

INTERNATIONAL SCIENCE AND ENGINEERING FAIR

Rules and Guidelines



Adult Roles and Responsibilities



- Adult Sponsor
- Designated Supervisor
- Qualified Scientist
- IRB
- 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 and must be completed before experimentation

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

Student's Name: _____

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.
- 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:

<input type="checkbox"/> Humans	Potentially Hazardous Biological Agents:	<input type="checkbox"/> Microorganisms	<input type="checkbox"/> rDNA	<input type="checkbox"/> Tissues
<input type="checkbox"/> Vertebrate Animals				
- 5) Forms to be completed for ALL Projects:

<input type="checkbox"/> Adult Sponsor Checklist (1)	<input type="checkbox"/> Research Plan
<input type="checkbox"/> Student Checklist (1A)	<input type="checkbox"/> Approval Form (1B)
<input type="checkbox"/> Regulated Research Institutional/Industrial Setting Form (1C) (when applicable)	
<input type="checkbox"/> Continuation Form (7) (when applicable)	

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

- Humans** (Requires prior approval by an Institutional Review Board (IRB), see pp. 13-16 for full text of the rules)
 - Human Subjects Form (4)
 - Qualified Scientist Form (2) (if applicable and/or required by the IRB)
- Vertebrate Animals** (Requires prior approval, see pp. 17-20 for full text of the rules)
 - Vertebrate Animal Form (5A) - for projects conducted in a non-regulated 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 Institutional Biosafety Committee (IBC), see pp. 21-24 for full text of the rules.)
 - Potentially Hazardous Biological Agents Form (6A)
 - Human and Vertebrate Animal Tissue Form (6B) - to be completed in addition to Form 6A when project involves the use of fresh tissue, primary cell cultures, blood, blood products and body fluids.
 - Qualified Scientist Form (2) (when applicable)
- Hazardous Chemicals, Activities and Devices** (No prior approval required, see pp.25-27 for full text of the rules.)
 - Risk Assessment Form (3)
 - Qualified Scientist Form (2) (required for projects involving DEA-controlled substances or when applicable)

Adult Sponsor's Printed Name

Signature

Date of Review
(Must be prior to experimentation.)

Phone

Email



Designated Supervisor

- Supervises project when Qualified Scientist cannot directly supervise
- “Animal Care Supervisor” for animal projects
- Supervises projects using Hazardous Chemicals, Activities or Devices



Qualified Scientist

- Required for some projects
- Doctoral/professional degree related to student research
- Completes Form 2 – QS Form



Qualified Scientist Form (2)

May be required for research involving human subjects, vertebrate animals, potentially hazardous biological agents, and DEA-controlled substances. Must be completed and signed before the start of student experimentation.

Student's Name _____

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 subjects yes no

b) Vertebrate animals yes no

c) Potentially hazardous biological agents (microorganisms, rDNA and tissues, including blood and blood products) yes no

d) DEA-classed substances. yes no

3) 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: _____

4) Describe the safety precautions and training necessary for this project: _____

To be completed by the Qualified Scientist:

I certify that I have reviewed and approved the Research Plan prior to the start of the experimentation. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in the Research Plan. I understand that a Designated Supervisor is required when the student is not conducting experimentation under my direct supervision.

Qualified Scientist's Printed Name

Signature Date of Approval

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

I certify that I have reviewed the Research Plan and have been trained in the techniques to be used by this student, and I will provide direct supervision.

Designated Supervisor's Printed Name

Signature Date of Approval

Phone Email

IRB (Institutional Review Board)



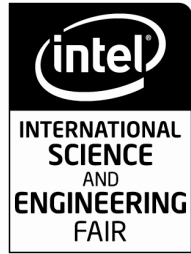
- Reviews human subject studies
- Membership
 - science teacher
 - school administrator
 - someone knowledgeable about evaluating risk: MD, PA, RN, psychiatrist, psychologist, licensed social worker

SRC (Scientific Review Committee)



- Reviews some projects before experimentation
- Reviews all projects just prior to competition
- Membership
 - biomedical scientist (Ph.D., M.D., D.V.M., D.D.S., D.O.)
 - science teacher
 - one other member

Forms required for all projects





Student Checklist (IA)

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) Is this a continuation from a previous year? Yes No
If Yes:
a) Attach the previous year's Abstract Form 1A and Research Plan
b) Explain how this project is new and different from previous years on Continuation Form (7)
- 6) This year's laboratory experiment/data collection will begin: (must be stated (mm/dd/yy))
Projected Start Date: _____ Projected End Date: _____
(Projected dates are required for projects that require SRC/IRB prior review)
ACTUAL Start Date: _____ ACTUAL End Date: _____
- 7) Where will you conduct your experimentation? (check all that apply)
 Research Institution School Field Home Other: _____
- 8) List name and address of all non-school work site(s):
Name: _____
Address: _____

Phone: _____
- 9) Complete a Research Plan as described on page 31 and attach to this form.
- 10) An abstract is required for all projects after experimentation (see page 28).



Research Plan

REQUIRED for ALL Projects Before Experimentation
A complete research plan must accompany Checklist for Student (IA)

Provide a typed research plan and attach to Student Checklist (IA).

The research plan for ALL projects is to include the following:

- A. Question being addressed
- B. Hypothesis/Problem/Engineering Goals
- C. Description in detail of method or procedures (The following are important and key items that should be included when formulating ANY AND ALL research plans.)
 - **Procedures:** Detail all procedures and experimental design to be used for data collection
 - **Data Analysis:** Describe the procedures you will use to analyze the data that answer research question or hypothesis
- D. **Bibliography:** List at least five (5) major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.
 - Choose one style and use it consistently to reference the literature used in the research plan
 - Guidelines can be found in the Student Handbook.

These are guidelines and should be followed where applicable. *Refer to Items 1-4 below.

1. **Human subjects research** (See instructions on p. 13 of the International Rules):
 - Detail all procedures, include what the participants are asked to do (see p. 13)
 - Describe Risk Assessment process and how risks will be minimized
 - Strategies used to protect privacy and confidentiality
 - Describe Study Sample/Human Subjects
 - Number of human subjects and estimated demographics (may include information such as: age, male/female, cultural background/breakdown, Socio-economic status)
 - Recruitment procedures (where and how subjects are recruited)
 - Procedures for obtaining informed consent must include statement about informing potential human subjects about voluntary nature of participation and right to withdraw at any time
 - Include survey or questionnaires if used, and critically evaluate the risk
 - List and describe the measures (questionnaires, surveys) used and how you measure the variable of interest (behavioral observations, time, length). Attach the questionnaires/survey
 - Consider emotional stress and potential consequences
 - Describe any physical activities or procedures, if used, and critically evaluate the risks
 - Type, duration of exercise or physical activity
 - Ingestion method, amount, intervals, etc.
2. **Vertebrate animal research** (See instructions on p.17 of the International Rules):
 - Briefly discuss **POTENTIAL ALTERNATIVES** and present a detailed justification for use of vertebrate animals
 - Explain potential impact or contribution this research may have
 - Detail all procedures to be used
 - Include methods used to minimize potential discomfort, distress, pain and injury to the animals during the course of experimentation
 - Detailed chemical concentrations and drug dosages
 - Detail animal numbers, species, strain, sex, age, etc.
 - Include justification of the numbers planned for the research
 - Describe housing and oversight of daily care
 - Discuss disposition of the animals at the termination of the study
3. **Potentially Hazardous Biological Agents** (See instructions on p.21 of the International Rules):
 - Describe Biosafety Level Assessment process and resultant BSL determination
 - Give source of agent, source of specific cell line, etc.
 - Detail safety precautions
 - Discuss methods of disposal
4. **Hazardous Chemicals, Activities & Devices** (See instructions on p.25 of the International Rules):
 - Describe Risk Assessment process and results
 - Detail chemical concentrations and drug dosages
 - Describe safety precautions and procedures to minimize risk
 - Discuss methods of disposal



Approval Form (1B)

This 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:

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own, and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs or the ISEF.

Student's Printed Name

Signature

Date Acknowledged
(Must be prior to experimentation.)

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

Parent/Guardian's Printed Name

Signature

Date of Approval
(Must be prior to experimentation.)

2) TO BE COMPLETED BY THE FAIR SRC

(REQUIRED FOR PROJECTS REQUIRING PRIOR SRC/IRB APPROVAL. SIGN 2a OR 2b AS APPROPRIATE.)

a) Required for projects that need prior SRC/IRB approval BEFORE experimentation

(humans, vertebrates or potentially hazardous biological agents)

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

SRC/IRB Chair's Printed Name

Signature

Date of Approval
(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 required institutional approvals (e.g. IACUC, IRB)

SRC Chair's Printed Name

Signature

Date of Approval

NOTE: If a stamp is used, it must be initialed by the chairperson.

3) FINAL ISEF AFFILIATED FAIR SRC APPROVAL. (REQUIRED FOR ALL PROJECTS)

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

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

Regional SRC Chair's Printed Name

Signature

Date of Approval

State/National SRC Chair's Printed Name

Signature

Date of Approval

(where applicable)



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



Regulated Research Institutional/Industrial Setting Form (IC)

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

This form **MUST** be displayed with your project.

Student's Name _____

Title of Project _____

To be completed by the Supervising Adult in the Setting (NOT the Student) after experimentation:

The student conducted research at my work site:

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

1) How did the student get the idea for her/his project?

(e.g. Was the project assigned, picked from a list, an original student idea, etc.)

2) Were you made aware of the ISEF rules before experimentation? Yes No

3) Did the student work on the project as a part of a research group? Yes No

If yes, how large was the group and what kind of research group was it (students, group of adult researchers, etc.)

4) What specific procedures or equipment did the student actually use and how independently did the student work?

Please list and describe. (Do not list procedures student only observed.)

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

Supervising Adult's Printed Name _____ Signature _____ Title _____

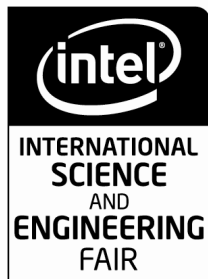
Institution _____ Date Signed _____

Address _____ Email/ Phone _____



Continuation studies

- 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 Projects Form (7)

Required for projects that are a continuation in the same field of study as a previous project.
This form must be accompanied by the previous year's abstract, Form (1A) and Research Plan.

Student's Name _____

To be completed by Student Researcher:

List all components of the current project that make it new and different from previous research. Use an additional form for 2004 and earlier projects.

Components	Current Research Project	Previous Research Project
1. Title		2006-2007: 2005-2006:
2. Objectives		2006-2007: 2005-2006:
3. Variables studied		2006-2007: 2005-2006:
4. Line of investigation		2006-2007: 2005-2006:
5. Additional changes		2006-2007: 2005-2006:

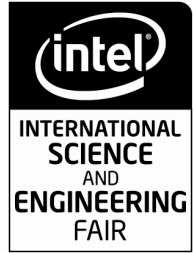
This form must be displayed at your project to help provide the judges a better understanding of your project and what research has been done in the current year.

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

Signature

Date of Signature



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



What types of projects not human subjects research?

- Product testing
 - No health hazards
 - No personal data collected
 - Feedback directly related to product
- Pre-existing data/record review studies
- Behavioral observations of unrestricted public settings
 - No interaction
 - No manipulation of environment
 - No recording of any personal identifiers



Human Subjects Studies

- Require IRB review and approval of research plan before experimentation begins
- IRB evaluates and determines
 - Risk level
 - Requirement for informed consent
 - Requirement for Qualified Scientist

Requirements for projects with pre-existing data sets



- Publicly available data – no IRB review
- Data not de-identified require IRB approval and may require informed consent
- Data de-identified/anonymous will not require IRB approval if:
 - Data provider certifies de-identification and compliance with HIPAA
 - Final SRC review confirms above

Risk Evaluation for Human Subjects Research





Risk Groups (vulnerable to coercion or undue influence)

- Naturally at risk because of disease (AIDS, psychiatric disorders, cardiac disorders, etc.)
- Members of vulnerable groups covered by federal regulations
 - Children/minors
 - Prisoners
 - Pregnant women

Risk activities (more than minimal risk)



- Exercise
- Ingestion
- Emotional stress – survey, stimuli
- Invasion of privacy
- Breach of confidentiality



Informed consent required

- When more than minimal risk
- If IRB determines that potentially there could be emotional stress
- When subjects belong to risk group

IRB can waive informed consent



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
 - Behavior study where no manipulation
 - Surveys of perception, cognition, game theory
 - Physical activity with no more than minimal risk (daily activity, routine physical activities)



IRB decisions and
documentation of informed
consent are noted on Form 4



Human Subjects Form (4)

Required for all research involving human subjects. IRB approval required before experimentation.

Student's Name _____

Title of Project _____

To be completed by Student Researcher in collaboration with the Designated Supervisor/Qualified Scientist:

(All questions must be answered; additional page may be attached.)

- 1) Describe the purpose of this study and list all of the research procedures in which the subject will be involved. Include the duration of the subject's involvement. Attach any survey or questionnaire.

- 2) Describe and assess any potential risk or discomfort, and, if any, potential benefits (physical, psychological, social, legal or other) that may be reasonably expected by participating in this research.

- 3) Describe the procedures that will be used to minimize risk, to obtain informed consent and/or assent, and to maintain confidentiality.

For questions or concerns regarding this research, contact: _____ at _____
Adult Sponsor Email/phone

To be completed by Institutional Review Board (IRB) prior to experimentation: Determination of risk, including physical and psychological risks (See risk evaluation, p. 14.) **MUST CHECK ONE OF THE BOXES**

- Minimal risk where informed consent is recommended, but not required. Justification for waiver of informed consent for research with subjects under 18 years of age: _____
- Minimal risk where informed consent is REQUIRED.
- More than minimal risk where informed consent & a Qualified Scientist are REQUIRED

IRB SIGNATURES (All three signatures are required; Conflict of interest must be avoided (See p.11))

1) Medical Professional: (*MUST circle one*) (a psychologist, psychiatrist, medical doctor, licensed social worker, physician's assistant, or registered nurse)

Printed Name (including title)	Signature	Date of Approval
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2) Science Teacher:

Printed Name	Signature	Date of Approval
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3) School Administrator:

Printed Name	Signature	Date of Approval
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To be completed by Human Subject:

(prior to participation)

Printed Name

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | I have read and understand the conditions and risks above and I consent/assent to voluntarily participate in this research study. |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | I realize I am free to withdraw my consent and to withdraw from this study at any time without negative consequences. |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | I consent to the use of visual images (photos, videos, etc.) involving my participation in this research. |
| yes | no | |

Signature	Date
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To be completed by Parent/Guardian:

(Prior to participation and when participant is under 18 and informed consent is required)

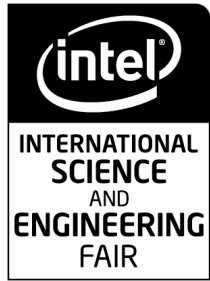
Printed Name

- | | | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | I have read and understand the conditions and risks above and consent to the participation of my child. |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | I have reviewed a copy of any survey or questionnaire used in the research. |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | I consent to the use of visual images (photos, videos, etc.) involving my child in this research. |
| yes | no | |

Signature	Date
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VERTEBRATE ANIMALS



What is a vertebrate animal?

- Live, nonhuman vertebrate mammalian embryos or fetus
- Bird and reptile eggs within 3 days of hatching
- All other nonhuman vertebrates at hatching or birth



Prohibited studies

- Induced toxicity
- Behavioral experiments with
 - Operant conditioning with aversive stimuli
 - Mother/infant separation
 - Induced/learned helplessness
- Studies of pain
- Predator/prey experiments



Additional restrictions

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



Research sites

- Examples of non-regulated sites

- Home
- School
- Farm
- Ranch
- Field

- Examples of regulated site

- IACUC Review and Approval process
- Universities
- Government research agencies
- Private research laboratories

Requirements for studies at non-regulated sites



- Agricultural, behavioral, observational and supplemental nutritional studies
and
- Non-invasive and non-intrusive with no negative effect on animal's health or well-being
and
- Require SRC review and approval

Also included are studies involving

- Animals in their natural environment
- Animals in zoological parks
- Livestock that use standard agricultural practices





Adult Supervisors

- SRC determines requirement of any or all of the following adults:
 - Designated supervisor
 - Veterinarian
 - Qualified scientist
- Form 5A required

Requirements for studies at regulated sites



- 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 at a Regulated Research Institution.
(IACUC approval required before experimentation.)

Student's Name _____

Title of Project _____

Title and Protocol Number of IACUC Approved Project _____

To be completed by Qualified Scientist or Principal Investigator:

1. Was this a student-generated idea or was it a subset of your work?
2. Have you reviewed the ISEF Rules relevant to this project?
3. What laboratory training, including dates, was provided to the student?
4. Species of animals used: _____ Number of animals used: _____
5. USDA Pain Category designated for this study:
6. Describe, in detail, the role of the student in this project: procedures and equipment they were involved with, oversight provided and safety precautions employed. (Attach extra pages if necessary.)

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

Certification or Documentation of Student Researcher Training

_____	_____	_____
List Certificate Number or Attach Documentation	Date(s) of Training	
_____	_____	_____
Qualified Scientist/Principal Investigator Printed Name	Signature	Date
_____	_____	_____
IACUC Chair/Coordinator Printed Name	Signature	Date

POTENTIALLY HAZARDOUS BIOLOGICAL AGENTS



Potentially Hazardous Biological Agents



- Microorganisms (including bacteria, viruses, fungi, etc.)
- Recombinant DNA technologies
- Human or animal fresh tissues, blood or body fluids
- All above studies require a risk assessment



Risk Assessment

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



Overview

- 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 biological agents form) required for all projects involving microorganisms, rDNA and fresh tissue

All Studies Involving Potentially Hazardous Biological Agents



- Must have prior approval by SRC/IACUC
- All studies are prohibited in a home environment
- Studies intended to produce or genetically engineer bacteria with multiple antibiotic resistance are prohibited
- Biosafety level 3 and 4 studies are prohibited



Exempt from prior SRC review

- Studies using baker's and brewer's yeast (except rDNA studies)
- Most studies involving protists, archae and similar microorganisms
- Composting and fuel production studies
- Studies using Lactobacillus, B. thuringiensis, nitrogen-fixing bacteria, oil-eating bacteria and algae-eating bacteria in natural environment



Unknown microorganisms

- BSL 1 if
 - Organisms cultured in plastic petri dish or petrifilm
 - 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 euthanized solely for student project – vertebrate animal study
- If animal euthanized for a purpose other than student project – tissue study



-
- Classification as BSL 1 or 2 based on source and possibility of containing infectious agents
 - All studies with human or wild animal blood – BSL 2. Domestic animal blood – BSL -1
 - Human body fluids identified with individual must have IRB approval



■ Exempt

- 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 tissue
 - Primary cell cultures
 - Blood and blood products
 - Body fluids



Human and Vertebrate Animal Tissue Form (6B)

Required for all projects using fresh tissue, primary cell 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 _____

Title of Project _____

To be completed by Student Researcher:

1) What tissue(s), organ(s), or part(s) will be used?

2) Where will the above tissue, organ, or part be obtained (identify each separately):

3) If the tissue is obtained from a source within a research institution, please provide information regarding the vertebrate study from which the tissue was obtained. Include the name of the research institution, the title of the study, the IACUC approval number and date of IACUC approval.

To be completed by the Qualified Scientist or Designated Supervisor:

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

AND/OR

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

Printed Name

Signature

Date Signed

(Must be prior to experimentation.)

Title

Phone/Email

Institution

HAZARDOUS CHEMICALS, ACTIVITIES OR DEVICES





Hazardous Chemicals, Activities or Devices

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



General Rules

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



-
- **DEA-Controlled Sustances**
 - Consult DEA list of controlled substances
 - All studies require Qualified Scientist
 - Schedule 1 requires DEA protocol review
 - **Prescription Drugs**
 - Cannot administer to human subjects
 - Animal administration must follow ISEF animal guidelines



■ Alcohol and Tobacco

- Must follow local laws for purchase, possession and consumption
- Home production of ethyl alcohol must follow U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations
- Alcohol distillation for fuel production can be conducted at school with TTB permit obtained by school officials



- Firearms and Explosives
 - Must check local training and certification requirements
- 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
 - Radiation
 - Non-ionizing
 - Ionizing



Form 3

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



Risk Assessment Form (3)

Required for projects using hazardous chemicals, activities or devices or regulated substances and some potentially hazardous biological agents. Must be completed before experimentation.

Student's Name _____

Title of Project _____

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

1. List/identify the hazardous chemicals, activities, or devices or microorganisms that will be used.
2. Identify and assess the risks involved.
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 and will provide direct supervision.

Designated Supervisor's Printed Name _____ Signature _____ Date of Review _____
(must be prior to experimentation)

Position & Institution _____ Phone or email contact information _____

Experience/Training as relates to the student's area of research _____