INTERNATIONAL SCIENCE AND ENGINEERING FAIR (ISEF)

2018-2019

Rules and Guidelines

Adult Roles and Responsibilities

* Adult Sponsor
* Qualified Scientist
* Designated Supervisor
* Institutional Review Board (IRB)
* Scientific Review Committee (SRC)

Adult Sponsor

* Oversees project to make sure that student
  - is informed of ISEF Rules and Guidelines
  - is aware of risks associated with project
  - is aware of forms required for project
  - will receive proper supervision during experimentation
  - if required, submits project to IRB or SRC
* Teacher usually serves as Adult Sponsor

Qualified Scientist

* Required for some projects
* Doctoral/professional degree related to student research

or

Masters degree with SRC approval

* Completes Form 2 – QS Form

Designated Supervisor

* Animal Care Supervisor for vertebrate animal projects
* Supervises projects involving hazardous chemicals, activities or devices
* Supervises projects requiring a Qualified Scientist when the Qualified Scientist cannot directly supervise the student

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: _____

Address: _____ Email/Phone: _____

1) Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐ No

2. Will any of the following be used?
   a. Human participants ☐ Yes ☐ No
   b. Vertebrate animals ☐ Yes ☐ No
   c. Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products) ☐ Yes ☐ No
   d. Hazardous substances and devices ☐ Yes ☐ No

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

4. Will you directly supervise the student? ☐ Yes ☐ No
   a. If no, who will directly supervise and serve as the Designated Supervisor? _____
   b. Experience/Training of the Designated Supervisor:

To be completed by the Qualified Scientist:

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

_____
Qualified Scientist's Printed Name

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

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

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

_____
Designated Supervisor's Printed Name

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

_____ _____
Phone Email

IRB (Institutional Review Board)

* Reviews human participants studies
* Membership must include:
  * an educator
  * a school administrator
  * someone knowledgeable about evaluating physical and/or psychological risk: MD, PA, RN, psychologist, licensed social worker or licensed clinical professional counselor

SRC
(Scientific Review Committee)

* Reviews some projects before experimentation
* Reviews all projects just prior to competition
* Membership must include:
  * a biomedical scientist (Ph.D., M.D., D.V.M., D.D.S., PharmD., D.O.)
  * an educator
  * one other member

Forms required for all projects

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 Intel ISEF Rules and Guidelines.

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
   - ☐ Vertebrate Animals
   - Potentially Hazardous Biological Agents
     - ☐ Microorganisms ☐ rDNA ☐ Tissues

5. ☐ Items to be completed for **ALL PROJECTS**
   - ☐ Adult Sponsor Checklist (1)
   - ☐ Student Checklist (1A)
   - ☐ Research Plan/Project Summary
   - ☐ 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)

Adult Sponsor's Printed Name	Signature	Date of Review (mm/dd/yy)
Phone	Email	

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: _____

   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

   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)

7. This year's laboratory experiment/data collection:

   _____

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

Name:	_____	_____
Address:	_____	_____
	_____	_____
Phone/ email	_____	_____

10. **Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.**

11. **An abstract is required for all projects after experimentation.**

A Research Plan is required for all projects. It must incorporate all of the relevant topics listed in the Research Plan Instructions.

Research Plan/Project Summary Instructions

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

1. All projects must have a Research Plan/Project Summary
   a. Written prior to experimentation following the instructions below to detail the rationale, research question(s), methodology, and risk assessment of the proposed research.
   b. If changes are made during the research, such changes can be added to the original research plan as an addendum, recognizing that some changes may require returning to the IRB or SRC for appropriate review and approvals. If no additional approvals are required, this addendum serves as a project summary to explain research that was conducted.
   c. If no changes are made from the original research plan, no project summary is required.

2. 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.

3. 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:
      - **Procedures:** Detail all procedures and experimental design including methods for data collection. 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.
   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 termination 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:**
   - Describe Risk Assessment process, supervision, safety precautions and methods of disposal.
   - Material Safety Data Sheets are not necessary to submit with paperwork.

Approval Form (1B)

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

1. To Be Completed by Student and Parent

a. Student Acknowledgment:

- I understand the risks and possible dangers to me of the proposed research plan.
- I have read the Intel ISEF Rules and Guidelines and will adhere to all International Rules when conducting this research.
- I have read and will abide by the following 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 the Intel 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 Intel ISEF Rules. **Attach (1C) and any required institutional approvals (e.g. IACUC, IRB).**

SRC Chair's Printed Name

Signature

Date of Approval (mm/dd/yy)

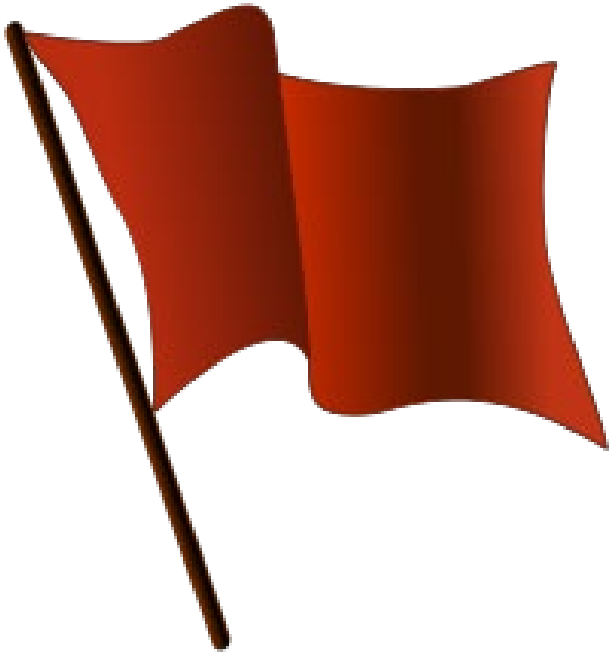
3. Final Intel ISEF Affiliated Fair SRC Approval (Required for ALL Projects)

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 Intel 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)

Some projects required even MORE FORMS



Studies conducted at a research institution, industrial setting or any work site other than home, school or field require Form 1C

Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed AFTER experimentation by the adult supervising the student research 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.)

The student(s) conducted research 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.

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
   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 approva
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 commu
the student research regarding any requirements for my review and/or restrictions of what is publicized.

Supervising Adult's Printed Name _____ Signature _____ Title _____

Institution _____ Date Signed (must be a
mentation) (mm/dd/yy)

Address _____ Email/Phone _____

Continuation studies

* Project based on prior research in the same field of study
* Longitudinal studies are permitted
  * Multi-year study
  * Studies time-based change
* Require form 7

Continuation/Research Progression Projects Form (7)

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

Student's Name(s) _____

To be completed by Student Researcher: List all components of the current project that make it new and different from previous research. The information must be on the form; use an additional form for 2016–2017 and earlier projects.

Components	Current Research Project (2018-2019)	Previous Research Project Year: _____
1. Title		
2. Change in goal/ purpose/objective		
3. Changes in methodology		
4. Variable studied		
5. Additional changes		

Attached are:
☐ 2017–2018 Abstract and Research Plan/Project Summary

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) _____

HAZA

Hazardous chemicals, activities or devices include

* Chemicals
* Equipment
* DEA-Controlled Substances
* Prescription Drugs
* Alcohol and Tobacco
* Firearms and Explosives
* Radiation

Risk Assessment Form (3)

Must be completed before experimentation.

Student's Name(s) _____

Title of Project _____

_____

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

1. List all hazardous chemicals, activities, or devices that will be used; identify microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules).

2. Identify and assess the risks involved in this project.

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

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

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

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

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

_____ _____
Position & Institution Phone or email contact information

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

Projects needing Pre-Approval by either the IRB or SRC

HUMAN

VERT

No vertebrate animal deaths due to the experimental procedures are permitted

* Studies designed or anticipated to cause vertebrate animal death are prohibited.
* Any deaths must be investigated by a qualified individual
* If death was the result of experimental procedure the study must be terminated and the study will not qualify for competition.

Behavioral observations of animals are exempt from SRC review if……..

* There is no interaction with the animals

and

* There is no manipulation of the environment

and

* All federal or state fish, game and wildlife regulations are followed

POTENTIALLY H… …S BIOLOG…

Studies exempt from prior SRC review and no additional PHBA forms required

* Studies using baker's and brewer's yeast (except rDNA studies)
* Studies using Lactobacillus, B. thurgensis, nitrogen-fixing bacteria, oil-eating bacteria, and algae-eating bacteria in natural environment. Not exempt if cultured in a petri dish environment
* Studies of mold growth on food items if experiment terminated at first sign of mold

Studies exempt from prior SRC review that require Form 3

* Studies involving protists, archae and similar microorganisms
* Research using manure for composting, fuel production, or other non-culturing experiments
* Studies using commercially available color change coliform water test kits
* Studies involving decomposition of vertebrate organisms (forensic studies)

Exempt as PHBA tissues

- Plant tissues
- Plant and non-primate established cell and tissue cultures
- Fresh or frozen meat, meat by-products, pasteurized milk, eggs – from grocery stores, restaurants, packing houses
- Hair
- Sterilized teeth
- Fossilized tissue/archeological specimens
- Prepared fixed tissue slides

Important to note:

* All projects involving Risks, Humans, Vertebrate animals and PHBAs require ADDITIONAL information on the research project plan.

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