

Checklist for Adult Sponsor (1)

This completed form is required for ALL projects.

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

Student's Name(s): _____

Project Title: _____

1. I have reviewed the ISEF Rules and Guidelines.
2. I have reviewed the student's completed Student Checklist (1A) and Research Plan/Project Summary.
3. I have worked with the student and we have discussed the possible risks involved in the project.
4. The project involves one or more of the following and requires prior approval by an SRC, IRB, IACUC or IBC:
 - Humans Potentially Hazardous Biological Agents
 - Vertebrate Animals Microorganisms rDNA Tissues
5. Items to be completed for **ALL PROJECTS**
 - Adult Sponsor Checklist (1) Research Plan/Project Summary
 - Student Checklist (1A) Approval Form (1B)
 - Regulated Research Institutional/Industrial Setting Form (1C) (when applicable; after completed experiment)
 - Continuation/Research Progression Form (7) (when applicable)

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

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

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.

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 end of the study.
3. **Potentially hazardous biological agents research:**
 - a. Give source of the organism and describe BSL assessment process and BSL determination.
 - b. Detail safety precautions and discuss methods of disposal.
4. **Hazardous chemicals, activities & devices:**
 - Describe Risk Assessment process, supervision, safety precautions and methods of disposal.
 - Material Safety Data Sheets are not necessary to submit with paperwork.

Bacteria Research Plan

Research plan should include:

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.

Approval Form (1B)

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

1. To Be Completed by Student and Parent

a. Student Acknowledgment:

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

Student's Printed Name

Signature

Date Acknowledged (mm/dd/yy)
(Must be prior to experimentation.)

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

Parent/Guardian's Printed Name

Signature

Date Acknowledged (mm/dd/yy)
(Must be prior to experimentation.)

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

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

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

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

SRC/IRB Chair's Printed Name

Signature

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

OR

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

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

SRC Chair's Printed Name

Signature

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

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

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

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

Regional SRC Chair's Printed Name

Signature

Date of Approval (mm/dd/yy)

State/National SRC Chair's Printed Name
(where applicable)

Signature

Date of Approval (mm/dd/yy)

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 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

Potentially Hazardous Biological Agents Risk Assessment Form (6A)

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

Student's Name(s) _____

Title of Project _____

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

SECTION 1: PROJECT ASSESSMENT

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

SECTION 2: TRAINING

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

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

- Experimentation on the microorganisms/cell lines/tissues to be used in this study will NOT be conducted at a Regulated Research Institution, but will be conducted at a (check one) ___ BSL-1 or ___ BSL-2 laboratory. 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 reviewed that the student received appropriate training and the project complies with ISEF rules.

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 above.

SRC Printed Name

Signature

Date of review (mm/dd/yy)