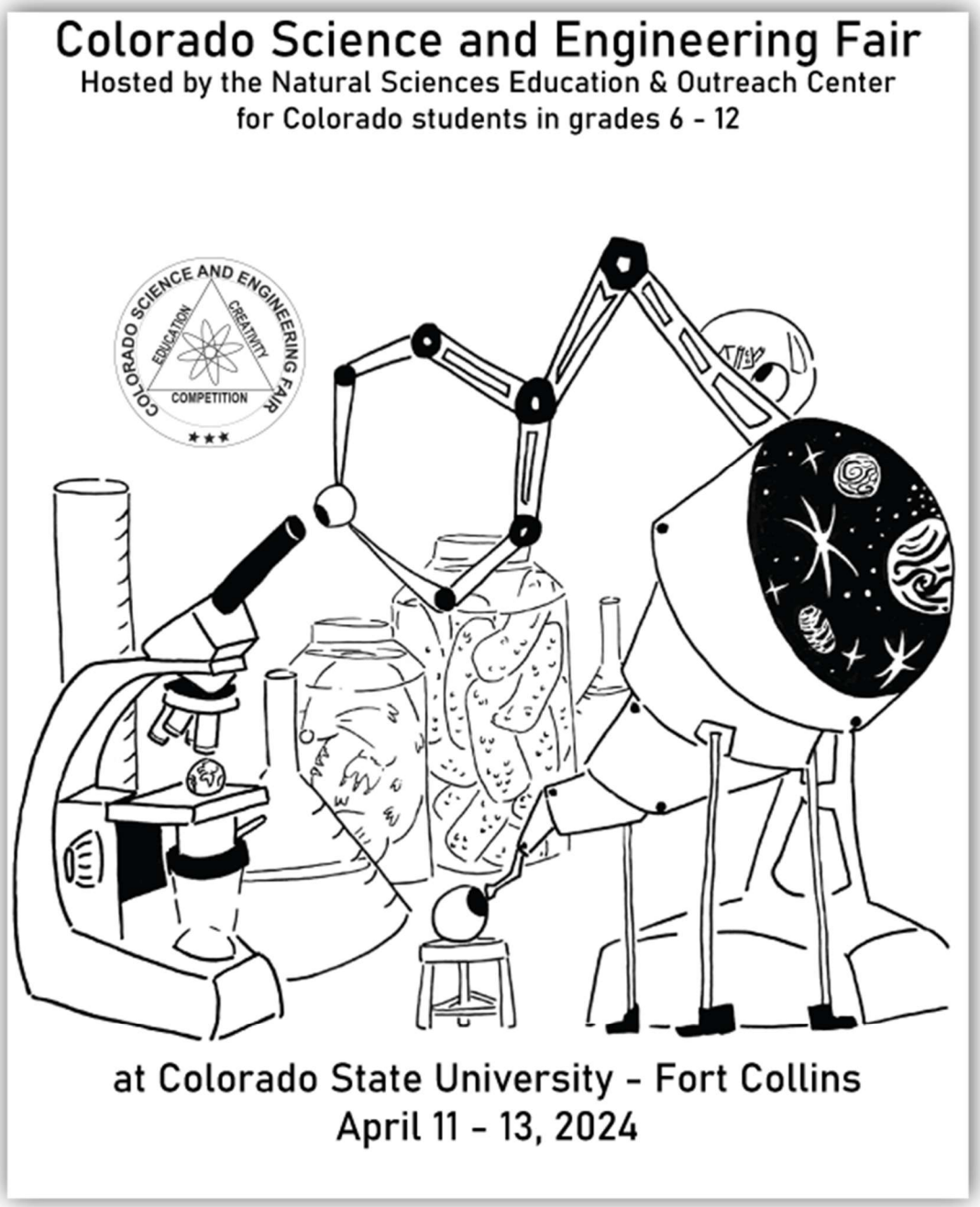

Middle School Rules & Guidelines

Copy and distribute freely!

Revised August 2023

Electronic version can be found at:
https://csef.natsci.colostate.edu/

Natural Sciences Education and Outreach Center

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Eligibility for Competition Requirements

The Colorado Science & Engineering Fair (CSEF) is affiliated with the Regeneron International Science & Engineering Fair (ISEF). For this reason, students participating in the regional and state science fairs in Colorado must adhere to the international rules and guidelines as set forth by the Society for Science's Scientific Review Committee. These rules outline the forms, supervision and risk assessments that are needed for all projects as well as those 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 they may be working with in their study. ***They 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, CSEF has created this rules and guidelines book to help them through the approval process. The rules and guidelines are EXACTLY like the Regeneron ISEF ones, just written in a manner that is more easily understood by middle schoolers. The forms in this booklet are ONLY FOR MIDDLE SCHOOL (grades 6-8) STUDENTS and may not be use by students in grades 9-12. **Please use only these middle school forms OR the Regeneron ISEF forms - don't mix them!**

- Each Regional Science Fair may only send the number of projects outlined in their affiliation agreement with the CSEF. This number can be split between the senior (9-12 grade) and junior (6-8 grade) divisions as the Regional Fair Director sees fit.
- Student Researchers must be selected by their Regional Science Fair in order to participate in the CSEF. Students should participate in the Regional Science Fair that is associated with the county they go to school in or where they live in the case of home schoolers or online school attendees.
- Regional Science Fairs may include students at any grade level (K-12) they choose, but only students in grades 6-12 (and not older than 20 years of age) are eligible to attend the CSEF.
- Each student is allowed to enter ONLY ONE project in a Regional Science Fair each year for competition. That project may include no more than 12 months of continuous data collection/experimentation and may not include data collection/experimentation performed prior to January 2023.
- Team projects intending to be entered in a Regional Science Fair may have no more than three members and should not cross division boundaries (elementary age with junior division or middle school age with senior division). Team membership cannot be changed during a given research year except under extenuating and clearly documented circumstances. **ONE** Team Leader MUST be identified.
- Students may compete in ONLY ONE CSEF affiliated Regional Science Fair.
- Projects that are demonstrations, library research or informational only, explanation models or kit based are not recommended or appropriate for the CSEF.
- A project may be a part of a larger study performed by a professional scientist, but the research presented by the student(s) must be only their own portion of the complete study.
- All students competing in any of the Regional Science Fairs must adhere to all of the rules set forth by the CSEF in this booklet regardless of whether or not the Regional Science Fair they compete in is directly affiliated with the Regeneron ISEF.

Ethics Statement

Adopted from the Regeneron ISEF.

Student researchers, as well as adults who have a role in their projects, are expected to maintain the highest ethical standards. These standards include, but are not limited to:

Integrity: Honesty, objectivity, and avoidance of conflicts of interest are expected during every phase of the project. The project should reflect independent research done by the student(s) and be free of fraudulent data and/or plagiarism and represent only one year's work.

Legality: Compliance with all federal, state and local laws and regulations is essential. All projects must be approved by a Scientific Review Committee (SRC) and when necessary, must also be approved by an Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and/or Institutional Biosafety Committee (IBC).

Respect for Confidentiality and Intellectual Property: Confidential communications, as well as patents, copyrights, and other forms of intellectual property must be honored. Unpublished data, methods or results may not be used without permission and credit must be given for all contributions to the research.

Stewardship for the Environment: It is the responsibility of the researcher and the adults involved to protect the environment from harm. Introduction or disposal of native, genetically-altered, and/or invasive species (i.e.: insects, plants, invertebrates, vertebrates), pathogens, toxic chemicals or foreign substances into the environment is prohibited. It is recommended that students reference their local, state or national laws and regulations.

Acknowledgement of Risks: All projects involve some amount of risk. Everyone is expected to recognize the hazards, assess the risks, minimize the risks and prepare for emergencies.

Animal Care: Proper care and respect must be given to vertebrate animals. The use of non-animal research methods and alternatives to animal research are strongly encouraged and must be explored before conducting a vertebrate animal project. The guiding principles for the use of animals in research include the following Four R's: Replace, Reduce, Refine, Respect.

Human Participant Protection: The highest priority is the health and well-being of the student researcher(s) and human participants.

Potentially Hazardous Biological Agents (PHBAs): It is the responsibility of the student and adults involved in the project to conduct and document a risk assessment, and to safely handle and dispose of organisms and materials associated with these types of projects.

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.

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 may 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 enlist the aid of a Qualified Scientist/Mentor.

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 and any humans or animals involved in the study;
- ensure that experimentation is done within local, state and federal laws and these 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/Mentor's qualifications are adequate for the type of project the student is doing.

Qualified Scientist/Mentor

Some projects MAY require the Student Researcher to work with a Qualified Scientist or Mentor. A Qualified Scientist/Mentor should possess an earned doctoral/professional degree in a scientific discipline 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 of study is acceptable.

The Adult Sponsor may also serve as a Qualified Scientist/Mentor for the project, if they are qualified as outlined above. A Qualified Scientist/Mentor does not have to be located within the same city/town or even state as the Student Researcher. In cases where the Qualified Scientist/Mentor 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 Researcher'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 that particular area of research. The Adult Supervisor may act as the Designated Supervisor.

The degrees of M.O.M. and D.A.D. (parents) need to be accompanied by an explanation of their qualifications to supervise a particular project. Just being the parent is not sufficient.

If the Student Researcher 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 Researcher'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 to compete – even if the prior review board approved the project.

Scientific Review Committee

The Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluating project procedures to make sure 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 the Student Researcher's project involves vertebrate animals and/or potentially hazardous biological agents (microorganisms, rDNA, tissue), then the experimental procedures must be approved by the local SRC BEFORE the Student Researcher may begin working on the experimental portion of the project.

Institutional Review Board

The 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 and 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 the 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/Mentor) BEFORE the Student Researcher may begin work on the experimental portion of the project. Some institutions may not review all of these types of projects – if they don't, then this must be certified by the Qualified Scientist/Mentor and approved by the school/local SRC on Form 6A.

Regional SRC

This group of people will review the Student Researcher's paperwork for compliance with the rules set forth here and paperwork completion.

State SRC

This group of people will review the paperwork for the Student Researchers who have been chosen 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/Mentor(s) and Designated Supervisor(s) of the Student Researcher MUST NOT serve on the SRC or IRB reviewing that project.

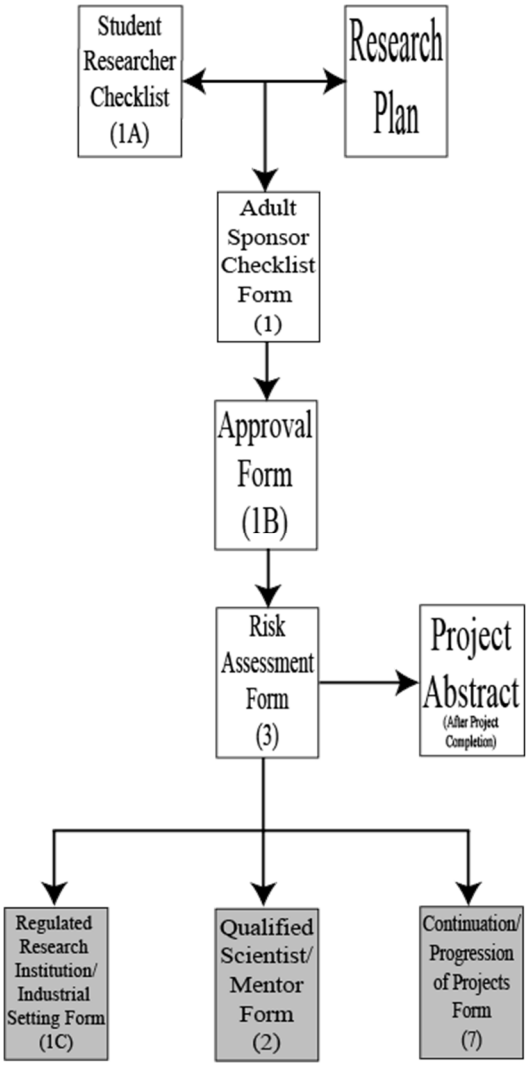
Questions regarding specific experimental procedures or the rules should be directed to the Student Researcher's school SCR/IRB, but inquires can be directed to the CSEF SRC or the Regeneron ISEF SRC as well at:

Regeneron ISEF SRC
SRC@societyforscience.org

CSEF SRC
csef@colostate.edu

Requirements for ALL Projects

ALL projects must have the following 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 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:** 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 PRIOR to experimentation and written in the present or future tense.
- **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 PRIOR to experimentation.
- **Approval Form (1B):** this is where the various people sign off their approval of the project. A separate Approval Form is required for each Student Researcher if it is a team project.
- **Risk Assessment Form (3):** this is a review of the risks that might be associated with the project. This is to be completed by the Student Researcher 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:

- **Qualified Scientist/Mentor Form (2):** this is used to document when the 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.
- **Regulated Research Institution/Industrial Setting Form (1C):** this is a summary of what the Student Researcher did at a professional lab. This is to be completed by the supervising adult who is affiliated with the laboratory and who has first-hand knowledge of the student's work and is completed AFTER experimentation.
- **Continuation/Progression of Projects Form (7):** this is used to document prior work that the Student Researcher has done in the same field of study as the current work. This is to be completed by the Student Researcher AFTER experimentation and include copies of the previous years' abstract and Research Plan.

Middle School - Adult Sponsor Checklist Form (1)

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/Team Leader.

Student's Name(s):_____

Project Title: _____

1. Adult Sponsor, please certify that you have reviewed the following with the Student Researcher 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 Risk Assessment Form (3) and approve of the chosen Designated Supervisor.

2. The Student Researcher ☐ ***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 school/local SRC or IRB may require a student to work with a Qualified Scientist.

3. The Student Researcher ☐ ***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 Regulated Research Institution/Industrial Setting Form 1C will be required AFTER the project is completed.

4. 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.

5. This project ☐ ***does*** / ☐ ***does not*** involve human testing of a student deigned invention, prototype or computer application. If yes, #6 needs to be marked for Human Subjects and Form 4 must be completed.

6. 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)

I attest to the information checked above and that I have read and agree to abide by the science fair ethics statement found on Page 4.

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

Middle School - Student Researcher Checklist Form (1A)

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

This form is to be completed by the Student Researcher/Team Leader before submitting it 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:_____ Phone:_____

Team Member 1:_____ Grade:_____

Team Member 2:_____ Grade:_____

2. 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** 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 experimentation at the following work site(s):
(check ALL that apply & explain in the Research Plan)

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

10. I/We will be getting our data from the following sources:

☐ Collected by self/mentor ☐ Other:_____
(please describe or give URL)

11. Non-school and non-home work site physical address(es) are:
(regulated research institutions, industrial settings, field sites – attach additional pages as needed)

Site 1 Name:_____ Site 2 Name:_____

Site 1 Address:_____ Site 2 Address:_____

_____ _____

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

Site 1 Email:_____ Site 2 Email:_____

Prepare a Research Plan following the instructions on page 10 and attach to this form for review.

Middle School - Research Plan Instructions

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 MUST 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 these tie 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. If you are working at more than one site, please explain what was done where (i.e.: What is being done at school vs. home?).
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 the **major references** (for example: 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 details listed on page 11.

Middle School - Research Plan Instructions cont.

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.

Human Subjects: Prior IRB approval and Form 4 *are* required. An Informed Consent Form and Qualified Scientist/Mentor (Form 2) *may* be required by the IRB.

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.

Vertebrate Animals: Prior SRC approval and Form 5A or 5B *are* required. A Qualified Scientist/Mentor Form 2 *may* be required by the SRC.

a. Briefly discuss potential ALTERNATIVES to vertebrate animal use in your project and a detailed justification for using vertebrate animals. Explain the potential impact or contribution to society this project may have.
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?

Potentially Hazardous Biological Agents: Prior SRC approval and Form 6A *are* required. A Form 6B and Qualified Scientist/Mentor (Form 2) may be required.

a. What biological agent (microorganism, rDNA, tissue, cell line, etc.) are you 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 are you going to dispose of the biological agents once your project is complete?

Middle School - Approval Form (1B)

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 science fair ethics statement found on page 4.

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.

Required for projects involving human subjects, vertebrate animals and/or potentially hazardous biological agents. **Check only ONE 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 Pre-college 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 School 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)

Middle School - Risk Assessment Form (3)

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

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

Student's Name(s): _____

Project Title: _____

1. **HAZARDS:** List **ALL** dangerous activities, hazardous devices, chemicals (household AND laboratory) and/or microorganisms exempt from pre-approval that are to be used in this project.

2. **RISKS:** Identify the risks involved in using **ALL** items listed in question #1. *(What is the worst that could happen if something went wrong when working on your project?)*

3. **SAFETY:** Describe the safety precautions you are going to take in order to minimize/reduce the risks identified in question #2. *(How are you going to keep yourself and others around you safe while you are working on your project?)*

4. **DISPOSAL:** Describe the disposal procedures you will use (when applicable) for items listed in question #1 *(How are you going to SAFELY dispose of any hazardous items used in the project?)*

5. **SOURCES:** 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)

Relation to Student Researcher(s)	Email

Experience/Training as it relates to the project:

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

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, industrial setting or any work site other than home, school or field and who has first-hand knowledge of the student's work done there. The Student Researcher/Team Leader should NOT complete any part of this form!

Student's Name(s): _____

Project Title: _____

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

   b. If yes, complete questions 2 – 5 and complete the certification box below.
2. The Student Researcher's project ☐ ***is*** / ☐ ***is not*** a subset of my ongoing research or work. Use questions 3, 4, & 5 to detail how the student's project was similar and/or different from ongoing research or work at your site. If this project is under a grant and needs to be acknowledged, please list the grant statement here.

3. Describe the independence and creativity with which the Student Researcher:
   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.

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

Student's Name(s):_____

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

5. The Student Researcher ☐ ***did*** / ☐ ***did not*** work on the project as a part of a research group.
If yes, how many individuals were in the group and who were they (high school students, graduate students, faculty, professional researchers, etc.)?

Institution Representative:

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

I further acknowledge that the Student Researcher will be presenting this work publicly in competition and I have communicated with the Student Researcher regarding 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

Middle School - Qualified Scientist/Mentor Form (2)

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/Team Leader should NOT complete any part of this form!</u>

Student's Name(s):_____

Project Title: _____

1. Qualified Scientist/Mentor's Name:_____
2. Educational Background_____ Degree(s):_____
3. My ***experience/training*** as it relates to the Student Researcher's project includes:

4. Institution:_____ Position:_____
5. Email:_____ Phone Number:_____
6. I ☐ ***have*** / ☐ ***have not*** reviewed the Rules and Guidelines for Middle School Science Research relevant to the Student Researcher's project. If not, please attach an explanation as to why.
7. 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)
☐ Hazardous Substances/Devices

☐ None of the Above

8. This project ☐ ***is*** / ☐ ***is not*** a subset of a larger study.
9. I ☐ ***will*** / ☐ ***will not*** directly supervise the Student Researcher during experimentation.
   a. If not, who will DIRECTLY supervise the Student Researcher?_____
   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 <u>ONLY</u> 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

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

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 Researcher(s) and MUST be completed AFTER experimentation.

This form is to be completed by the Student Researcher/Team Leader and accompanied by previous year(s)' abstract and Research Plan. 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 multiple years.

Student's Name(s):_____

	Current Research Project (2023-2024)	Previous Research Project Year:_____
1. Title		
2. Change in Goal/Purpose/Objective		
3. Changes in Methodology		
4. Variables Studied		
5. Additional Changes		

Student Researcher or Team Leader:

☐ I have attached the relevant previous year's abstract and Research Plan 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 (2023/2024).

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

Human Participant Project Rules

Student Researchers must follow **federal guidelines** to protect the human research participants and the Student Researcher. When students conduct research with humans, the rights and welfare of the participants must be must be the highest priority.

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

- **Research Plan Requirements:** The Student Researcher must include ALL parts (a-g) of the Human Subjects Research Plan requirements found on page 11.
- **Prior Review Requirements:** Student research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) BEFORE any interaction with subjects may begin. It is the responsibility of the IRB (not just the student) to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for both the student researcher and the participants.
  - Projects that are conducted at school, at home or in the community and not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the school or regional IRB before the student may begin recruiting and/or interacting with the human participants. Documentation of review and approval is done on Form 4 for these projects.
  - Projects that are 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 Qualified Scientist/Mentor is NOT ACCEPTABLE.
- **IRB Approval:** The student must comply with all determinations made by the IRB before beginning any interaction with human participants:
  - If the IRB requires that a Qualified Scientist/Mentor is a consulted about the project, then Form 2 must be completed and reviewed before the IRB approves the project.
  - If the IRB requires written informed consent, parental consent or minor assent, then a sample Informed Consent Form must be completed and reviewed before the IRB approves the project.
- **Privacy Laws:** The study must be in compliance with all privacy laws (FERPA and HIPAA) when they apply to the project (i.e.: the project involves medical information).
- **Medical Diagnoses:** Student Researchers **are prohibited** from independently diagnosing disease, administering medication and/or performing medical procedures on human participants.
  - The Student Researchers may observe and collect data for analysis of medical procedures, medication/treatment efficacy and diagnosis of illness, only under the DIRECT SUPERVISION of a licensed health care provider/professional.
  - The healthcare provider/professional MUST BE NAMED in the research plan approved by the IRB. The IRB must also confirm that the student is not violating the appropriate medical practice (medical, nursing, pharmacy, etc.) act of Colorado.
  - The Student Researchers are prohibited from providing diagnostic or medical information to participants without direct supervision and involvement of a medical professional. This includes publishing diagnostic apps on public websites or app stores without appropriate FDA approval.

- **Publishing Information:** The Student Researcher 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.
- **Use of Published Instruments:** All published 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.
- **Surveys Using the Internet:** Studies that involve the collection of data using the internet are allowed, but the Student Researcher should be aware that they can pose challenges with the following:
  - Collecting anonymous data. In order to protect the confidentiality of the participants, it is extremely important that IP addresses, as well as the data provided, be safeguarded. Precautions must be explained in the Research Plan.
  - Obtaining informed consent, especially when minors are used in the study. Studies that involve the use of minors in conducting online surveys **must** have Informed Consent and the parent/guardian of the minor must provide written parental permission before the survey may be given to the minor. The procedures used to obtain parental permission must be described in the Research Plan.
  - Ensuring that participants are of the appropriate age to give informed consent.

  Students should consult the ISEF Guidelines for Online Survey Consent Procedures prior to conducting an online survey.
- **Student Designed Inventions:** Student Researcher-designed invention, prototype, computer application, engineering/design and product testing projects that involve testing of the invention by any human participant requires an assessment of the potential risks to the individual(s) testing or trying out the invention/prototype.
  - If the invention/prototype is tested by human participants OTHER THAN the Student Researcher(s) or a single adult guardian (Adult Sponsor, Qualified Scientist/Mentor, Designated Supervisor, Parent – ONLY when the testing requires an adult tester), then **IRB review and PRIOR approval is required**. This includes surveys regarding potential use, review of the product and/or opinions regarding the project/product.
  - Projects in which the invention, prototype or project involves a medical diagnosis or intervention and is tested on human subjects must follow the above rules regarding the prohibition of medical procedures and be supervised by a health care professional with appropriate credentials and specialization in the area of medical diagnosis or intervention or consumer product.
- **Changing Procedures:** Once a study has been approved, if the Student Researcher has any proposed changes to the methods and/or procedures, they must repeat the review process before continuing with data collection/experimentation.

Informed Consent Guidelines

If required by the IRB, participation in a research study may begin ONLY AFTER research participants have voluntarily given informed consent/assent (and in some cases, parental permission). The school/local IRB will determine whether this can be verbal or must be written, depending on the level of risk, type of study and demographics of the subjects.

- Adult research participants may give their own consent.
- Research participants under 18 give their assent with parent/guardian providing permission.
- 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 and is an on-going process – subjects may choose to stop participating AT ANY TIME.
- When written parental permission is required and the study includes a survey or questionnaire, these MUST BE ATTACHED to the consent form for the parent to review.
- The student researcher may request that the IRB waive the requirement for written informed consent/parental permission if the project meets specific requirements (see page 21).

Studies Requiring IRB Review/Approval

These are examples of studies involving human participants that require IRB review and pre-approval and **may require** written informed consent/minor assent/parental permission. Remember, this is not an all inclusive list.

- 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 and questionnaires).
- Studies where the Student Researcher is the subject of the research.
- Subjects testing student-designed inventions, prototypes, applications, etc. This includes surveys conducted regarding potential use, review of the product and/or opinions regarding the project.
- 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 has modified the environment;
  - Occur in non-public or restricted access settings; and/or
  - Involve the recording of personally identifiable information.

Studies Exempt from IRB Review/Approval

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

- When the testing of a student-designed invention, prototype or computer application is done **ONLY** by the Student Researcher (or a single adult guardian when the testing requires an adult tester) **AND** where the testing does not pose a health or safety hazard.
- Data/record review studies where the data are 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 has **no interaction** with the subjects being observed; **AND**
  - The Student Researcher **does not manipulate** the environment in any way; **AND**
  - The Student Researcher **does not record any personally identifiable** data about the subjects being observed.
- Projects in which the Student Researcher receives pre-existing 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 have been appropriately de-identified before being given to the Student Researcher and are in compliance with all privacy and HIPPA laws, **AND**
  - The Regional Science Fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Human Subject Risk Assessment (for the local IRB)

All human participant projects are considered to have some level of risk.

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.

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.

Privacy Concerns

The Student Researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to an invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level 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.

Please remember that the following examples 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.

Examples of Greater than Minimal Physical Risk

Studies where more than minimal **PHYSICAL** risk exists and informed consent/assent and parental consent should be obtained, include, but are not limited to:

- 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

Studies where more than minimal **PSYCHOLOGICAL** risk exists and informed consent/assent and parental consent should be obtained, include, but are not limited to:

- 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.

At-Risk Groups

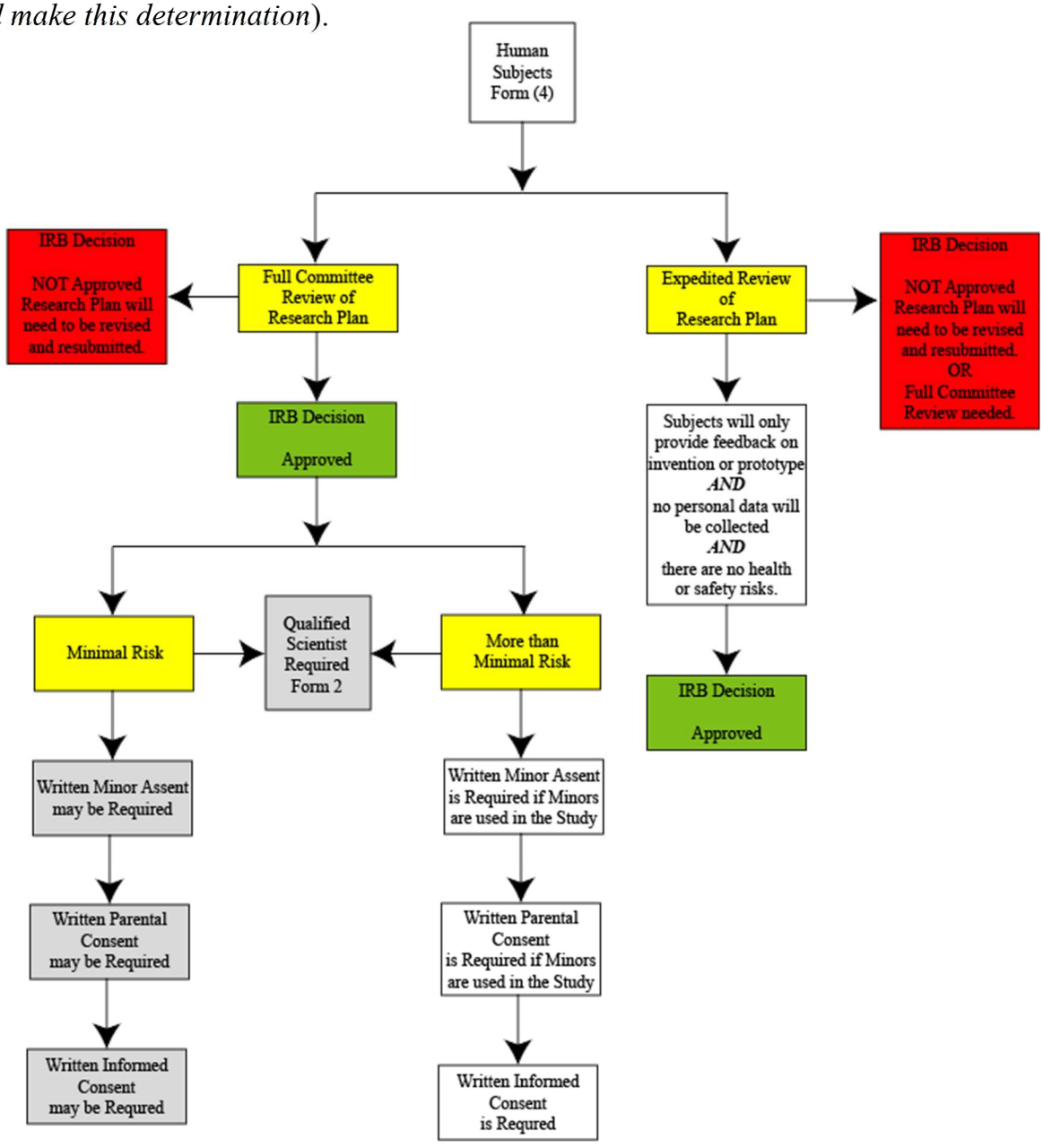
If the research study purposely targets participants from any of the following groups, the IRB must consider whether the nature of the study requires special protections or accommodations.

- 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.

Waiver of Written Informed Consent

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the project involves only minimal risk AND anonymously collected data AND if involves one of the following:

- Normal educational practices (*the school administrator must make this determination*).
- Individual or group behavior or characteristics of individuals where the Student Researcher(s) does not manipulate the subjects' behavior AND does not involve more than minimal psychological risk (*a mental health professional should make this determination*).
- Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, game theory, etc. AND that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress (*a mental health professional should make this determination*).
- Physical activity where there is no more than minimal risk AND where the probability and magnitude of harm or discomfort are NOT greater than those ORDINARILY encountered in daily life or during the performance of ROUTINE physical activities (*a medical health professional should make this determination*).



Middle School - 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/Team Leader in collaboration with the Adult Sponsor.

Student's Name(s):_____

Project Title:_____

Adult Sponsor:_____ Email:_____

1. ☐ Attached to this form is the Research Plan, which addresses ALL areas under the Human Subjects section of the Research Plan Instructions (page 10).
2. 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 MUST be submitted to the IRB for review.
3. This project ☐ ***will*** / ☐ ***will not*** include any published instrument(s) If yes, documentation of my permission to use such material is attached.
4. ☐ Attached is a copy of an Informed Consent Form that I/we will use, if required by the IRB.
5. 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. All questions must be answered for the approval to be valid. (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)

I attest that I have reviewed the Student Researcher's project, that ALL of the above have been properly marked indicating the IRB determination and that I agree with the decisions. *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 (medical doctor, physician's assistant, doctor of pharmacy, registered nurse) or **Mental Health Professional** (psychologist, licensed social worker, licensed clinical professional counselor) 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: (school principal or assistant principal)

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

Middle School - Human Subjects Informed Consent Form

Instructions to the Student Researcher/Team Leader:

- 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/Team Leader 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 it 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 if photographs of people other than the Student Researcher(s) are to be used in the display.

Student's Name(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.

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 Rules

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

Vertebrate animals are defined as:

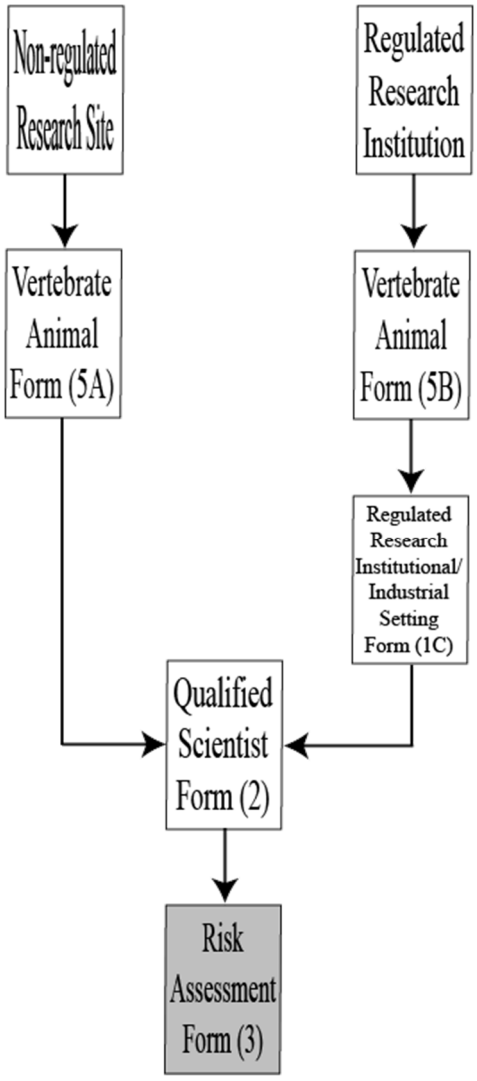
- Live, nonhuman vertebrate mammalian embryos or fetuses;
- Tadpoles;
- Bird and reptile eggs within three days (72 hours) prior to hatching; and
- All other nonhuman vertebrates (including fish) at hatching or birth.
- One exception to these guidelines are zebrafish. Because of their delayed cognitive 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 34.

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.

- **Research Plan Requirements:** Student Researcher(s) must include ALL parts (a-e) of the Vertebrate Animals Research Plan requirements found on page 11.
- **Supervision:** ALL vertebrate animal studies require the DIRECT supervision of a Qualified Scientist/Mentor or Designated Supervisor.

- **Prior Review Requirements:** Student research involving vertebrate animals must be reviewed and approved by the appropriate review board BEFORE any experimentation with the animals may begin. It is the responsibility of the review board (not just the student) to evaluate potential physical and/or psychological risks of the project and make a determination about whether the project is appropriate for student research and safe for both the student researcher and the animals.
  - Projects that are conducted at school, at home or in the field and not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the school or regional SRC before the student may begin recruiting and/or interacting with the human participants. Documentation of review and approval is done on Form 5A for these projects.
  - Projects that are conducted at a Regulated Research Institute must be reviewed and approved by THAT INSTITUTION'S IACUC – NOT the school or regional SRC. A copy of the IACUC approval for the entire project is required. A letter from the Qualified Scientist/Mentor is NOT ACCEPTABLE. Documentation of review and approval is done on Form 5B for these projects.
- **Animal Use Justification:** 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.
- **Laws:** 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.
- **Wild Animals:** 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:** Fish may be obtained from the wild only if the Student Researcher 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.
- **Prohibited Projects:** Student Researchers are PROHIBITED from designing or participating in any experiment associated with the following types of studies on vertebrate animals:
  - Those that 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;
  - Those that study pain; AND
  - Those involving predator/prey interactions.
- **Animal Monitoring:** All animals must be monitored for signs of distress. Because significant weight loss is one sign of stress, weight MUST be recorded at least weekly, with 15% being the maximum allowed weight loss or growth retardation as compared to the control of any animal (experimental or control). If weighing of animals cannot be done in a manner that is safe for both the researcher and the animal, then an explanation and approval by an SRC or IACUC needs to be included in the research plan along with an alternative method to address signs of distress. Additionally, body conditioning scoring (BCS) system should be included in the design of any study utilizing live vertebrate animals and the results regularly recorded.

- **Animal Illness:** 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.**
- **Animal Death:** No vertebrate animal deaths due to the experimental procedures are allowed.
  - 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 ANY science fair competition.**
- **Changing Procedures:** Once a study has been approved, if the Student Researcher has any proposed changes to the methods and/or procedures, they must repeat the review process before continuing with data collection/experimentation.

Animal Care

Animals must be treated kindly and cared for properly. Documentation of the animal care procedures must be included in the Research Plan, making sure to include the following items:

- **Environment:** Animals must be housed in a clean, ventilated, comfortable environment appropriate for the species.
- **Food & Water:** Animals must be given a continuous, clean water and food supply.
- **Housing:** Cages, pens and fish tanks must be cleaned frequently.
- **Care:** Proper care must be provided at all times, including weekends, holidays and vacation periods.
- **Observation:** Animals must be observed daily to assess their health and well-being.
- **Oversight:** 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 (the act of intentionally ending an animal's life) 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:

- Euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted when done by a QUALIFIED adult. 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.
- 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.

Middle School - Vertebrate Animal Form (5A)

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/Team Leader in collaboration with the Adult Sponsor, Designated Supervisor and/or Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

Student's Name(s):_____

Project Title:

_____

1. Common name (or Genus, species) and number of each animal used.
2. 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.
3. What will happen to the animals after experimentation?
4. 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 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:

☐ 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.

Designated Supervisor's Printed Name	Email or Phone

Designated Supervisor's Signature	Date of Approval

Middle School - Vertebrate Animal Form (5B)

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/Team Leader is NOT to complete any part of this form!</u> All questions MUST be answered and additional pages may be attached.

Student's Name(s):_____

Project Title:

_____

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

_____

2. Species and number of each animal used.

3. 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.

4. 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.

5. The Student Researcher's project ☐ ***did*** / ☐ ***did not*** involve the use of tissues? If yes, Forms 6A and 6B must be completed.

6. 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

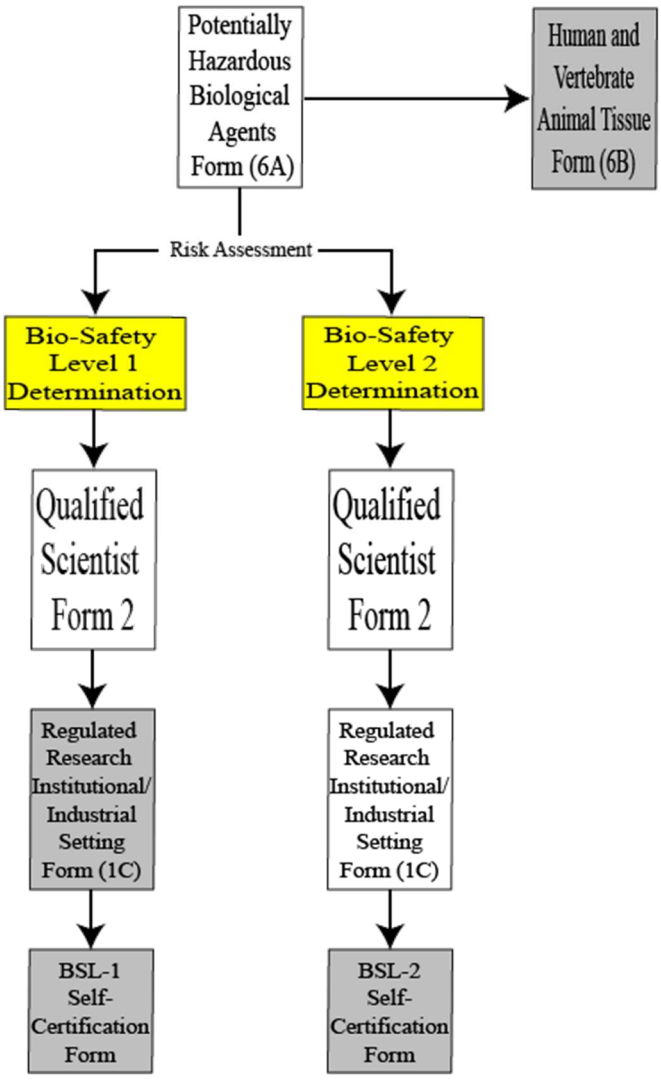
_____ _____
Signature Date (mm/dd/yy)

Potentially Hazardous Biological Agents Rules

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 33) 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.



ALL PHBA Study Guidelines

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

- **Research Plan Requirements:** Student Researcher(s) must include ALL parts (a-e) of the Potentially Hazardous Biological Agents Research Plan requirements found on page 11.
- **Prior Review Requirements:** Student research involving PHBAs must be reviewed and approved by the appropriate review board BEFORE any experimentation with the animals may begin. It is the responsibility of the review board (not just the student) to evaluate potential risks of the project and make a determination about whether the project is appropriate and safe for student research.
  - Projects that are conducted at school, at home or in the field and not affiliated with a Regulated Research Institution (RRI) must be reviewed and approved by the school or regional SRC before the student may begin recruiting and/or interacting with the human participants. Documentation of review and approval is done on Form 6A for these projects.
  - If a project is conducted at a Regulated Research Institute, then it should be reviewed and approved by THAT INSTITUTION'S IBC. If the IBC does not review the Student Researcher's type of project, then that needs to be noted by the Qualified Scientist. Documentation of review and approval is done on Form 6A for these projects.
- **Risk Assessment:** The initial risk assessment determination done by the Student Researcher/Team Leader and Qualified Scientist/Mentor must be confirmed by the appropriate review board.

- **Work Site Restrictions:** 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 school/local SRC. *Specimen collection sites must be de-identified on the project board (use labels like Site A, B, etc.)*
- **Training:** Student Researchers must be trained in standard microbiological practices.
- **Disposal:** ALL PHBAs must be properly disposed of, by the Designated Supervisor or Qualified Scientist/Mentor, 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.
- **Changing Procedures:** Once a study has been approved, if the Student Researcher has any proposed changes to the methods and/or procedures, they must repeat the review process before continuing with data collection/experimentation.

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 https://csef.natsci.colostate.edu/Guidelines_BSL1.pdf).
  - 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.
    - Studies involving commercially available rDNA technology 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 experimentation.
      - The **SEALED** Petri dish is disposed of via autoclaving or disinfection by the Designated Supervisor or Qualified Scientist/Mentor.
    - Studies that insert antibiotic resistant markers for the clonal selection of bioengineered organisms.

- **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 at http://www.csef.colostate.edu/Guidelines/Guidelines_BSL2.pdf).
  - 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), *Steptococcus 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, , VISA/VRSA, VRE, CRE and ESBL 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.
    - 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:

Student Researchers are NOT ALLOWED to conduct any of the following types of projects:

- 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 recombinant containing DNA coding for human, plant or animal toxins (including viruses).
- The introduction or disposal of non-native, genetically-altered and/or invasive species, pathogens, toxic chemicals or foreign substances into the environment.

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 thurgensis* (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 where the Student Researcher(s) is 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 or archaea.
- 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. The device must remain sealed and be properly disposed.

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

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/Team Leader. All questions MUST be answered and additional pages may be attached.

Student's Name(s):_____

Project Title:

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

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

3. 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.?)

4. The final biosafety level I recommend for this project is: ☐ **BSL-1 or** ☐ **BSL-2**

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

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

7. 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: (check only 1 certification statement below)

☐ I certify that the 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 the 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 the 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 Fluids & 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).

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

- **Tissue Origin:**
  - 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.
  - In a tissue study, a Student Researcher may observe the vertebrate animal study, but may not manipulate or have any direct involvement in the vertebrate animal experimentation procedures.
  - Use of tissue obtained from agricultural/aquacultural studies require 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 24-26 and Form 5B.
- **RRI Approval:** Use of tissue from research conducted at a Regulated Research Institution requires a copy of an IACUC certification with the name of the research institution, the title of the study, the IACUC approval number and the date of IACUC approval on it.
- **Embryonic Human Stem Cells:** 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.
- **Blood/Bodily Fluids:**
  - 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.

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.
- Human capillary blood collection (i.e.: finger stick) of the Student Researcher to themselves; blood collection from any other human participants must be reviewed and approved by an IRB.
- 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 pathogens 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.

Examples of BSL-1 Tissue Studies:

Tissue studies that may be conducted at a BSL-1 laboratory include, but are not limited to:

- 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 an experimental procedure has 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-2 Tissue Studies:

Tissue studies that must be conducted at a BSL-2 laboratory include, but are not limited to:

- 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.

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

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/Team Leader in collaboration with the Qualified Scientist/Mentor. All questions MUST be answered and additional pages may be attached.

Student's Name(s):_____

Project Title:

1. 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(s)
- ☐ Blood
- ☐ Body Fluids
- ☐ Primary Cell/Tissue Cultures
- ☐ Human or Other Primate Established Cell Lines

2. 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

Risk Assessment Guidelines

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 a Designated Supervisor to DIRECTLY supervise the student while working on the project. The following guidelines 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.
- The Student Researcher must review the Materials Safety Data Sheets for ALL chemicals (household and laboratory) used in the project.
- 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.
- 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.
- The Student Researcher should take into account a chemical's toxicity, reactivity, flammability and corrosiveness when completing the risk assessment form.
- There is a list of chemicals that are prohibited and restricted for use in Colorado schools that can be found on the Colorado Division of Environmental Health & Sustainability's web site: https://www.colorado.gov/pacific/sites/default/files/DEHS_Schools_ChemicalShelfLifeDesignations_rev2.xlsx

The mission of environmentally responsible chemistry is to avoid the use or production of hazardous substances during chemical process. The principles of green chemistry are described on the EPA website (https://www.epa.gov/greenchemistry/basics-green-chemistry). Whenever possible, these principles should be incorporated into the research plan.

Computer Use

Research projects that rely on heavy computer usage should consider extended computer/screen time as a potential risk to the Student Researchers. These could include, but are not limited to eye strain, red, watery irritated eyes, tired, aching or heavy eyelids, problems focusing, muscle spasms of the eye or eyelid, headaches, backaches, etc. The Risk Assessment Form 3 should include ways in which the student plans on minimizing these risks while working on a project that uses the computer significantly.

Hazardous Devices & Activities

Students and supervisors should think about ALL potentially hazardous devices 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:

- 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. Student should be clear in their research plan about the type of tools they plan on using (manual or power tools).
- The use of all laboratory equipment should be examined for risks, including such things as Bunsen burners, hot plates, high temperature ovens, heated oil baths, and high vacuum equipment.
- 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 of non-ionizing radiation, including the spectrum of ultraviolet, visible light, infrared, microwave, radiofrequency and extremely low frequency.

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 web site (https://www.deadiversion.usdoj.gov/schedules/index.html). Special precautions must be taken when Student Researcher utilizes DEA-controlled substances in a project:

- It is the responsibility of the Student Researcher/Team Leader in consultation with the 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 being used.
- All studies using DEA-controlled substances must be conducted at a Regulated Research Institution and NOT at a school.
- 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.

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) web site for more details. (https://www.faa.gov/uas/getting_started/register_drone/).

Prescription Drugs

Prescription drugs are controlled substances regulated by federal laws to protect against inappropriate or unsafe use. It is unlawful for any person knowingly or intentionally to possess a controlled substance unless it was obtained directly from a valid prescription or order of a practitioner while acting in the course of their professional practice. Special precautions must be taken when Student Researchers utilize prescription drugs in a project:

- Studies involving prescription drugs require a Qualified Scientist/Mentor.
- Student Researchers are prohibited from providing prescription drugs to human participants.
- Prescription drugs may be administered to vertebrate animals ONLY under a veterinarian's supervision and with a prescription provided for that specific purpose.
- It is the responsibility of the Qualified Scientist/Mentor to properly acquire the drugs from a doctor or pharmacist, using a prescription written out specifically for Science Fair research ONLY and NOT to an individual.
- All prescription drugs used in a student research project must be kept in a locked cabinet, accessible by the Qualified Scientist/Mentor ONLY, when not being used by the Student Researcher.
- Any unused prescriptions drugs must be disposed of in a proper manner by the Qualified Scientist/Mentor.

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. Remember that Colorado law prohibits alcohol and drugs on school property.
- 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 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 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 and the CSEF 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 and the CSEF 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 paintball guns are not considered firearms unless they are intended to be used as weapons, but they must be treated as hazardous devices.