is intended to be a helping tool but cannot account for all specifics and situations of individual projects. There is a common saying, “if in doubt, fill it out.” Having more documentation or more pre-approval for a project than is strictly necessary is both good practice for all students to go through the process and a safeguard that a project does not inadvertently skip an important step as they begin.

OVERVIEW OF FORMS AND DATES

The ISEF forms constitute written documentation of what will occur, or in some cases, has already occurred, in a research project. They are designed to provide the information that is needed to review the project to ensure compliance with the ISEF rules and with laws and regulations that apply to the project. The forms should be filled out and signed before any research takes place. (Only the Regulated Research Setting Form 1C, the Vertebrate Animal Form 5B, the Continuation Form 7 and the abstract are done after the research.) The dates of the signatures reflect when the approval or consent is given. Use MM/DD/YY format for all dates.

Below there is a description of each form, its core purpose and areas of focus for the SRC reviewing the documentation either in the pre-approval process or in the SRC review and approval just prior to competition.



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: _____

1. ☐ I have reviewed the ISEF Rules and Guidelines, including the science fair ethics statement.
2. ☐ I have reviewed the student's completed Student Checklist (1A) and Research Plan/Project Summary.
3. ☐ I have worked with the student and we have discussed the possible risks involved in the project.
4. ☐ The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC:
   ☐ Humans ☐ Potentially Hazardous Biological Agents
   ☐ Vertebrate Animals ☐ Microorganisms ☐ rDNA ☐ Tissues
5. ☐ Items to be completed for **ALL PROJECTS**
   ☐ Adult Sponsor Checklist (1) ☐ Research Plan/Project Summary
   ☐ Student Checklist (1A) ☐ Approval Form (1B)
   ☐ Regulated Research Institutional/Industrial Setting Form (1C) (when applicable; after completed experiment)
   ☐ 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) _____

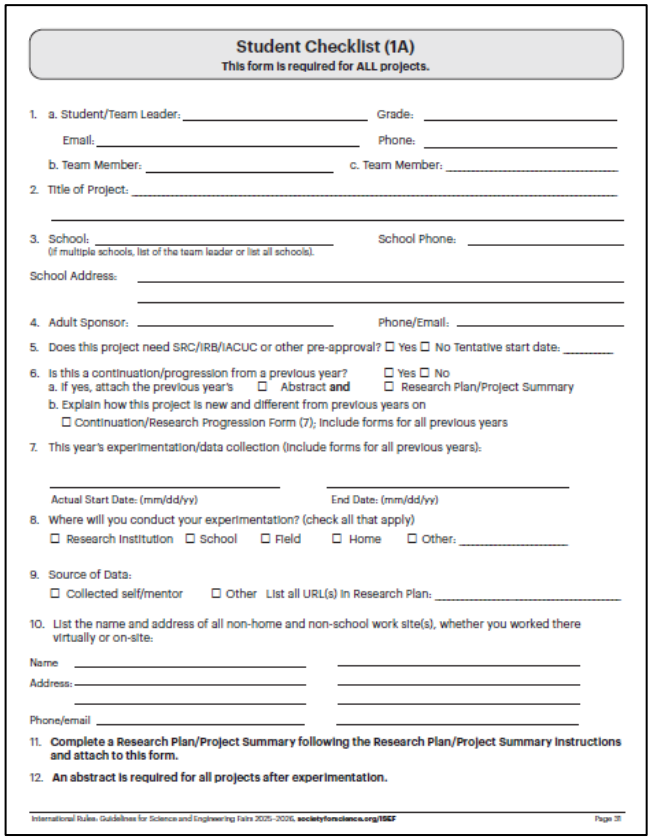
Phone _____ Email _____

Page 30 International Rules: Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF

CHECKLIST FOR ADULT SPONSOR (1)

This checklist is intended to support the adult sponsor's initial review of the project and help determine what information (and therefore which forms) must be completed before the project starts. The form asks more specifically about projects that require pre-approval (humans, animals, PHBA's). It is another support structure to indicate the other forms that will be required. The answers to this checklist need to be consistent with the answers on other forms.

The date signed is the date that the sponsor first reviews the project plan before the experiment begins. The signature is attesting that the Adult Sponsor has read the International Rules and agrees to the Ethics Statement.



Student Checklist (1A)
This form is required for ALL projects.

1. a. Student/Team Leader: _____ Grade: _____
   Email: _____ Phone: _____
   b. Team Member: _____ c. Team Member: _____
2. Title of Project: _____
3. School: _____ School Phone: _____
   (If multiple schools, list of the team leader or list all schools).
   School Address: _____
4. Adult Sponsor: _____ Phone/Email: _____
5. Does this project need SRC/IRB/IACUC or other pre-approval? ☐ Yes ☐ No Tentative start date: _____
6. Is this a continuation/progression from a previous year? ☐ Yes ☐ No
   a. If yes, attach the previous year's ☐ Abstract **and** ☐ Research Plan/Project Summary
   b. Explain how this project is new and different from previous years on
   ☐ Continuation/Research Progression Form (7); include forms for all previous years
7. This year's experimentation/data collection (include forms for all previous years):
   Actual Start Date: (mm/dd/yy) _____ End Date: (mm/dd/yy) _____
8. Where will you conduct your experimentation? (check all that apply)
   ☐ Research Institution ☐ School ☐ Field ☐ Home ☐ Other: _____
9. Source of Data:
   ☐ Collected self/mentor ☐ Other List all URL(s) in Research Plan: _____
10. 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 _____ _____
11. **Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.**
12. **An abstract is required for all projects after experimentation.**

International Rules: Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF Page 31

STUDENT CHECKLIST (1A)

The Student Checklist (1A) is the form on which the student provides contact information for themselves and their adult sponsor and indicates key details about the planned project – whether it needs pre-approval, whether it is a continuation, the start and end date, intended experimentation location(s), etc.

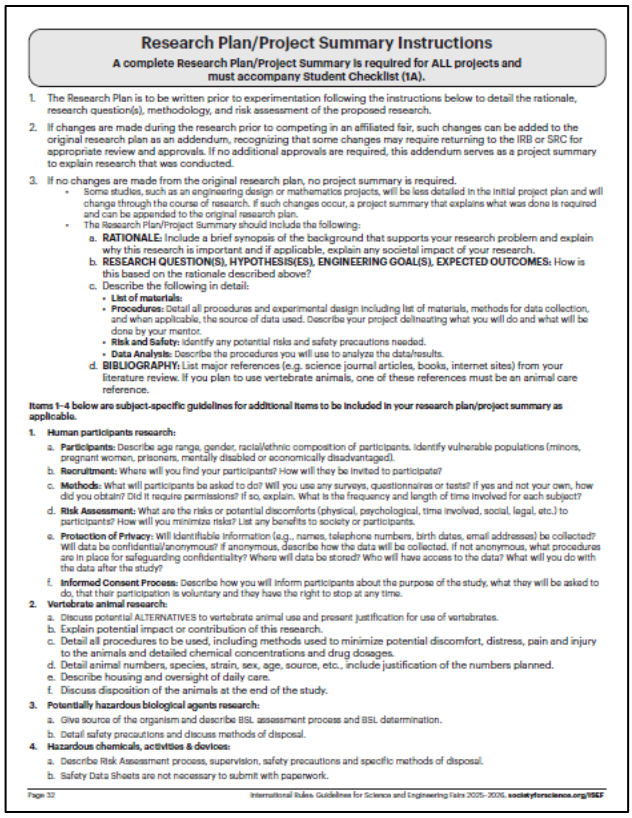
Key points to go over with your students:

#6 Continuation Y/N: Any project conducted in a similar area of research as previous projects should be considered a continuation. If a student researcher is in doubt, they should indicate it is a continuation. Continuation Form 7 provides a format to describe the differences between this project and a prior project. Student researchers should review the continuation rules and ensure that the project demonstrates significant progress (changes in the methodology and or more than running additional trials.) There are ethical considerations if a student says "no," and it is found through authenticity checks by fair officials that they have done research in the same or similar area.

#7: Start/End Dates: A project may only be one year in length and may not have started before January of the previous year. Explain when the actual experimental procedure (not the background literature review) will begin and end. Be as accurate as possible recognizing that these dates might change relative to when pre-approvals are provided.

#8: Information regarding Research Site: List where the experimental research will be done and check all that apply: research institution, school, field, home. If other than home or school, please list the address of the facilities on the form. (Note: There are several restrictions, particularly working with PHBAs, in a home environment. Review the rules carefully to ensure the appropriate environment for the study being conducted.)

If the location is something other than home or school, it is likely that a Regulated Research Institution or Industrial Setting Form 1C will need to be completed. The 1C helps inform not just the location of the research but what level of mentorship and guidance was given to the student from other individuals. The 1C should be completed after experimentation by the adult who supervised the project at that location.



Research Plan/Project Summary Instructions

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

1. 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.
2. If changes are made during the research prior to competing in an affiliated fair, 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.
3. 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:
     a. **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.
     b. **RESEARCH QUESTION(S), HYPOTHESIS(ES), ENGINEERING GOAL(S), EXPECTED OUTCOMES:** How is this based on the rationale described above?
     c. Describe the following in detail:
        - **List of materials:**
        - **Procedures:** Detail all procedures and experimental design including list of materials, methods for data collection, and when applicable, the source of data used. Describe your project delineating what you will do and what will be done by your mentor.
        - **Risk and Safety:** Identify any potential risks and safety precautions needed.
        - **Data Analysis:** Describe the procedures you will use to analyze the data/results.
     d. **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:**
   a. **Participants:** Describe age range, gender, racial/ethnic composition of participants. Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
   b. **Recruitment:** Where will you find your participants? How will they be invited to participate?
   c. **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?
   d. **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.
   e. **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?
   f. **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:**
   a. Discuss potential ALTERNATIVES to vertebrate animal use and present justification for use of vertebrates.
   b. Explain potential impact or contribution of this research.
   c. 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.
   d. Detail animal numbers, species, strain, sex, age, source, etc., include justification of the numbers planned.
   e. Describe housing and oversight of daily care.
   f. Discuss disposition of the animals at the end of the study.
3. **Potentially hazardous biological agents research:**
   a. Give source of the organism and describe BSL assessment process and BSL determination.
   b. Detail safety precautions and discuss methods of disposal.
4. **Hazardous chemicals, activities & devices:**
   a. Describe Risk Assessment process, supervision, safety precautions and specific methods of disposal.
   b. Safety Data Sheets are not necessary to submit with paperwork.

RESEARCH PLAN/POST PROJECT SUMMARY INSTRUCTIONS

As has been covered in the Research Plan section of the Guide above, this "form" provides the instructions on the required elements of a student's research plan relative to the specific areas of research they will be conducting. This information can also be found in the Documentation section of the Humans, Vertebrate Animals, Potentially Hazardous Biological Agents, Tissues and Hazardous Chemicals, Materials and Devices areas of the International Rules.

The following is what the review body (IRB, SRC, etc.) will be emphasizing as they review the Research Plan (either as the pre-approval or in the review and approval just prior to competition):

Human Participants:

All projects involving human participants must demonstrate IRB pre-approval with the signatures of the 3 core members and their decisions clearly indicated on Form 4. In the research plan, look for information about participants (any risk groups), recruitment, methods, risks & benefits, protection of privacy (HIPPA & FRPA), and informed consent and parental permission for all projects involving students under age 18. (Participant knows what they are being asked to do, that they may withdraw at any time, there is no coercion, etc.).

Is the level of risk appropriate? What risk assessment was done? Should the study have written Consent/Permission/Assent? Is the survey attached?

Vertebrate Animals:
Most projects involving vertebrate animals require pre-approval by an SRC and if conducted at a Regulated Research Institution (RRI), an IACUC. In the research plan, pay particular attention to the detailed procedures and care of the animals in the research, if they looked for alternatives to animal research and the final disposition of the animals.

Other areas to consider: Any animal deaths due to experimental procedures, weight loss ≥15% in any group or subgroup, toxicity studies, studies designed to kill, studies which cause more than momentary pain or suffering, predator/prey, inappropriate water or food restriction, euthanasia by student, etc. Ensure that an allowable embryonic study didn't hatch and become a vertebrate study that is not permitted.

Potentially Hazardous Biological Agents:
Projects involving Potentially Hazardous Biological Agents require pre-approval and the appropriate laboratory setting. The source, quantity, and Biosafety Level (BSL) must be indicated for all microorganisms including established cell lines.

a. Give source of the organism and describe BSL assessment process and BSL determination.

b. Detail safety precautions and discuss methods of disposal.

In the research plan, the source of all organisms, the BSL-assessment process and determination as well as clearly indicated procedures to minimize risk

should be addressed. Proper disposal methods must be listed.

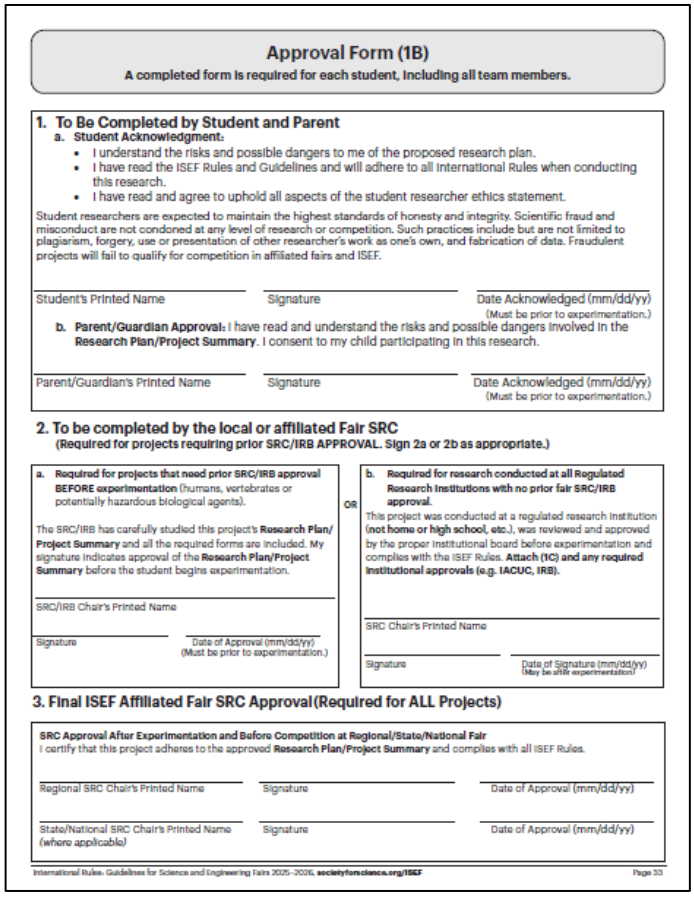
An SRC will be reviewing the research plan to confirm the appropriate laboratory, laboratory conditions, supervision and safety equipment meet the biosafety level required for the study, including procedures to minimize risk must be clearly indicated.

- Culturing of microorganisms may NOT be conducted at home
- If a petri dish or culture container with unknown or BSL-1 microorganisms is opened, it becomes a BSL-2 study and may only be conducted at a BSL-2 facility

Students and the adults supporting their projects should review the International Rules carefully to ensure full compliance with the pre-approval and biosafety level requirements.

Hazardous Chemicals, Activities, or Devices: Most projects involving hazardous chemicals, activities or devices require a Risk Assessment Form 3; all projects are strongly recommended to complete a risk assessment to ensure the safety of the student researcher and all involved in a project.

In the research plan, the SRC will look for detailed descriptions of risks and safety precautions and procedures used including methods of disposal.



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 agree to uphold all aspects of the student researcher 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 *(where applicable)* | Signature | Date of Approval (mm/dd/yy)

International Rules. Guidelines for Science and Engineering Fairs 2025-2026, **societyforscience.org/ISEF** Page 33

APPROVAL FORM (1B)

The Approval Form 1B is what its name suggests – a form to present the signatures and attestations of understanding of the rules and the details of the project by those needing to sign-off on the project. These statements attest that each of these people (or committee) approves or consents to this project. Signatures must be obtained and dated as described below and are before experimentation unless otherwise indicated:

Student: Date they attest that they understand the possible risks, that they have read and will follow the rules, and that they will abide by the ethics statement.

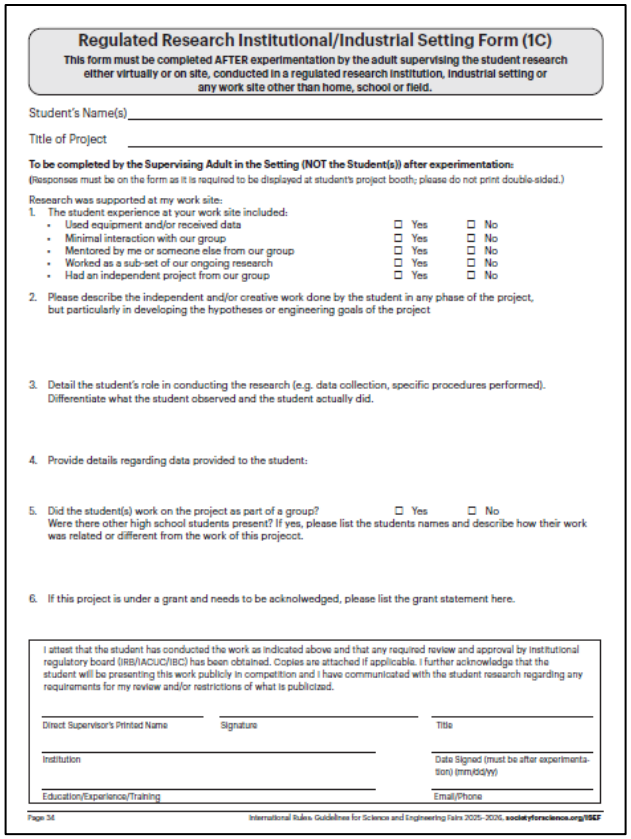
Parent/Guardian: Date they consent to their child doing this project and attest that they have reviewed the project and understand the risks involved.

SRC Approval BEFORE: Date that the committee reviews this project BEFORE the experimentation. Projects that require preapproval should have this date in this first box.

SRC Approval AFTER: This applies only to projects that needed pre-approval by the SRC but were done at an RRI and were pre-approved by that institution instead of the affiliated fair SRC. The date signed indicates when the affiliated fair SRC approved this project after it was completed. All documentation from the research institution showing approval of the project must be attached.

Final SRC Approval: All projects must be reviewed by the SRC after the experimentation is complete and shortly BEFORE competition in the affiliated fair. The date signed shows the date that SRC gives final approval to this project to compete at the initial affiliated fairs and if advancing to a state fair, there is an additional SRC approval line.

The SRC will review this document and its signatures as related to the Checklist (1) and Checklist (1A) and other forms completed.



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. The student experience at your work site included:
   - Used equipment and/or received data ☐ Yes ☐ No
   - Minimal interaction with our group ☐ Yes ☐ No
   - Mentored by me or someone else from our group ☐ Yes ☐ No
   - Worked as a sub-set of our ongoing research ☐ Yes ☐ No
   - Had an independent project from our group ☐ Yes ☐ No
2. Please describe the independent and/or creative work done by the student in any phase of the project, but particularly in developing the hypotheses or engineering goals of the project
3. Detail the student's role in conducting the research (e.g. data collection, specific procedures performed). Differentiate what the student observed and the student actually did.
4. Provide details regarding data provided to the student:
5. Did the student(s) work on the project as part of a group? ☐ Yes ☐ No
   Were there other high school students present? If yes, please list the students names and describe how their work was related or different from the work of this project.
6. If this project is under a grant and needs to be acknolwedged, please list the grant statement here.

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.

Direct Supervisor's Printed Name | Signature | Title

Institution | Date Signed (must be after experimentation) (mm/dd/yy)

Education/Experience/Training | Email/Phone

Page 34 International Rules, Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF

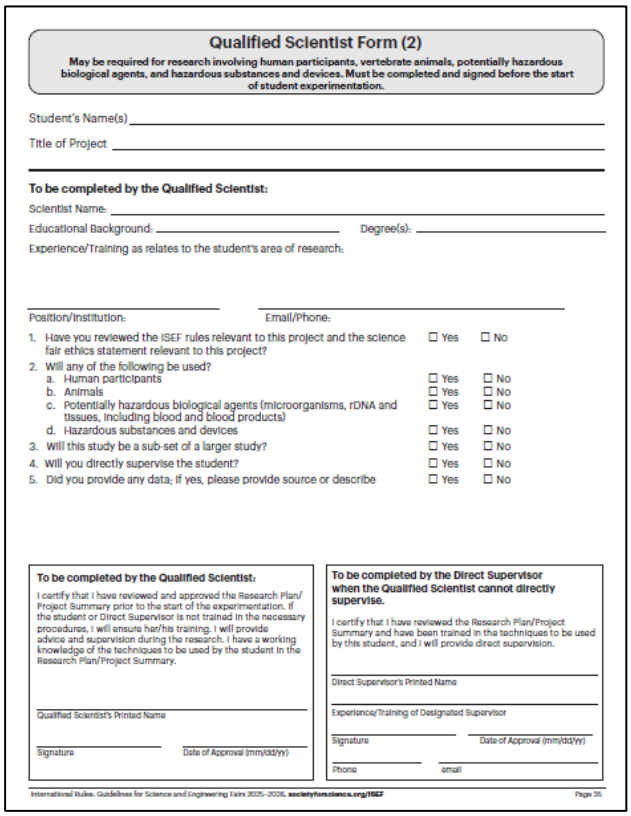
REGULATED RESEARCH INSTITUTIONAL OR INDUSTRIAL SETTING FORM (1C)

The Regulated Research Institutional or Industrial Setting Form (1C) is required if the research was done at a research institution (university lab, for example) or in an industrial setting. The supervising adult from the RRI or industrial setting should complete this form to provide information about what the student did, the supervision provided and how it relates to the work ongoing at the site.

If a student did not physically work at a research institution or industrial setting but received significant virtual mentorship from an adult at that site, that adult should complete a 1C. This provides the SRC with context for the adult's involvement and guidance.

This form is completed at the conclusion of the project as a summary and must not be filled out by the student. This form is posted so the judges can easily see exactly what the student did rather than what the mentor or others in the research group did. All information must be on the form and not listed as "see attached" as the form is required to be posted at the project booth.

In a review of this form, the SRC will look for consistency of the adult mentor's responses in comparison to what the student has indicated on other forms or in the research plan. Statements on the 1C can indicate other students involved with the project (potential team issues) or provide explanation of multiple years of engagement (This could indicate that the study is too old, too long, or that the student is presenting multiple years of research or that it is a continuation.)



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. 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
5. Did you provide any data; if yes, please provide source or describe ☐ Yes ☐ No

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 Direct 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.

Qualified Scientist's Printed Name

Signature | Date of Approval (mm/dd/yy)

To be completed by the Direct 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.

Direct Supervisor's Printed Name

Experience/Training of Designated Supervisor

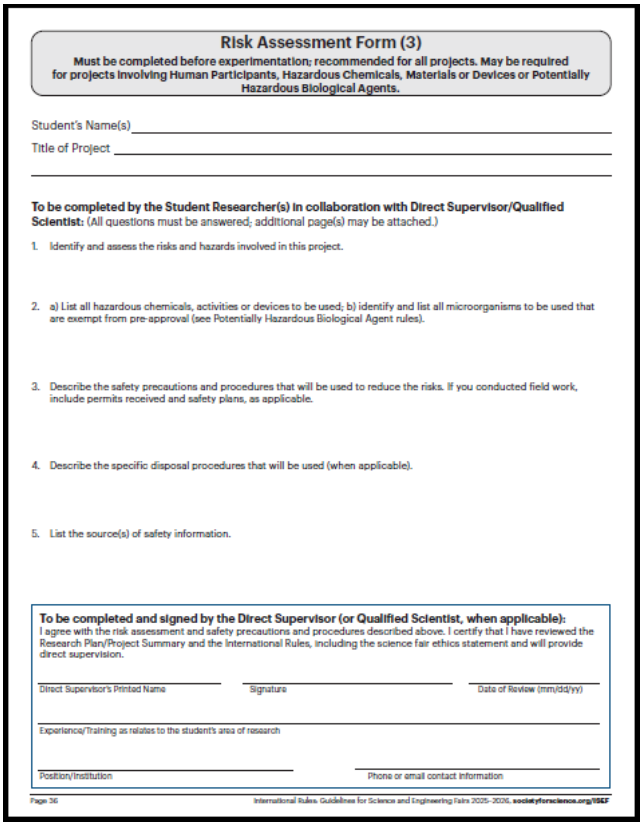
Signature | Date of Approval (mm/dd/yy)

Phone | email

International Rules, Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF Page 35

QUALIFIED SCIENTIST FORM (2)

The Qualified Scientist Form (2) is to be completed by the scientist overseeing the project. On this form, the scientist will attest to their expertise, their understanding of the project and the rules and that they will be supervising the student. If they will not always be directly supervising, there is also a signature block for a Direct Supervisor (DS) that can sign with the date that they approve this project (before experimentation takes place).



Risk Assessment Form (3)

Must be completed before experimentation; recommended for all projects. May be required for projects involving Human Participants, 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 Direct 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. If you conducted field work, include permits received and safety plans, as applicable.
4. Describe the specific disposal procedures that will be used (when applicable).
5. List the source(s) of safety information.

To be completed and signed by the Direct 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.

Direct 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

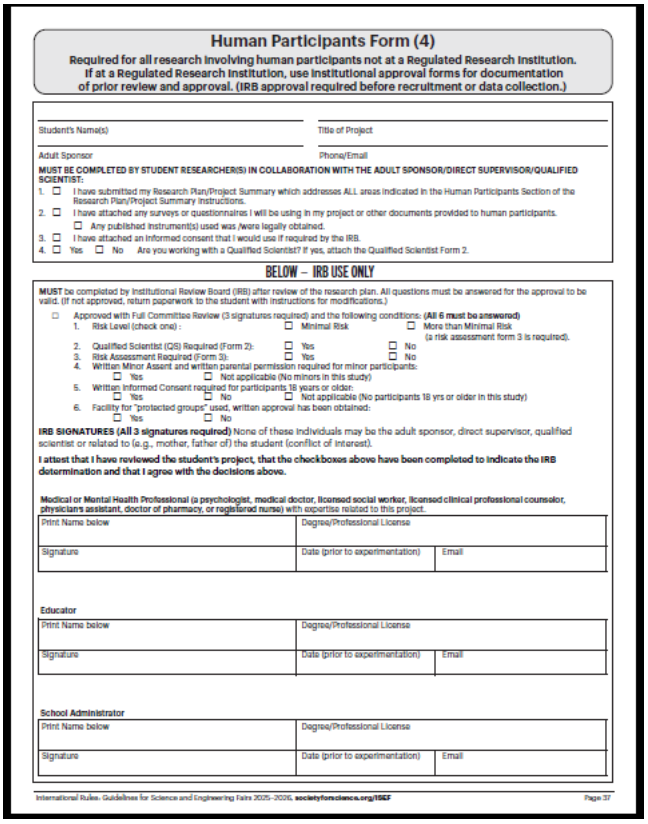
Page 36 International Rules, Guidelines for Science and Engineering Fairs 2025–2026, **societyforscience.org/ISEF**

RISK ASSESSMENT FORM 3

This Risk Assessment Form is required for hazardous chemicals, activities, or devices, and for PHBA projects and is recommended for all projects to address any potential risks and to provide safety precautions to take place. It must be signed by the Direct Supervisor (or Qualified Scientist) involved in the project.

All projects involve some level of risk and this form provides a chance for the student and any adults involved in the project, to discuss the importance of safety in science research and how to minimize risks.

The SRC is looking for complete responses and that the safety precautions to be taken align with the organisms or hazards involved.



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/DIRECT 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 (a risk assessment form 3 is required).
2. Qualified Scientist (QS) Required (Form 2): ☐ Yes ☐ No
3. Risk Assessment Required (Form 3): ☐ Yes ☐ No
4. Written Minor Assent and written parental permission required for minor participants: ☐ Yes ☐ Not applicable (No minors in this study)
5. Written Informed Consent required for participants 18 years or older: ☐ Yes ☐ No ☐ Not applicable (No participants 18 yrs or older in this study)
6. Facility for "protected groups" used, written approval has been obtained: ☐ Yes ☐ No

IRB SIGNATURES (All 3 signatures required) None of these individuals may be the adult sponsor, direct 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.

Print Name below	Degree/Professional License	
Signature	Date (prior to experimentation)	Email

Educator

Print Name below	Degree/Professional License	
Signature	Date (prior to experimentation)	Email

School Administrator

Print Name below	Degree/Professional License	
Signature	Date (prior to experimentation)	Email

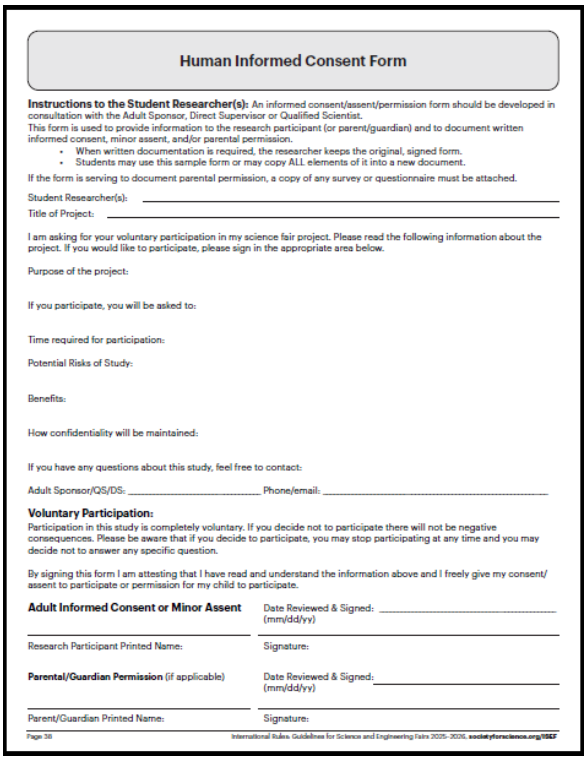
International Rules, Guidelines for Science and Engineering Fairs 2025–2026, **societyforscience.org/ISEF** Page 37

HUMAN PARTICIPANT FORM (4)

The Human Participant Form (4), along with the research plan, is submitted by the student researcher to explain to the IRB how the safety and well-being of the human participants and the confidentiality of results will be ensured. The IRB reviews the project, checks the risk level and determines if written documentation of assent/consent/ permission is required. All questions must be answered and boxes checked. Each IRB member signs with the date they approve this project. This review and the date signed must be **BEFORE** any experimentation takes place.

When required by the IRB and required for all projects involving participants under the age of 18, a written informed assent/consent/parental permission form is used to explain to the research participant and their parent/guardian the risks and benefits associated with participation. (See Human Informed Consent Form.) Any questionnaires, survey instruments, sample tests, etc. MUST be given to the IRB as part of their review and be provided to the parent/guardian for any human participants under 18. If the participant wishes to participate and when required, the parent/guardian also agrees, they each sign the Informed Consent Form with the date that they approve. (**Before** experimentation begins).

The SRC in reviewing Human Participant Form 4 is looking to ensure that it has been fully completed including decision checkmarks in the box and all 3 signatures. (Missing checkmarks or signatures indicates no documentation of prior review and therefore the project could fail to qualify; it is imperative that you confirm that the form that your student has actually indicates the final IRB review and approval.) All approval dates must be before research begins. (Start date on 1A.) The IRB should not include the adult sponsor, designated supervisor, qualified scientist or a relative (e.g. parent) of the student because of conflicts of interest.



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, Direct 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:

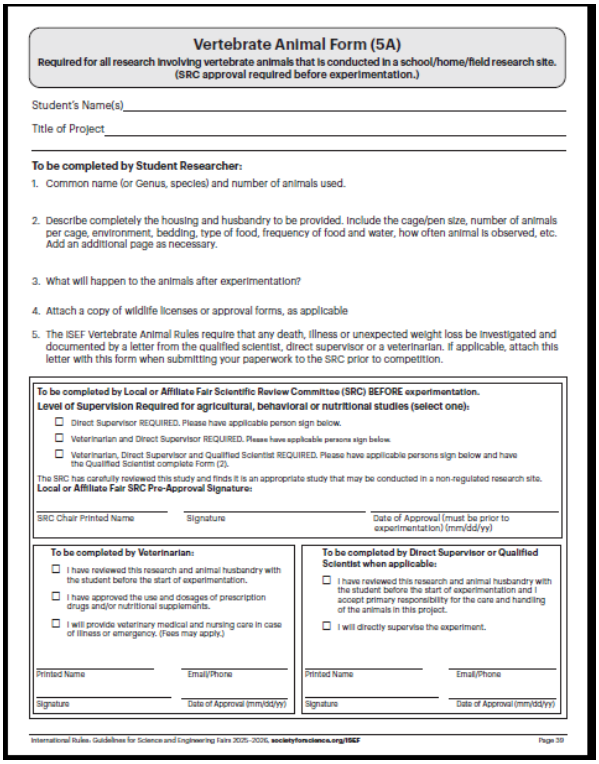
Page 38 International Rules. Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF

HUMAN INFORMED CONSENT FORM

As referenced above, this form provides the participant the information about the study for them (and their parent/guardian if they are under 18) to provide consent/assent.

The SRC will be reviewing the consent form for the following: A clear explanation of what the participant is being asked to do; how long it will take, the potential risks and steps that will be taken to mitigate risk, the benefits to the participant or to society, how confidentiality will be maintained, that it is completely voluntary and that they may withdraw at any time.

Adult participants sign giving their consent, minors give their assent, and parents of participants give permission. All approval signatures must be before research begins (Start date on 1A).



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, direct 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):

- ☐ Direct Supervisor REQUIRED. Please have applicable person sign below.
- ☐ Veterinarian and Direct Supervisor REQUIRED. Please have applicable persons sign below.
- ☐ Veterinarian, Direct 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 Direct 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)

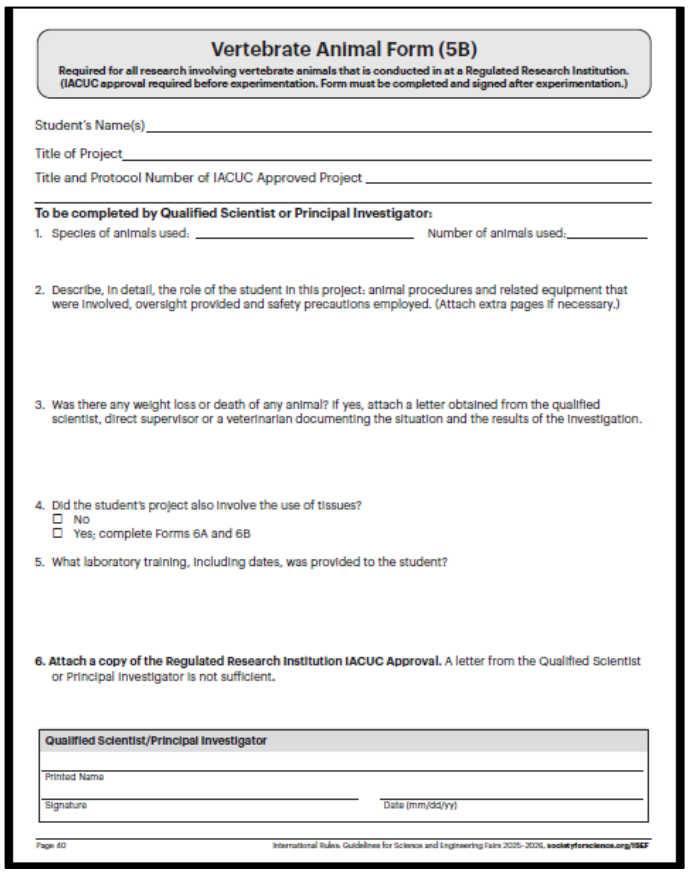
International Rules. Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF Page 39

VERTEBRATE ANIMAL FORM (5A)

The Vertebrate Animal Form 5A is required for projects involving vertebrate animals conducted in a Non-Regulated Research Site such as home or school. The student on this form provides a description of the animals to be used, the housing and care that the animals will receive and the final disposition of the animals. The SRC reviews this document and determines the level of supervision required for the study and signs and dates BEFORE experimentation begins. The bottom of the form is filled out by the veterinarian and/or direct supervisor and is signed and dated when they approve this project with these housing conditions. (**Before** experimentation begins.)

If there was any illness, unexpected weight loss or death of an animal during the experimentation, the cause must be investigated and a letter from the Qualified Scientist, Direct Supervisor, or a veterinarian which documents the situation and the results of the investigation must be attached. If there were any deaths due to the experimental procedure, the project will fail to qualify.

All approval signatures must be obtained before research begins (Start date on 1A). Capture & Release approvals must be attached when applicable.



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, direct 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)

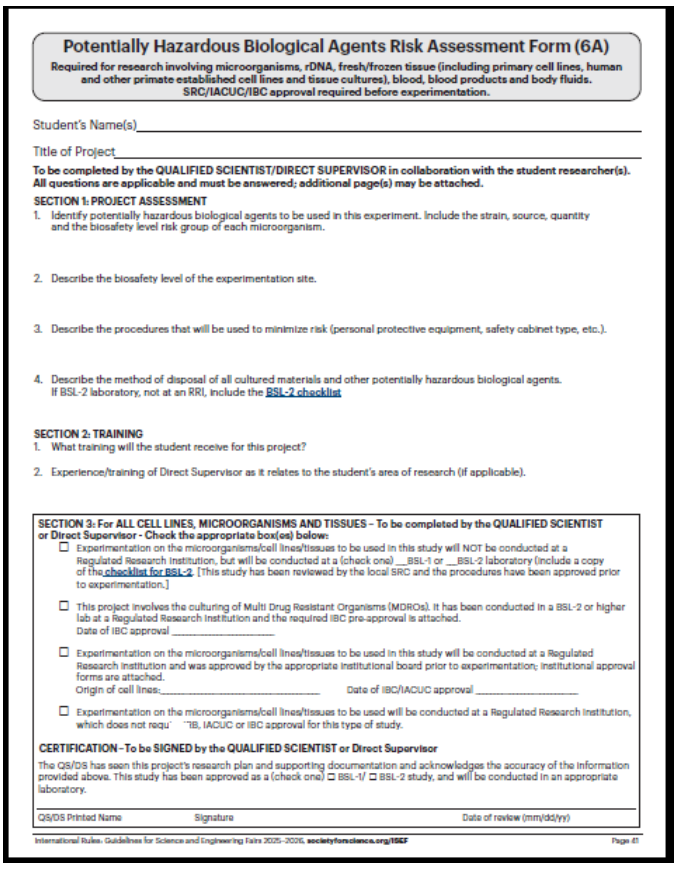
Page 40 International Rules, Guidelines for Science and Engineering Fairs 2025-2026, **societyforscience.org/ISEF**

VERTEBRATE-ANIMAL FORM (5B)

The Vertebrate Animal Form (5B) is filled out by the Qualified Scientist or Direct Supervisor at a Regulated Research Institution when the research is conducted at an RRI. The IACUC approval forms must be attached. This documentation must clearly cover the student's research study and must indicate that the study was approved before the start of the student research. Not all IACUC approval documentation will list the student individually, but the student research training must be indicated on the Form 5B. A letter from the Qualified Scientist or Principal Investigator indicating that the study had IACUC approval is not sufficient.

The SRC reviewing Vertebrate Animal Form (5B) and the research plan will review the methodology and confirm that the research did not cause more than momentary pain or suffering and that any use of anesthetics, analgesics and/or tranquilizers is documented.

Euthanasia by student researchers is prohibited so the final disposition of the animals should also be indicated. If there were any deaths due to the experimental procedure, the project will fail to qualify. If tissues were collected, how they were obtained and how they will be used must be described.-



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/DIRECT 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 strain, source, quantity and the biosafety level risk group of each microorganism.
2. Describe the biosafety level of the experimentation site.
3. Describe the procedures that will be used to minimize risk (personal protective equipment, safety cabinet type, etc.).
4. Describe the method of disposal of all cultured materials and other potentially hazardous biological agents. If BSL-2 laboratory, not at an RRI, include the **BSL-2 checklist**

SECTION 2: TRAINING

1. What training will the student receive for this project?
2. Experience/training of Direct 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 Direct 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.]
- ☐ This project involves the culturing of Multi Drug Resistant Organisms (MDROs). It has been conducted in a BSL-2 or higher lab at a Regulated Research Institution and the required IBC pre-approval is attached. Date of IBC approval _____
- ☐ 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 IBC/IACUC approval _____
- ☐ Experimentation on the microorganisms/cell lines/tissues to be used will be conducted at a Regulated Research Institution, which does not requ` `IB, IACUC or IBC approval for this type of study.

CERTIFICATION - To be SIGNED by the QUALIFIED SCIENTIST or Direct 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)

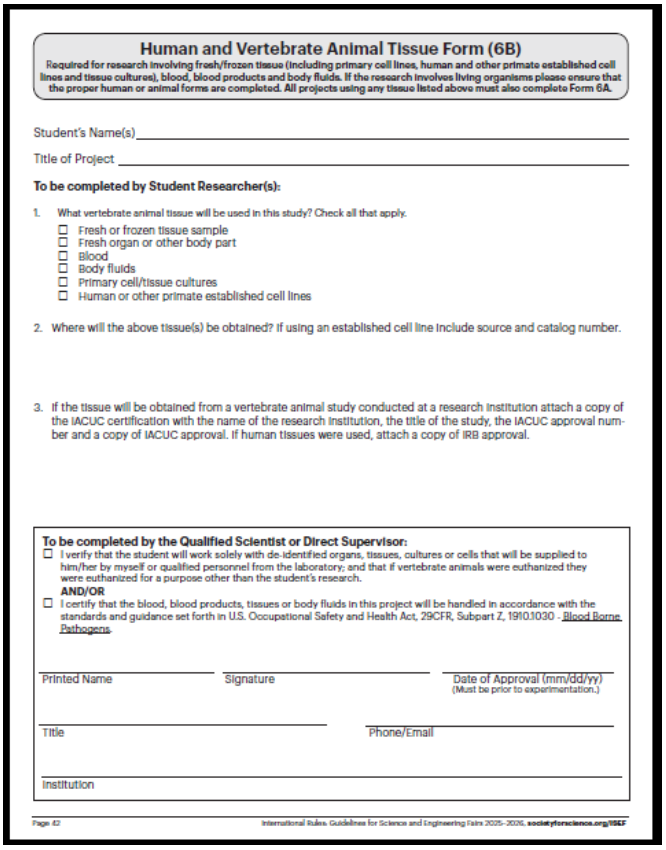
International Rules, Guidelines for Science and Engineering Fairs 2025-2026, **societyforscience.org/ISEF** Page 41

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS (6A)

The Potentially Hazardous Biological Agents Form (6A) is completed by the student researcher and is required for all research involving microorganisms, rDNA and 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/RAC approval is required **BEFORE** experimentation.

The strain, source, quantity, and biosafety level of all biological agents being used in the study must be listed as well as an explanation of minimizing risk and the planned disposal methods of all materials. In section 3, the qualified scientist or direct supervisor will check off on where the study is taking place and what type of approval is needed. The Qualified Scientist or Direct Supervisor will then sign the document before experimentation acknowledging that the experiment will be conducted in an appropriate laboratory.

The SRC will review this form and the research plan to confirm all details, safety precautions and laboratory conditions are appropriate for the study.



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. If human tissues were used, attach a copy of IRB approval.

To be completed by the Qualified Scientist or Direct Supervisor:

☐ I verify that the student will work solely with de-identified 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

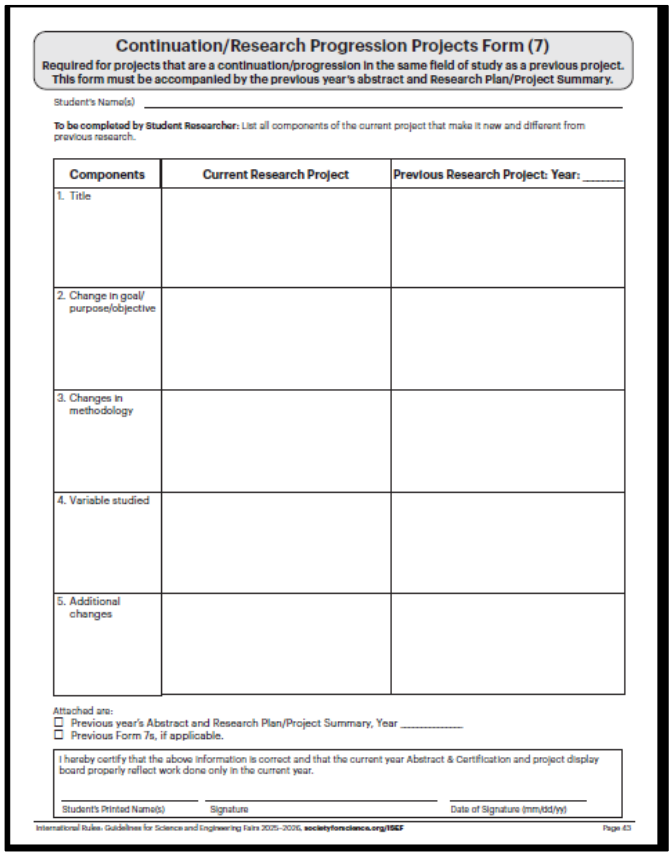
Institution

Page 62 International Rules, Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF

HUMAN & VERTEBRATE ANIMAL TISSUE (6B)

The Human and Vertebrate Animal Tissue Form (6B) is required for all projects involving tissue and must be accompanied by PHBA Form 6A. This form is filled out by the student researcher and explains the source of the tissue. The Qualified Scientist or Direct Supervisor signs and dates to document the source and handling of this tissue (**before** experimentation).

The SRC is reviewing Forms 6A and 6B as well as the research plan to understand the source of the tissues, that the appropriate approvals are in place and that research was conducted in the appropriate laboratory setting with the proper Biosafety Level conditions.



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.

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:

☐ Previous year's Abstract and Research Plan/Project Summary, Year _____

☐ Previous Form 7s, if applicable.

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)

International Rules, Guidelines for Science and Engineering Fairs 2025-2026, societyforscience.org/ISEF Page 63

CONTINUATION PROJECTS FORM (7)

The Continuation Form (7) is required for projects that are in a similar area of research as any previous project of the student or any team member. Similar projects do not have to have been conducted in the most immediate prior year or entered into competition; if the student researcher has done a previous project, they should complete the Continuation Form (7). Student researchers must describe thoroughly how the project is different from previous experimentation. The date signed is the date the student researcher is certifying that this information is correct.

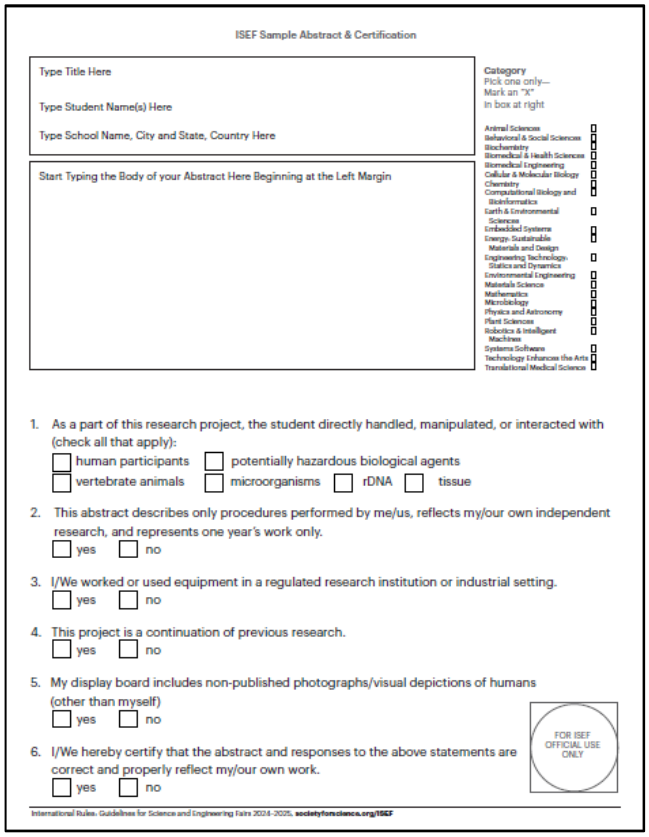
This form is posted with the project so that the judges can tell at a glance exactly what was new and different about this year's study. All information must be on the form, not on attached pages. Because research projects may only be one year's work, they will be judged on the current work only not on previous work, and this form is used to document current vs. previous research.

Frequently, students don't wish to call their project a continuation, but it's good research to continue a line of investigation even when the focus is now totally different. If the study is in the same field, if anything they learned in a previous year helped with the current study, or if the current study refers to any earlier research, then it is a continuation and Form 7 and previous abstract and research plan are required. If it

is a multi-year continuation, a Form 7 is required for each previous year, as well as the most recent year's abstract and research plan.

Repetition of a previous study that reflects no changes but simply retests or increases sample size is not permitted. A longitudinal study, in which time is a critical variable, is permitted but the original data from previous years cannot be presented only the comparison between years.

The SRC will be reviewing and comparing the current research plan with the prior year's documentation as well as the descriptions of differences on the form to verify that this year's project reflects significant change.



ISEF Sample Abstract & Certification

Type Title Here

Type Student Name(s) Here

Type School Name, City and State, Country Here

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

Category
Pick one only—
Mark an "X"
in box at right

Animal Sciences
Behavioral & Social Sciences
Biochemistry
Biomedical & Health Sciences
Biomedical Engineering
Cellular & Molecular Biology
Chemistry
Computational Biology and Bioinformatics
Earth & Environmental Sciences
Embedded Systems
Energy: Sustainable Materials and Design
Engineering Technology: Statics and Dynamics
Environmental Engineering
Materials Science
Mathematics
Microbiology
Physics and Astronomy
Plant Sciences
Robotics & Intelligent Machines
Systems Software
Technology Enhances the Arts
Translational Medical Science

1. As a part of this research project, the student directly handled, manipulated, or interacted with (check all that apply):
   ☐ human participants ☐ potentially hazardous biological agents
   ☐ vertebrate animals ☐ microorganisms ☐ rDNA ☐ tissue
2. This abstract describes only procedures performed by me/us, reflects my/our own independent research, and represents one year's work only.
   ☐ yes ☐ no
3. I/We worked or used equipment in a regulated research institution or industrial setting.
   ☐ yes ☐ no
4. This project is a continuation of previous research.
   ☐ yes ☐ no
5. My display board includes non-published photographs/visual depictions of humans (other than myself)
   ☐ yes ☐ no
6. I/We hereby certify that the abstract and responses to the above statements are correct and properly reflect my/our own work.
   ☐ yes ☐ no

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OFFICIAL ABSTRACT

At the conclusion of the project, a 250-word abstract is to be written to summarize the research study. It should be written by the student using their own words (and not written using AI or plagiarizing language from their literature review.)

It is recommended that the abstract include the following:

- purpose of the experiment
- procedure/methodology used
- most important/significant results you found
- conclusions/research applications.

Only minimal reference to previous work may be included. Students must avoid including the following:

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

Students must then answer the six questions at the bottom of the Abstract Form.

The SRC will use the checkboxes on the abstract to verify key areas of the student research project and what documentation they can expect to see.

Checkbox 1. Project involved human participants, vertebrate animals, or PHBA's. Requires preapproval and additional forms. Exempt studies do not check this box.

- Human Participants: Does the study mention people, interviews, responses, answers, consent, etc? (requires Form 4). Exempt studies include prototype/invention testing if only done by student researcher, public data review, some observational studies. All others require IRB preapproval.
- Animals: Look for indications of type of study and research site. Strictly observational studies with no interaction are exempt. Tissue studies in which the student is given the tissue and did not interact with the animal do not need animal forms but will still need preapproval as a PHBA tissue study.
- Projects may be conducted at home, school, or field ONLY IF the study involved agricultural, behavioral, observational, or supplemental nutrition AND was non-invasive AND had no negative effects on health and wellbeing (requires Form 5A).
- Projects must be conducted at research institution with IACUC preapproval in all other cases (requires Form 5B).
- PHBA's Study included microorganisms, rDNA, or fresh/frozen tissue, blood, body fluids. Used terms like culturing, plating, tissue, source of tissue, etc.

Checkbox 2. Abstract should only reflect the work of the student researcher and not the mentor's. If this is marked "yes," further review may be required to ensure that a rewrite and a "no" response is not more appropriate.

Checkbox 3. Worked at a Regulated Research Institution or Industrial Setting. (Requires 1C)

- Was the study done at a Regulated Research Institute/Industrial Setting (RRI)?

- Is the terminology or equipment very sophisticated? Look for possible RRI. (Form 1C)

Checkbox 4. Project is a continuation. (Requires Form 7, previous abstract & research plan)

- Does this appear to be a Continuation? Any mention of previous research? Uses terms like previously, earlier research, improved, redesigned, year 3, etc. (Form 7)
- Any discussion of a Partner in a non-team study? Uses "we" consistently (the use of "we" can be a form of scientific writing and does not always indicate a group). Form 1C answers this question for studies done at a university.

Checkbox 5. Display Board images of other humans requiring consents

- If a student has other humans depicted, it is possible that they used human participants and will require IRB approval. However this is primarily to address having proper photo permissions and consents on the display.

Checkbox 6. Certification that the project is their independent work

- This is another attestation at the conclusion of the project that the student researcher(s) has presented their own work and is in compliance with the Ethics Statement.

Pre-Approval Prior to Experimentation

INDEX

Many research projects require review and approval prior to experimentation. This review and approval process is provided by several committees that are formed with the appropriate expertise to properly assess the research being planned and to guide the final plan to ensure the safety of the student researcher, any human participants and/or vertebrate animals. If your project works with human participants, vertebrate animals or tissues or potentially hazardous biological agents, it will require pre-approval by the appropriate committee. What follows is an explanation of each committee and its potential role.

THE 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 is 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.

To avoid conflict of interest, no Adult Sponsor, parent or other relative of the student(s), the Qualified Scientist, or the Direct Supervisor who oversees the project may serve on the SRC reviewing that project. Additional members are recommended to diversify and to increase the expertise of the committee.

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 projects requiring prior SRC review (human participants; vertebrate animals; PHBAs; Hazardous Chemicals, Activities and Devices) the SRC should deliberate, resulting in one of the following decisions:

- Approval of research done at home, school or field. If a project is approved, the SRC Chair signs the box in #2a on the Approval Form (1B). The approved forms

should be returned to students as soon as possible, so that they can begin experimentation.

- Approval of research done at all Regulated Research Institutions with no prior fair SRC/IRB approval: If the project was conducted at a regulated research institution and was reviewed and approved by the proper institutional board before experimentation and complies with ISEF rules, sign box #2a on the approval Form (1B). Attach (1C) and any required institutional approvals (e.g. IACUC, IRB). If the approved project involved potentially hazardous biological agents, the SRC chair will also complete and sign the bottom section on Form 6A.
- Disapproval: The SRC Chair should provide the student and sponsor with a list of reasons for disapproval and suggestions for changes needed for approval. If suitable corrections are made, the revised project forms should be re- reviewed. If the revised project is then approved, the student and sponsor should be notified immediately so that the student can begin experimentation.

SRC Review Shortly Before Competition

- An SRC is required to reconvene before the fair to review supporting documentation of all projects prior to competition. The SRC chair will document this approval by signing #3 at the bottom of Approval Form (1B).
- Projects requiring pre-approval that were conducted at a Regulated Research Institution and were approved by the institution's approval bodies (IACUC, IRB, etc.) should be reviewed by the SRC/IRB to ensure documentation demonstrates pre-approval and compliance with the ISEF rules. If this review satisfies the pre-approval and compliance with the rules, the SRC chair will sign the box in #2b to indicate approval. If the approved project involved potentially hazardous biological agents, the SRC chair will also complete and sign the bottom section on Form 6A.

For Human Participant Projects Review –

THE INSTITUTIONAL REVIEW BOARD (IRB)

An Institutional Review Board (IRB), is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving 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. A School 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.

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

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.

An IRB is responsible for assessing risk and documenting the determination of risk level on Human Participant Form 4. However, 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 above.

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
- Radiation Safety 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 must complete the Regulated Research Institution/Industrial Setting Form 1C to address the adult supervision and conditions of research.

THE ISEF SCIENTIFIC REVIEW COMMITTEE (REGENERON 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.

Specialized Areas of Research

Protecting the Environment

Do no harm. This is a core principle of many tenets of science and engineering and is embedded into the International Rules' Ethics Statement:

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 for appropriate collection, handling and disposal procedures.

As students begin to develop a research project and to write their research plan, it is important that they consider any potential impacts on the environment and mitigate any risks as they conduct their risk assessment.

The International Rules address the environment throughout the rules. Here are a few key examples:

- All projects must follow local, state, national and international regulations and laws. Many such laws require permits or licenses or prohibit taking actions that will harm the environment.
- 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 for appropriate collection, handling, and disposal procedures.
- All local, state and national laws and permit requirements must be followed regarding the transport and use of microorganisms such as, but not limited to the Asian citrus psyllid (ACP) which spreads citrus greening or tobacco mosaic virus, etc.
- Disposal procedures shall be described in sufficient detail to ensure compliance with EPA Guidelines as outlined in the appropriate Safety Data Sheets. Examples include minimal quantities of chemicals that will require subsequent disposal; ensuring that all disposal is done in an environmentally safe manner. Proper chemical, sharps and other hazardous materials disposal must follow local, state, and federal guidelines.

FIELD WORK SAFETY PLAN

Scientists who study environmental topics plan their field studies very carefully. This allows them to make the minimal impact on the environment and to ensure their safety while conducting the study. Students and teachers should also make a plan before undertaking any field work. What items need to be packed for your safety if your time in the field is extended? Do you have food, water and first aid materials? Make sure that you have let people know where you will be working and when to expect your return. Do you have a means of getting help in an emergency? Environmental work can involve a myriad of topics and questions. Make sure that your plan addresses the specific environmental concerns and safety measures for your topic.

The following table, excerpted from the **Field Work Safety Plan**, provides some of the key details that should be included in a student's research plan if field work is planned:

Three key considerations in planning for field work:

- **Encountering Harmful Algal Blooms (HABs).** Harmful Algal Blooms can occur in fresh, salt, or brackish water. They occur when colonies of microorganisms grow out of control. Not all blooms produce toxins, but the toxins produced are harmful to humans, aquatic life, and pets. Students should consult local and state resources to confirm that the body of water being explored has no bloom active at the time of planned water sample collection. If the project involves collecting water samples from an active HAB, all necessary precautions, including appropriate BSL precautions must be followed.
- **Cross contamination prevention**: If a project involves sampling or visiting several different locations, prior to going into the field it is important to consider how your sampling methodology, equipment and even PPE will not cross-contaminate either the environments that you are entering or the samples you are gathering. What steps will be taken to minimize the chance of cross contamination? Ex: Decontamination by rinsing shoes worn during collection before leaving collection site.
- **Transport of samples:** Similar to the cautions necessary to collect the samples, how to store and transport the samples must be considered. Samples suspected to be contaminated need to be placed in separate containers for transport to

a testing facility. They need to be secured so that spillage doesn't occur.

Testing/Collection	Yes	No	Concerns to be addressed in RP
Soil sampling			Transport, testing facility, cross contamination prevention.
Water sampling			Are water test kits used? What happens to water samples? Transport, testing facility, cross contamination prevention.
Air sampling			Device and method to be used
Device deployment			Time period of deployment. Environmental impact
Chemicals			Disposal. Personal safety. Environmental impact. Review of SDS planned.
Microorganism collection			BSL2 for all unknowns. Transport, testing facility, cross contamination prevention.
Plant collection			Specify if invasive/toxic or if specimen carries invasive/toxic agents. Follow all state/federal transportation, relocation, and disposal laws. Cross contamination prevention

The **Field Work Study Plan** is meant to help students and teachers in developing a safe, environmentally responsible project. It should be reviewed with the research plan before starting your field work. It's loosely based on the requirements for scientists who collect air, water, and/or soil samples in the field.

HUMAN PARTICIPANTS

INDEX

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 if involving students under 18, will always require minor assent with the permission of parent or guardian.

Examples of Greater than Minimal Physical Risk

- Exercise other than ordinarily encountered in everyday life.
- 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.
- Exposure to any potentially hazardous material.

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.

Privacy Concerns

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

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

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 protection or accommodation:

- 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.)
- 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).

If the risk is more than minimal, a Risk Assessment Form 3 is required.

GUIDELINES FOR ONLINE SURVEY CONSENT PROCEDURES

Online surveys require **Informed Consent** (from human research participants age 18 and older) and **Minor Assent** (from participants under age 18). Additionally, minor participants will require **documentation of Parental Permission.**

1. **All information required in a consent form (e.g., voluntary nature of participation, what participation entails, risks, etc.) must be presented to the participants before they begin the survey.**
    a. Due to privacy risks inherent in online research, the following statement or something similar should be included: There is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security

breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question.

b. The survey should be set up in a way that the potential participant must click on a 'button' or type in a response indicating that he/she/they has read the consent/assent information (as described in 1 above) and agrees to participate. Once the 'button' is selected, the potential participant will be directed to the research survey questionnaire. That is, the survey questions are not viewed by participant until he/she/they clicks on or types in a response to indicate his/her/their voluntary participation.

- All questions must be voluntary for the survey participants to complete; there cannot be required questions.
- The following procedures should be used to protect confidentiality of downloaded data:

a. If IP addresses are collected by the survey tool, the addresses should be deleted from the downloaded data file. All responses should then be deleted from the online survey. The resulting data file that is used for data analysis should be free of any identifiers, including IP addresses or other electronic identifiers.

b. The data file should be stored on a password protected computer. Any back up data files should be also be stored in a secure location.

Documented Parental Permission

The following are several ways to obtain documented/written parental permission prior to a minor participant completing a survey on-line after recruiting participants in person.

- A traditional, hard copy of the parental permission/consent form may be sent to or brought to the parent who will review and possibly sign it, if giving permission for a minor child to participate. This permission form will be returned to the researcher and the participant may complete the survey online with a computer provided by the researcher (such as at school). A traditional, hard copy of the parental permission/consent form may be sent to or brought to parent for review. If the parent signs the form and returns it, the parent will be given a link for the minor participant to complete the on-line survey,
- Parental consent may be obtained using valid electronic signatures and emailed to the researcher, after which the researcher can email the link to the parent for the online survey.
- A copy of a signed permission document may be scanned and e-mailed back to the researcher, after which the researcher can email the link to the parent for the online survey.

If the recruiting of participants is going to be done online, it is recommended that an existing survey platform be utilized that can contact potential participants anonymously. It should have an informed consent embedded in the survey and that will restrict participants to those 18 years of age and older.

BEHAVIORAL & SOCIAL SCIENCES RESEARCH INVOLVING HUMAN PARTICIPANTS: GUIDANCE IN RISK ASSESSMENT & RISK REDUCTION

This guidance is written to assist student researchers, teachers/mentors and local School IRB's to assess and reduce risk as they design and review research projects so that the rights and welfare of human participants are protected.

A. Introduction to Risk Assessment and Reduction and the Role of the IRB

Risk Assessment involves the consideration of **physical** and **psychological** risks along with the **protection of privacy**. The student researcher, adult sponsor and qualified scientist must develop procedures that reduce and minimize any risks to human participants.

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. Members of the IRB will collaboratively make the following determinations which are documented on Human Participants Form 4:

- whether the study contains no more than minimal risk or more than minimal risk (see definitions below) to potential participants. The IRB will consider characteristics (e.g., age, health status, vulnerability to coercion) of the study population, the specific risks (e.g., physical, psychological, social, privacy) associated with the research activity and local norms when making a risk level determination;

- whether documentation of informed consent can be waived
- whether a qualified scientist is required
- Finally, whether the study is a) approved as it is written, b) must be revised or c) is not appropriate for a student research project (due to level of risk to the student researcher and/or participants). The IRB will sign Form 4 only if the project is approved.

No more than minimal risk exists when 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 or psychological examinations or tests. Research projects considered no more than minimal risk typically involve anonymous data collection (i.e., the data/responses cannot be linked to a particular person). In summary, physical, psychological or possibility of sharing a person's private information must be very small to be considered no more than minimal risk.

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.

B. Types of Risk

1. Physical Risks:

- Exercise other than ordinarily encountered in daily life by that participant would be considered more than minimal risk. One must consider characteristics of potential research participants as well as the type of exercise involved in the study.

Examples:

- Walking the length of standard hallway
    - For most healthy participants, this activity could be considered "minimal risk."
    - For the elderly or someone recovering from knee surgery, this might be considered "more than minimal risk."
    - Swimming 500 meters
    - For the general population, this activity would be considered "more than minimal risk."
    - For members of the varsity high school swim team, some IRBs may consider this activity to be "no more than minimal risk."
    a. Ingestion, tasting, smelling, application of a substance that pose any health risk are considered "more than minimal risk". Ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB who will determine risk level based upon the nature of study and local norms around food typically encountered in the research setting.

Example:

- Some school IRBs may consider a tasting study minimal risk based on the fact that the food being studied is commonly available to all students in their school.
- Conversely, an IRB at another school may deem the same study more than minimal risk if the food being studied is not commonly available to students or they believe that parents in their community would want to provide parental permission before their minor child could participate in the study.

2. Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress** would be considered **more than minimal risk**. For example, answering questions related to personal experiences such as sexual or physical abuse, experiences of trauma and/or psychological well-being (e.g. depression, anxiety, suicide) must be considered more than minimal risk and should have documented informed consent/minor assent/ parental permission (as applicable). **A licensed mental health professional must be on the IRB reviewing these types of projects.**

Additionally, research activities that involve exposing participants to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk.

Examples include violent or distressing video images, distressing questions, materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in participants.

Reducing Risk associated with Emotional Distress: Care must be taken to try to reduce potential emotional distress. For example, to reduce risk in a study involving a survey about depression and suicide, a mental health professional should be made available to talk with students while they are completing the survey.

3. Risks due to Invasion of Privacy & Breach of Confidentiality

The student researcher and the IRB must consider whether any activity could potentially result in negative consequences for the participant due to **invasion of privacy or breach of confidentiality**. For example, if the study involved collecting a student's GPA and the data were accidentally made available to unauthorized persons, the research participant could suffer embarrassment and feelings of distress related to the invasion of his privacy. Research projects that collect information of a personal nature (e.g., weight, private family information such as divorce, income, opinions about sensitive topics, sexual or gender, orientation, thoughts about suicide) put research participants at

risk related to possible disclosure of personal information to others. Adults and student researchers must consider the ramifications of anyone (including the student researcher) becoming aware of a research participant's personal information. Breach of confidentiality can be especially complicated and problematic when a student researcher is collecting data from his/her peers at school. Adults and student researchers need to anticipate the possibility of inadvertent breach of confidentiality in the context of collecting data from known peers.

Reducing Risk:

Risk level can be reduced by appropriately protecting confidentiality or collecting data that is anonymous and uses data collection procedures that make it impossible to link any identifying information with his/her responses or data.

a. **Anonymity** involves collecting research data in such a way that it is impossible to connect research data (e.g. responses, questionnaires) with the individual who provided the data. That is, personal identifiers (e.g. names, birthdates, student ID number, social security numbers) are not collected. **Whenever possible, student researchers should collect data anonymously.** While collecting data anonymously does reduce risk, not all anonymous studies are considered minimal risk**.**

   - To collect data anonymously, student researchers must not require participants to give their name or any other identifiable information (birth date, email address, etc.)
   - Adults and student researchers need to anticipate challenges to anonymous data collection. For example, if a student researcher collects data from known peers that includes both personal, sensitive information and demographic, personal information (e.g., sports they are involved in, favorite band), it is possible that the student researcher could inadvertently deduce who a given participant is based on the demographic data, even if names are not collected. It is recommended that a professional researcher with experience in the field research be consulted and named as a qualified scientist when data collection involves sensitive and personal topics.
   - If documented informed consent, assent, and/or parental permission is/are required, the forms must always be kept in a secure location separate from the data.

b. **Confidentiality** is necessary when personal identifiers such as name, birth date, telephone number, photograph, email address or mailing/street address are collected.

   - Protecting confidentiality involves taking careful measures to ensure that the research data and/or responses are not disclosed to the public or unauthorized individuals with identifiable information.
   - Confidentiality must also be considered when research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints, emotional functioning, grades) or health-related data (genetic material, blood, urine, tissue). The IRB reviewing a project involving sensitive mental or physical health issues, must consider the appropriateness of the study as a student research project with regards to the mental welfare of the human participants, especially if minors are involved.
   - If the research involves data from the same participant on multiple occurrences, the data or survey would need to be labeled with an identifier to be linked with the data collected at a later date. In this case, confidentiality could be maintained by labeling the surveys or data with a participant number and keeping a list of names and participant numbers in a separate and secure (e.g., locked file cabinet, password protected computer) location. Once the second round of data is collected, the surveys/data may be matched using the participant number and any identifiers should be removed from the data/surveys. At this point, the list of names and participant numbers should be securely discarded (e.g., shred). If documented informed consent, assent, and/or parental permission is/are required, the forms must be kept in a secure location separate from the data.

Special Considerations:

THREATS TO ANONYMITY

- If the number of participants is relatively small and/or all participants are from an identifiable source (e.g., an English class, softball team), the anonymity of the data could be threatened. That is the student researcher or anyone with access to the data could potentially link the survey responses to an individual. In addition, presenting the results of the study (even in aggregate) could threaten the participants' privacy or result in negative consequences for the participants.
- If informed consent/assent/ parental permission forms (which include names) are collected and the sample is relatively small, it could be possible for the student researcher or an unauthorized person to link the survey responses with participants.

MAKING DATA ANONYMOUS

- Sometimes data may not be collected anonymously, but can be made anonymous after data collection. For example, if the student researcher uses interviews or observations to collect the data, the data would not be anonymous at the time of collection. However, if names are not collected or are

removed from the data soon after collection, the data set would then be anonymous.

RISKS RELATED TO THREATS TO ANONYMITY

- Be sure to consider any ramifications of the student researcher being able to link responses with participants. Most importantly, would there be any negative consequences for the research participants if the student researcher could link responses with the participants. This is especially important when the research participants are peers to the researcher. When the participants are peers of the student researcher, the researcher/QS/IRB should give extra consideration to any potential risks related to the student researcher having knowledge of his/her peers' data (e.g., grades, body weight, etc.). To eliminate such risks, it may be prudent to have an adult collect the data and hand it over to the student research after identifiers are removed and it is anonymous.
- Be sure to consider the possibility of and ramifications of an unauthorized person (e.g., another student, parent, teacher, administrator) getting access to the data and being able to link responses to individual participants or groups of participants (e.g., softball team).
- Consider the nature of the study/data collected. Issues of anonymity and confidentiality are most salient for studies involving sensitive and personal information. Examples of data that should receive special consideration include grades, health/mental health information, experiences of child abuse, illegal behavior, socially unaccepted behavior, anything that could cause the participant embarrassment or legal or disciplinary negative consequences.

4. Risk Groups:

As noted above, the physical, psychological and other risks of participation in a study may depend on the specific sample of participants involved. The physical risk of an activity such as jumping rope will be much higher for elderly (or even middle-aged participant) than for a middle or high school participant. In contrast, the risks of a breach of confidentiality or anonymity would be greater for a group of high school students answering questions about alcohol use than for a group of older adults for whom it would be easier to collect the data in an anonymous fashion.

Some groups deserve special consideration. If the research study includes participants from any of the following groups described below, the student researcher and the IRB must consider whether the nature of the study requires consider special protections or accommodations for participants in these risk groups.

a. Any member of a group that is naturally at-risk (*e.g.*, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who suffer from a medical condition or disability such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, learning disorders, etc.). The nature of the study is an important consideration when determining if special protections are required. For example, special protections would not typically be necessary to include pregnant women in a study involving performance on a cognitive test or completion of a simple survey.

b. Special vulnerable groups that are covered by federal regulations (*e.g.* children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act). Specifically, the IRB and the student researcher should consider whether potential study participants who are receiving services under the Individual Disabilities Education Act need special accommodations and/or are appropriate for inclusion in the study as research participants. Confidentiality must be maintained so as not to identify/isolate students.

5. Informed Consent

Informed consent refers to the process of ensuring that potential human participants understand that they may choose whether or not to participate in a study. Individuals should never be forced or coerced to participate in a research study. A teacher, school administrator or anyone requiring students to participate in a research study as a human participant would be considered a serious violation of informed consent principles. That is, the research participant must freely decide to participate and not feel coerced or forced into doing so.

To make an informed decision about whether an individual wants to participate, the human participants must be informed about what they will be asked to do and if there are any risks or benefits involved. For example, if the participant will be asked to complete an interview or a survey, the nature of the survey should be described (e.g., questions about emotional functioning, students' experiences around divorce, grades and SAT scores). The informed consent process should include a description of the purpose of the study. The IRB may require a QS to help develop appropriate informed consent procedures which respect the rights of human participants but do not threaten the validity of the study.

Participants 18 years and older must be provided with all the information mentioned above and give their Informed Consent before participating in a research study. If participants are under 18, a parent or legal guardian must be presented with all

the information described above before giving Parental Permission for their minor child to participate. **Minor Assent refers to procedures giving developmentally appropriate information to children and adolescents about the study and giving them a choice as to whether they will participate. High school students should be supplied with ALL the information mentioned above and give their verbal and/or written assent to participate.**

OBTAINING WRITTEN INFORMED CONSENT, PARENTAL PERMISSION OR MINOR ASSENT

An informed consent form is typically used to provide written information to the human participant or parent/guardian and to document written informed consent/parental permission/minor assent. This form typically includes the purpose of the study, what the participant will be asked to do, the nature of any surveys, questionnaires or interviews, any risks and any benefits to the participant. The form should also contain information that explains to the potential research participant or parent/guardian that participation in the study is voluntary and that the participant is free to stop participating at any time.

The Informed Consent Form in the International Rules provides an example of how this information can be presented.

If a study involves a survey or a questionnaire, the Informed Consent process should include attaching a copy of the survey or questionnaire to the form. This process allows the parent to review the material to which their child will be exposed and make an informed decision about whether they want their child to participate. If sharing the survey is a violation of a copyrighted test publisher's regulations or has other consequences that will invalidate the study, the IRB will need to determine if a description of the survey to the parents is enough or if this will not properly inform the parents and the study will need to be deemed inappropriate for student research.

WAIVER OF WRITTEN INFORMED CONSENT

Obtaining informed consent from an adult is always required. However, the IRB may waive the requirement for documentation of written informed consent for adults (all participants under the age of 18 MUST have written parental permission and minor assent) if the research involves **only minimal risk and anonymous data collection and if it is one of the following**:

a. Research involving normal educational practices

b. Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.

c. Surveys and questionnaires that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

d. Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

As explained above, informed consent is always required. It is merely the process of obtaining a signature to document informed consent for adults that can be waived in the circumstances mentioned above. **If there is any uncertainty regarding the appropriateness of waiving written informed consent, it is strongly recommended that documentation of written informed consent be obtained.**

HUMAN INTERACTION WITH STUDENT-DESIGNED APPS

Student designed inventions, prototypes or computer applications which are tested or used by human participants, other than the student researcher are considered human participant projects and must comply with all human participant rules including having an appropriate IRB.

Students are prohibited from providing advice, diagnostic or medical information to participants without direct supervision and involvement of a medical professional. Students are prohibited from publishing diagnostic apps on public websites or app stores without appropriate FDA approvals.

If a student designed invention, prototype or computer application is used on human participants, the results produced shall not be disclosed to the participants.

ANIMALS

This Guide is to assist in developing Science Fair Projects for the Regeneron International Science and Engineering Fair which use animals in their experimentation. Animal research requires additional ethical consideration to ensure the welfare and safety of the animal subjects and should be the researcher's highest priority. For this Guideline, animals encompass all those in the animal kingdom, but we will focus on vertebrates, cephalopods and invertebrates. Please also note that there are more detailed Rules and Guidelines in the Rulebook under Vertebrate Animal Rules. Please make yourself fluent with these rules.

The foundational cornerstone of all animal research includes the 4R's: Replace; Reduce; Refine; Respect. Respect for one's animal subjects is key. Considerations for alternatives, including using lower phylogenetic models, fewer subject numbers, minimizing the impact of experimental protocols, and the sophistication of the experimental location should be reviewed. Consider any pain and distress that the animal may be subjected to. Justification must be provided, as well as a detailed description of the methods, including a timeline of procedures each animal will undertake.

ANIMALS:

Treat all animals as if they feel as you feel – both physically and emotionally. If you would not do it to yourself or someone you love, do not do it on an animal.

Prior SRC review and approval is required before a project can begin.

An animal's husbandry, specific procedures, and monitoring must be detailed in the research plan.

If experimentation is done in a Regulated Research Institution, then the experimentation must have written prior IACUC approval.

CEPHALOPODS:

As more is being learned about these species we must adjust how we work with them. Cephalopods should be treated in accordance with the same rules and concerns as we require for vertebrates, including the 4R's. This includes prior SRC approval before experimentation. Their physical and emotional well-being must be considered.

As they have a short lifespan, their daily care is critical to a successful research project, as it is with all animals. Their basic husbandry needs must be considered and included in the research plan, including: size of tank, number of animals per tank (consider social needs vs overcrowding), food source for appropriate diet requirements, frequency of cleaning, etc.

For All Animal, especially Vertebrate and Cephalopod experiments:

Experiments that are prohibited include: induced toxicity, behavioral experiments using aversive stimuli, studies of pain, and predator/vertebrate prey experiments.

INVERTEBRATES:

It is important that we are stewards of the environment. When working with invertebrates, proceed with caution to make certain no chemicals or hazards are introduced that are harmful to the invertebrate subjects or other invertebrates that are in the surrounding area.

This is especially true of experimenting with or in proximity to pollinators. Pollinators play an outsized role in promoting a healthy environment and any potential experimentation that could damage the relationship among pollinators or their environment needs to be scrutinized and altered to minimize the risk.

There are a large number of insects that act as vectors for infectious diseases of varying severities for people, animals and crops. Whenever such an insect is being used, all necessary precautions, including appropriate BSL precautions must be followed.

Exempt: Studies for All Animals that are exempt from prior SRC review and approval:

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's environment in any way, AND
c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.

Basic husbandry is defined as regular care of research animals. Husbandry tasks include but are not limited to: providing food and water, cleaning enclosures, health monitoring, maintenance of equipment and other daily care tasks. Husbandry does NOT include administering experimental procedures, performing invasive surgery or introducing new stimuli to the environment. Students are not allowed to practice Veterinary Medicine without a license.

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

INDEX

When a student research project involves potentially hazardous biological agents (microorganisms including bacteria, viruses, viroids, rickettsia, fungi, parasites, rDNA, and tissues), it is the responsibility of the student and all of the adults involved in a research project to conduct and document a risk assessment 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, under what laboratory facility conditions (with the correct equipment) and that all personnel are trained and appropriate supervision is planned.

PROJECTS PROHIBITED IN A HOME ENVIRONMENT

Students are prohibited from doing any culturing in a home environment and it is a safe assumption that if the project involves microorganisms, rDNA or tissue that are not exempted from the PHBA rules, the project must not be conducted in a home environment. This includes an area in the home that has been set aside as a "laboratory" and/or if a parent is a Qualified Scientist.

PHBA RISK ASSESSMENT

Risk assessment defines the potential level of harm, injury or disease to plants, animals and humans that may occur when working with biological agents. The end result of a risk assessment is the assignment of a 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 Direct 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 tuberculosis, Streptococcus pneumoniae, Salmonella choleraesui*s.

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.

BSL-1 AND BSL-2 SELF-ASSESSMENT CHECKLISTS

These Safety Checklists are intended to support an assessment of a laboratory to determine if it meets the qualifications to qualify as a BSL-1 or BSL-2 laboratory. It is encouraged that a high school educator conduct this Self-Assessment annually, make any appropriate modifications or corrections to ensure they are in compliance and then share this information with their administration. The checklists are based on information within the "Laboratory Biosafety Manual", 4th edition, World Health Organization, 2020.

BSL-1 SELF-ASSESSMENT CHECKLIST

BSL-2 SELF-ASSESSMENT CHECKLIST

TISSUES AND BODY FLUIDS

Students are permitted to conduct research that involves the use of human or animal cells, tissues, and cellular-/tissue-based products and such studies should follow the potentially hazardous biological agent rules. Examples of these products include, but are not limited to, human or animal cells, including established cell lines, blood and blood products, body fluids, bone, skin, unfixed tissues or organs, hematopoietic stem/progenitor cells derived from peripheral and cord blood, or other potentially infectious materials. These human or animal materials can contain bloodborne pathogens, which are pathogenic microorganisms present in blood and are capable of causing disease in humans, therefore added precaution is necessary when working with such materials.

Examples of activities related to the handling of any of the above materials that put a person "at risk" for exposure to bloodborne pathogens include:

- *In vitro* work with human cells
- Processing human blood or other bloodborne pathogen-risk body fluids
- Human cell/tissue/organ cultures with unknown bloodborne pathogen status
- Use of blood/organs/tissues from experimental animals infected with human bloodborne pathogens
- Handling untreated waste contaminated with human blood

SAFETY

Equipment that is designed to reduce the risk of bloodborne pathogen exposure is considered an engineering control and can include the following:

- Biological safety cabinets
- Sharps disposal containers
- Self-sheathing needles
- Eye wash stations that are readily available and functioning properly
- Disinfectants that are EPA-registered for the destruction of viruses
- Storage/transport and secondary containers that will effectively contain a spill

Personal Protective Equipment (PPE) is considered to be appropriate for protection against bloodborne pathogen exposure, only if it does not permit blood or other potentially infectious material to pass through or reach the researcher's clothing, skin, eyes, mouth, or mucous membranes for the duration of use.

Best practices to ensure your safety and the safety of those around you:

1. Wash hands with soap and water after removal of gloves and/or other personal protective equipment when work is complete and before leaving the laboratory
2. Contaminated needles and other sharps should not be bent, recapped, or removed, unless there is no demonstrable feasible alternative. In the event of no other alternative, needle removal should be accomplished using a mechanical device or a one-handed technique.
3. Immediately after use, contaminated reusable sharps should be placed in appropriate containers that are puncture resistant, labeled with the biohazard symbol, leak-proof, and designed in such a manner that does not require anyone to reach by hand into the container.
4. The use of glass should be minimized, as broken glass presents a puncture and abrasion hazard that can lead to a high-risk exposure scenario.
5. Eating, drinking, applying cosmetics or lip balm, handling contact lenses, and food or drink storage should be prohibited in all laboratories, but especially in those where tissues and body fluids are being used.
6. Splashing, spraying, or other actions that generate droplets of blood or other potentially infectious materials should be minimized during all procedures.

CELL CULTURES

Cell lines are cultures of human or animal cells that can be propagated repeatedly. They can be immortalized through transformation via spontaneous mutation or natural/laboratory infection with an immortalizing agent. Some vendors classify certain human or animal cell lines as appropriate to use at BSL-1, however, if unclassified, it is strongly recommended that experimentation be done in a BSL-2 laboratory, following BSL-2 procedures. Importantly, cell cultures containing a known (or suspected) etiologic agent or oncogenic virus are classified at the same biosafety level as that recommended for the agent, which may be higher than BSL-2, and are therefore prohibited in accordance with ISEF rules.

TISSUES VS. VERTEBRATE OR HUMAN PARTICIPANT STUDIES

A project is considered a tissue study if the tissue obtained was obtained from an animal that was euthanized for a purpose other than the student's project. 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. Similarly, if a project involves human tissue or body fluids where the sample can be identified with a specific person, the study must have IRB review and approval, and informed consent.

DOCUMENTATION

Projects utilizing human/vertebrate animal established cell lines or tissue cultures must include documentation regarding the source of the cells/tissues, even if the project is exempt from IRB approval and even if the lab has been in possession of the cell line for many years.

a. If obtained from a commercially available collection (e.g., ATCC) the catalog number is required. If catalog number is unavailable, student can provide a receipt and/or letter from mentor regarding the origin of the items.

b. If obtained from a private/non-commercial source (public or private laboratory, museum, etc.), documentation from the supplier must be uploaded in the application, including IACUC approvals for the original study.

c. If obtained from mentor's study or another lab's study, upload original study's IACUC approval OR reference to the original study's publication.

Adapted from: Occupational Safety and Health Administration (OSHA)'s Bloodborne Pathogens (BBP) Standard; Food and Drug Administration (FDA)'s Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products: Minimal Manipulation and Homologous Use; Vanderbilt University Medical Center's Best Practices for Use of Human-Derived Materials & Bloodborne Pathogens in Basic Research Applications

HAZARDOUS CHEMICALS, ACTIVITIES and DEVICES

INDEX

The definition of hazardous is “dangerous and involving risk, particularly to one’s health.” Eye, ear, breathing, skin, and temperature protection should be considered when working with a hazardous chemical, activity, or device.

In the International Rules, areas that are considered hazardous 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.

The intent of deeming a chemical, device or activity as “hazardous” is to protect the student researcher by ensuring proper supervision and the consideration of all potential risks so that the appropriate safety precautions are taken.

As mentioned in the risk assessment section of the research planning process,

Hazards x Exposure = Risk

Limiting the quantity of the hazard and limiting the exposure to the hazard will reduce the risk. Careful consideration of materials to be used, in what quantity, at what dilution to achieve the goals of the project is one way to mitigate risk. Another is to have proper supervision or even adult assistance in managing the more hazardous activities of the project. And of course, proper safety precautions must include the appropriate laboratory environment (using appropriate safety equipment) and ensuring that students are wearing personal protective equipment. And as the project concludes, proper disposal of any hazardous materials must be considered.

CHEMICALS

All chemicals can be hazardous if not handled properly. A proper risk assessment of chemicals must include review of the following factors:

- **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.
- **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).
- **Flammability** — the tendency for a chemical substance 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)
- **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 and as stated above, the least amount used at the lowest concentrations possible. 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 (SDS) provided by the vendor to ensure that proper safety precautions are taken. SDS sheets (e.g., Flinn, Sigma Aldrich, and Fisher Scientific) rank the degree of hazard associated with a chemical. This rating assists students and adult sponsors in determining risk associated with the use of a chemical.

TIPS FOR READING AN SDS

A Safety Data Sheet (SDS) can be pages long and daunting for students to read and understand. Reading the entire SDS is advised but there are some sections that are especially critical for students and teachers to read and understand when designing a research plan. This guide is to help you identify those critical sections.

First, there are a plethora of sources for SDS online. Three sources that are readily available in a Google search and easy to read are:

a. Fisher Scientific
b. Flinn Scientific
c. Sigma Aldrich

Let's start with chloroform as an example. You can simply google: SDS for chloroform and Fisher Scientific pops up.

CHLOROFORM SDS FROM FISHER SCIENTIFIC

https://www.fishersci.com/store/msds?partNumber=AC610281000&productDescription=CHLOROFORM+ANHYD&vendorId=VN00033901&countryCode=US&language=en

Section 2: Hazard(s) Identification (GHS ratings)

- This section is critical in determining chemical safety. What are the specific hazards? Where must the chemical work be conducted? Can it be done at school? Does it require a lab in an RRI? Can it be used at home for its intended use?

Section 4: First Aid Measures

- Discuss and make sure that the student knows where all safety equipment is located in the lab.

Section 5: Firefighting Precautions:

- This is where you'll find the NFPA code.

Section 8: Exposure Controls and PPE

- This section is very specific to the type of PPE and engineering that needs to be in place to use this chemical. Is the right type of goggles available? Does the student have access to the correct thickness of gloves? Is a respirator required or a fume hood?

Section 10: Stability and Reactivity

- This section explains storage and work conditions to avoid.

Section 13: Disposal

- This section provides guidelines for disposal. If state and local regulations are referenced, you need to call your local landfill and find out what their rules are regarding the chemical. If EPA requirements are mentioned, make sure you read and understand those requirements.

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 as safe as possible
- Maximization of energy efficiency
- Minimization of accident potential and avoiding the use of reactive substances

GHS CLASSIFICATIONS

The Global Harmonized System (GHS) classifies the variety of dangers that chemicals can have. The GHS is a framework that standardizes the classification and labeling of chemicals worldwide. Its goal is to establish criteria for the classification of health, physical and environmental hazards, and specify what information should be included on hazard labels as well as safety data sheets.

The following pictograms help identify the workplace hazards of chemicals and gases:

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Explosive

Flammable

Corrosive

Toxic

Irritant

Oxidizing

Compressed Gas

Health Hazard

Environmentally Damaging

The ISEF Scientific Review Committee is reviewing an update to the International Rules that will use these GHS ratings to determine the location and supervision required for projects involving chemicals. Most particularly, a chemical that has a GHS rating of 1 in any area can be extremely dangerous and should be in a laboratory with appropriate safety equipment and expert supervision. The 2025 International Rules requires review and adherence to the precautions as articulated in the SDS for each chemical being used.

PROPER DISPOSAL

The proper disposal method must be a priority as you plan your project. All Safety Data Sheets have a disposal section and it is critical that this is reviewed and followed to ensure the safety of the researcher and the environment. Local, state and federal law may also apply and should be researched through contacting your local waste management or health department. Dependent on the research, student researchers should also consider any applicable EPA guidelines. Special consideration should also be taken to prevent environmental contamination, including water supply contamination via disposal down the drain.

HAZARDOUS DEVICES

When a student researcher works with potentially hazardous/dangerous equipment and/or other devices, in or outside a laboratory setting that requires a moderate to high level of expertise to ensure their safe usage, a risk assessment should be conducted to discuss and plan for appropriate safety precautions. 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. All students must consider risk as part of their research planning.

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.

PRESCRIPTION DRUGS

In the United States, the Food and Drug Administration (FDA) tightly regulates the issuance of prescription drugs including non-controlled medications. State laws further regulate the use of prescription drugs, and it is unlawful for any person to knowingly or intentionally possess a non-controlled medication 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 a prescription for persons or purposes outside of the original intent of the prescription or for the person it was originally prescribed for. All applicable federal, state, and country laws must be followed.

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.

See Alcohol and Tobacco Tax and Trade Bureau (TTB) website for details.

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.

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 (https://www.faa.gov/uas/).

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.

Non-ionizing radiation includes the spectrum of ultraviolet (UV), visible light, infrared (IR), microwave (NW), radiofrequency (RF) and extremely low frequency (ELF).

Kvolts are energy units for x-ray machine. 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

KeV (kilo electron volts) are units used to describe the energy associated with radioisotopes. For sealed radioactive sources it is advised that if an emitting gamma/high-energy beta or activity >1 μCi, that the Radiation Safety Committee provide pre-approval and that the project is supervised by a radiation-trained adult who can ensure the appropriate shielding and dosimetry is in place. Most likely such projects will be limited to an RRI setting.

Additional Resources

TABLE 1. ACRONYMS COMMONLY USED IN THE INTERNATIONAL RULES

Acronym	Meaning
AIC	Adult in Charge (part of the Official Party at ISEF)
ATCC	American Type Culture Collection (cells that can be purchased)
BSL-1	Bio Safety Level 1
BSL-2	Bio Safety Level 2 (there is also 3 &4)
COI	Conflict of Interest
D&S	Display and Safety Committee
FTQ	Failure to Qualify
GHS	Globally Harmonized System (chemical classification system)
HUB	Not an acronym. Central hub at Regeneron ISEF
IAUCC	Institutional Animal Use and Care Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
Regeneron ISEF	Regeneron International Science and Engineering Fair
JAC	Judging Advisory Committee (ISEF)
NAS	National Academy of Sciences
NFPA	National Fire Protection Association (chemical classification system)
NRC	Nuclear Regulatory Commission
NSTA	National Science Teachers Association
OFP	Official Party (affiliated fair delegation at Regeneron ISEF)
PHBA	Potentially Hazardous Biological Agents
RAO	Regional Award Organizations (at Regeneron ISEF Affiliated Fairs)
SAO	Special Award Organizations (at Regeneron ISEF)
SRC	Scientific Review Committee
Regeneron STS	Regeneron Science Talent Search

Sources of Information

FOR ALL PROJECTS

1. **Patents**

- United States Patent and Trade Office: **https://www.uspto.gov/patents**
  - Customer Service: 1-800-786-9199 (toll-free); 571-272-1000 (local); 571-272-9950 (TTY)
  - USPTO Resources: **https://www.uspto.gov/learning-resources**
  - Free Services: **https://www.uspto.gov/learning-and-resources/access-our-free-services**
  - Search Strategy Guide and Video Tutorial: **https://www.uspto.gov/video/cbt/prelim-patent-search/index.html**
  - Law School Clinic Certification Program: **https://www.uspto.gov/learning-and-resources/ip-policy/public-information-about-practitioners/law-school-clinic-1**
  - Pro Se Assistance Program: **https://www.uspto.gov/patents/basics/using-legal-services/pro-se-assistance-program**
- European Patent Office: https://www.epo.org/en
  - Applying for a European Patent: https://www.epo.org/en

2. **Plagiarism and Ethics**

- Institute of Electrical and Electronics Engineers (IEEE) Resource Center: **https://resourcecenter.cis.ieee.org/**
- Scribbr Plagiarism Checker: **https://www.scribbr.com/plagiarism-checker/**

3. **Invasive Species**

- Aquatic Nuisance Species (ANS) Task Force: **https://www.fws.gov/program/aquatic-nuisance-species-task-force**
- USDA Animal and Plant Health Inspection Service (APHIS): **https://www.aphis.usda.gov/operational-wildlife-activities/invasive**
- Agricultural Pests and Diseases: **https://www.aphis.usda.gov/plant-pests-diseases**
- Global Invasive Species Database: **https://www.iucngisd.org/gisd/**

4. **Environmental Research**

- United States Environmental Protection Agency Health and Safety Plan Template: **https://response.epa.gov/_healthsafetymanual/forms/Health%20and%20Safety%20Plans/HASP%20Template.docx**
- United States EPA Contract Laboratory P Guidance for Field Samplers: **https://www.epa.gov/clp/clp-information-field-samplers**
- Harmful Algal Blooms
  - U.S. National Office for Harmful Algal Blooms: **https://hab.whoi.edu/impacts/impacts-human-health/**
  - Centers for Disease Control (CDC) One Health Harmful Algal Bloom System: **https://www.cdc.gov/ohhabs/about/index.html**
  - National Oceanic and Atmospheric Administration (NOAA): **https://oceanservice.noaa.gov/hazards/hab/#regional**
  - Ohio River Valley Water Sanitation Commission (ORSANCO) Harmful Algae Bloom Monitoring, Response and Communication Plan: **https://www.orsanco.org/wp-content/uploads/2021/02/FINAL-2021-HAB-Monitoring-and-Response-Plan.pdf**
  - Texas Department of State Health Services Guide for Public Health Response to Cyanobacterial Harmful Algae in Recreational Freshwater in Texas: **https://www.dshs.texas.gov/sites/default/files/tscc/docs/HAB%20Guidance%20Texas_Final_20220310.pdf**
- Surface Water Sampling
  - EPA Surface Water Sampling Operating Procedure: **https://www.epa.gov/sites/default/files/2017-07/documents/surface_water_sampling201_af.r4.pdf**

HUMAN PARTICIPANTS

- 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/index.html**
- National Institutes of Health (NIH) Training and Resources for Human Subjects:

https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/training-and-resources#training

- NIH Protecting Human Research Participants: https://grants.nih.gov/sites/default/files/PHRP_Archived_Course_Materials_English.pdf
- The Belmont Report, April 18, 1979: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
- American Psychological Association: https://www.apa.org/
  - Contact Info: (202) 336-5500; 800-374-2721
  - 750 First Street NE, Washington, DC 20002-4242
  - Information for Students: https://www.apa.org/about/students
  - Information Regarding Publications: https://www.apa.org/pubs/index
  - Standards for Educational and Psychological Testing. (1999). Washington, DC: AERA, APA, NCME: https://www.apa.org/science/programs/testing/standards
  - Testing Office for the APA Science Directorate: https://www.apa.org/science/programs/testing/
  - Contact Info: (202) 336-6000; testing@apa.org
- The Children's Online Privacy Protection Act of 1998 (COPPA): https://www.ftc.gov/legal-library/browse/rules/childrens-online-privacy-protection-rule-coppa
- U.S. Department of Health and Human Services: https://www.hhs.gov/ohrp/about-ohrp/index.html
  - Office for Human Research Protections 45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
  - IRBs: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html
- Food and Drug Administration Guide to Informed Consent: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

VERTEBRATE ANIMALS

- Animal Care and Use
  - National Academies Institute for Laboratory Animal Research: https://nap.nationalacademies.org/author/ILAR/division-on-earth-and-life-studies/institute-for-laboratory-animal-research
  - NIH Guide for the Care and Use of Laboratory Animals, 8th Edition (2011): https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf
  - National Research Council Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research (2003): https://nap.nationalacademies.org/catalog/10732/guidelines-for-the-care-and-use-of-mammals-in-neuroscience-and-behavioral-research
  - Federal Animal Welfare Act (AWA): https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act
  - Animal Welfare Information Center (AWIC): https://www.nal.usda.gov/programs/awic
  - Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching 4th Edition (2020): https://www.aaalac.org/pub/?id=E900BDB6-CCCF-AB13-89B6-DA98A4B52218
  - American Fisheries Society Guidelines for the Use of Fish in Research: https://fisheries.org/docs/wp/Guidelines-for-Use-of-Fishes.pdf
  - American Veterinary Medical Association Guidelines on Euthanasia (2020): https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals
- Alternative Research and Animal Welfare
  - National Library of Medicine MEDLINE: https://pubmed.ncbi.nlm.nih.gov/
  - Reference & Customer Services National Library of Medicine
    8600 Rockville Pike
    Bethesda, MD 20894
    888-FIND-NLM or 888-346-3656; (301) 594-5983
  - USDA National Agricultural Library Animal Use Alternatives (3 Rs):

https://www.nal.usda.gov/animal-health-and-welfare/animal-use-alternatives

- Animal Welfare Information Center | National Agricultural Library
  10301 Baltimore Avenue, Room 410
  Beltsville, MD 20705-2351
  phone: (301) 504-6212 fax: (301) 504-7125
  email: awic@ars.usda.gov
- Board on Animal Health Sciences, Conservation, and Research (BAHSCR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in BAHSCR Journal: https://www.nationalacademies.org/bahscr/board-on-animal-health-sciences-conservation-and-research
- BAHSCR – The Keck Center of the National Academies
  500 Fifth St. NW, Keck 687
  Washington, DC 20001
  phone: (202) 334-2590 fax: (202) 334-1687
  email: BAHSCR@nas.edu
- 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@teh.nlm.nih.gov
  https://www.nlm.nih.gov/
- Johns Hopkins Center for Alternatives to Animal Testing (CAAT): https://caat.jhsph.edu/
- Quality Assurance Manuals (for appropriate species), such as:
- USDA Best Management Practices Handbook: A Guide to the Mitigation of *Salmonella* Contamination at Poultry Hatcheries: https://www.poultryimprovement.org/documents/BestManagementPracticesHatcheries.pdf
- Beef Quality Assurance National Manual: https://www.bqa.org/Media/BQA/Docs/nationalmanual.pdf
- Pork Checkoff Safe Pig Care & Handling Resources: https://porkcheckoff.org/certification-tools/producer-tools/safe-pig-care/

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

- American Biological Safety Association: https://absa.org/
  - ABSA Risk Group Database: https://my.absa.org/Riskgroups
- American Type Culture Collection: https://www.atcc.org/
- Bergey's Manual of Systematic Bacteriology: https://www.bergeys.org/
- CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition: https://www.cdc.gov/labs/bmbl/index.html
- World Health Organization Publications: https://www.who.int/publications
  - WHO Laboratory Safety Manual 4th Edition: https://www.who.int/publications/i/item/9789240011311
- Canada Agency of Public Health Pathogen Safety Data Sheets: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html
  - American Society for Microbiology: https://asm.org/
  - Microbiology Society: https://microbiologysociety.org/
  - NIH Guidelines for Research Involving Recombinant DNA Molecules: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
  - Occupational Health and Safety Administration (OSHA): https://www.osha.gov/
  - OSHA Biological Agents Listing: https://www.osha.gov/biological-agents

GENERAL LAB/CHEMICAL SAFETY

- Safety in Academic Chemistry Laboratories: https://www.acs.org/content/dam/pldp/center/lab-safety/publications/safety-in-academic-chemistry-laboratories-students.pdf
- EPA Green Chemistry: https://www.epa.gov/greenchemistry
- Flinn Scientific Safety Data Sheets: https://www.flinnsci.com/sds/
- Interactive Learning Paradigms, Incorporated Safety Data Sheet Resource: https://www.ilpi.com/msds/find.html
- Globally Harmonized System (GHS) of Classification and Labeling of Chemicals: https://pubchem.ncbi.nlm.nih.gov/ghs/
  - GHS Chapter 5, Acute Toxicity: https://webapps.ilo.org/static/english

/protection/safework/ghs/ghsfinal/ghsc05.pdf

- National Fire Protection Association 704 Standard for Guidance on Chemical Reactivity and Instability: https://www.nfpa.org/news-blogs-and-articles/blogs/2021/11/05/hazardous-materials-identification
- Pesticides
  - National Pesticide Information Center: https://npic.orst.edu/ingred/ptype/natbio.html
  - EPA Pesticide Product and Label System: https://ordspub.epa.gov/ords/pesticides/f?p=PPLS%3A1%20
- U.S. Drug Enforcement Administration: https://www.dea.gov/

CONTROLLED SUBSTANCES:

https://www.deadiversion.usdoj.gov/schedules/schedules.html

- U.S. Alcohol and Tobacco Tax and Trade Bureau: https://www.ttb.gov/
- U.S. Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF): https://www.atf.gov/

RADIATION

- CDC Radiation Safety: https://www.cdc.gov/radiation-health/safety/index.html
- U.S. Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards: https://www.nrc.gov/about-nrc/organization/nmssfuncdesc
  - U.S. Nuclear Regulatory Commission Quantities of Licensed Material Requiring Labeling: https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-appc
- CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition: https://www.cdc.gov/labs/bmbl/index.html
- Occupational Health and Safety Administration (OSHA): https://www.osha.gov/
- Reactive Chemicals: https://www.osha.gov/chemical-reactivity
- Laser Hazards: https://www.osha.gov/laser-hazards
  - Ionizing Radiation: https://www.osha.gov/ionizing-radiation