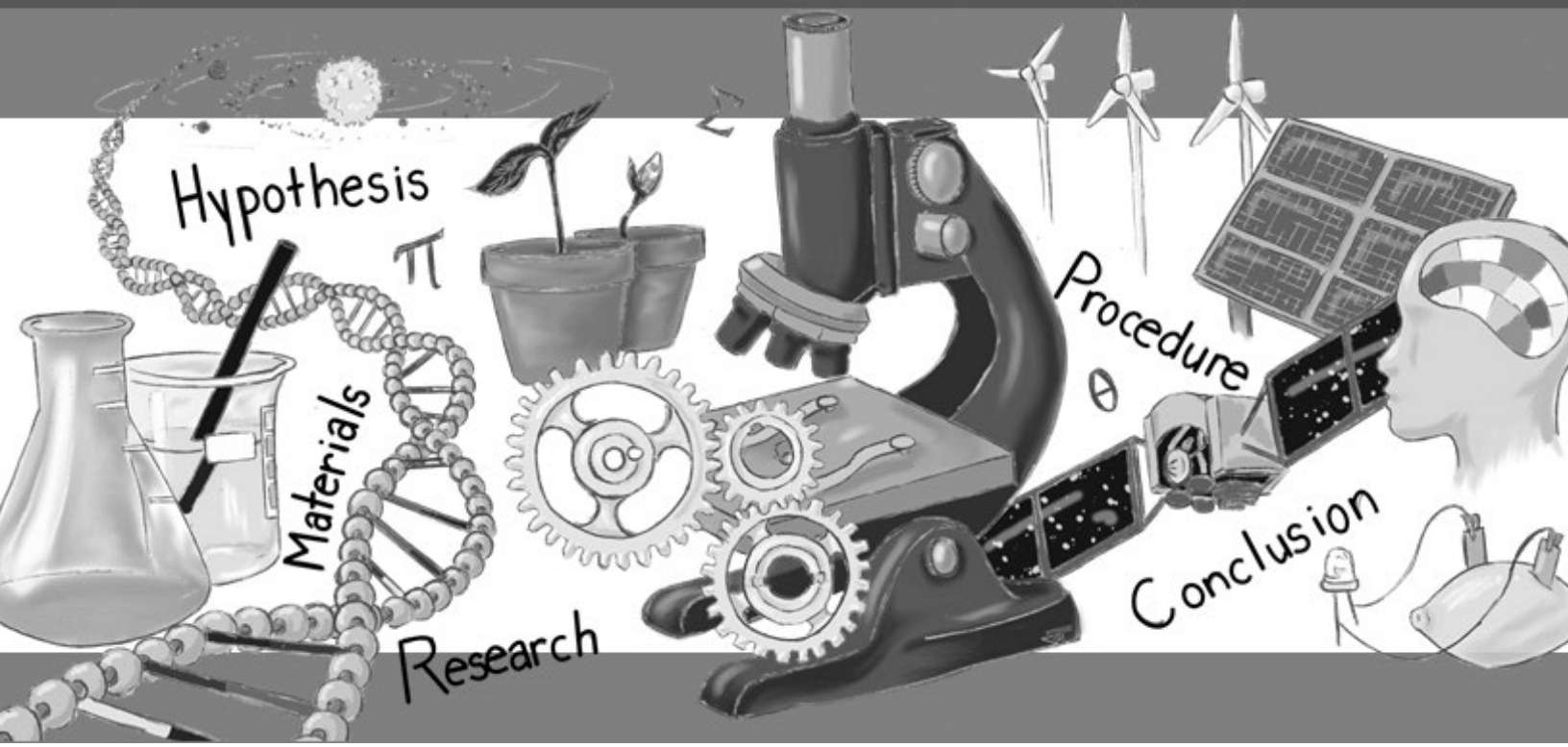
LPSEF



Longs Peak Science & Engineering Fair

February 26, 2020

Middle School Rules & Guidelines
Copy & distribute freely!
Revised December 2019

LPSEF

Colorado Science and Engineering Fair
Education Creativity Competition

MAST Institute
Mathematics and Science Teaching

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Eligibility for Competition Requirements

Scientific fraud and misconduct are not condoned at any level of research or competition. This includes 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. The Colorado State Science Fair, Inc. reserves the right to revoke recognition of a project subsequently found to have been fraudulent.

The Longs Peak Science & Engineering Fair (LPSEF) is affiliated with the Colorado Science & Engineering Fair (CSEF) and the Intel International Science and Engineering Fair (Intel ISEF). For this reason, students participating in regional and state science fairs in Colorado must adhere to the international rules and guidelines as set forth by the Society for Science & the Public's Scientific Review Committee. These rules outline the forms and supervision that are needed for all projects as well as those projects that involve human subjects, vertebrate animals, potentially hazardous biological agents and hazardous chemicals, devices and activities. Please remember that these rules are in place to ensure the safety of the Student Researcher(s) as well as the subjects (human or animal) that may be part of the study. *These rules are NOT trivial and are based on what working scientists must adhere to, as well as federal laws and regulations.*

As a service to middle school students and teachers, as well as parents of students involved in science fair research projects around Colorado, the LPSEF/CSEF have created this rules and guidelines book to help with navigation through the approval process. The rules and guidelines are EXACTLY like those of the Intel ISEF, only written in a manner that is more easily understood by middle schoolers. The forms in this booklet are ONLY FOR MIDDLE SCHOOL (6-8 grade) STUDENTS and may not be used by students in grades 9-12.

- Only students attending schools in or residing in Weld, Larimer, or Jackson counties may participate in the LPSEF. Home schoolers and online school attendees are also welcome.
- *Participating schools* may select and send any number of projects to the LPSEF until otherwise notified that a cap has been set.
- Students attending *non-participating schools* may register for the LPSEF as independent researchers.
- The number of projects the LPSEF may send to the state competition is determined by the CSEF. This number can be split between the senior (9-12 grades) and junior (6-8 grades) divisions as determined by the LPSEF Director. All CSEF participants must be selected by a regional fair.
- Students in grades 5-12 may participate in the LPSEF; however, only students in grades 6-12 (but not older than 20 years of age) may qualify for state competition.
- Each student is allowed to enter ONLY ONE project at the LPSEF each year. That project may include no more than 12 months of continuous data collection/experimentation. *(Data collection/ experimentation may start as early as Jan. 2016)*
- Team projects intending to be entered in the LPSEF may have no more than *three members* and *cannot cross division boundaries* (middle school age with high school age). Team membership cannot be changed during a given research year except under extenuating and clearly documented circumstances.
- Students may compete in ONLY ONE Colorado affiliated Regional Science Fair each year.
- Projects that are demonstrations, library research or information projects, explanation models or kit buildings are *not appropriate for competition* at any level (regional, state or international).
- A research project may be a part of a larger study performed by a professional scientist/mentor, however, the project entered into competition and presented by the student must be their own portion of the complete study.
- All students competing in the LPSEF must adhere to all of the rules set forth by the CSEF.

Project Supervision

Adult Sponsor

Every Student Researcher MUST identify an Adult Sponsor for their project. The Adult Sponsor can be anyone (teacher, parent, university professor, scientist, etc.), as long as that person has a *solid background in science* and will have *close contact* with the Student Researcher during the course of the project. The Adult Sponsor must be familiar with the regulations that govern *potentially* dangerous research as they may apply to the Student Researcher's project. Because some experiments involve procedures or materials that are regulated by state and federal laws, if the Adult Sponsor is not thoroughly familiar with the regulations, they should help the Student Researcher(s) enlist the aid of a Qualified Scientist.

The Adult Sponsor's job is to:

- assist the Student Researcher in evaluating any possible risks involved with the project in order to ensure the health and safety of the student(s) and any humans or animals involved in the study;
- ensure that experimentation is done within local, state and federal laws and the LPSEF/CSEF guidelines;
- ensure that the necessary forms are completed by the other adults involved in approving and/or supervising any part of the experiment; and
- ensure that the Qualified Scientist's qualifications are adequate for the type of project the student is conducting.

Qualified Scientist

Some projects MAY require a student to work with a Qualified Scientist. A Qualified Scientist should possess an earned doctoral/professional degree in the biological or medical sciences as it relates to the Student Researcher's project. However, a master's degree with equivalent experience and/or expertise in the Student Researcher's area is acceptable.

The Adult Sponsor may also serve as a Qualified Scientist on a project, if they are qualified as outlined above. A Qualified Scientist does not have to be located within the same city/town or even state as the Student Researcher. In cases where the Qualified Scientist is unable to directly supervise the Student Researcher, a Designated Supervisor (see below), who has been trained in the techniques the Student Researcher will use, must be obtained.

Designated Supervisor

The Designated Supervisor is an adult who is directly responsible for overseeing the student's experimentation. The Designated Supervisor does not need an advanced degree, but should be thoroughly familiar with the Student Researcher's project and must be trained in the student's area of research. The Adult Supervisor may also act as the Designated Supervisor.

The degrees of M.O.M. and D.A.D. need to be accompanied by an explanation of any training or experience they have that makes them qualified to supervise a particular project.

If a student is experimenting with live vertebrates and the animals are in situations where their behavior is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

Project Review

In Colorado, there are three to five levels of review that a student's project may need to pass through for competition purposes. If any of the review groups feel that there was a serious breach of ethical or safety protocols when the student did their project, they can deem the project has failed to qualify and not allow the Student Researcher(s) to compete – even if the prior review board approved the project.

Local or School Scientific Review Committee

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluating project procedures to make sure that all safety and legal requirements will be met and that the appropriate forms have been completed. The committee is composed of at least 3 people: a biomedical scientist with an earned doctoral degree, an educator and one other member.

If a student's project involves *vertebrate animals and/or potentially hazardous biological agents* (microorganisms, rDNA, tissue), then the experimental procedures must be approved by the local/school SRC BEFORE a Student Researcher may begin working on the experimental portion of their project.

Local or School Institutional Review Board

An Institutional Review Board (IRB) is a group of individuals that is responsible for evaluating project procedures involving *human subjects* to make sure that all safety, legal and confidentiality requirements will be met and that the appropriate forms have been completed. The committee is composed of at least 3 people: an educator, a school administrator, and a psychologist, doctor (MD) or nurse (RN).

Regulated Research Institution Review Board

If a Student Researcher is working in a laboratory at a university or other research institution, projects involving vertebrates, humans, tissue, rDNA and microorganisms must be reviewed and approved by that institution's review board (not the Qualified Scientist) BEFORE a Student Researcher may begin work on the experimental portion of their project. If an institution does not have protocol in place to review all of these types of projects – get certification from the Qualified Scientist and approval by the local/school SRC on Form 6A.

LSPEF SRC

This group of professionals will review and approve all student forms for participation in the LPSEF with the rules set forth here.

State SRC

This group of professionals will review the forms for the students who have been chosen by the regional fairs to compete at the state level for compliance with the rules set forth here and paperwork completion.

In order to eliminate conflict of interest, the Adult Sponsor, parents, Qualified Scientist(s) and Designated Supervisor(s) MUST NOT serve on any SRC or IRB reviewing that project.

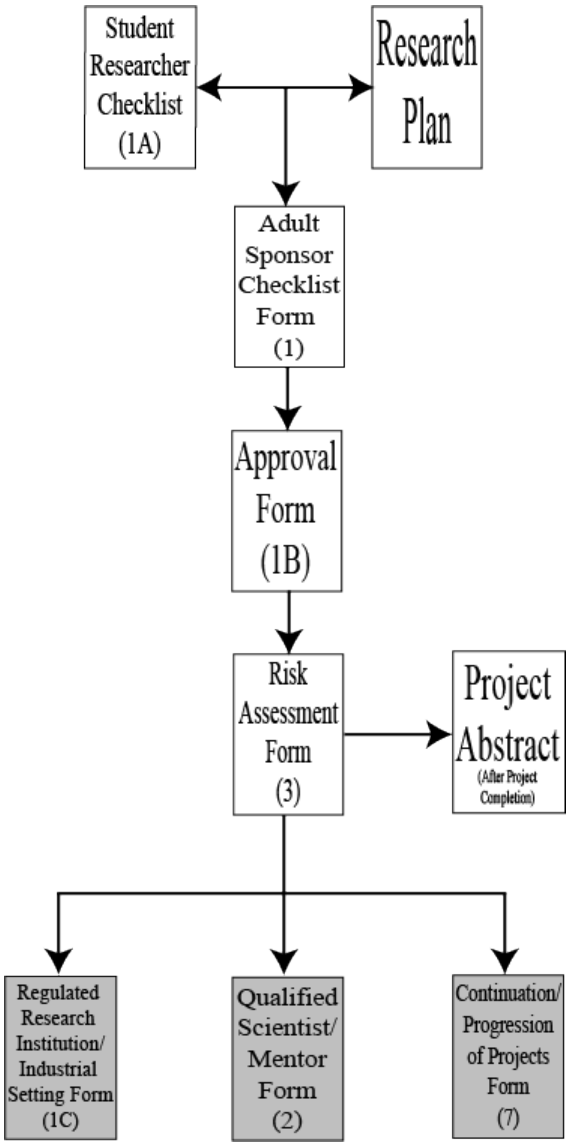
Inquiries regarding specific experimental procedures or questions regarding the rules can be directed to either the LPSEF SRC, CSEF SRC or the Intel ISEF SRC at:

LPSEF SRC	CSEF SRC	Intel ISEF SRC
Nschmidt2387@gmail.com	csef@colostate.edu	SRC@societyforscience.org
Nissa Schmidt, Member	Doug Steward, Chair	Dr. Chris Miller, Chair

'Tis better to ask permission than forgiveness.'

Requirements for ALL Projects

All projects must have the following forms completed:



- **Student Researcher Checklist Form (1A)** – This is information about the student(s) working on the project, when the experimentation will take place and where. This is to be completed by the Student Researcher(s) before submitting it along with the Research Plan, Approval Form 1B, Risk Assessment Form 3, and other relevant forms to the Adult Sponsor for approval.
- **Research Plan** – This should include a brief, but detailed explanation of the rationale behind the project idea, the research question(s), the procedures/methodology, the risk assessment and background exploration. This is to be completed by the Student Researcher(s) PRIOR to experimentation.
- **Adult Sponsor Checklist Form (1)** – This is a review of the details about the project and whether or not it requires prior approval or not. This is to be completed by the Adult Sponsor in collaboration with the Student Researcher(s) PRIOR to experimentation.
- **Approval Form (1B)** – This is where various people sign off their approval of the project. For a team project, each Student Researcher must complete a separate Approval Form.
- **Risk Assessment Form (3)** – This is a review of the risks that might be associated with the project. This form should be completed by the Student Researcher(s) in collaboration with the Adult Sponsor, Designated Supervisor and/or Qualified Scientist/Mentor PRIOR to experimentation.
- **Project Abstract** – this is a summary of the project that is completed once the experimentation is done and the data has been analyzed.

Some additional forms that MIGHT be required include:

- *Research Institution/Industrial Setting Form (1C)* – This is a summary of what the Student Researcher(s) did at a professional lab or an industrial setting. This is to be completed by the supervising adult who is affiliated with the laboratory/industrial setting and who has first-hand knowledge of the student(s) work completed there. Do not complete form until AFTER experimentation.
- *Qualified Scientist/Mentor Form (2)* – this is used to document when a Student Researcher works with a mentor who is a professional in the area of their project. This is to be completed by the Qualified Scientist/Mentor who is advising and/or supervising the Student Researcher(s) PRIOR to experimentation.
- *Continuation/Progression of Projects Form (7)* – this is used to document prior work that the Student Researcher(s) have done in the same field of study as the current work. This is to be completed by the Student Researcher(s) AFTER experimentation and should include copies of the previous years' abstract and Research Plan. Each page should be labeled in the top right corner (example: Abstract 2016).

Adult Sponsor Checklist Form (1) – Middle School

This form is required for ALL projects and MUST be completed PRIOR to experimentation.

This form is to be completed by the Adult Sponsor in collaboration with the Student Researcher(s).

1. Student's Name(s):_____

2. Project Title:_____

_____

3. Adult Sponsor, please certify that you have reviewed the following (forms listed in b - e are REQUIRED for all projects) with the Student Researcher(s) and agree with them by initialing each line.

_____a. I have reviewed the Rules & Guidelines for Middle School Science Research that apply to this project.

_____b. I have reviewed the completed Student Researcher Checklist Form (1A).

_____c. I have read and reviewed the proposed Research Plan and have determined it is appropriate.

_____d. I have reviewed the completed Approval Form (1B).

_____e. I have reviewed the completed Risk Assessment Form (3) and approve of the chosen Designated Supervisor.

4. The Student Researcher(s) _____ ***will /*** _____ ***will not*** employ the expertise of a qualified Scientist/Mentor. If yes, a Qualified Scientist/Mentor Form 2 is required. Please note, that the SRC or IRB may require a student to work with a Qualified Scientist.

5. The Student Researcher(s) _____ ***will /*** _____ ***will not*** work on the project at a Regulated Research Institution (i.e. university or college) or an Industrial Setting (i.e. hospital, water treatment plant, private lab, etc.). If yes, a Research Institution/Industrial Setting Form 1C will be required AFTER the project is completed.

6. This project _____ ***is /*** _____ ***is not*** a continuation/progression from a previous year. If yes, a Continuation Form 7 is required along with all previous years' abstracts and research plans.

7. This project _____ ***does /*** _____ ***does not*** involve one or more of the following, requiring PRIOR approval by an SRC and/or an IRB. *Please check all that apply:*

☐ **Human Subjects** – Projects involving human subjects require PRIOR approval by an IRB and the following:
- Human Participants Form (4) **AND POSSIBLY**
- Unsigned Sample of Informed Consent Form (if required by the IRB) **AND POSSIBLY**
- Qualified Scientist/Mentor Form 2 (if required by the IRB)

☐ **Vertebrate Animals** – Projects involving vertebrate animals require the following:
- Vertebrate Animal Form 5A – if project is conducted at school, home or in a field setting; PRIOR school/local SRC approval is required in this case **OR**
- Vertebrate Animal Form 5B – if project is conducted at a Regulated Research Institution; PRIOR Institutional Animal Care and Use Committee (IACUC) approval is required in this case **AND POSSIBLY**
- Qualified Scientist/Mentor Form 2 (if required by the SRC)

☐ **Potentially Hazardous Biological Agents** – Projects involving microorganisms (known and unknown), rDNA and human or animal tissue require PRIOR approval by either the school/local SRC or university regulatory board and the following:
- Potentially Hazardous Biological Agents Risk Assessment Form 6A **AND POSSIBLY**
- Human and Vertebrate Animal Tissue Form 6B (to be completed along with Form 6A when a project involves fresh or frozen tissue, primary cell cultures, blood, blood products and bodily fluids) **AND POSSIBLY**
- Qualified Scientist/Mentor Form 2 (if required by the SRC)

Adult Sponsor's Printed Name	Adult Sponsor's Signature	Date of Review (mm/dd/yy) (MUST be PRIOR to experimentation)

Phone Number Email

Student Researcher Checklist Form (1A) – Middle School

This form is required for ALL projects and MUST be completed PRIOR to experimentation.

This form is to be completed by the Student Researcher(s) before submitting it along with the Research Plan, Approval Form 1B, Risk Assessment Form 3 and other relevant forms to the Adult Sponsor for approval.

1. This project will be an _____ ***Individual /*** _____ ***Team*** project. The student(s) working on this project will be:

Individual/Team Leader:_____ Grade:_____

Email:_____ Home Phone:_____

Team Member 1:_____ Grade:_____

Team Member 2:_____ Grade:_____

2. Proposed Project Title:_____

3. School:_____ School Phone:_____

School's Physical Address:_____

_____

4. Adult Sponsor:_____ Email:_____

MUST match person signing Form 1!

5. This project _____ ***does /*** _____ ***does not*** require PRIOR SRC or IRB approval.

6. I/We plan on starting our experimentation/data collection/engineering of the project on:_____

(mm/dd/yy)

7. This project _____ ***is /*** _____ ***is not*** a continuation or progression from a previous year. If yes, a Continuation/ Progression Form 7 is required along with all previous years' abstracts and research plans.

8. The **ACTUAL** laboratory experimentation/data collection/engineering designing began and ended on the following dates (this can be filled in once the project is completed):

_____ _____

ACTUAL Start Date (mm/dd/yy) ACTUAL End Date (mm/dd/yy)

9. I/We will be conducting our laboratory experimentation/data collection/engineering designing at the following locations (check ALL that apply):

☐ School ☐ Home ☐ Research Institution ☐ Field ☐ Other:_____

10. Non-school work site physical address(es) include (additional sites can be attached on a separate page):

Site 1 Name:_____ Site 2 Name:_____

Site 1 Address:_____ Site 2 Address:_____

_____ _____

Site 1 Phone Number:_____ Site 2 Phone Number:_____

Site 3 Name:_____ Site 4 Name:_____

Site 3 Address:_____ Site 4 Address:_____

_____ _____

Site 3 Phone Number:_____ Site 4 Phone Number:_____

11. Prepare a Research Plan following the instructions on page 9 and attach to this form.

Research Plan Instructions – Middle School

A typed, detailed research plan is required for ALL projects and MUST accompany the Student Researcher Checklist Form (1A) and Risk Assessment Form (3) and be completed PRIOR to experimentation.

The Research Plan is a brief, but detailed explanation of the rationale behind the project idea, the research question(s), the procedures/methodology, the risk assessment and background exploration. This MUST be completed PRIOR to experimentation in order to be approved by the Adult Sponsor and the SRC/IRB (if required). Any changes to this plan MUST be documented (make an amendment to the original document) and approved by the Adult Sponsor and the SRC/IRB (if required) before work can continue on the project.

The research plan for ALL projects should include the following parts:

1. What is the **rationale/reason** for doing this project? Include a brief summary of the background research you did in relation to your project and explain why this research is important scientifically and, if applicable, any impacts to society in general your research has.
2. State your **hypothesis(es)**, **research question(s)**, **engineering goal(s)**, and/or **expected outcomes** (predictions) for your project. Be sure it ties into your rationale/reason.
3. Detail ALL **procedures** and **experimental design** processes that you are going to follow. Be sure to include exactly how data is going to be collected.
4. Identify ANY and ALL **potential risks** and safety precautions you need to be aware of in completing your project. This should include the building of any apparatus needed to collect data for your project. Include this information on the Risk Assessment Form 3.
5. Describe the procedures you will use to analyze the data/results to answer your research question(s) or hypothesis(es).
6. List at least **five (5) major references** (i.e. science journal articles, books, internet sites, etc.) that you read in your background exploration in the proper works cited format. If you plan on using vertebrate animals in your project, one of these MUST be an animal care reference. *Please note that Wikipedia should NOT be one of the five references – it can be included only if you have more than five.*

If your project includes Human Subjects, Vertebrate Animals and/or Potentially Hazardous Biological Agents (microorganisms, rDNA, tissue), then your research plan MUST also include the following:

1. **Human Subjects** (prior IRB approval and Form 4 are required; Informed Consent and Form 2 may be required)
   a. Describe in general the type of people who will participate in your study (age range, gender, racial/ethnic composition, etc.).
   b. How will you recruit your participants? How will they be invited to participate?
   c. What exactly will the participants be asked to do? Include any surveys, questionnaire or test questions that you plan on using. How often and for how long will each participant be asked to commit to?
   d. What are the potential risks or discomforts *(remember to think about emotional as well as physical*) to the participants? How will you minimize those risks?
   e. What are the potential benefits to the individual participants as well as to society in general?
   f. Will you be collecting any identifiable information (i.e. name, age, grade, phone numbers, birth dates, emails, etc.)? Is this a confidential or anonymous study?
   Confidential studies may collect identifiable information, but must be kept separate from the data being analyzed using a number key that only the researcher and adult sponsor has access to.
   Anonymous studies don't collect any identifiable information along with the study so that not even the researcher or adult sponsor knows who gave what answers.
   g. How will you 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? This can be done via an Informed Consent Form or on the survey directly if informed consent is not required by the IRB.

2. **Vertebrate Animals** (prior SRC approval and Form 5A or 5B are required; Form 2 may be required)
   a. Briefly discuss potential ALTERNATIVES to vertebrate animal use in your project and a detailed justification for using vertebrate animals.
   b. All procedures must be DETAILED and include methods used to minimize potential discomfort, distress, pain and injury to the animals during experimentation. If chemicals or drugs are used, concentrations and dosages MUST be exact.
   c. What is the species, strain, sex, age, etc. of the animals being used? How many animals will you be using in the study and why is that number appropriate? What is the source of the animals?
   d. Where will the animals be housed (cage/housing size, bedding, etc.)? What will be included in the daily care of the animals (food, water, exercise, etc.)?
   e. What will happen to the animals at the end of the study?

3. **Potentially Hazardous Biological Agents** (prior SRC approval and Form 6A are required; Form 6B and Form 2 may be required)
   a. What biological agent (microorganism, rDNA, tissue, cell line, etc.) are your using and where did it come from?
   b. What Biosafety Level did you determine your project involved and why?
   c. How are you going to keep yourself and others in the lab safe while you are working with the biological agents?
   d. How and where are you going to dispose of the biological agents once your project is complete?

Approval Form (1B) – Middle School

A SEPARATE approval form is required for ALL Student Researchers.

1. To be completed by Student Researcher and Parent/Guardian PRIOR to experimentation.

a. Student Acknowledgement:

- I understand the risks and possible dangers to me associated with the proposed research plan.
- I have read the Rules and Guidelines for Middle School Science Research and will adhere to all rules while 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 Colorado regional and state science fairs.

Student's Printed Name	Student's 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 to my child associated with the proposed research plan. I consent to my child participating in this research project.

Parent/Guardian's Printed Name	Parent/Guardian's Signature	Date Acknowledged (mm/dd/yy) (MUST be PRIOR to experimentation)

2. To be completed by the school or local SRC/IRB PRIOR to experimentation if required.

(Required for projects involving human subjects, vertebrate animals and/or potentially hazardous biological agents. Check only ONE appropriate box.)

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

☐ This project was conducted at a regulated research institution (**not home, school, etc.**), was reviewed and approved by the proper institutional review board before experimentation AND complies with the CSEF Rules and Guidelines for Middle School Science Research. **Form 1C, Form 2 and institutional approval documentation (i.e. IACUC, IRB, etc.) are attached.**

SRC/IRB Chair's Printed Name	SRC/IRB Chair's Signature	Date of Approval (mm/dd/yy)

3. To be approved by the Regional Science Fair SRC BEFORE competition.

(Required for all projects attending the Colorado Science and Engineering Fair.)

I certify that this project adheres to the approved Research Plan and complies with all Rules and Guidelines for Middle Science Research.

Regional SRC Chair's Printed Name	Regional SRC Chair's Signature	Date of Approval (mm/dd/yy)

4. To be approved by the CO Science & Engineering Fair SRC BEFORE competition.

(Required for all projects attending the Colorado Science and Engineering Fair.)

I certify that this project adheres to the approved Research Plan and complies with all Rules and Guidelines for Middle School Science Research.

CSEF SRC Chair's Printed Name	CSEF SRC Chair's Signature	Date of Approval (mm/dd/yy)

Risk Assessment Form (3) – Middle School

This form is required for ALL projects and MUST be completed PRIOR to experimentation.

This form is to be completed by the Student Researcher(s) in collaboration with the Adult Sponsor, Designated Supervisor and/or Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____
2. Project Title:_____

_____

3. List **ALL** chemicals (household AND laboratory), dangerous activities, hazardous devices and/or exempt microorganisms that are to be involved in this project.

4. Identify the risks involved in using **ALL** items listed in question #3. (What is the worst that could happen if something went wrong when working on your project?)

5. Describe the safety precautions you are going to take in order to minimize/reduce the risks identified in question #4. (How are you going to keep yourself and others around you safe while you are working on your project?)

6. Describe the disposal procedures you will use (when applicable) for items listed in question #3. (How are you going to SAFELY dispose of any hazardous items used in the project?)

7. List the source(s) of your safety information (in works cited format). Material Safety Data Sheets MUST be referenced when using chemicals (household AND laboratory.), but not attached.

Designated Supervisor:

I agree with the risk assessment and safety precautions described above. I certify that I have thoroughly reviewed the Research Plan and will provide **DIRECT supervision** of the Student Researcher(s) during experimentation.

Supervising Adult's Printed Name	Supervising Adult's Signature	Date of Review (mm/dd/yy) (MUST be PRIOR to experimentation)

Position & Institution	Email

Experience/Training as it relates to the project:

_____

_____

Research Institution/Industrial Setting Form (1C) – Middle School

This form is only required for those projects conducted at a work site that is not a school, home or field and MUST be completed AFTER experimentation.

This form is to be completed by the supervising adult who is affiliated with the regulated research institution or industrial setting and who has first-hand knowledge of the student's work done there. <u>The Student Researcher(s) should NOT complete any part of this form!</u>

1. Student's Name(s):_____
2. Project Title:_____

_____

3. I or my proxy (grad student, postdoc, employee, etc.) _____ ***did*** / _____ ***did not*** mentor or provide substantial guidance to the Student Researcher(s).
   If no, describe your and/or your institution's role with the Student Researcher(s) and the project (i.e. supervised use of equipment on site without on-going mentorship) and sign below.

   If yes, complete questions 4 – 7 and sign below.
4. The Student Researcher(s)' research project _____ ***is*** / _____ ***is not*** a subset of my ongoing research or work. Use questions 5, 6 & 7 to detail how the student's project was similar and/or difference from ongoing research or work at your site.
5. Describe the independence and creativity with which the student(s):
   a. developed the expected outcomes or engineering goals for the research project.

   b. designed the methodology for his/her research project.

   c. analyzed and interpreted the data.

6. Detail the student's role in conducting the research (data collection specific procedures performed, etc.). Differentiate what the student(s) observed and what the student actually did.

7. The student(s) _____ ***did*** / _____ ***did not*** work on the project as a part of a research group.
   If the student(s) did work as part of a group, how many individuals were in the group and who were they (high school students, graduate students, faculty, professional researchers, etc.).

I attest that the student has conducted the work as indicated above and that any required review and approval by institutional regulatory board (IRB/IACUC/IBC) has been obtained. Copies are attached if applicable.

I further acknowledge that the student will be presenting this work publicly in competition and I have communicated with the Student Researcher regarding any requirements for my review and/or restrictions of what is publicized.

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

Institution	Title

Email	Phone Number

Qualified Scientist/Mentor Form (2) – Middle School

This form MAY BE required for projects involving human subjects, vertebrate animals and/or potentially biological agents and MUST be completed PRIOR to experimentation.

This form is to be completed by the Qualified Scientist or Mentor who is advising and/or supervising the Student Researcher(s) on the project and has expertise in the area of research. <u>The Student Researcher(s) should NOT complete any part of this form!</u>

1. Student's Name(s):_____

2. Project Title:_____

_____

3. Scientist/Mentor's Name:_____

4. Degree(s)/Certification(s):_____ Field(s) of Study:_____

5. My ***experience/training*** as it relates to the Student Researcher(s)' project includes:

6. Institution:_____ Position:_____

7. Email:_____ Phone Number:_____

8. I _____ ***have /*** _____ ***have not*** reviewed the Rules and Guidelines for Middle School Science Research relevant to the student's project.

9. The following will be used as part of this research project (check ALL that apply)

☐ Human Subjects
☐ Vertebrate Animals
☐ Microorganisms
☐ DEA-controlled Substances
☐ Tissues (including blood and blood products)
☐ rDNA

☐ None of the Above

10. This research _____ ***is /*** _____ ***is not*** a subset of a larger study.

11. I _____ ***will /*** _____***will not*** directly supervise the Student Researcher(s) during experimentation.

a. If not, who will DIRECTLY supervise the Student Researcher(s)?_____
b. The ***experience/training*** of the Designated Supervisor as it relates to the project includes:

Qualified Scientist/Mentor
I certify that I have reviewed and approved the Research Plan PRIOR to the start of experimentation. I will ensure that the Student Researcher(s) and/or Designated Supervisor(s) are trained in the necessary procedures related to the project. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the Student Researcher(s) as outlined in the Research Plan. I understand that a Designated Supervisor is required when I am not available to directly supervise the Student Researcher(s).
_____ Scientist/Mentor's Printed Name
_____ _____ Scientist/Mentor's Signature Date of Approval

Designated Supervisor
To be used only when the Qualified Scientist/Mentor is unavailable to directly supervise the student(s). I certify that I have reviewed the Research Plan and have been trained in the techniques to be used by the Student Researcher(s) and I will provide DIRECT supervision during experimentation.
_____ Designated Supervisor's Printed Name
_____ _____ Designated Supervisor's Signature Date of Approval
_____ Email

Continuation/Progression of Projects Form (7) – Middle School

This form is required for ALL projects that are a continuation/progression in the same field of study as a previous project done by the Student Research(s) and MUST be completed AFTER experimentation.

This form is to be completed by the Student Researcher(s) and accompanied by previous years' abstract(s) and Research Plan(s). List all components of the current project that make it new and different from previous research. ALL questions MUST be answered and be on this form. Use additional Form 7's for years before 2014/2015.

Student's Name(s):_____

	Current Research Project	Previous Research Projects
1. Title		2015/2016:
		2014/2015:
2. Change in Goal/Purpose/Objective		2015/2016:
		2014/2015:
3. Changes in Methodology		2015/2016:
		2014/2015:
4. Variables Studied		2015/2016:
		2014/2015:
5. Additional Changes		2015/2016:
		2014/2015:

Student Researcher or Team Leader:

☐ I have attached the relevant previous year(s)' abstracts and Research Plans to this form.

AND

☐ I hereby certify that the above information is correct and that the current year's abstract and project display board properly reflect work done ONLY in this current year (2016/2017).

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

Human Participant Project Guidelines

Student Researchers must follow **federal guidelines** to protect the human research participant and the Student Researcher(s). When students conduct research with humans, the rights and welfare of the participants must be protected.

Studies Exempt from IRB Review/Approval

The following are the ONLY human subject type projects that are exempt from IRB pre-approval and informed consent:

- When the testing of a student-designed invention or prototype is done **ONLY** by the Student Researcher(s) **AND** where the testing does not pose a health or safety hazard.
- Data/record review studies where the data is taken from pre-existing data sets that are publicly available and/or published and do not involved any interaction with humans or the direct collection of any data from a human participant.
- Behavioral observations of unrestricted, **public settings** in which **all** of the following apply:
  - The Student Researcher(s) has **no interaction** with the subjects being observed;
  - The Student Researcher(s) **does not manipulate** the environment in any way; **AND**
  - The Student Researcher(s) **does not record any personally identifiable** data about the subjects being observed.
- Projects in which the Student Researcher(s) receives pre-existing/retrospective data in a **de-identified/anonymous** format and complies with both of the following conditions:
  - The professional providing the data certifies **in writing** that the data has been appropriately de-identified before being given to the Student Researcher(s) and is in compliance with all privacy and HIPPA laws, and
  - The Regional Science Fair SRC ensures that the data was appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Studies Needing Expedited IRB Review

An expedited IRB review (requiring only 1 signature on Form 4) can be done with studies that involved either of the following:

- Human participants will only provide feedback on the design of a student-designed invention, computer application or engineering prototype where **no personal data will be collected** and there are no health or safety hazards involved.
- The Student Researcher(s) is the only subject of the research and **no more than minimal risk** is involved.

Studies Needing Full IRB Review

All other human subject projects **REQUIRE** IRB review and pre-approval and **may require** written informed consent/minor assent/parental permission. Examples of such studies include, but are not limited to:

- Subjects participating in physical activities.
- Subjects ingesting any substance.
- Subjects participating in any medical procedure.
- Subjects participating in any psychological, educational and/or opinion studies (surveys & questionnaires).
- Studies where the Student Researcher(s) is the subject of the research.
- Subjects test student-designed inventions or concepts where personal data may be collected and/or there is more than minimal risk.
- Data/record review projects that include data that are not de-identified/anonymous.
- Behavioral observations that:
  - Involve any interaction with the observed individual(s);
  - Where the Student Researcher(s) has modified the environment;
  - Occur in non-public or restricted access settings; and/or
  - Involve the recording of personally identifiable information.

Informed Consent Guidelines

If required by the IRB, research participants must voluntarily give informed consent/assent (and in some cases, parental/guardian permission) **BEFORE** participating in the study. The local/school IRB will determine whether this can be verbal or must be written, depending on the level of risk, the type of study and the demographics of the subjects.

- Informed consent requires that the subject be provided with ALL information about POTENTIAL risks and benefits of participating in the study.
- Participation MUST BE VOLUNTARY, with no adverse consequences of not participating and subjects may stop participating at any time.
- Informed consent MUST NOT involve coercion.
- When written parental/guardian permission is required and the study includes a survey or questionnaire, these MUST BE ATTACHED to the consent form for the parent/guardian to review.

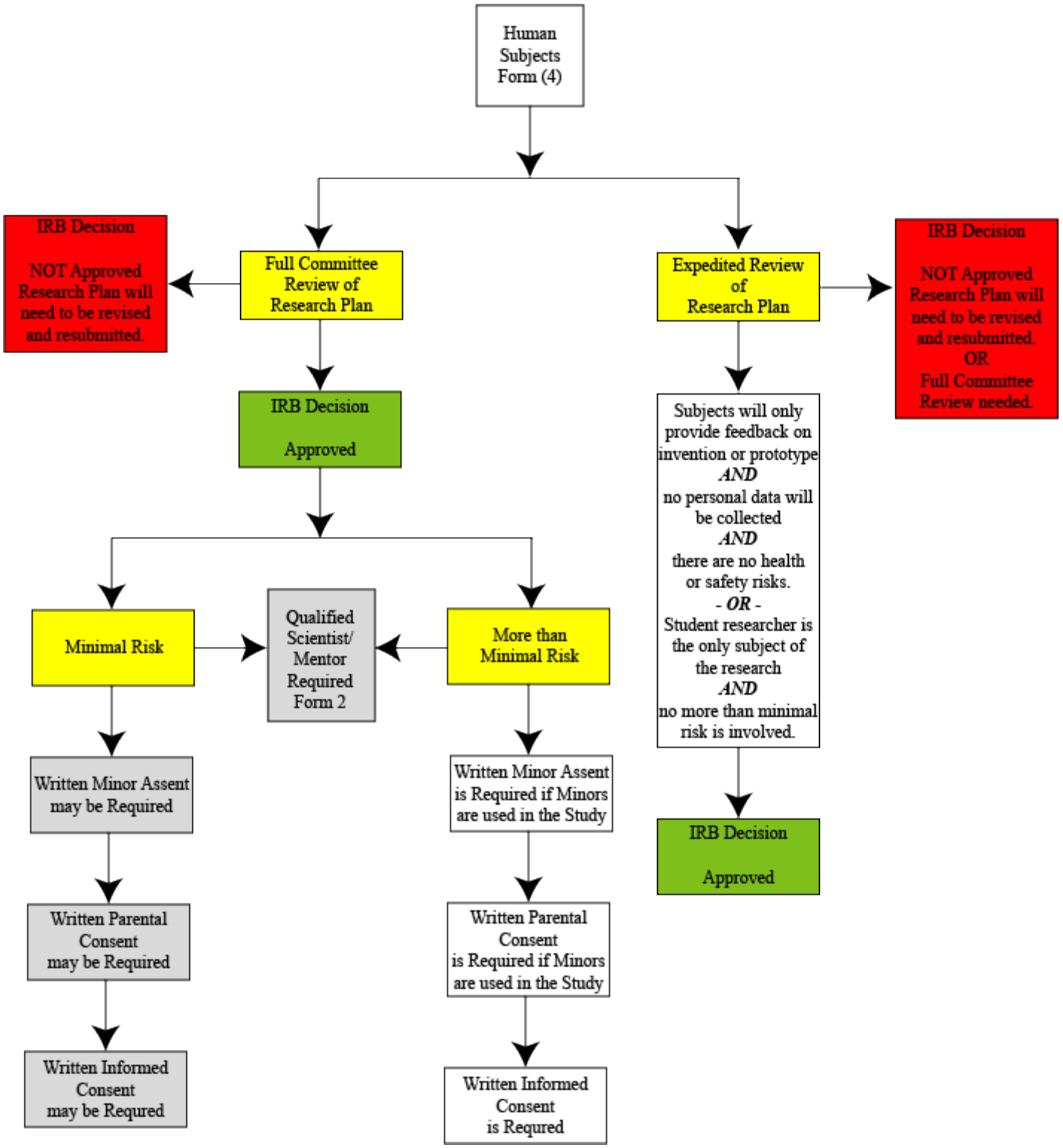
Other Human Subject Guidelines

The following are various guidelines that may or may not apply to a student's project.

- Student Researchers must include ALL parts (a-g) of the Human Subjects Research Plan requirements found on page 9.
- The study should be in compliance with all privacy laws (FERPA and HIPAA) when they apply to the project (i.e. the project involves medical information).
- Once the study has been approved, a Student Researcher with any proposed changes to the methods and/or procedures must repeat the review process before continuing with data collection/ experimentation.
- Research conducted at a Regulated Research Institute must be reviewed and approved by THAT INSTITUTION'S IRB – NOT the school or regional IRB. A copy of the IRB approval for the entire project and/or an official letter from the IRB attesting to approval is required. A letter from the mentor is NOT ACCEPTABLE.
- Student Researchers may observe and collect data for analysis of medical procedures and medication administration only under the DIRECT SUPERVISION of a qualified medical professional.
- Student Researchers are prohibited from administering medication and/or performing invasive medical procedures on human subjects.
- Student Researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photos) without written consent from the participants.
- All published psychological testing instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist/Mentor as required by the publisher of the instrument. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.
- Studies that involve the collection of data using the Internet are allowed, but Student Researchers should be aware that they can pose challenges in:
  - Collecting anonymous data;
  - Obtaining written informed consent; and
  - Ensuring that participants are of the appropriate age to give informed consent.

Human Subject Risk Assessment (for the local IRB)

It is the local IRB's job to assess the level of potential risk associated with participating in the study.



Human Subject Risk Assessment continued (for the local IRB)

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or test **by the subject population** being studied. The IRB may decide not to require informed consent/minor assent/parental permission in these cases.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life **by the subject population** being studied. Informed consent/minor assent/parental permission MUST BE REQUIRED in these cases.

Risk levels can be reduced by protecting confidentiality or collecting data that is strictly anonymous – where it is impossible to connect research data with the individual who provided the data.

Examples of Greater than Minimal Physical Risk

- Exercise other than that ordinarily encountered in everyday life (by that particular subject population).
- Ingestion, tasting, smelling, or application of any substance.
- Exposure to any potentially hazardous material.

Examples of Greater than Minimal Psychological Risk

- Answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety, etc.
- Answering questions that could result in feelings of depression, anxiety, or low self-esteem; etc.
- Viewing violent or distressing video images.
- Any research activity (survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress.

Please remember that these example lists are not all inclusive and it is the IRB's responsibility to assess the potential risk to the Student Researcher(s) as well as the human subjects participating in the study.

At-Risk Groups

If the research study purposely targets participants from any of the following groups, the IRB must consider whether the nature of the study requires special protections or accommodations.

- Pregnant women;
- Developmentally disabled persons;
- Economically or educationally disadvantaged persons;
- Individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.;
- Children/minors;
- Prisoners; and/or
- Students receiving services under the Individuals with Disabilities Education Act.

Human Subjects Form (4)

This form is required for ALL projects involving human subjects and MUST be completed and approved by the IRB PRIOR to experimentation.

To be completed by the Student Researcher(s) in collaboration with the Adult Sponsor.

1. Student's Name(s):_____
2. Project Title:_____
3. Adult Sponsor:_____ Email:_____
4. ☐ Attached to this form is the Research Plan, which addresses ALL areas under the Human Subjects section of the Research Plan Instructions (page 9).
5. This project _____ ***will*** / _____ ***will not*** include giving my human participants any surveys, questionnaires, tests, photos, videos, or other items to view or complete. If yes, a copy of ALL such materials is attached.
6. This project _____ ***will*** / _____ ***will not*** include any published psychological testing instrument(s) If yes, documentation of my permission to use such material is attached.
7. ☐ Attached is a copy of an Informed Consent Form that I/We would use, if required by the IRB.
8. I/We _____ ***will*** / _____ ***will not*** be working with a Qualified Scientist/Mentor. If yes, a copy of the Qualified Scientist/Mentor Form 2 is attached.

To be completed by the Institutional Review Board (IRB) after review of the research plan.

Mark only ONE designation (Full Committee Approval OR Expedited Review Approval). DO NOT sign 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 5 must be answered to be valid):

1. Risk Level (check one): ☐ Minimal Risk ☐ More than Minimal Risk
2. Qualified Scientist/Mentor Required: ☐ Yes ☐ No
3. Written Minor Assent Required (for participants under the age of 18):
   ☐ Yes ☐ No ☐ Not Applicable (no minors used in this study)
4. Written Parental Permission Required (for participants under the age of 18):
   ☐ Yes ☐ No ☐ Not Applicable (no minors used in this study)
5. Written Informed Consent Required (for participants 18 years and older):
   ☐ Yes ☐ No ☐ Not Applicable (no participants over 18 used in this study)

☐ **Approved with Expedited Review** (1 signature required) and the study meets one of the following conditions:

☐ Human participants will only provide feedback on the project design, student-designed invention, prototype, etc., no personal data will be collected AND there are no health or safety hazards.

☐ The Student Researcher(s) is/are the only subject(s) of the research and there is no more than minimal risk involved.

I attest that I have reviewed the student(s)' project, that ALL of the above have been properly marked indicating the IRB determination and that I agree with the decision. *None of the individuals signing below may be the adult sponsor, designated supervisor, qualified scientist/mentor or a relative of the Student Researcher(s) (conflict of interest).*

Medical or Mental Health Professional (psychologist, medical doctor, licensed social worker, licensed clinical professional counselor, physicians' assistant, or registered nurse) with expertise related to this project

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

Educator

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

School Administrator

Printed Name:	Degree/Professional License:
Signature:	Date of Approval (must be PRIOR to experimentation):

Human Subjects Informed Consent Form

Instructions to the Student Researcher(s):

- An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor.
- This form is used to provide information to the research participant (or parent/guardian) about the study.
- This form documents written informed consent, minor assent, and/or parental permission when required.
- All signed informed consent forms are to be kept by the Student Researcher(s) or Adult Sponsor in a safe, non-public place and NEVER sent to the regional, state or international competition SRCs.
- Student Researchers may use this sample form or copy ALL elements of the form into a new document. Documents not incorporating ALL of the elements below will make the Informed Consent Form invalid.
- A separate photo release form should be developed and used by the Student Researcher(s) if photographs of people other than the Student Researcher(s) are to be used in the display.

Student Researcher(s):_____

Project Title:_____

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 box below.

The purpose of the project is to:

If you participate, you will be asked to:

The time required for participation is:

The potential risks of participating in the study include, but may not be limited to:

The benefits to you personally include, but may not be limited to:

Confidentiality will be maintained by:

If you have any questions about this study, feel free to contact:

Adult Sponsor:_____ Email:_____

Participation Disclaimer: Participation in this study is completely voluntary. If you decide not to participate, there will not be any negative consequences. Please be aware that if you do decide to participate, you may stop participating AT ANY TIME and you may decide not to answer any specific question(s).

By signing this form, I am attesting that I have read and understood the information above and I freely give my consent/assent to participate or permission for my child to participate.

Adult Informed Consent/Minor Assent:

Participant's Printed Name	Signature	Date Reviewed (mm/dd/yy)

Parental/Guardian Permission (if applicable):

Parent/Guardian's Printed Name	Signature	Date Reviewed (mm/dd/yy)

Vertebrate Animal Project Guidelines

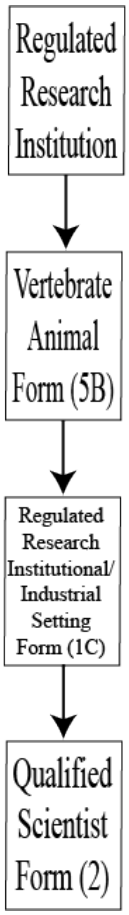
CSEF strongly encourages Student Researchers to use alternatives to animal research if at all possible. If the use of vertebrate animals is absolutely necessary, Student Researchers must follow **federal guidelines** to protect the welfare of both the animal subjects and the Student Researcher(s). When students conduct research with animal subjects, health and well-being are of the highest priority.

Vertebrate animals are defined as:

- Live, nonhuman vertebrate mammalian embryos or fetuses;
- Tadpoles;
- Bird and reptile eggs within three days (72 hours) prior to hatching; and
- All other nonhuman vertebrates (including fish) at hatching or birth.

One exception to these guidelines are zebrafish. Because of their delayed cognitive neural development, zebrafish embryos are not considered vertebrate animals until 7 days (168 hours) post-fertilization.

Note: A project is considered a tissue study and NOT a vertebrate animal study if the tissue is obtained from an animal that was euthanized for a purpose OTHER THAN the Student Researcher's project. In these cases, Student Researchers may observe the vertebrate animal study, but may not have any direct involvement with the vertebrate animal experimental procedures. See the guidelines regarding Tissue studies on page 30.



ALL vertebrate animal studies must be reviewed and approved before experimentation begins by the appropriate review board: IACUC (Institutional Animal Care & Use Committee for studies done at a research institution) or SRC (Scientific Review Committee for studies done in a school, home or field setting). The ONLY exception to this is as follows in regards to behavioral observations.

Studies involving behavioral observations of animals are exempt from prior SRC review as long as ALL of the following apply:

- There is NO INTERACTION with the animals being observed;
- There is NO MANIPULATION of the animal's environment in any way; AND
- The study meets all federal and state agriculture, fish, game and wildlife laws and regulations.

ALL Vertebrate Animal Study Guidelines

The following are various guidelines that may or may not apply to a student's project.

- Student Researchers must include ALL parts (a-e) of the Vertebrate Animals Research Plan requirements found on page 9.
- Student Researchers performing vertebrate animal research must follow US federal laws as well as local and state laws and regulations of the jurisdiction in which the research is performed.
- ALL vertebrate animal studies require the DIRECT supervision of a Qualified Scientist/Mentor or Designated Supervisor (except for observational studies).

- Once the study has been approved, a Student Researcher with any proposed changes to the methods and/or procedures must repeat the review process before continuing with data collection/experimentation.
- Student Researchers are PROHIBITED from designing or participating in any experiment associated with the following types of studies on vertebrate animals:
  - Those which cause more than momentary or slight pain or distress;
  - Those that induce toxicity with known toxic substances that could cause pain, distress or death; including, but not limited to alcohol, acid rain, pesticides or heavy metals;
  - Those using conditioning with aversive stimuli, mother/infant separation or induced helplessness; AND
  - Those involving predator/prey interactions.
- All animals must be monitored for signs of distress. One sign of stress is significant weight loss. The maximum permissible weight loss or growth retardation (as compared to the controls) of any experimental or control animal is 15%.
- Any illness or unexpected weight loss must be investigated and a veterinarian consulted to receive required medical care. This investigation must be documented by the Qualified Scientist/Mentor or a veterinarian. **If the illness or distress is found to be caused by the study, the experiment must be terminated IMMEDIATELY.**
- Studies that are designed or anticipated to cause vertebrate animal death are PROHIBITED.
  - ANY death of a vertebrate animal subject that occurs must be investigated by a veterinarian or Qualified Scientist/Mentor to determine the cause of death. The project MUST BE SUSPENDED until the cause of death is determined and the results of the investigation must be in writing.
  - **If the cause of death was due to the experimental procedure, the study MUST BE TERMINTATED IMMEDIATELY and the project will not qualify for science fair competition.**
- Justification is required for any experiment design that involves food or fluid restrictions and must be appropriate to the species. These studies MUST be conducted at a regulated research institution and reviewed and approved by their IACUC.
- Animals may not be captured from or released into the wild without documented approval of authorized wildlife officials. All appropriate methods and precautions must be used to decrease stress to the animal.
- Fish may be obtained from the wild only if the Student Researcher(s) releases the fish unharmed, has the proper license and adheres to state, local and national fishing laws and regulations. Students are prohibited from performing electrofishing.
- A veterinarian must supervise Student Researcher administration of any prescribed drugs to vertebrate animals.

<u>Animal Care</u>

Animals must be treated kindly and cared for properly.

- Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species.
- Animals must be given a continuous, clean 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 husbandry of the animals.

Guidelines for Studies Conducted at a School, Home or Field Site

Vertebrate animal studies that may be conducted at a home, school, farm, ranch, field setting, etc. include:

- Studies of animals in their natural environment;
- Studies of animals in zoological parks;
- Studies of livestock that use standard agricultural practices; and
- Studies of fish that use standard aquaculture practices.

These projects must adhere to BOTH of the following:

- The research involves only agriculture, behavioral, observational or supplemental nutritional studies on animals.

AND

- The research involves only non-invasive and non-intrusive methods that do not negatively affect an animal's health or well-being.

Vertebrate animal studies that do not meet the above guidelines MUST be conducted at a Regulated Research Institution and reviewed and approved by their IACUC.

The local SRC must determine if a veterinarian's review and certification of the research plan and animal husbandry is required prior to experimentation. A veterinarian must certify experiments that involve supplemental nutrition, administration of prescription drugs and/or activities that would not be ordinarily encountered in the animal's daily life.

Studies in which livestock or fish are being raised for food using standard agricultural practices are allowed. The livestock or fish raised may be euthanized by a qualified adult for carcass evaluation. Euthanasia for tissue removal and/or pathological analysis is not permitted for a project conducted in a school, home or field site setting.

Guidelines for Studies Conducted at a Regulated Research Institution Site

A Regulated Research Institution is defined as a professional research/teaching institution that is regularly inspected by the USDA and is licensed to use animals covered by the Animal Welfare Act and may also be subject to the US Public Health Service Policy. Also included are all federal laboratories such as National Institutes of Health, Veteran's Affairs Medical Centers and the Centers for Disease Control. In addition, pharmaceutical and biotechnology companies and research institutions that utilize research animals that are not covered by the Animal Care and Use Act, but have an operational IACUC and are in compliance with US federal laws are included in this definition.

There are some protocols that may be permitted in a Regulated Research Institution, but are not permitted by Student Researchers. These include:

- Student Researchers are prohibited from performing euthanasia. Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted when done by the Qualified Scientist/Mentor or Designated Supervisor. All methods of euthanasia must adhere to current American Veterinarian Medical Association Guidelines.
- Studies that cause more than momentary or slight pain or distress to vertebrate animals are prohibited unless approved anesthetics, analgesics and/or tranquilizers are used by the Qualified Scientist/Mentor or Designated Supervisor.
- Research in nutritional deficiency or research involving substances or drugs of unknown effect are permitted to the point that any clinical sign of distress is noted. If distress is observed, the project must be suspended and measures taken to correct the deficiency or drug effect. Only when the appropriate steps are taken to correct the causing factors may the project resume.

Vertebrate Animal Form (5A) – Middle School

This form is only required for projects involving vertebrate animals being conducted in a school, home or field research setting and MUST be completed and approved by the SRC PRIOR to experimentation.

To be completed by the Student Researcher(s) in collaboration with the Adult Sponsor, Designated Supervisor and/or Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____
2. Project Title:_____

_____

3. Common name (or Genus, species) and number of each animal used.
4. Describe in detail the housing and husbandry to be provided for each type of animal. 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.
5. What will happen to the animals after experimentation?
6. If applicable, attach a copy of wildlife licenses or approval forms.

The CSEF Vertebrate Animal Rules require that ANY death, illness or unexpected weight loss be investigated, explained, and documented by a letter from the qualified scientist, designated supervisor or veterinarian. Attach this letter to this form when submitting paperwork to the SRC prior to competition. ***If the death, illness or unexpected weight loss is found to be due to the experiment, then it must be terminated IMMEDIATELY.***

To be completed by the local or school Scientific Review Committee PRIOR to experimentation.

The SRC has carefully reviewed this study and finds it is an appropriate study and may be conducted in a non-regulated research site. The Student Researcher(s) MUST have at least the following level of supervision (mark highest level required):

☐ Designated Supervisor REQUIRED. Please have applicable person sign in the appropriate box below.

☐ Veterinarian and Designated Supervisor REQUIRED. Please have the applicable people sign in the appropriate boxes below.

☐ Veterinarian, Designated Supervisor and Qualified Scientist/Mentor REQUIRED. Please have the applicable people sign in the appropriate boxes below and complete a Qualified Scientist/Mentor Form 2.

SRC Chair's Printed Name	SRC Chair's Signature	Date of Approval (mm/dd/yy)

Veterinarian

☐ I have reviewed this research plan and animal husbandry with the student(s) PRIOR to the start of experimentation.

☐ I have approved the use and dosages of prescription drugs and/or nutritional supplements (if applicable).

☐ I will provide veterinary medical and nursing care in case of illness or emergency.

Veterinarian's Printed Name	Email or Phone

Veterinarian's Signature	Date of Approval

Designated Supervisor or Qualified Scientist/Mentor

☐ I have reviewed this research and animal husbandry with the student(s) PRIOR to experimentation and I accept primary responsibility for the care and handling of the animals in this project.

☐ I will provide DIRECT supervision during experimentation.

Veterinarian's Printed Name	Email or Phone

Designated Supervisor's Signature	Date of Approval

Vertebrate Animal Form (5B) – Middle School

This form is only required for projects involving vertebrate animals being conducted at a Regulated Research Institution and may be completed after experimentation. IACUC approval is required PRIOR to experimentation.

To be completed by the Qualified Scientist or Principal Investigator. <u>The Student Researcher(s) are NOT to complete any part of this form!</u> All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____
2. Project Title:_____

_____

3. Title and Protocol Number of IACUC Approved Project:_____

_____

4. Species and number of each animal used.

5. 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.

6. Was there any weight loss or death of any animal? If yes, attach a letter obtained from the Student Researcher(s)' qualified scientist, designated supervisor or veterinarian documenting the situation and the results of the investigation.

7. The Student Researcher(s)' project _____ ***did*** / _____ ***did not*** involve the use of tissues? If yes, Forms 6A and 6B must be completed.
8. What laboratory training (include specific dates) was provided to the student?

A copy of the Regulated Research Institution IACUC Approval MUST be attached to this form. ***A letter from the Qualified Scientist or Principal Investigator will NOT satisfy this requirement.***

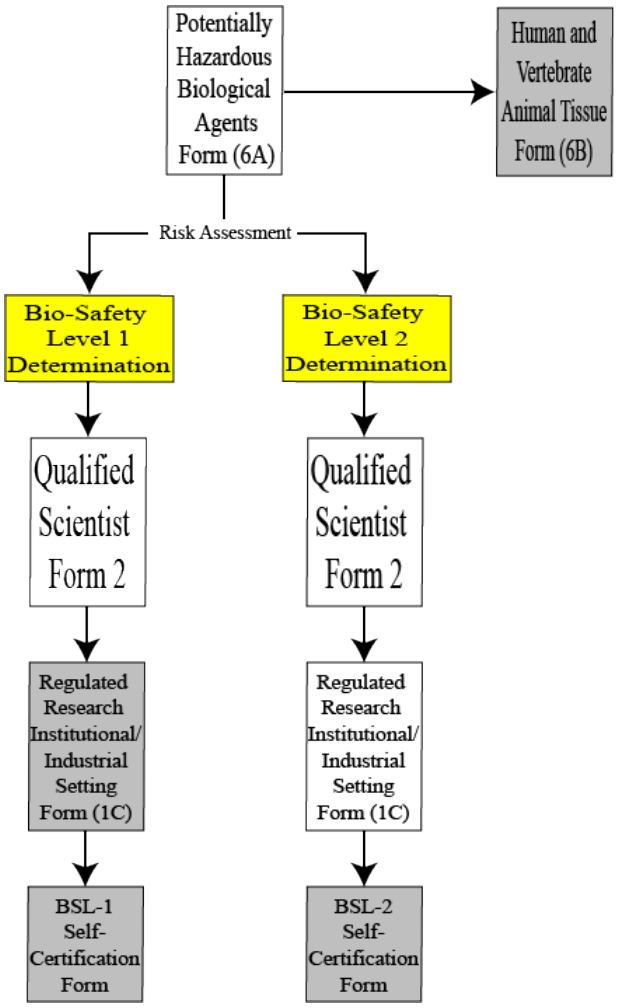
Qualified Scientist/Mentor or Principal Investigator:

_____
Printed Name

_____ _____
Signature Date (mm/dd/yy)

Potentially Hazardous Biological Agents Guidelines

Research using microorganisms (including bacteria, viruses, viroids, prions, rickettsia, fungi, parasites), recombinant DNA technologies or human or animal fresh/frozen tissue, blood, or bodily fluids may involve potentially hazardous biological agents.



When dealing with potentially hazardous biological agents, it is the responsibility of the Student Researcher(s) and ALL of the adults involved in a research project to conduct and document a risk assessment (Form 6A on page 29) to define the potential level of harm, injury or disease to PLANTS, ANIMALS and HUMANS that may occur when working with biological agents.

The risk assessment determines the biosafety level, which in turn determines if the project can proceed, and if so, the laboratory facilities, equipment, training and supervision required.

Studies Exempt from Prior SRC Review/Approval

The following types of studies are exempt from prior SRC review and approval, but **MUST** be included on the Risk Assessment Form 3.

- Studies involving baker's yeast and brewer's yeast, except in rDNA studies.
- Studies involving *Lactobacillus* (starter cultures for controlled fermentation), *Bacillus thurgiensis* (typically found in insecticides), nitrogen-fixing/oil-eating bacteria, and algae-eating bacteria introduced into their NATURAL ENVIRONMENT. **None of these studies are exempt if they are cultured in a Petri dish.**
- Studies involving water or soil not purposely culturing bacteria.
- Studies of mold growth on food items, **IF the experiment is TERMINATED at the first sign of mold.**
- Studies of edible mushrooms and slime molds.
- Studies involving *E. coli K-12* which are done at school and are not rDNA studies.
- Studies involving protists, archaea and **KNOWN** nonpathogenic microorganisms.
- Studies using manure for composting, fuel production or other non-culturing experiments.
- Studies involving the use of commercially-available color change coliform water test kits. These kits must remain sealed and be properly disposed.
- Studies involving the decomposition of vertebrate organisms (such as in forensic projects).
- Studies with microbial fuel cells.

ALL Potentially Hazardous Biological Agent Study Guidelines

All other projects involving potentially hazardous biological agents must be reviewed and approved before experimentation begins by the appropriate review board: IBC (Institutional Biosafety Committee for studies done at a research institution) or SRC (Scientific Review Committee for studies done in a school setting).

- Experimentation involving the culturing of any organism (even BSL-1) is **PROHIBITED in a home environment**. Specimens may be collected at home or other field sites as long as they are immediately transported to a laboratory with the appropriate BSL containment as determined by the local/school SRC.
- The initial risk assessment determination done by the Student Researcher(s) and Qualified Scientist/Mentor must be confirmed by the appropriate review board.
- Student Researchers must be trained in standard microbiological practices.
- Once the study has been approved, a Student Researcher with any proposed changes to the methods and/or procedures must repeat the review process before continuing with data collection/ experimentation.
- ALL PHBAs must be properly disposed of at the end of experimentation in accordance with their biosafety level. Acceptable disposal methods for BSL-1 and BSL-2 organisms include:
  - Autoclave at 121°C for 20 minutes;
  - Use of a 10% bleach solution (1:10 dilution of domestic bleach);
  - Incineration;
  - Alkaline hydrolysis;
  - Biosafety pick-up; or
  - Other manufacturer recommendations.

Potentially Hazardous Biological Agent Study Biosafety Levels (BSL)

- BSL-1 – biological agents that pose low risk to personnel and the environment; highly unlikely to cause disease in healthy laboratory workers, animals or plants.
  - BSL-1 research projects must be conducted in a BSL-1 or higher laboratory. This MAY be a middle or high school science lab if it meets ALL of the standards for a BSL-1 lab (see the self-certification form at http://www.societyforscience.org/document.doc?id=330).
  - BSL-1 research projects must be reviewed by a Qualified Scientist/Mentor but can be directly supervised by a TRAINED Designated Supervisor at a verifiable BSL-1 laboratory.
  - Examples of BSL-1 Organisms: *Agrobacterium tumefaciens* (soil bacteria), *Micrococcus luteus, Neurospora crassa* (red bread mold), *Bacillus subtilis* (normal human gut bacteria).
  - Examples of BSL-1 Studies (this is not an exhaustive list):
    - Studies involving naturally-occurring plant pathogens where they are not cultured or introduced into the environment.
    - rDNA studies involving BSL-1 organisms and BSL-1 host vector systems such as the cloning of DNA in *E. coli K-12, S. cerevisiae,* and *B. subtilis* host vector systems.
    - Studies involving commercially available rDNA kits using BSL-1 organisms.
    - Studies of mold growth on food items where the project is NOT terminated at the first sign of mold.
    - Studies involving unknown microorganisms collected from the environment as long as **ALL of the following conditions are followed**:
      - Culturing is done in a plastic Petri dish and is **SEALED**.
      - The Petri dish remains **SEALED** throughout the experiment.
      - The **SEALED** Petri dish is disposed of via autoclaving or disinfection by the Designated Supervisor or Qualified Scientist/Mentor.

- BSL-2 – biological agents that pose moderate risk to personnel and the environment; exposure in a lab situation would result in limited risk of spreading and it would rarely cause infection that would lead to serious disease; in the event that infection occurs, treatment and preventive measures are available
  - BSL-2 research projects must be conducted in a BSL-2 or higher laboratory. This is usually a regulated research institution, but a high school science lab MAY QUALIFY if it meets ALL of the standards for a BSL-2 lab (see the self-certification form on the SSP web site at http://www.societyforscience.org/document.doc?id=25).
  - BSL-2 research projects must be reviewed and directly supervised by a Qualified Scientist/ Mentor at a verifiable BSL-2 laboratory.
  - Examples of BSL-2 Organisms: *Mycobacterium* (typically found in water and food sources), *Streptococcus pneumoniae* (part of the normal upper respiratory tract flora), *Salmonella choleraesuis* (typically found in raw food sources such as eggs and meat).
  - Examples of BSL-2 Studies (this is not an exhaustive list):
    - Studies culturing known MRSA, VRE and KPC can only be done at a Regulated Research Institution and must include written justification for their usage with documented IBC review and approval.
    - Studies that select and subculture antibiotic-resistant organisms. Use **EXTREME CAUTION** when doing this type of project.
    - Studies that culture human or animal waste (including sewage sludge).
    - Studies that insert antibiotic resistant markers for the clonal selection of bioengineered organisms.
    - rDNA studies using BSL-1 agents that may convert to BSL-2 agents during the course of experimentation.
    - rDNA studies involving BSL-2 organisms and/or BSL-2 host vector systems.
    - Studies involving unknown organisms collected from the environment where the culturing container (Petri dish) is opened for any purpose (except for disposal disinfection).
- BSL-3 - biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences.
- BSL-4 - biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable.

Prohibited PHBA Studies:

- Research that cultures Carbapenem Resistant Enterbacteriacae (CRE).
- Genetically engineered organisms with multiple drug resistance traits with the intended purpose of investigating the pathology or treatment of antibiotic-resistant infections.
- Insertion of antibiotic-resistant traits or selection of organisms expressing traits that may affect the ability to provide effective treatment of infections acquired by humans, animals or plants.
- BSL-3 AND BSL-4 research projects.
- Propagation of recombinants containing DNA coding for human, plant or animal toxins (including viruses).

Potentially Hazardous Biological Agents Form (6A) – Middle School

This form is required for ALL projects involving microorganisms, rDNA, fresh/frozen tissue, blood, blood products and body fluids. SRC/IACUC/IBC approval is required PRIOR to experimentation.

This form is to be completed by the Qualified Scientist/Mentor in collaboration with the Student Researcher(s). All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____
2. Project Title:_____

_____

3. Identify ALL of the potentially hazardous biological agents to be used in this experiment. Include where you will obtain them, how much you are using and the biosafety level of each one.

4. Where will you be conducting the experimentation? Include the level of biosafety containment available at each site.

5. How will you minimize any risk associated in working with these agents? (What personal protective equipment will you be wearing; what type of hood is being used; will you be sealing the Petri dishes and not opening them; etc.)?

6. What biosafety level do you recommend for this project? ☐ **BSL-1** or ☐ **BSL-2**

7. How are you going to dispose of all cultured materials and other potentially hazardous biological agents?

8. What training will the Student Researcher(s) receive?

9. What experience/training does the Designated Supervisor (for BSL-1 studies only) have as it relates to the student's area of research?

Qualified Scientist/Mentor:

☐ I certify that experimentation **was not** conducted at a Regulated Research Institution, but was conducted at a (check one) _____BSL-1 or _____BSL-2 laboratory. The study has been reviewed by the local or school SRC and the procedures have been approved PRIOR to experimentation. **OR**

☐ I certify that experimentation **was** conducted at a Regulated Research Institution and was approved by the appropriate institutional board PRIOR to experimentation. Institutional approval forms are attached. Date of IACUC/IBC Approval:_____ **OR**

☐ I certify that experimentation **was** conducted at a Regulated Research Institution that does not require pre-approval for this type of study. The local or school SRC has reviewed that the student received appropriate training and the project complies with the CSEF Middle School rules.

Qualified Scientist's Printed Name	Qualified Scientist's Signature	Date of Acknowledgement (mm/dd/yy)

To be completed by the local or school Scientific Review Committee.

The SRC has seen this project's research plan and supporting documentation and acknowledges the accuracy of the information provided above.

SRC Chair's Printed Name	SRC Chair's Signature	Date of Approval (mm/dd/yy)

Tissue, Body Fluid & Blood Guidelines

Studies involving fresh or frozen tissue, blood or body fluids obtained from humans and/or vertebrate animals may contain microorganisms and have the potential of causing disease. For this reason, a proper risk assessment (Form 6A) is required along with a tissue certification form (Form 6B).

Studies Exempt from Prior SRC Review/Approval

The following types of tissue do not need to be treated as potentially hazardous biological agents and are thus exempt from prior SRC review and approval, but **MUST** be included on the Risk Assessment Form 3.

- Plant tissue (except those known to be toxic or hazardous).
- Plant and non-primate established cell lines and tissue culture collections (for example those obtained from the American Type Culture Collection). The source and/or catalog number **MUST BE IDENTIFIED** in the Research Plan.
- Fresh or frozen meat, meat by-products, pasteurized milk or eggs obtained from food stores, restaurants or packing houses.
- Hair, hooves, nails and feathers.
- Teeth that have been sterilized to kill any blood-borne pathogen that may be present. The dentist who provided the teeth must provide a letter certifying the sterilization.
- Fossilized tissue or archeological specimens.
- Prepared fixed tissue.

ALL Tissue, Body Fluid, Blood & Blood Product Study Guidelines

The following items may or may not apply to a Student Researcher's project.

- If tissues are obtained from an animal that was euthanized for a purpose OTHER THAN the Student Researcher's project, it may be considered a tissue study and not a vertebrate animal study.
- Use of tissue from research conducted at a Regulated Research Institution required documentation of the IACUC approval for the original animal study.
- Use of tissues obtained from agricultural/aquacultural studies required prior SRC approval.
- If tissues are obtained from an animal that was euthanized solely for the Student Researcher's project, the study must be treated as a vertebrate animal project and is subject to the vertebrate animal rules found on pages 21-23 and Form 5B.
- Studies of human body fluids, where the sample can be identified with a specific person, must be considered a human subjects study and have IRB review and approval and informed consent.
- Studies involving embryonic human stem cells must be conducted in a Regulated Research Institution and be reviewed and approved by their Embryonic Stem Cell Research Oversight (ESCRO) Committee.
- All blood must be handled in accordance with standards and guidelines set forth in the OSHA, 29CFR, Subpart Z.
- Any tissue or instrument with the potential of containing blood-borne pathogens must be properly disposed of after experimentation.
- Any study involving the collection and examination of body fluids or blood that may contain biological agents belonging to BSL-3 or BSL-4 are prohibited.

Examples of BSL-1 Tissue Studies:

- Studies involving the collection and examination of fresh/frozen tissue and/or body fluids (not blood or blood products) from a non-infectious source with little likelihood of microorganisms present.
- Studies involving domestic animal blood.
- Studies involving a Student Researcher using their own body fluids (if not cultured). Will need IRB approval if the body fluid is serving as a measure of an effect of an experimental procedure on the Student Researcher.
- Studies involving human and/or non-human primate established cell lines and tissue culture collections indicated as BSL-1 by the source. The source and/or catalog number of the cultures MUST BE IDENTIFIED in the Research Plan and on Form 6B.

Examples of BSL-1 Tissue Studies:

- Studies involving the collection and examination of fresh/frozen tissues or body fluids or meat, meat by-products, pasteurized milk or eggs NOT obtained from food stores, restaurants or packing houses.
- Studies involving human breast milk of unknown origin, unless certified free of HIV and Hepatitis C and domestic unpasteurized animal milk.
- Studies involving human or wild animal blood or blood products.
- Studies involving human and/or non-human primate established cell lines and tissue culture collections indicated as BSL-2 by the source. The source and/or catalog number of the cultures MUST BE IDENTIFIED in the Research Plan and on Form 6B.

Human and Vertebrate Animal Tissue Form (6B) – Middle School

This form is required for ALL projects involving fresh/frozen tissue, blood, blood products and body fluids. Form 6A MUST also be completed. If the research also involves living organisms (human or vertebrate animals), please ensure that the proper forms are completed.

This form is to be completed by the Student Researcher(s) in collaboration with the Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

1. Student's Name(s):_____

2. Project Title:_____

_____

3. What type of 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
- ☐ Other:_____

4. From where will you obtain the above tissue(s)? Established cell lines must be identified by the source and catalog number.

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 the date of IACUC approval included.

Qualified Scientist/Mentor:

☐ I verify that the student will work solely with organs, tissues, cultures or cells that will be supplied to him/her/them 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 Researcher(s)' project.

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 of Review (mm/dd/yy) (MUST be PRIOR to experimentation)

Title	Email

Institution

Hazardous Chemicals, Activities & Devices Guidelines

The following guidelines are to be used in completing the Risk Assessment (Form 3) that is **required** for all middle school projects. They are designed to help protect the Student Researcher by ensuring they have proper supervision, all potential risks are considered and appropriate safety precautions are taken. Special attention has been brought to substances and devices that are also regulated by local, state and federal law.

Hazardous Chemicals

Student Researchers utilizing chemicals (household and laboratory) in their studies should consider all of the following when completing their Risk Assessment Form 3:

- Chemicals must be acquired and used in accordance with all local, state and federal laws.
- Student Researchers must review the Materials Safety Data Sheets for ALL chemicals (household and laboratory) used in the project.
- For all chemicals requiring a federal and/or state permit, the Designated Supervisor must obtain the permit PRIOR to experimentation and a copy of the permit must be submitted to the Regional Science Fair and/or CSEF in order for the project to qualify for competition.
- Student Researchers should take into account a chemical's toxicity, reactivity, flammability and corrosiveness when completing their risk assessment.
- Student Researchers must minimize the impact of an experiment on the environment by using minimal quantities of chemicals and making sure all disposal is done in an environmentally safe manner and in accordance with good laboratory practices.

DEA-Controlled Substances

The US Drug Enforcement Agency (DEA) regulates substances that can be diverted from their intended use to make illegal drugs. DEA controlled substances and their schedule number are available at the DEA website (http://www.deadiversion.usdoj.gov/schedules/). Special precautions must be taken when Student Researchers utilize DEA-controlled substances in a project:

- It is the responsibility of the Student Researcher in consultation with their Designated Supervisor to consult the DEA schedule list if there is a possibility that substances used in experimentation could be regulated.
- All studies using DEA-controlled substances must be supervised by a Qualified Scientist/Mentor who is licensed by the DEA for use of the controlled substance.
- All studies using DEA Schedule 1 substances (including marijuana) must have the research plan approved by the DEA PRIOR to experimentation.
- Schedule 2, 3 and 4 substances do not require prior approval by the DEA.

Prescription Drugs

Prescription drugs are drugs regulated by federal laws to protect against inappropriate or unsafe use. Special precautions must be taken when Student Researchers utilize prescription drugs in a project:

- It is the responsibility of the Designated Supervisor to properly acquire from a doctor or pharmacist, using a prescription written out specifically for Science Fair research ONLY and NOT to an individual.

Alcohol & Tobacco

The US Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the production of alcohol and distribution of alcohol and tobacco products. Special precautions must be taken when Student Researchers work on projects that include alcohol and tobacco given their age:

- Fermentation studies in which small quantities of ethyl alcohol are produced are permitted.
- It is the responsibility of the Designated Supervisor to properly acquire, store and dispose of any alcohol and/or tobacco used in the study.
- Student Researchers are allowed to design and conduct research projects, under DIRECT parent supervision, involving the LEGAL production of wine or beer. It is the responsibility of the Designated Supervisor to make sure the home production meets all of the TTB regulations for such production.
- Studies involving the production of consumable ethyl alcohol by distillation are PROHIBITED.
- Studies involving the production of ethyl alcohol by distillation for fuel or other non-consumable products is allowed at a school or Regulated Research Institution only.

Weapons, Firearms & Explosives

The US Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) regulates the purchase and use of firearms and explosives. Special precautions must be taken when Student Researchers utilize firearms and/or explosives in a project:

- A firearm is defined as a small arms weapon from which a projectile is fired by gunpowder.
- An explosive is any chemical compound, mixture or device whose primary purpose is to function by explosion. These include, but are not limited to, dynamite, black powder, pellet powder, detonators and igniters.
- It is the responsibility of the properly TRAINED Designated Supervisor to lawfully purchase any firearms and/or ammunition to be used by the Student Researcher.
- A diagram of the shooting area must be included with the Research Plan. All buildings and roads need to be included in the diagram as well as where the Student Researcher(s) will be shooting from and the target area.
- Studies involving firearms and ammunition are allowable under the DIRECT supervision of a Designated Supervisor who has completed a hunter safety program or similar firearms safety course. Proof of training will be required when submitting paperwork to the Regional Science Fair for competition.
- Student Researchers using firearms in a project must have completed a hunter safety course. Proof of training will be required when submitting paperwork to the Regional Science Fair for competition. The Colorado Parks & Wildlife provide hunter safety classes.
- Projects involving explosives are allowable under the DIRECT supervision of a Designated Supervisor and when in compliance with all federal, state and local laws.
- Studies involving a fully assembled rocket motor, reload kit or propellant modules containing more than 62.5 grams of propellant are subject to the permitting, storage and other requirements of federal explosive laws and regulations.

- All bows and arrows are not considered firearms, but the Student Researcher and Designated Supervisor should have appropriate training in the safe use of such weapons. The Colorado Parks & Wildlife provide bowhunter education classes.
- Potato guns and paintballs are not considered firearms unless they are intended to be used as weapons, but they must be treated as hazardous devices.

Drones

Studies involving unmanned aircraft systems/drones must follow all federal, state and local laws. Typically a permit or registration of the aircraft will be required for certain sized drones/unmanned aircraft to be flown outside. Check out the Federal Aviation Administration (FAA) website for more details (www.faa.gov.registration).

Other Hazardous Devices & Activities

Due to middle school Student Researcher's young age and limited experience, the CSEF requires that ALL projects complete a Risk Assessment (Form 3) and assign and Designated Supervisor to DIRECTLY supervise the student while working on the project. Students and supervisors should think about ALL potentially hazardous devices, chemical and/or activities that might be associated with the project they are working on and how to best keep everyone safe. The following are common hazards that are overlooked:

- Household chemicals and solutions should be treated the same as laboratory chemicals and students should read the Materials Safety Data Sheets that can be found online on how to safely use them – especially if they are using them for purposes other than their intended household use in a science project.
- Cooking stoves and ovens should be treated the same as laboratory devices and students should be taught how to use them in a safe manner – especially when heating items to high temperatures.
- The use of power tools must be supervised by a Designated Supervisor who has significant training or experience using such devices. Students should be clear in their research plan about the type of tools they plan on using (manual or power tools).
- Studies involving radiation that is beyond that normally encountered in everyday life must consider the level and duration of exposure.
    - Normal radiation found in everyday life comes in the form on non-ionizing radiation including the spectrum of ultraviolet, visible light, infrared, microwave, radiofrequency and extremely low frequency.
    - Ionizing radiation has enough energy to remove tightly bound electrons from atoms, thus creating ions and health hazards when exposed for long periods of time. Examples include high frequency UV, x-rays, and gamma rays.
    - Lasers usually emit visible, ultraviolet or infrared radiation and are allowed to be used by Student Researchers as long as they are in a fixed position. **Remember that lasers and laser pointers are not allowed to be used during science fair competitions.**
    - All studies involving exposure to radiation may not exceed the dose limits set by the Nuclear Regulatory Commission of 0.5 mrem/hr or 100 mrem/year of exposure.
    - Any study requiring between 10 and 25 kvolts must be conducted at a Regulated Research Institution and be preapproved by the local/school SRC.
    - Any study requiring more than 25 kvolts must be conducted at an institution with a Licensed Radiation Program and be preapproved by their Radiation Safety Officer or Committee that oversees the use of ionizing radiation.