

# A Hike Through The Guide

Regeneron International Science and Engineering  
Fair International Rules and Guidelines 2024

[https:  
//sspcdn.blob.core.windows.net/files/Documents/SE  
P/ISEF/2024/Rules/Book.pdf](https://sspcdn.blob.core.windows.net/files/Documents/SE<br/>P/ISEF/2024/Rules/Book.pdf)

**sefh**

Science & Engineering Fair of Houston

# When in doubt, read the rules

## Regeneron International Science and Engineering Fair International Rules and Guidelines 2024

<https://www.societyforscience.org/isef/international-rules/>

### Contact

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# Alaina Garza, M.Ed.

## Scientific Review Co-Chair

- Science Fair Sponsor, Clear Brook High School; SRC, Clear Creek ISD
- 2022 Truman T. Bell Extraordinary Service Award (TXSEF)
- 2019 Sigma Xi-Rice University- Outstanding Teacher of the Year
- 2018 Terry Berry Teacher of the Year (Senior Division) (SEFH)
- 2016 Claude L. Wilson Award for Teaching Excellence in STEM



Science & Engineering Fair of Houston

# John Glenn Ramon, PhD

## Scientific Review Co-Chair

- Been involved in SEF since 2007
- 2011 Jessie Dorrington Teacher of the Year (Ninth Grade) (SEFH)
- 2019 Terry Berry Teacher of the Year (Senior Division) (SEFH)
- Science Fair Coordinator, Hightower HS
- SRC, Fort Bend ISD since 2011



# Scientific Review: The Why

TO ENSURE THE  
HIGHEST  
LEVELS OF  
ETHICAL  
STANDARDS  
FOR RESEARCH

The Scientific Review Process exist to ensure the following:

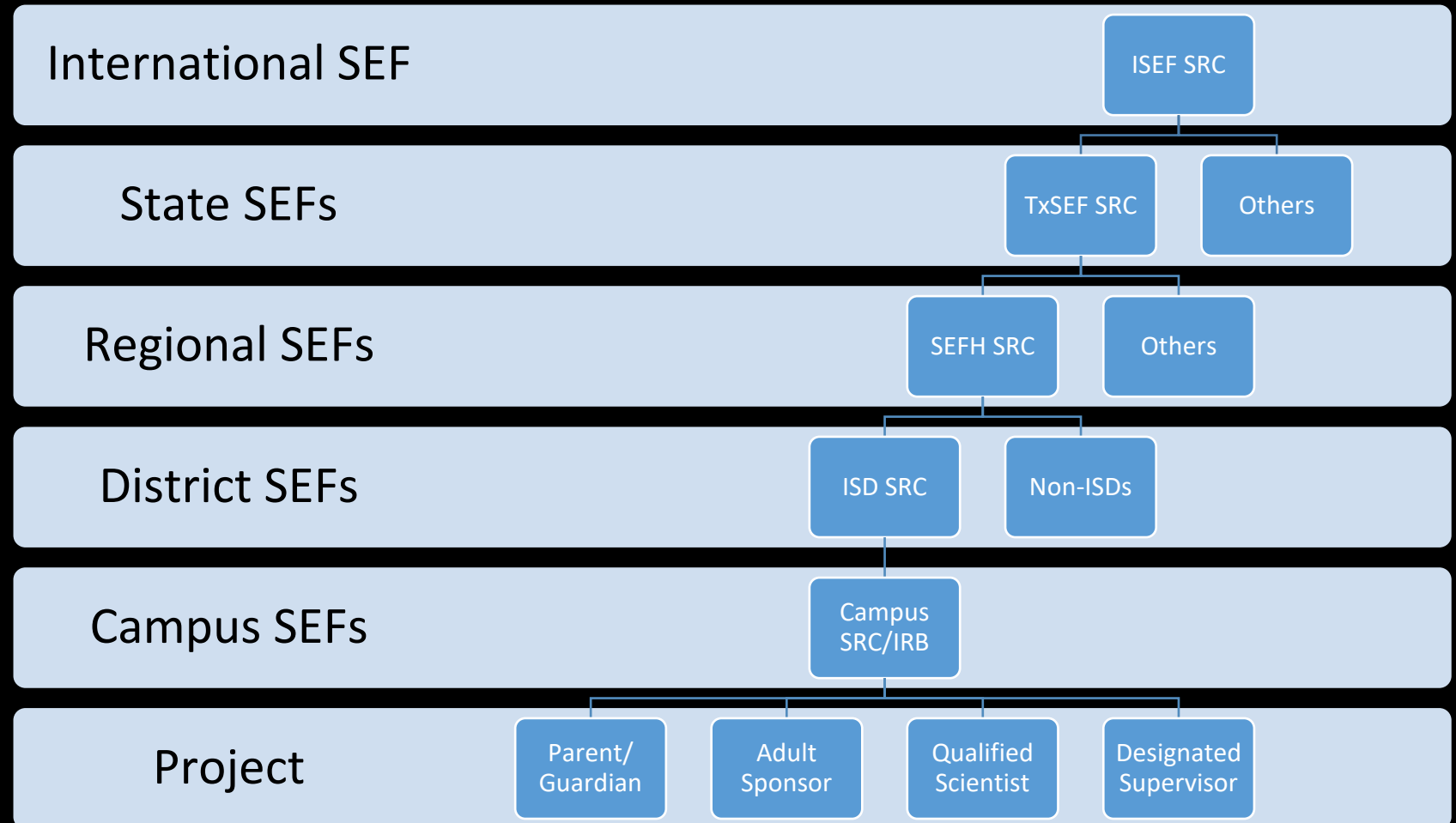
- protect the rights and welfare of the student researcher
- protect the rights and welfare of human participants
- protect the health and welfare of vertebrate animal subjects
- protect and promote good stewardship of the environment
- ensure adherence to federal regulations
- ensure use of safe laboratory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



Science & Engineering Fair of Houston

# Scientific Review Process

SCIENTIFIC REVIEW  
IS A  
PROCESS  
  
(NOT JUST A  
COMMITTEE)



# Scientific Review Process

NEW FORM  
FOR  
MIDDLE SCHOOL!

Found in the  
Resources on  
SEFHouston.org

**Safety and Consent Form**  
Texas Middle School Science Fair Students

**Student and Project Information**

Team Project:  # of Participants:

	First Name	Last Name	Grade	District
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

School:   
Teacher Name:   
Teacher Email:

Project Title:

**BEFORE Experimentation Begins – Project Safety Concerns and Pre-Approval Signatures**

Certain projects require additional considerations and supervision. Read through each of the following restrictions carefully. Determine if any of these apply to your project. Some projects may be subject to multiple restrictions. If any of these restrictions apply to your project, check the box for that area. **If no restrictions apply only the science teacher signature is required. Before beginning experimentation, you will need to obtain any additional signatures listed in the restrictions.**

☐ **Human Test Subjects** (Example: surveys, tests, tests, play a game or interact with another human in any way)  
If you are working with humans of ANY age, you need PRE-approval from a Science Teacher, School Administrator, AND a Psychologist, Medical Doctor or Registered Nurse to make sure your research is safe. This includes the student researcher participating in the experiment or testing their product. During the review, if it is determined that there is more than minimal risk to the human subjects involved in the project, the student must receive written consent from each of the participants and written parental consent for students under 18 years old if required.  
**Required Signatures:** Science Teacher, School Administrator, AND a Psychologist, Medical Doctor, or Registered Nurse. A copy of the surveys or test you intend to use must be attached.

☐ **Non-Human Vertebrate Animals** (Example: fish, rats, rabbits, dogs, cats, etc.)  
Experiments involving laboratory animals or pets (fish, rats, mice, hamsters, gerbils, rabbits, etc.) cannot be conducted in a student's home except for behavior studies on pets. Proper animal care must be provided daily, including weekends, holidays and vacations. Experimental procedures that cause unnecessary pain or discomfort are prohibited. Experiments designed to kill vertebrate animals are not permitted. Death of any animals due to experimentation will disqualify the project. Behavioral studies or supplemental nutritional studies involving pets or livestock may be done at home.  
**Required Signatures:** Science Teacher AND a Veterinarian or other Biomedical/Biological Scientist

☐ **Potentially Hazardous Biological Agents** (Bacteria, Mold, Fungi, Viruses, Parasites, Recombinant DNA (rDNA), Human or Animal fresh tissues, blood or body fluids, etc.)  
All Biosafety Level 1 projects can be performed in a school laboratory. **BACTERIA MAY NOT BE GROWN AT HOME.** Standard microbiological practices must be used and all hazardous agents must be properly disposed of at the end of experimentation. The experiment must be supervised by a qualified scientist or a trained designated supervisor.  
**Required Signatures:** Science Teacher AND a Biomedical/Biological Scientist

☐ **Controlled Substances** (Example: Over the counter or prescription drugs, tobacco, and alcohol)  
Students must adhere to all federal, state and local laws when acquiring and handling controlled substances. Only under the direction of a qualified scientist or designated supervisor may a student use federally controlled or experimental substances for experimentation.  
**Required Signatures:** Science Teacher AND a Designated Supervisor or Qualified Scientist (the adult monitoring the student)

☐ **Hazardous Chemicals, Substances, Activities, or Devices** (Chemicals, firearms, power tools, welders, lasers, radioactive substances, radiation)  
Students must adhere to federal and state regulations governing hazardous substances or devices. An adult must directly supervise experiments. Students working with hazardous substances or devices must follow proper safety procedures for each chemical or device used in the research.  
**Required Signatures:** Science Teacher AND a Designated Supervisor or Qualified Scientist (the adult monitoring the student)

**Projects Involving Human Test Subjects**  
(may require additional paperwork)

☐ Consent forms are required for all participants.  
☐ Parental consent forms required for all participants under 18.  
☐ Consent forms are not required. The project involves minimal risk.

**School Administrator APPROVAL**  
(required for ALL projects with human test subjects)

I have reviewed and approved this student's research plan prior to experimentation.

**Safety APPROVAL – Psychologist, Doctor or Nurse, Biomedical/Biological Scientist, Veterinarian**

Approval 1

Name:  Phone:   
Institution/Position:   
Email:   
Signature/Date:

Approval 2

Name:  Phone:   
Institution/Position:   
Email:

Student Name(s):

Project Title:

**Supervisor or Qualified Scientist:**

Students must have an adult supervisor when working on the project. This may be a parent or guardian, a teacher, or a laboratory supervisor. I, the Designated Supervisor, certify that:

- I have read the student's plan and understand all safety requirements.
- I have been trained in the techniques to be used by this student prior to the start of experimentation.
- I will provide direct supervision and take responsibility for the safety of my student(s) and any possible participants.
- I will review the project and make sure that only the student's work will be presented by the student at the fair.

Designated Supervisor's Name:  Email or phone:   
Signature:  Date:

**Teacher APPROVAL** (required for ALL projects):

I have reviewed and approved this student's research plan prior to experimentation and certify that it will comply with all the experimental rules of the Texas Science & Engineering Fair.

Teacher Signature:  Date:  Phone:

**Research Location:**

**Locations:** Please list the names, addresses, and type of location for each place you plan to conduct your research or work on your problem. If you work or collect data at a place of business or university, you will need a document showing you have permission to work there.

Facility Type (check all that apply): Home ☐ School ☐ University ☐ Business ☐ Public Facility (Park, Library, etc.) ☐ Other ☐

Location #1:  Location #2:

**Continuation Project:** Any project that expands on your previous science fair project by changing a variable or new line of investigation.

Is this project a continuation from last year?

If YES, submit your research plan and abstract from last year and explain how this year's project is different.

**Student & Parent/Guardian Signatures:**

If this is a team project, each team member and member parent/guardian must sign below.

**Students** - I certify the following (must agree to all in order to participate):

- ☐ My science project complies with all the experimental rules of the Science Fair.
- ☐ I have attached a written Research Plan for my project, indicating all materials needed and my planned procedure.
- ☐ I have attached any additional paperwork required for review (surveys and/or tests for human subjects, last year's paperwork, permission to work at business, etc.)
- ☐ I will respect other projects and property.
- ☐ I will treat all fellow participants, judges, volunteers and other science fair staff with respect and courtesy.
- ☐ I understand any violation of the above could result in removal from the competition.

**Parents** - I have read the agreements above and understand the risks and possible dangers involved in the project plan. I consent to my child participating in this project and I authorize my child to create an online account to enter necessary information for use with their science fair project. I authorize the publication of photos/videos taken of my child at Science Fair events.

Signature:  Signature Parent/Guardian:  Date:   
Signature:  Signature Parent/Guardian:  Date:   
Signature:  Signature Parent/Guardian:  Date:

# Guide to the ISEF/SEFH Project Approval Forms

GUIDE TO THE SEFH PROJECT APPROVAL FORM				
Form No.	Title	Projects requiring form	Person to fill up form*	Remarks
(1)	Checklist for Adult Sponsor	All	Adult Sponsor	
(1A)	Student Checklist	All	Student Researcher	
	Research Plan	All	Student Researcher	
(1B)	Approval Form	All	Student Researcher and Parent/Guardian	Every student in a team must have one
(1C)	Regulated Research Institution/ Industrial Setting Form	Projects done in a RRI, IS or worksite other than home, school or field	Supervising Adult	To be filled after experimentation
(2)	Qualified Scientist Form	Projects involving human subjects, vertebrate animals, potentially hazardous biological agents, DEA-controlled substances	Qualified Scientist	
(3)	Risk Assessment Form	Projects involving hazardous chemicals, activities or devices	Student Researcher in collaboration with DS/ QS	
(4)	Human Subject Form	Projects involving human subjects	Student Researcher in collaboration with DS/ QS	Requires IRB Approval
	Sample of Informed Consent Form			
(5A)	Vertebrate Animal Form	Projects involving vertebrate animal conducted in a Non-RRI site	Student Researcher	Requires SRC Approval
(5B)	Vertebrate Animal Form	Projects involving vertebrate animal conducted in a RRI site	Qualified Scientist/ Principal Investigator	Requires IACUC Approval
(6A)	Potentially Hazardous Biological Agents Risk Assessment Form	Projects involving microorganisms, rDNA, tissue, blood and body fluids	Student Researcher	
(6B)	Human and Vertebrate Animal Tissue Form	Projects involving fresh/frozen tissue, primary cell culture, blood, blood products and body fluids	Student Researcher and QS/DS	
(7)	Continuation Project Form	Projects that are continuation in the same field as previous project	Student Researcher	

\* Refer to the Rules and Guidelines for definition and roles of each person.

# Adult Sponsor & Checklist Forms 1 & 1A

**Checklist for Adult Sponsor (1)**  
This completed form is required for ALL projects.

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

Student's Name(s): \_\_\_\_\_

Project Title: \_\_\_\_\_

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

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

- a. Student/Team Leader: \_\_\_\_\_ Grade: \_\_\_\_\_  
Email: \_\_\_\_\_ Phone: \_\_\_\_\_  
b. Team Member: \_\_\_\_\_ c. Team Member: \_\_\_\_\_
- Title of Project: \_\_\_\_\_
- School: \_\_\_\_\_ School Phone: \_\_\_\_\_  
School Address: \_\_\_\_\_
- Adult Sponsor: \_\_\_\_\_ Phone/Email: \_\_\_\_\_
- Does this project need SRC/IRB/IACUC or other pre-approval? ☐ Yes ☒ No Tentative start date: \_\_\_\_\_
- Is this a continuation/progression from a previous year? ☐ Yes ☒ No  
If Yes:  
a. 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)
- This year's experimentation/data collection:  
\_\_\_\_\_  
Actual Start Date: (mm/dd/yy) \_\_\_\_\_ End Date: (mm/dd/yy) \_\_\_\_\_
- Where will you conduct your experimentation? (check all that apply)  
☐ Research Institution ☐ School ☐ Field ☐ Home ☐ Other: \_\_\_\_\_
- Source of Data:  
☐ Collected self/mentor ☐ Other Describe/url: \_\_\_\_\_
- List name and address of all non-home and non-school work site(s):  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Phone/ email: \_\_\_\_\_
- Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.**
- An abstract is required for all projects after experimentation.**

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# Adult Sponsor & Checklist

## Forms 1 & 1A

## 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.

☐ Vertebrate Animal Form (6B) for projects conducted at a regulated research institution. (Vertebrate 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

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\_\_\_\_\_  
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 Describe/url: \_\_\_\_\_

10. List name and address of all non-home and non-school work site(s):

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.

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## Adult Sponsor & Checklist

### Forms 1 & 1A

## 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

# Approvals

## Form 1B

<b>Approval Form (1B)</b>		
A completed form is required for each student, including all team members.		
<b>1. To Be Completed by Student and Parent</b>		
<b>a. Student Acknowledgment:</b>		
<ul style="list-style-type: none"><li>• I understand the risks and possible dangers to me of the proposed research plan.</li><li>• I have read the ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.</li><li>• I have read and will abide by the science fair ethics statement.</li></ul>		
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) <small>(Must be prior to experimentation.)</small>
<b>b. Parent/Guardian Approval:</b> I have read and understand the risks and possible dangers involved in the <b>Research Plan/Project Summary</b> . I consent to my child participating in this research.		
Parent/Guardian's Printed Name	Signature	Date Acknowledged (mm/dd/yy) <small>(Must be prior to experimentation.)</small>
<b>2. To be completed by the local or affiliated Fair SRC</b> <b>(Required for projects requiring prior SRC/IRB APPROVAL. Sign 2a or 2b as appropriate.)</b>		
<b>a. Required for projects that need prior SRC/IRB approval BEFORE experimentation</b> (humans, vertebrates or potentially hazardous biological agents).		
The SRC/IRB has carefully studied this project's <b>Research Plan/Project Summary</b> and all the required forms are included. My signature indicates approval of the <b>Research Plan/Project Summary</b> before the student begins experimentation.		
SRC/IRB Chair's Printed Name		
Signature	Date of Approval (mm/dd/yy) <small>(Must be prior to experimentation.)</small>	
OR		
<b>b. Required for research conducted at all Regulated Research Institutions with no prior fair SRC/IRB approval.</b>		
This project was conducted at a regulated research institution <b>(not home or high school, etc.)</b> , was reviewed and approved by the proper institutional board before experimentation and complies with the ISEF Rules. <b>Attach (1C) and any required institutional approvals (e.g. IACUC, IRB).</b>		
SRC Chair's Printed Name		
Signature	Date of Signature (mm/dd/yy) <small>(May be after experimentation)</small>	
<b>3. Final ISEF Affiliated Fair SRC Approval (Required for ALL Projects)</b>		
<b>SRC Approval After Experimentation and Before Competition at Regional/State/National Fair</b>		
I certify that this project adheres to the approved <b>Research Plan/Project Summary</b> 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 <small>(where applicable)</small>	Signature	Date of Approval (mm/dd/yy)

# Regulated Research Institution Form 1C

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

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

Student's Name(s) \_\_\_\_\_

Title of Project \_\_\_\_\_

**To be completed by the Supervising Adult in the Setting (NOT the Student(s)) after experimentation:**  
(Responses must be on the form as it is required to be displayed at student's project booth; please do not print double-sided.)

Research was supported at my work site:

1. Did you or your proxy (e.g. graduate student, postdoc, employee) mentor or provide substantial guidance to the student researcher? ☐ Yes ☒ No

a. If no, describe your and/or your institution's role with the student researcher and his/her project (e.g. supervised use of equipment on site without ongoing mentorship and sign below.

\_\_\_\_\_

b. If yes, complete questions 2-5.

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

\_\_\_\_\_

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

\_\_\_\_\_

b. designed the methodology for his/her research project

\_\_\_\_\_

c. analyzed and interpreted data

\_\_\_\_\_

(Continued on next page)

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

Student's Name(s) \_\_\_\_\_

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

\_\_\_\_\_

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

\_\_\_\_\_

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

Supervising Adult's Printed Name \_\_\_\_\_

Signature \_\_\_\_\_

Title \_\_\_\_\_

Institution \_\_\_\_\_

Date Signed (must be after experimentation) (mm/dd/yy) \_\_\_\_\_

Address \_\_\_\_\_

Email/Phone \_\_\_\_\_

# Qualified Scientist

## Form 2



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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? <input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Will any of the following be used?	
a. Human participants	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Vertebrate animals	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products)	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Hazardous substances and devices	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Will this study be a sub-set of a larger study? <input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Will you directly supervise the student? <input type="checkbox"/> Yes <input type="checkbox"/> No	
a. If no, who will directly supervise and serve as the Designated Supervisor?	
b. Experience/Training of the Designated Supervisor: _____	
To be completed by the Qualified Scientist:	
I certify that I have reviewed and approved the Research Plan/Project Summary prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the Research Plan/Project Summary. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my direct supervision.	
Qualified Scientist's Printed Name _____	
Signature _____	Date of Approval (mm/dd/yy) _____
To be completed by the Designated Supervisor when the Qualified Scientist cannot directly supervise.	
I certify that I have reviewed the Research Plan/Project Summary and have been trained in the techniques to be used by this student, and I will provide direct supervision.	
Designated Supervisor's Printed Name _____	
Signature _____	Date of Approval (mm/dd/yy) _____
Phone _____	Email _____

International Rules: Guidelines for Science and Engineering Fairs 2021-2022, [societyforscience.org/ISEF](http://societyforscience.org/ISEF) Page 37

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Sc

## The Qualified Scientist

### Qualifications:

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

## Form 2



Science & Engineering Fair of Houston

... primary research involving agents (microorganisms, chemicals, tissues, including blood and blood products)

d. Hazardous substances and devices ☐ Yes ☐ No

3. Will this study be a sub-set of a larger study? ☐ Yes ☐ No

4. Will you directly supervise the student? ☐ Yes ☐ No

a. If no, who will directly supervise and serve as the Designated Supervisor?

b. Experience/Training of the Designated Supervisor:

**To be completed by the Qualified Scientist:**

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

Qualified Scientist's Printed Name \_\_\_\_\_

Signature \_\_\_\_\_ Date of Approval (mm/dd/yy) \_\_\_\_\_

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

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

Designated Supervisor's Printed Name \_\_\_\_\_

Signature \_\_\_\_\_ Date of Approval (mm/dd/yy) \_\_\_\_\_

Phone \_\_\_\_\_ Email \_\_\_\_\_

International Rules: Guidelines for Science and Engineering Fairs 2021-2022, [societyforscience.org/ISEF](http://societyforscience.org/ISEF) Page 37

## The Qualified Scientist

### Qualifications:

- Earned a doctoral/professional degree in a scientific discipline related to student's area of research AND/OR
- Individual with extensive experience and expertise in the student's area of research
- Must be thoroughly familiar with the following regulations that govern the student's area of research including all local, state, Federal and if applicable, non-U.S. national regulations and laws.
- Can also serve as the Adult Sponsor, if that person meets both sets of qualifications
- May live elsewhere and not be local to the student, in which case, a Designated Supervisor 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 Designated Supervisor to serve in this capacity
- Ensuring the proper training of the Student Researcher and/or Designated Supervisor in the necessary procedures
- Completing the required documentation which may include the Regulated Research Institutional Setting Form (1C), the Qualified Scientist Form (2) and the Risk Assessment Form (3), when applicable.



# Designated Supervisor

## Form 3



Science & Engineering Fair of Houston

Risk Assessment Form (3)		
Must be completed before experimentation. May be required for projects involving Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents; recommended for all projects.		
Student's Name(s) _____		
Title of Project _____		
_____		
<b>To be completed by the Student Researcher(s) in collaboration with Designated Supervisor/Qualified Scientist:</b> (All questions must be answered; additional page(s) may be attached.)		
1. Identify and assess the risks and hazards involved in this project.		
_____		
2. a) List all hazardous chemicals, activities or devices to be used; b) identify and list all microorganisms to be used that are exempt from pre-approval (see Potentially Hazardous Biological Agent rules).		
_____		
3. Describe the safety precautions and procedures that will be used to reduce the risks.		
_____		
4. Describe the disposal procedures that will be used (when applicable).		
_____		
5. List the source(s) of safety information.		
_____		
<b>To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):</b> I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan/Project Summary and the International Rules, including the science fair ethics statement and will provide direct supervision.		
_____	_____	_____
Designated Supervisor's Printed Name	Signature	Date of Review (mm/dd/yy)
_____		
Experience/Training as relates to the student's area of research		
_____		
_____	_____	
Position/Institution	Phone or email contact information	

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# Designated Supervisor

## Form 3

**Risk Assessment Form (3)**  
Must be completed before experimentation. May be required for projects involving Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents; recommended for all projects.

Student's Name(s) \_\_\_\_\_  
Title of Project \_\_\_\_\_

### The Designated 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

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

**To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):**  
I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan/Project Summary and the International Rules, including the science fair ethics statement and will provide direct supervision.

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

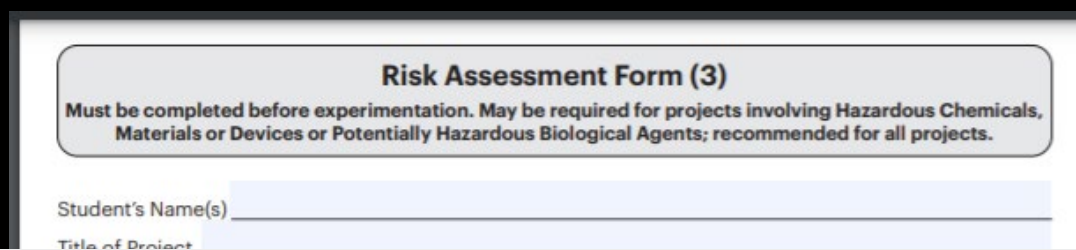
Experience/Training as relates to the student's area of research \_\_\_\_\_

Position/Institution \_\_\_\_\_ Phone or email contact information \_\_\_\_\_

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# Designated Supervisor

## Form 3



**Risk Assessment Form (3)**  
Must be completed before experimentation. May be required for projects involving Hazardous Chemicals, Materials or Devices or Potentially Hazardous Biological Agents; recommended for all projects.

Student's Name(s) \_\_\_\_\_  
Title of Project \_\_\_\_\_

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

<https://www.societyforscience.org/isef/international-rules/roles-and-responsibilities-of-students-and-adults/>



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

Position/Institution \_\_\_\_\_ Phone or email contact information \_\_\_\_\_

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# Hazardous Chemicals, Activities or Devices

- Need to follow local, state and federal laws
- Upload S.D.S for chemicals
- Drones – check FAA site - [https://www.faa.gov/uas/recreational\\_fliers/](https://www.faa.gov/uas/recreational_fliers/)



# Human Subjects

## Form 4



Science & Engineering Fair of Houston

### Human Informed Consent Form

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

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

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

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

Student Researcher(s): \_\_\_\_\_

Title of Project: \_\_\_\_\_

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

Purpose of the project: \_\_\_\_\_

If you participate, you will be asked to: \_\_\_\_\_

Time required for participation: \_\_\_\_\_

Potential Risks of Study: \_\_\_\_\_

Benefits: \_\_\_\_\_

How confidentiality will be maintained: \_\_\_\_\_

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

Adult Sponsor/QS/DS: \_\_\_\_\_ Phone/email: \_\_\_\_\_

#### Voluntary Participation:

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

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

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

Research Participant Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

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

Parent/Guardian Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

# Human Subjects- IRB

## Who is on your campus IRB?

- Must have all 3
  - An educator-not student's teacher
  - A school administrator
  - M.D., PA, RN, psychologist, licensed social worker or licensed clinical professional counselor

<b>Human Participants Form (4)</b> 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
<b>MUST BE COMPLETED BY STUDENT RESEARCHER(S) IN COLLABORATION WITH THE ADULT SPONSOR/DESIGNATED SUPERVISOR/QUALIFIED SCIENTIST:</b>	
1. <input type="checkbox"/> 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. <input type="checkbox"/> I have attached any surveys or questionnaires I will be using in my project or other documents provided to human participants. <input type="checkbox"/> Any published instrument(s) used was/were legally obtained. 3. <input type="checkbox"/> I have attached an informed consent that I would use if required by the IRB. 4. <input type="checkbox"/> Yes <input type="checkbox"/> No Are you working with a Qualified Scientist? If yes, attach the Qualified Scientist Form 2.	
<b>BELOW – IRB USE ONLY</b>	
<b>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.)</b>	
<input type="checkbox"/> Approved with Full Committee Review (3 signatures required) and the following conditions: <b>(All 6 must be answered)</b>	
1. Risk Level (check one): <input type="checkbox"/> Minimal Risk <input type="checkbox"/> More than Minimal Risk 2. Qualified Scientist (QS) Required (Form 2): <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Risk Assessment Required (Form 3): <input type="checkbox"/> Yes <input type="checkbox"/> No 4. Written Minor Assent required for minor participants: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable (No minors in this study) 5. Written Parental Permission required for minor participants: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable (No minors in this study) 6. Written Informed Consent required for participants 18 years or older: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable (No participants 18 yrs or older in this study)	
<b>IRB SIGNATURES (All 3 signatures required)</b> None of these individuals may be the adult sponsor, designated supervisor, qualified scientist or related to (e.g., mother, father of) the student (conflict of interest). <b>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.</b>	
<b>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.</b>	
Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)
<b>Educator</b>	
Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)
<b>School Administrator</b>	
Printed Name	Degree/Professional License
Signature	Date of Approval (Must be prior to experimentation.) (mm/dd/yy)
<small>International Rules: Guidelines for Science and Engineering Fairs 2021-2022. <a href="http://societyforscience.org/ISEF">societyforscience.org/ISEF</a></small>	

# Human Subjects

## What does IRB do?

- Review and approve the research plan **before** experimentation begins.
- Determine if student is doing it through a research facility or through the school. Research Facility will have their own IRB.
- Determine if informed consent is needed or written parental permission (a must for minors).
- Evaluates risk level.
- Decides if QS and/or DS is needed.
- IRB training documents:  
<https://www.societyforsciences-for-fair-committees/>



# Human Subject

## What risk choices does the IRB have to make?

- No more than minimal risk
- More than minimal risk (these require written consent and parental permission)
- May require other forms such as biohazards, depending on project

### Human Informed Consent Form

**Instructions to the Student Researcher(s):** An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist. This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

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

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

Student Researcher(s): \_\_\_\_\_  
Title of Project: \_\_\_\_\_

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

Purpose of the project: \_\_\_\_\_

If you participate, you will be asked to: \_\_\_\_\_

Time required for participation: \_\_\_\_\_

Potential Risks of Study: \_\_\_\_\_

Benefits: \_\_\_\_\_

How confidentiality will be maintained: \_\_\_\_\_

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

Adult Sponsor/QS/DS: \_\_\_\_\_ Phone/email: \_\_\_\_\_

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

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

<b>Adult Informed Consent or Minor Assent</b>	Date Reviewed & Signed: _____ (mm/dd/yy)
Research Participant Printed Name: _____	Signature: _____
<b>Parental/Guardian Permission</b> (if applicable)	Date Reviewed & Signed: _____ (mm/dd/yy)
Parent/Guardian Printed Name: _____	Signature: _____

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# Human Subjects

- Students are prohibited from diagnosing disease, administering medications and/or performing medical procedures
- Students must keep all information confidential and may not publish or identify human participants
- QS/DS will be verified by IRB



# Human Subjects Points of Concern

- Make sure all the IRB committee members sign off. Must be dated before the project begins.
- Evaluate the appropriate risk level.
- Does not go to SRC unless other forms that require SRC are required.
- Students must have all surveys and/or forms with them when they set attend the fair.
- Protecting the anonymity of subjects is important.
- If experimentation is at a Regulated Research Institution, then their IRB must approve it and student will need to obtain documentation.
- Student will need to clarify where data is from, if it is not publicly available and is provided to the student, they will need documentation that it was deidentified prior to receipt.



# Vertebrate Animals

## Form 5

### 4 R's for Vertebrate Animals

- Replace** with invertebrates when possible
- Reduce** the number of animals without compromising statistical validity.
- Refine** experimental protocol to minimize pain and distress of animal
- Respect** animals and their contribution to research.

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 _____	
<b>To be completed by Student Researcher:</b>	
1. Common name (or Genus, species) and number of animals used. _____	
2. Describe completely the housing and husbandry to be provided. Include the cage/pen size, number of animals per cage, environment, bedding, type of food, frequency of food and water, how often animal is observed, etc. Add an additional page as necessary. _____ _____	
3. What will happen to the animals after experimentation? _____	
4. Attach a copy of wildlife licenses or approval forms, as applicable	
5. The ISEF Vertebrate Animal Rules require that any death, illness or unexpected weight loss be investigated and documented by a letter from the qualified scientist, designated supervisor or a veterinarian. If applicable, attach this letter with this form when submitting your paperwork to the SRC prior to competition.	
<b>To be completed by Local or Affiliate Fair Scientific Review Committee (SRC) BEFORE experimentation.</b>	
<b>Level of Supervision Required for agricultural, behavioral or nutritional studies (select one):</b>	
<input type="checkbox"/> Designated Supervisor REQUIRED. Please have applicable person sign below.	
<input type="checkbox"/> Veterinarian and Designated Supervisor REQUIRED. Please have applicable persons sign below.	
<input type="checkbox"/> Veterinarian, Designated Supervisor and Qualified Scientist REQUIRED. Please have applicable persons sign below and have the Qualified Scientist complete Form (2).	
The SRC has carefully reviewed this study and finds it is an appropriate study that may be conducted in a non-regulated research site.	
<b>Local or Affiliate Fair SRC Pre-Approval Signature:</b>	
SRC Chair Printed Name _____	Signature _____ Date of Approval (must be prior to experimentation) (mm/dd/yy) _____
<b>To be completed by Veterinarian:</b>	
<input type="checkbox"/> I have reviewed this research and animal husbandry with the student before the start of experimentation.	
<input type="checkbox"/> I have approved the use and dosages of prescription drugs and/or nutritional supplements.	
<input type="checkbox"/> 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) _____
<b>To be completed by Designated Supervisor or Qualified Scientist when applicable:</b>	
<input type="checkbox"/> 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.	
<input type="checkbox"/> I will directly supervise the experiment.	
Printed Name _____	Email/Phone _____
Signature _____	Date of Approval (mm/dd/yy) _____

# Vertebrate Animals

## Who signs off for animal projects?

- Veterinarian or animal care specialist
- In cases of observation only need a designated supervisor.

## Who decides who signs off?

- SEFH SRC committee member

## What happens if an animals dies during experimentation?

- All testing must stop on experimental group.
- If done at a research facility, they must be euthanized by QS and have IACUC (Institutional Animal Care and Use Committee) review.

Vertebrate Animal Form (5B)	
Required for all research involving vertebrate animals that is conducted 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 _____	
<b>To be completed by Qualified Scientist or Principal Investigator:</b>	
1. Species of animals used: _____ Number of animals used: _____	
2. Describe, in detail, the role of the student in this project: animal procedures and related equipment that were involved, oversight provided and safety precautions employed. (Attach extra pages if necessary.) _____	
3. Was there any weight loss or death of any animal? If yes, attach a letter obtained from the qualified scientist, designated supervisor or a veterinarian documenting the situation and the results of the investigation. _____	
4. Did the student's project also involve the use of tissues? <input type="checkbox"/> No <input type="checkbox"/> 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.	
<b>Qualified Scientist/Principal Investigator</b>	
Printed Name _____	
Signature _____	Date (mm/dd/yy) _____

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# Vertebrates Points of Caution

1. With pets and farm animals, only standard practices can be done.
2. Animals cannot undergo any pain or distress.
3. Animals' water and food intake cannot affect health of animal. *Veterinarians have to be QS* and sign on experiments using nutritional supplements.
4. If swabs of animal saliva are used, then it counts as a bacteria project and will need the appropriate forms.
5. A designated supervisor is required to oversee daily husbandry of animals.
6. Tissue can only be used if not euthanized for purpose of project.
7. Make sure 5B (institution) is filled out after experimentation.



# Vertebrates

**What other animals are also considered vertebrates?**

- Bird and reptile eggs within 3 days of hatching – eggs cannot hatch
- Tadpoles
- Mammalian embryos and fetuses
- Fish after hatching
- Zebra fish 168 hours after post fertilization



# Vertebrates

## What are the rules for using wild animals?

- If using wildlife all local, county, state and national laws that apply.
- Any wildlife caught (with prior approval of authorized officials) must be released unharmed, including fish.
- QS/DS must directly supervise all vertebrate projects, except for observational studies.
- Studies involving behavioral observations only are exempt of SRC approval.



# Potentially Hazardous Biological Agents Forms 6A & 6B

## Potentially Hazardous Biological Agents Risk Assessment Form (6A)

Required for research involving microorganisms, rDNA and other vertebrate fresh/frozen tissue, blood, blood products and body fluids.

SRC/IACUC/IBC approval required before experimentation.

Student's Name(s) \_\_\_\_\_

Title of Project \_\_\_\_\_

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

### SECTION 1: PROJECT ASSESSMENT

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

### SECTION 2: TRAINING

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

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

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

### CERTIFICATION - To be SIGNED by the QUALIFIED SCIENTIST or DESIGNATED SUPERVISOR

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

\_\_\_\_\_  
QS/DS Printed Name                      Signature                      Date of review (mm/dd/yy)

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

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

\_\_\_\_\_  
SRC Printed Name                      Signature                      Date of review (mm/dd/yy)

## Human and Vertebrate Animal Tissue Form (6B)

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

Student's Name(s) \_\_\_\_\_

Title of Project \_\_\_\_\_

To be completed by Student Researcher(s):

1. What vertebrate animal tissue will be used in this study? Check all that apply.  
☐ Fresh or frozen tissue sample  
☐ Fresh organ or other body part  
☐ Blood  
☐ Body fluids  
☐ Primary cell/tissue cultures  
☐ Human or other primate established cell lines
2. Where will the above tissue(s) be obtained? If using an established cell line include source and catalog number.  
\_\_\_\_\_  
\_\_\_\_\_
3. If the tissue will be obtained from a vertebrate animal study conducted at a research institution attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and a copy of IACUC approval.  
\_\_\_\_\_  
\_\_\_\_\_

### To be completed by the Qualified Scientist or Designated Supervisor:

- ☐ I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.
- AND/OR**
- ☐ I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in U.S. Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

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

\_\_\_\_\_  
Title                      Phone/Email

\_\_\_\_\_  
Institution

# Potentially Hazardous Biological Agents

**I have a student that wants to do a bacteria project that uses a restricted bacteria. What steps do I need to follow?**

- Check Q.S. recommendation because what they consider BSL-1 may differ from fair requirements.
- Identify BSL level. Identify type of bacteria if student is opening petri dish. K-12 bacteria is a BSL-1.

**How do I know if the bacteria is restricted?**

- Check biological supply house ordering instructions.



# Points of Caution

- BSL can only be determined by SEFH SRC member, not campus.
  - BSL-1 is typical for school lab.
  - BSL-2 is a Regulated Research Institution
  - BSL-3 and BSL-4 levels are not allowed.
- Check ISEF rules carefully for bacteria.
- If project is done at research institution, the source of all bacteria, cell lines, blood and tissue strains have to be documented by the Qualified Scientist.
  - Make sure form 1C is completed **after** experimentation. Scienceteer will not let the student complete their entry until this form is signed by QS.
- Mold growth of food must be terminated at first evidence of growth. Look at rules for exemptions.



# Final Points

Follow the recommendation from the STEMWizard/ISEF Rules Wizard survey for forms.

Make sure all 5 bibliographies on research plans are filled out in proper format. If using animals, must have animal care reference.

Address for testing location needs to be complete, including CITY, STATE, ZIP CODE.

Make sure research plan is written in 3<sup>rd</sup> person- preferred.

Make sure all forms are completely filled out by all parties.

Read Research Plan and Post Project Summary Instruction for guidelines that are subject specific- found after bibliography.

Abstract is required after experimentation is completed.

Make sure you read all the rules and have your students read them!