SCIENCE FAIR SERIES:

RESEARCH PLAN

Forms – Rules and Guidelines

Forms

- Required to participate at District Level of Science Fair
- Assure students are working with proper safety protocols
- Assure students have sufficient oversight when dealing with risk

Adult roles and responsibilities

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

Adult sponsor

- Oversees project
- Completes Form 1 – Checklist for Adult Sponsor

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

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

☐ **Humans,** including student designed inventions/prototypes. (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.)
- ☐ Human Participants Form (4) or appropriate Institutional IRB documentation
- ☐ Sample of Informed Consent Form (when applicable and/or required by the IRB)
- ☐ Qualified Scientist Form (2) (when applicable and/or required by the IRB)

☐ **Vertebrate Animals** (Requires prior approval, see full text of the rules.)
- ☐ Vertebrate Animal Form (5A)-for projects conducted in a school/home/field research site (SRC prior approval required.)
- ☐ Vertebrate Animal Form (5B)-for projects conducted at a Regulated Research Institution. (Institutional Animal Care and Use Committee (IACUC) approval required prior experimentation.)
- ☐ Qualified Scientist Form (2) (Required for all vertebrate animal projects at a regulated research site or when applicable)

☐ **Potentially Hazardous Biological Agents** (Requires prior approval by SRC, IACUC or IBC, see full text of the rules.)
- ☐ Potentially Hazardous Biological Agents Risk Assessment Form (6A)
- ☐ Human and Vertebrate Animal Tissue Form (6B)-to be completed in addition to Form 6A when project involves the use of fresh or frozen tissue, primary cell cultures, blood, blood products and body fluids.
- ☐ Qualified Scientist Form (2) (when applicable)
- ☐ The following are exempt from prior review but require a Risk Assessment Form 3: projects involving protists, archae and similar microorganisms, for projects using manure for composting, fuel production or other non-culturing experiments, projects using color change coliform water test kits, microbial fuel cells, and projects involving decomposing vertebrate organisms.

☐ **Hazardous Chemicals, Activities and Devices** (No SRC prior approval required, see full text of the rules.)
- ☐ Risk Assessment Form (3)
- ☐ Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable)

☐ **Other**
- ☐ Risk Assessment Form (3)

☐ **I attest to the information checked above and that I have read and agree to abide by the science fair ethics statement.**

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

Phone	Email

Qualified Scientist

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

  or

  Masters degree with SRC approval

- Completes Form 2 – QS Form

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 and the science fair ethics statement 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

Designated Supervisor

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

IRB (Institutional Review Board)

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

SRC (Scientific Review Committee)

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

FORMS REQUIRED FOR ALL PROJECTS

Checklist for Adult Sponsor (1)

This completed form is required for ALL projects.

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

Student's Name(s): _____

Project Title: _____

1. ☐ I have reviewed the ISEF Rules and Guidelines, including the science fair ethics statement.
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:
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   - ☐ Vertebrate Animals
   - ☐ Potentially Hazardous Biological Agents
     - ☐ Microorganisms ☐ rDNA ☐ Tissues
5. ☐ Items to be completed for **ALL PROJECTS**
   - ☐ Adult Sponsor Checklist (1)
   - ☐ Student Checklist (1A)
   - ☐ Research Plan/Project Summary
   - ☐ Approval Form (1B)
   - ☐ Regulated Research Institutional/Industrial Setting Form (1C) (when applicable; after completed experiment)
   - ☐ Continuation/Research Progression Form (7) (when applicable)

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

☐ **Humans,** including student designed inventions/prototypes. (Requires prior approval by an Institutional Review Board (IRB); see full text of the rules.)
- ☐ Human Participants Form (4) or appropriate Institutional IRB documentation
- ☐ Sample of Informed Consent Form (when applicable and/or required by the IRB)
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- ☐ Risk Assessment Form (3)
- ☐ Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable)

☐ **Other**
- ☐ Risk Assessment Form (3)

☐ **I attest to the information checked above and that I have read and agree to abide by the science fair ethics statement.**

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. Source of Data:
   ☐ Collected self/mentor ☐ Other Describe/url: _____
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

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

Research Plan/Project Summary Instructions

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

- 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.

- 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.

- 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, and when applicable, the source of data used. 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.

- **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.

- 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.

- 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.

- 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, and when applicable, the source of data used. 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.

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 science fair 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)

Research Institutions

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

Regulated Research Institutional/Industrial Setting Form (1C)

This form must be completed AFTER experimentation by the adult supervising the student research conducted in a regulated research institution, industrial setting or any work site other than home, school or field.

Student's Name(s) _____

Title of Project _____

To be completed by the Supervising Adult in the Setting (NOT the Student(s)) after experimentation:
(Responses must be on the form as it is required to be displayed at student's project booth; please do not print double-sided.)

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

1. Did you or your proxy (e.g. graduate student, postdoc, employee) mentor or provide substantial guidance to the student researcher? ☐ Yes ☒ No
   a. If no, describe your and/or your institution's role with the student researcher and his/her project (e.g. supervised use of equipment on site without ongoing mentorship and sign below.

   b. If yes, complete questions 2–5.

2. Is the student's research project a subset of your ongoing research or work? ☐ Yes ☐ No
   Use questions 3, 4 and 5 to detail how the student's project was similar and/or different from ongoing research or work at your site. If this project is under a grant and needs to be acknowledged, please list the grant statement here.

3. Describe the independence and creativity with which the student:
   a. developed the hypotheses or engineering goals for the research project

   b. designed the methodology for his/her research project

   c. analyzed and interpreted data

Continuation Research

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

Continuation/Research Progression Projects Form (7)

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

Student's Name(s) _____

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

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

Attached are:
☐ Abstract and Research Plan/Project Summary, Year _____

I hereby certify that the above information is correct and that the current year Abstract & Certification and project display board properly reflect work done only in the current year.

Student's Printed Name(s)	Signature	Date of Signature (mm/dd/yy)

HUMAN SUBJECTS

What are human subjects' studies?

Human Subjects studies involve living individuals where there is

- Intervention or interaction with subjects

and/or

- Collection of identifiable private information

Exempt human studies – do not require IRB review nor human subject forms

- Product testing of a student invention, program, concept, etc.
  - 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 subjects research

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

Human subjects research

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

Human subjects research (continued)

- The IRB evaluates the project and determines
  - Risk level
  - Requirement for Qualified Scientist
  - 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
- Subject member of an at-risk group

IRB Can Waive Requirement of Informed Consent If..

- Study with minimal risk

  and

- Anonymous data collection

  and

- One of the following
  - Study of normal educational practices
  - Behavioral study with no manipulation
  - Surveys of perception, cognition, game theory
  - Physical activity with no more than minimal risk (routine physical activities, tasting of commonly available food or drink, etc.)

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 recruitment or data collection.)

Student's Name(s)

Title of Project

Adult Sponsor

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/Project Summary which addresses ALL areas indicated in the Human Participants Section of the Research Plan/Project Summary 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 6 must be answered)**

1. Risk Level (check one) : ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist (QS) Required (Form 2): ☐ Yes ☐ No
3. Designated Supervisor (DS) Required (Form 3): ☐ 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)

IRB SIGNATURES (All 3 signatures required) 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, doctor of pharmacy, or registered nurse) with expertise related to this project.

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

Educator

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

School Administrator

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

Written Informed Consent

- Written informed consent is obtained from the research subject on a form like the sample provided

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 area 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 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 (mm/dd/yy) Date Reviewed & Signed: _____

_____ _____

Research Participant Printed Name: Signature:

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

_____ _____

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

Prohibited Animal Studies

- Induced toxicity studies involving a poison or toxin that could impair health or destroy life
- Behavioral experiments with
  - Operant conditioning with aversive stimuli
  - Mother/infant separation
  - Induced/learned helplessness
- Studies of pain
- Predator/vertebrate prey experiments

Additional Restrictions

- A weight loss or growth retardation greater than 15% is not permitted
- A death rate of 30% or greater in any group or subgroup is not permitted

Behavioral observations of animals are exempt from SRC Review

- 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

Regulated Facilities

- Examples of non-regulated sites
  - Home
  - School
  - Farm, ranch
  - Zoological parks
  - Field

- Examples of regulated sites (must have an IACUC review and approval process)
  - Universities
  - Government research agencies
  - Private research laboratories

Non-Regulated Facility Requirements

- 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

Additional Non-Regulated Facility Requirements

- SRC determines 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 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 (select one):

- ☐ 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)

Regulated Facility Requirements

- Must be approved by IACUC (Institutional Animal Care and Use Committee)
- Local SRC should review project before experimentation
- Experimentation must follow ISEF guidelines and adhere to restrictions regarding pain
- QS 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 (mm/dd/yy)

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS

Potentially hazardous biological agents include

- 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

- Must have prior approval by SRC/IACUC
- Most studies are prohibited in a home environment
- Studies intended to genetically engineer bacteria with multiple antibiotic resistance are prohibited

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 (continued)

- 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

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 seen and approved the research plan and supporting documentation and acknowledges the accuracy of the responses above.

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)

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

- Studies using baker's and brewer's yeast (except rDNA studies)
- Studies using Lactobacillus, B. thurgensis, nitrogen-fixing bacteria, oil-eating bacteria, slime mold and algae-eating bacteria in natural environment. No exempt if cultured in a petri dish environment.

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 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 QS or trained DS
- Experiments with BSL 2 organisms must be done in a regulated research institution with a QS

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

Classifications

- 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
- Established cell and tissue cultures
- Meat and meat by-products – grocery stores, restaurants, packing houses
- Hair
- Sterilized teeth
- Fossilized tissue/archeological specimens
- Prepared fixed tissue slides

Form 6B

- Required for all projects using
  - Fresh/frozen tissue
  - Primary cell 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 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

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES

Hazardous chemicals, activities or devices include

- 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

Risk Form

- Required for all projects involving
  - DEA-Controlled Substances
  - Prescription Drugs
  - Alcohol and Tobacco
  - Hazardous Chemicals
    - Refer to MSDS Sheets for safety and handling guidelines
  - Hazardous Devices
    - Involve level of risk beyond that encountered in student's everyday life
  - Hazardous Activities
  - Radiation
    - Non-ionizing
    - Ionizing

Risk Assessment Form (3)

Must be completed before experimentation.

Student's Name(s) _____

Title of Project _____

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

1. List all hazardous chemicals, activities, or devices that will be used; identify microorganisms exempt from pre-approval (see Potentially Hazardous Biological Agent rules).
2. Identify and assess the risks and hazards involved in this project.
3. Describe the safety precautions and procedures that will be used to reduce the risks.
4. Describe the disposal procedures that will be used (when applicable).
5. List the source(s) of safety information.

To be completed and signed by the Designated Supervisor (or Qualified Scientist, when applicable):
I agree with the risk assessment and safety precautions and procedures described above. I certify that I have reviewed the Research Plan/Project Summary and the International Rules, including the science fair ethics statement 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

Visit NEOHSTEM Alliance Website

- For more project information
- http://neohstem.org/

Contact the Science & Technology Division at Akron-Summit County Public Library

- 330-643-9075
- stdiv@akronlibrary.org