IRB Project Submission: Vertebrates and Invertebrates

Read this section first for parameters on Vertebrates

- Animals must be treated kindly and cared for properly.
- Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species. They must be given a continuous, clean (uncontaminated) water and food supply. Cages, pens and fish tanks must be cleaned frequently.
- Proper care must be provided at all times, including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and well-being. A Designated Supervisor is required to oversee the daily care of the animals.
- Projects involving any vertebrate organisms will require a SRC approval.
- Projects involving guppies require SRC approval
- Projects that require manipulation of an animal's environment require SRC approval.
- Elementary students may only use personal pets as vertebrate studies
- No genetic modifications allowed to ANY organisms
- Almost all vertebrate projects require a Veterinarian's signature. (Goldfish and guppies are exempt from vet signature.)
- Poisonous and venomous organisms may not be used in projects
- Organisms with the potential to carry harmful diseases or infections must obtain IRB approval. (Examples: Roaches, fleas)
- Animals may not be captured from or released into the wild without approval of authorized wildlife or other regulatory officials. All appropriate methods and precautions must be used to decrease stress.
- Studies involving behavioral observations of animals are exempt from prior SRC review if ALL of the following apply:

    a. There is no interaction with the animals being observed

    b. There is no manipulation of the animal environment in any way.

    c. The study meets all federal and state agriculture, fish, game and wildlife laws and regulations

Instructions for filling out the forms

- Please fill out the paperwork digitally, do not handwrite.
- Browser recommendation: Chrome
- Projects started prior to IRB approval may be disqualified.
- Your teacher will be notified of the approval status.
- Projects which are continuations of a previous year's work and which require IRB/SRC approval must undergo the review process with the current year proposal prior to experimentation/data collection for the current year.
- Please see your teacher for continuation paperwork if you are continuing to work on a previous project.
- 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. Ask your teacher which are required for your project. To access the forms, follow this link.

Forms REQUIRED for this category are attached below

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 Vertebrate Animal Forms (5A and 5B).

4) Form 6B will be required if Human and Vertebrate Animal Tissue are used

Rules pertaining to vertebrates were developed to help student researchers adhere to the federal regulations governing professional scientists and to protect the welfare of both animal subjects **and** the student researcher. Health and well-being is of high priority when students conduct research with animal subjects.

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)

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

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. (Fees may apply.)

Printed Name	Email/Phone
Signature	Date of Approval (mm/dd/yy)

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 (mm/dd/yy)

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 (mm/dd/yy)

The 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: _____

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**:

3. Explain why animals must be used in this project, including the reasons for the choice of species, **the source of animals and the number of animals to be used; description, explanation, or identification of alternatives to animal use that were considered**, and the reasons these alternatives were unacceptable.

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

5. **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.

6. **Detail the safety precautions and procedures that will be used to reduce risk:**

7. **List your sources of safety information:**

8. **Discuss methods of disposal (when applicable):**

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

10. **Teacher's name:**_____

11. **Teacher's Signature:**_____

12. Name of Principal**:** _____

13. Principal's Signature: _____

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

14. A Qualified Scientist or Designated Supervisor must directly supervise all research involving vertebrate animals, except for observational studies. 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 relates to the student's research:

19. **Signature of Qualified Scientist:** _____**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.

The use of hazardous chemicals and devices and involvement in hazardous activities require direct supervision by a Designated Supervisor.

20. Name of Designated Supervisor: _____
21. Phone Number of Designated Supervisor: _____
22. **Signature of Designated Supervisor:** _____**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.

https://www.scribd.com/document/382276110/Intel-Isef-2018-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: _____

Notes: _____

Human and Vertebrate Animal Tissue Form (6B)

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

Student's Name(s)_____

Title of Project _____

To be completed by Student Researcher(s):

1. What vertebrate animal tissue will be used in this study? Check all that apply.
   - ☐ Fresh or frozen tissue sample
   - ☐ Fresh organ or other body part
   - ☐ Blood
   - ☐ Body fluids
   - ☐ Primary cell/tissue cultures
   - ☐ Human or other primate established cell lines

2. Where will the above tissue(s) be obtained. If using an established cell line include source and catalog number.

3. If the tissue will be obtained from a vertebrate animal study conducted at a research institution attach a copy of the IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and a of IACUC approval.

To be completed by the Qualified Scientist or Designated Supervisor:

☐ I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her by myself or qualified personnel from the laboratory; and that if vertebrate animals were euthanized they were euthanized for a purpose other than the student's research.

AND/OR

☐ I certify that the blood, blood products, tissues or body fluids in this project will be handled in accordance with the standards and guidance set forth in U.S. Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

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

Title	Phone/Email

Institution