INTEL INTERNATIONAL SCIENCE AND ENGINEERING FAIR

2016 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
  - is provided proper supervision during experimentation
  - if required, submits project to IRB or SRC

- Teacher usually serves as Adult Sponsor

Qualified Scientist

- Required for **some** projects
- Completes Form 2 – QS Form
- Should have a doctoral/professional degree related to student research

Or

Have applicable experience and expertise with review and approval by the SRC

Qualified Scientist Form (2)

May be required for research involving human participants, vertebrate animals, potentially hazardous biological agents, and DEA-controlled substances. 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. DEA-controlled substances ☐ Yes ☐ No

3. Was this study 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 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. 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

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

I certify that I have reviewed the Research Plan 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

_____ _____
Phone Email

Designated Supervisor

- Supervises projects involving hazardous chemicals, activities or devices
- Supervises projects requiring a Qualified Scientist when the Qualified Scientist cannot directly supervise the student
- For vertebrate animal projects, an Animal Care Supervisor is required

Institutional Review Board (IRB)

- Reviews human participant 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

Scientific Review Committee (SRC)

- Reviews **some** projects before experimentation
- Reviews **all** projects just prior to competition
- Membership must include:
  - a biomedical scientist with an earned doctoral degree
  - an educator
  - one other member

Combined IRB/SRC

- Membership must include:
  - a biomedical scientist with an earned doctoral degree
  - a school administrator
  - an educator
  - someone knowledgeable about evaluating physical and/or psychological risk: MD, PA, RN, psychologist, licensed social worker or licensed clinical professional counselor

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.
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
   - ☐ Approval Form (1B)
     - ☐ Regulated Research Institutional/Industrial Setting Form (1C) (when applicable after completed experiment)
     - ☐ Continuation/Research Progression Form (7) (when applicable)
6. **Additional forms required if the project includes the use of one or more of the following** (check all that apply):
   - ☐ **Humans** (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 (6A)—for projects conducted in a school/home/field research site (SRC prior approval required.)
     - ☐ Vertebrate Animal Form (6B)—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 Institutional Biosafety Committee (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)
   - ☐ **Hazardous Chemicals, Activities and Devices** (No 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)

Note: The following are exempt from prior review but require a risk assessment: projects involving protists, archae and similar microorganisms, for projects using manure for composting, fuel production or other non-culturing experiments, for projects using color change coliform water test kits, microbial fuel cells, and for projects involving decomposing vertebrate organisms.

Adult Sponsor's Printed Name _____ Signature _____ Date of Review _____

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: _____

6. Does this project need 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

   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-school work site(s):

   Name: _____ _____

   Address: _____ _____

   _____ _____

   Phone: _____ _____

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

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

Research Plan/Project Summary

- Required for all projects
- Should incorporate all of the relevant topics listed in the Instructions
- Should summarize what was actually done in the project

Research Plan and Post Project Summary Instructions

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

1. The Research Plan/Project is a succinct detailing of the rationale, research question(s), methodology, and risk assessment of your research project and should be completed before experimentation. For all projects requiring preapproval, this document must be reviewed and approved by the appropriate approval committee (e.g. IRB, IACUC, SRC) before experimentation. ALL changes made to the original plan should be added to the final document as part of the Post Project Summary. For projects not requiring preapproval, this document may be completed either pre- or post-experimentation.
2. All projects should complete a Post Project Summary after experimentation.

The research plan for ALL projects should include the following:

a. What is the **RATIONALE** for your project? Include a brief synopsis of the background that supports your research problem and explain why this research is important scientifically and if applicable, explain any societal impact of your research.
b. State your **HYPOTHESIS(ES), RESEARCH QUESTION(S), 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 that answer research questions or hypotheses.
   - **Discussion of Results and Conclusions:** Discuss the data/results and the conclusions that can be drawn.
d. **Bibliography:** List at least five (5) major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.

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

1. **Human participants research:**
   - **Participants.** Describe who will participate in your study (age range, gender, racial/ethnic composition). Identify any vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
   - Recruitment. Where will you find your participants? How will they be invited to participate?
   - Methods. What will participants be asked to do? Will you use any surveys, questionnaires or tests? What is the frequency and length of time involved for each subject?
   - Risk Assessment
     - Risks. What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize the risks?
     - Benefits. List any benefits to society or each participant.
   - **Protection of Privacy.** Will any identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential or anonymous? If anonymous, describe how the data will be collected anonymously. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will the data be stored? Who will have access to the data? What will you do with the data at the end of the study?
   - **Informed Consent Process.** Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.
2. **Vertebrate animal research:**
   - Briefly discuss potential **ALTERNATIVES** to vertebrate animal use and present a detailed justification for use of vertebrate animals
   - Explain potential impact or contribution this research may have
   - Detail all procedures to be used
     - Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experimentation
     - Detailed chemical concentrations and drug dosages
   - Detail animal numbers, species, strain, sex, age, source, etc.
     - Include justification of the numbers planned for the research
   - Describe housing and oversight of daily care
   - Discuss disposition of the animals at the termination of the study
3. **Potentially hazardous biological agents research:**
   - Describe Biosafety Level Assessment process and resultant BSL determination
   - Give source of agent, source of specific cell line, etc.
   - Detail safety precautions
   - Discuss methods of disposal
4. **Hazardous chemicals, activities & devices:**
   - Describe Risk Assessment process and results
   - Detail chemical concentrations and drug dosages
   - Describe safety precautions and procedures to minimize risk
   - Discuss methods of disposal

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

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs 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**. 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** and all the required forms are included. My signature indicates approval of the **Research Plan** 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 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** and complies with all Intel ISEF Rules.

Regional SRC Chair's Printed Name _____ Signature _____ Date of Approval _____

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

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.

This form MUST be displayed with your project; responses must be on the form.

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 remain on the form as it is required to be displayed at student's project booth.)

The student(s) conducted research at my work site:

a. ☐ to use the equipment b. ☐ to perform experiment(s)/conduct research

1. Have you reviewed the Intel ISEF rules relevant to this project? ☐ Yes ☐ No
2. Is this research a subset of your work? ☐ Yes ☐ No
3. How did the student get the idea for her/his project?
   (e.g. Was the project assigned, picked from a list, an original student idea, etc.)
4. Did the student(s) work on the project as a part of a research group? ☐ Yes ☐ No
   If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)
5. What specific procedures or equipment did the student(s) actually use for the project?
   Please list and describe. (Do not list procedures student only observed.)
6. How independent or creative was the student's/students' work?

Student research projects dealing with human participants, vertebrate animals or potentially hazardous biological agents require review and approval by an institutional regulatory board (IRB/IACUC/IBC). **Copy of approval(s) must be attached, if applicable.**

Supervising Adult's Printed Name _____ Signature _____ Title _____

Institution _____ Date Signed (must be after experimentation) _____

Address _____ Email/Phone _____

Continuation/Research Progression Studies

- Current 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.

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 2014–2015 and earlier projects.

Components	Current Research Project	Previous Research Project
1. Title		2014–2015 2013–2014
2. Change in goal/purpose/ objective		2014–2015 2013–2014
3. Changes in methodology		2014–2015 2013–2014
4. Variables studied		2014–2015 2013–2014
5. Additional changes		2014–2015 2013–2014

Attached are:

☐ 2014–2015 Abstract and Research Plan ☐ 2013–2014 Abstract

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

Human Participants

What are Human Participant Studies?

Human participant studies involve living individuals where there is

- Intervention or interaction with participants

and/or

- Collection of identifiable private information

Exempt studies that do not require IRB review or human participant forms

- Testing of a student-designed invention or prototype
  - Student researcher is the **only one** doing the testing
  - No health hazards
  - No personal data collected
  - Feedback directly related to product
- Studies using pre-existing, publicly available human data

Additional Exempt Studies

- Behavioral observations in unrestricted public settings
  - No interaction
  - No manipulation of environment
  - No recording of any personal identifiers
- Studies using certified de-identified/ anonymous data

Human Participants Research

- The IRB must review and approve the research plan **before** experimentation begins
- Research participants 18 years of age or older must give **informed consent**
- Research participants under 18 must give **assent** and their parents may be required to give **written permission**

Human Participants Research, cont'd

- The IRB evaluates the project and determines
  - Risk level
  - Requirement for Qualified Scientist and/or Designated Supervisor
  - Requirement for written informed consent/assent/parental permission

Risk Evaluation

- No more than minimal risk

  Anticipated harm and discomfort not greater than encountered in daily life

- More than minimal risk

  Anticipated harm or discomfort is greater than encountered in daily life

- More than minimal risk studies should require **written** consent/assent and parental permission. Final determination for this requirement made by the IRB

Types of Risk

- Physical risks
  - Exercise
  - Ingestion, tasting, smelling, application of substances
  - Exposure to potentially hazardous material
- Psychological risks
- Invasion of privacy
- Participant is a member of an at-risk group

Expedited Review

- IRB may elect to do an expedited (one member) review
- Can only be used for projects where
  - Human participants test the functionality of a student-designed invention or prototype with no health of safety hazards and no personal data is collected
  - The student researcher is the only subject of the research that involves no more than minimal risk

IRB Decisions are Documented on Form 4

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 experimentation.)

Student's Name(s) | Title of Project

Adult Sponsor Contact | Phone/Email

Must be completed by Student Researcher(s) in collaboration with the Adult Sponsor/Designated Supervisor/Qualified Scientist:

1. ☐ I have submitted my Research Plan which addresses ALL areas indicated in the Human Participants Section of the Research Plan 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 5 must be answered)

1. Risk Level (check one): ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required: ☐ Yes ☐ No
3. Designated Scientist (DS) Required: ☐ Yes ☐ No
4. Written Minor Assent required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
5. Written Parental Permission required for minor participants:
   ☐ Yes ☐ No ☐ Not applicable (No minors in this study)
6. Written Informed Consent required for participants 18 years or older:
   ☐ Yes ☐ No ☐ Not applicable (No participants 18 yrs or older in this study)

☐ Approved with Expedited Review (1 signature required). Study involves either of the following:

☐ Human participants will only provide feedback on project design/student-designed invention or prototype, etc., no personal data will be collected and there are no health or safety hazards.

☐ Student is the only subject of the research and no more than minimal risk is involved.

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

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

Medical or Mental Health Professional (a psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physician's assistant, or registered nurse)

Printed Name | Degree/Professional License

Signature | Date of Approval (Must be prior to experimentation.)

Educator

Printed Name | Degree

Signature | Date of Approval (Must be prior to experimentation.)

School Administrator

Printed Name | Degree/Professional License

Signature | Date of Approval (Must be prior to experimentation.)

If IRB determines that written informed consent/assent or parental permission is required, documentation is obtained on an "informed consent" document

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 box 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 any 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: _____

_____ _____

Research Participant Printed Name: Signature:

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

_____ _____

Parent/Guardian Printed Name: Signature:

Vertebrate Animals

What is a Vertebrate Animal?

- Live, nonhuman vertebrate mammalian embryos or fetuses
- Bird and reptile eggs within 3 days of hatching
- All other nonhuman vertebrates (including fish) at hatching or birth
- Tadpoles
- Zebrafish embryos 7 days (168 hours) post fertilization

Prohibited Studies

- Induced toxicity studies involving known toxic substances that cause pain, distress or death
- Behavioral experiments with
  - Conditioning using aversive stimuli
  - Mother/infant separation
  - Induced/learned helplessness
- Studies of pain
- Predator/vertebrate prey experiments

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.

SRC Exemptions for Behavioral Observations of Animals

- 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

Research Sites

- School/Home/Field
- Regulated Research Institution
  (must have an IACUC review and approval process)
  - Universities
  - Government research agencies
  - Private research laboratories

Vertebrate Animal Studies Conducted at School/Home/Field may Include

- Studies of animals in their natural environment
- Studies of animals in zoological parks
- Studies of livestock that incorporate standard agricultural practices
- Studies of fish that incorporate standard aquaculture practices

Requirements for Studies at School/Home/Field

- Agricultural, behavioral, observational or supplemental nutritional studies

and

- Non-invasive and non-intrusive with no negative effect on animal's health or well-being

and

- Require SRC pre-review and approval

Requirements for Studies at School/Home/Field (cont'd.)

- SRC must determine the level of supervision appropriate for the study:
  - Designated supervisor
  - Veterinarian
  - Qualified scientist
- Form 5A required

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

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

Level of Supervision Required for agricultural, behavioral or nutritional studies:

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

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

Local or Affiliate Fair SRC Pre-Approval Signature:

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

To be completed by Veterinarian:

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

Printed Name | Email/Phone

Signature | Date of Approval

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

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

Printed Name | Email/Phone

Signature | Date of Approval

Requirements for Studies at Regulated Research Institutions

- Must be approved by IACUC (Institutional Animal Care and Use Committee)
- Local SRC should review project before experimentation
- Experimentation must follow ISEF rules
- Qualified Scientist completes Form 5B which includes documentation of IACUC approval

Vertebrate Animal Form (5B)

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

Student's Name(s) _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

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

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

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

4. Did the student's project also involve the use of tissues?
   - ☐ No
   - ☐ Yes; complete Forms 6A and 6B

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

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

Qualified Scientist/Principal Investigator

Printed Name

Signature Date

Potentially Hazardous Biological Agents

Potentially Hazardous Biological Agents

- Microorganisms (including bacteria, viruses, fungi, etc.)
- Recombinant DNA
- Human or animal fresh/frozen tissues, blood or body fluids

All studies involving potentially hazardous biological agents

- Studies must have prior approval by SRC/IACUC/IBC
- Most studies are prohibited in a home environment
- Studies intended to genetically engineer bacteria with multiple antibiotic resistance are prohibited
- Lab studies utilizing MRSA, VRE and KPC must be conducted in a Regulated Research Institution under documented IBC review and approval. Students are prohibited from culturing CRE.

Risk Assessment

- Required of all PHBA projects
- Defines potential level of harm, injury or disease to plants, animals or humans
- Involves
  - Assignment of biological agent to risk group
  - Determination of level of biological containment
  - Assessment of expertise of adult(s)
  - Assignment of final biosafety level

Risk Assessment, cont'd

- **BSL 1** studies can usually be conducted in a high school or college teaching laboratory.
- **BSL 2** studies are usually conducted in a regulated research institution
- **BSL 3** and **BSL 4** studies are prohibited for ISEF projects
- Form 6A (Potentially Hazardous Biological Agents form) required for most projects involving microorganisms, and for all projects involving rDNA and fresh human and vertebrate animal tissues

Resources to find BSL Level

American Biological Safety Association website:
www.absa.org

American Type Culture Collection website:
www.atcc.org

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 Student Researcher(s) in collaboration with Qualified Scientist/Designated Supervisor:

(All questions are applicable and must be answered; additional page(s) may be attached.)

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 equip., 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.

To be completed by Qualified Scientist or Designated Supervisor

1. What training will the student receive for this project?
2. Do you concur with the biosafety information and recommendation provided by the student researcher above?
   ☐ Yes ☐ No If no, please explain.
3. Experience/training of Designated Supervisor as it relates to the student's area of research (if applicable)

QS/DS Printed Name _____ Signature _____ Date of Signature (mm/dd/yy) _____

To be completed by Local or Affiliate Fair SRC: (Check all that apply.)

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-1 study, which must be conducted at a BSL-1 or above laboratory.
Date of SRC approval (prior to experimentation) _____

☐ The SRC has carefully studied this project's Research Plan and the risk level assessment above **prior to experimentation** and approves this study as a BSL-2 study, which must be conducted at a BSL-2 or above laboratory.
Date of SRC approval (prior to experimentation) _____

☐ This project was conducted at a Research Institution and was reviewed and approved by the appropriate institutional board (e.g. IACUC, IBC) before experimentation at a BSL-1 or BSL-2 laboratory and complies with the Intel ISEF rules. The required institutional forms are attached.
Date of SRC approval (after experimentation) _____

☐ The Research Institution where this study was conducted does not require approval for this type of study. Attached is institutional documentation certifying the above. The student has received proper training and the project complies with Intel ISEF rules.
Date of SRC approval _____

SRC Chair's Printed Name _____ Signature _____

Studies Exempt from Prior SRC Review and Do Not Require PHBA Forms

- Studies using baker's and brewer's yeast (except rDNA studies)
- Studies using Lactobacillus, nitrogen-fixing bacteria, B. thuringinensis, 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 involving water or soil not concentrated in media conducive to growth
- Studies of mushrooms and slime mold
- Studies with E.coli K-12 done at school, except in rDNA studies

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)
- Studies with microbial fuel cells

Studies Involving Unknown Microorganisms

- **BSL 1** if
  - Organisms cultured in plastic petri dish
  - Culture dish remains sealed throughout experiment
  - Culture dish disposed of in appropriate manner
- **BSL 2** if
  - petri dish is opened

rDNA Technologies

- Experiments with **BSL 1** organisms can be done in BSL 1 lab with a Qualified Scientist or trained Designated Supervisor

- Experiments with **BSL 2** organisms must be done in a regulated research institution with a Qualified Scientist

Tissues

- If animal is euthanized solely for student project – vertebrate animal study which requires IACUC approval
- If animal is euthanized for a purpose other than student project – tissue study
- Classification as **BSL 1** or **2** based on source of tissue and possibility of containing infectious agents
- All studies with human or wild animal blood are **BSL 2**. Studies with domestic animal blood are **BSL 1**.
- Studies with human body fluids which can be associated with a person must have IRB approval

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, hooves, nails and feathers
- Sterilized teeth
- Fossilized tissue/archeological specimens
- Prepared fixed tissue slides

Form 6B

- Required for all projects using
  - Fresh/frozen tissue
  - Primary cell cultures
  - Human and other primate established cell lines and tissue cultures
  - Blood and blood products
  - Body fluids

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 date 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 Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

Printed Name _____ Signature _____ Date of Approval (Must be prior to experimentation.) _____

Title _____ Phone/Email _____

Institution _____

Hazardous Chemicals, Activities, or Devices

Hazardous Chemicals, Activities or Devices

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

General Rules

- Studies do not require prior SRC review and approval
- All studies require a Risk Assessment documented on Form 3
- DEA - controlled substances require a Qualified Scientist
- All other studies require a Designated Supervisor

DEA-Controlled Substances

- Consult DEA list of controlled substances
- All studies require Qualified Scientist
- Controlled substances on Schedule 1 require DEA protocol review

Firearms and Explosives

- Must adhere to local training and certification requirements

Alcohol and Tobacco

- Students must adhere to U.S. regulations as well as local and country laws
- Production of wine or beer by adults is allowable. Parents must directly supervise any student research involving legal home production
- Alcohol distillation for fuel production or other non consumable products can be conducted at school with TTB permit obtained by school officials

Prescription Drugs

- Cannot be administered to human subjects
- Animal administration must follow ISEF vertebrate animal guidelines

Hazardous Chemicals

- Refer to MSDS Sheets for safety and disposal information

Hazardous Devices

- Involve level of risk beyond that encountered in student's everyday life
- Follow handling guidelines

Radiation

- Studies using non-ionizing radiation and studies of ionizing radiation using voltage < 10 kvolts require a documented risk assessment on Form 3

- Studies of ionizing radiation using voltage between 10 and 25 kvolts must be preapproved by the SRC and have a documented risk assessment

- Studies of ionizing radiation using voltage exceeding 25 kvolts must be conducted in a site with a Licensed Radiation Program and preapproved by the institution

Form 3

- Required for all projects involving
  - DEA-Controlled Substances
  - Prescription Drugs
  - Alcohol and Tobacco
  - Hazardous Chemicals
  - Hazardous Devices
  - Hazardous Activities
  - Radiation

Risk Assessment Form (3)

Required for projects using hazardous chemicals, activities or devices and microorganisms exempt from pre-approval. 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. Identify and assess the risks involved in this project.

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

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

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 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 _____