

IRB Project Submission: Bacteria, Viruses, Viroids, Fungi and Parasites

Please read parameters for Bacteria projects first:

- Students are prohibited from designing or participating in BSL-3 or BSL-4 research
- Although BSL-1 projects do not need SRC approval, BSL-1 bacteria MAY not be cultured at home, cultures must be done in a school laboratory that houses an incubator that is away from the general population of students.

Instructions for filling out forms:

- Please fill out the paperwork digitally using Chrome.
- Please do not handwrite.
- Projects started prior to IRB approval may be disqualified. Your teacher will be notified of the approval status.
- In addition to forms needed for the IRB, for projects moving on to AZSEF and ISEF, please fill out and gather signatures for the following and keep these for your own records: Forms 1, 1A, and 3. Some projects may also require 1C and 6A. Ask your teacher which are required for your project. To access the forms, follow this link.

Forms REQUIRED for this category:

1) Complete Approval form (1B) (Only fill out Box #1. Print, obtain signatures and submit to teacher with all of your paperwork.

2) Qualified Scientist (2)

3) Complete Potentially Hazardous Biological Agents Risk Assessment Form (6A)
Student fills out name and title of project and Section 1, Student will ask the Qualified Scientist to fill out section 2. IRC will send paperwork to SRC to fill out Section 3 and Section 4.

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.)
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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.)
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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)
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State/National SRC Chair's Printed Name (where applicable)	Signature	Date of Approval (mm/dd/yy)
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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: _____

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

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 MICROORGANISMS, CELL LINES 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 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 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 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 Intel 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)

The IRB Research Plan is REQUIRED for all projects.

This plan is for IRB approval only and differs from requirements for ISEF.

Project Title: _____

Original Submission Date: _____ Revised Submission Date: _____

Student 1 _____ Grade: _____

Student 2 _____ Grade: _____

Student 3 _____ Grade: _____

School: _____ Teacher: _____

BSL-1 _____ BSL-2 _____ (SRC approval required for BSL 2)

Project Summary

Number of students working on the project cannot exceed 3 students:

1. **Project Title:**

2. **List all locations of where the experimentation will occur:**

Home: _____ School: _____ Research Facility: _____

Other: (Please Describe): _____

3. **Materials:** (List all items to be used in the experiment/test. Include quantities. Concentrations, dimensions, and units, etc.)

4. **Give the source of the organisms being used in the project:**

5. **Describe the BSL assessment process and BSL Determination:**

6. **Procedures:** (List all procedures from start of experimentation to the end, please include projected start date. This list should be clear enough that the IRB could duplicate the experiment using the exact same methods as the student)

7. **Discuss the risks involved in the project:**

8. **Detail the safety precautions:**

9. **Discuss methods of disposal:** (BSL-1 and BSL-2 organisms must be disposed of at the end of experimentation by following their biosafety level disposal guidelines. Example: Autoclave or 10% bleach solution, biosafety pick up or check manufacturer's suggestions for disposal. IF a biosafety pick up will occur, please include the contact information of the company.)

10. **Print and attach SDS Forms to this packet**

Teacher Name _____

Teacher Signature _____ Date _____

Principal's Name _____

Principal's Signature _____ Date _____

This page is only to be use if not enough space was available in the above fillable forms. CLEARLY IDENTIFY WHICH SECTION IS BEING ADDED.

All Bacteria, Viruses, Viroids, Fungi and Parasite projects require a Qualified Scientist OR a Qualified Scientist and a Designated Supervisor.

The **Qualified Scientist (QS)** is required to have a degree, certification or expertise in the area of experimentation. A parent may be the QS if he/ she meets the requirements. The QS certifies that they have reviewed and approves of the Research Plan/Project Summary prior to the start of the experimentation. QS is responsible for training student for all safety requirements related to the project. QS is responsible for having student supervised by a designated supervisor if they are not present to directly supervise during the experimentation.

15. Name of Qualified Scientist _____

16. Phone Number of Qualified Scientist: _____

17. Educational background of QS: _____

18. Experience/Training as it relates to project:

19. Signature of QS: _____ Date: _____

The **Designated Supervisor, (DS)**, certifies that they have reviewed the Research Plan/Project Summary and have been trained in the techniques to be used by the student and agrees to provide direct supervision in the absence of the Qualified Scientist. The DS may be a teacher or a parent if they are trained to supervise.

20. Name of Designated Supervisor: _____

21. Phone Number of Designated Supervisor: _____

22. Signature of DS: _____ Date: _____

STUDENT AND PARENT SIGNATURES:

I understand that SRC approvals might take up to 8 weeks in some cases. Any changes that may occur following SRC/IRB submission will require an additional review by the boards. Students and parents have reviewed the forms and paperwork and agree to follow safety protocol as set forth by ISEF guidelines.

23. Student 1 signature _____

24. Parent 1 Signature: _____

25. Student 2 Signature: _____

26. Parent 2 Signature: _____

27. Student 3 Signature: _____

28. Parent 3 Signature: _____

Site Coordinator Signature: _____

Date: _____

Approved: _____ Not approved at this time: _____

Please revise: _____

Revision Date: _____

Approved: Yes _____ No _____

Teacher Signature: _____

Site Coordinator Signature: _____