Contents
Overview ............................................................................................................................................. 1
The Research Plan .................................................................................................................................... 2
Approval Dates ........................................................................................................................................ 4
Projects which require pre-approval ........................................................................................................ 5
  Bacteria .................................................................................................................................................. 5
  Human Participant Studies ....................................................................................................................... 6
  Hazardous Chemicals, Activities or Devices .............................................................................................. 7
  Vertebrate Animals .................................................................................................................................. 8
Summary .................................................................................................................................................. 10
Appendix 1 Form 1A Student Checklist ................................................................................................... 11
Appendix 2 Bibliography Help .................................................................................................................. 13
Appendix 3 Sample Human Consent Form .............................................................................................. 15
Overview

Covestro PRSEF’s Scientific Review Committee (SRC) reviews all proposed project and their approval forms, research plans and references. This review process is in place to:

- Protect the rights and welfare of the student researcher and human subjects
- Protect the health and well-being of vertebrate animal subjects
- Follow federal regulations governing research
- Ensure that safe laboratory practices are used
- Address environmental concerns
- Provide consistency with Intel International Science & Engineering Fair requirements

Note: Covestro PRSEF's SRC and IRB have final approval of all projects submitted to the competition.

The following forms must be submitted for ALL projects:
Form 1 — Checklist for Adult Sponsor
Form 1A — Student Checklist
Research Plan (Must include detailed description of research and at least five (5) references listed in a recognized format (MLA, APA etc). URLs alone are not acceptable as references)
Form 1B — Approval Form
Student Registration Form
Abstract (Abstracts must be submitted online on the registration form on or before February 7, 2020. They do not need to be included in the SRC review paperwork.)

These forms and all other forms specified in this document can be found at http://www.carnegiesciencecenter.org/stemcenter/stemcenter-science-fair-registration-and-forms/.

Projects involving potentially hazardous biological agents (bacteria), human participants, hazardous chemicals, activities, or devices and/or vertebrate animals require additional forms and pre-approval before experimentation can begin. More information about these projects can be found below.

There are several common problems which are found during the SRC review process. These problems result in more than half of the projects being returned to the student for further information before they are approved by the SRC and research can commence.

Common problems include:
- Incomplete research plans
- Incomplete, missing or improperly formatted references pages
- Out of order approval dates
- Studies requiring additional forms, review and approvals
  - Potentially Hazardous Biological Agents (bacteria)
  - Human participants
  - Hazardous chemicals, activities, or devices
  - Vertebrate animals
Strategies for avoiding these common problems and getting your paperwork approved on the first submission can be found in this document.

**The Research Plan**

Acceptable research plans include:

- Problem statement
- Hypothesis
- Detailed procedure
  - Plan for data analysis
- Bibliography with at least 5 valid references

Detailed requirements can be found on the second page of Form 1A Student Checklist in Appendix 1. Please note that if changes are made during research, they can be added to the original research plan. Additional approvals may be required for some changes.

There are several common research plan problems which are found in SRC review. Common problems include:

- Procedure is not described sufficiently
  - Reviewers cannot understand what project involves. The reviewer must be able to determine if the procedure is safe and falls within the rules set forth by Intel ISEF. If the procedure is vague, it is difficult for the SRC to evaluate the safety of the project.

- Safety precautions are not identified
  - Form 3 Risk Assessment should be completed to address the risks of the project and what will be done to keep the researcher and any other humans or animals involved in the study safe.

- Students fail to perform a literature review using sources like science journal articles, books, internet sites
Each research plan must include references to at least five high quality sources.

- High quality sources are peer reviewed and from reputable sources

- Students fail to format their references properly in a recognized format
  - References which are listed as website urls only are not acceptable
  - A recognized format like APA or MLA must be used.
  - See Appendix 2 Bibliography Help for more information about how to reference sources in a scientific document.
**Approval Dates**

There is a specific order in which projects need to be completed.

The following dates must be in order:

- Student and parent/guardian must approve BEFORE adult sponsor
  - Date acknowledged by student and by parent on Form 1B must be BEFORE date of review by sponsor on Form 1
- Experimentation must begin AFTER student, parent/guardian, and adult sponsor approve
  - Data collection dates on Form 1A must be AFTER date of review by sponsor on Form 1 and date acknowledged by student and by parent on Form 1B
  - For projects requiring pre-approval, experimentation may not begin until after paperwork has been reviewed and approved by the SRC at the Carnegie Science Center.

- The correct order of dates is:
  - Student acknowledgement on Form 1B
  - Parent acknowledgement on Form 1B
  - Review by sponsor on Form 1
  - Laboratory experiment/Data collection Project Start Date on Form 1A

**Sample Research Paper/Poster Process**

1. Develop an idea and turn it into a workable hypothesis
2. Perform literature review and determine if SRC pre-approval is needed
3. Submit all required paperwork for SRC review
4. Perform project as outlined
5. Write up paper (optional) and create poster
6. Present project at PRSEF in March
Projects which require pre-approval

Some projects pose a greater risk to students and/or the participants in their studies than others do. Those projects which involve bacteria, human participants, hazardous chemicals/activities/devices or vertebrate animals fall into this category. The deadline to submit paperwork for these projects is earlier than that to submit lower risk projects. **Students may not begin experimentation until they have received approval from their school’s IRB and from PRSEF SRC.**

Bacteria

Bacteria is defined as a “Potentially Hazardous Biological Agent”. Student and adults must conduct a risk assessment using Form 6A which defines 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 a biosafety level to determine if the project can proceed, and if so, what type of laboratory facilities, equipment, training, and supervision required.

Complete rules and guidelines for PBHA studies can be found at [https://student.societyforscience.org/Potentially-Hazardous-Biological-Agents](https://student.societyforscience.org/Potentially-Hazardous-Biological-Agents).

Here you can find the answers to the following questions:

- Which studies are exempt from prior Covestro PRSEF SRC review and require no additional forms?
- Which studies are exempt from prior Covestro PRSEF SRC review, but require a Risk Assessment Form 3?
- What types of tissue studies do not need to be treated as potentially hazardous biological agents?
- How do I to assess the risk involved in PHBA studies?
- What are the four levels of biological containment (Biosafety Level 1–4)?
- What are the guidelines for laboratory facilities, safety equipment and laboratory practices and techniques?

In addition to the forms required for all projects, the paperwork for these projects must include:

- Form 2 — Qualified Scientist
- Form 6A — Potentially Hazardous Biological Agents

If applicable, the paperwork must also include

- Form 1C — Regulated Research Institution/Industrial Setting Form (if conducted in a Regulated Research Institution)
- Form 3 — Risk Assessment
- Form 6B — Human and Vertebrate Animal Tissue Form (for all studies involving tissues and body fluids.)
**Common SRC approval problems with bacteria studies include:**

- SRC approval was not requested prior to experimentation (before project was started).
- Projects involving mold were not terminated at first evidence of mold.
- The project includes growing bacteria at home.
  - Experimentation involving the culturing of potentially hazardous biological agents, even BSL-1 organisms, is prohibited in a home environment.
  - Specimens may be collected at home as long as they are immediately transported to a laboratory with the BSL containment and remain sealed thereafter.
  - Appropriate level of containment is determined by Covestro PRSEF.
- The project includes the use of hair and teeth which are not considered a PHBA study.
  - Teeth are to be sterilized to kill any blood-borne pathogen that may be present.
  - Chemical disinfection or autoclaving at 121 degrees Celsius for 20 minutes is recommended.
- Form 2 (Qualified Scientist) and/or Form 6A (Potentially Hazardous Biological Agents Risk Assessment Form) were not submitted.
- Proper disposal techniques were not described.
- Proper safety equipment was not used.

**Human Participant Studies**

Human participant studies involve living individuals where there is intervention or interaction with participants and/or collection of identifiable private information. The Covestro PRSEF’s SRC and School’s IRB must review and approve the research plan before experimentation begins.

The following types of human participant studies are prohibited:

- Experiments which may result in dangerous health consequences
  - Potential for severe reaction from allergic reactions
  - Lack of research and regulation associated with energy drinks
  - Potential for significant mental or emotion distress

In addition to the forms required for all projects, the paperwork for these projects must include:

- Form 4 — Human Subjects Form with applicable consent forms and a copy of any surveys or questionnaires to be used

If applicable, the paperwork must also include

- Form 1C — Regulated Research Institution/Industrial Setting Form (if conducted in a Regulated Research Institution)
- Form 2 — Qualified Scientist (required if more than minimal risk is involved)

Please contact the Covestro PRSEF office or see [https://student.societyforscience.org/human-participants](https://student.societyforscience.org/human-participants) for any clarifications. The following information can be found on the Society for Science website:

- Learn when pre-approval is not required
• Learn when pre-approval AND human participant forms are not required
• Learn about other exempt studies such as behavioral observations
• Learn how to assess risk
• Learn when informed consent is required
• Learn about studies that involve the collection of data via use of the internet (e.g., email, web-based surveys)

When using human participants, informed consent must be acquired prior to experimentation.

• Research participants 18 years of age or older must give informed consent
• Research participants under 18 must give assent and their parents may be required to give permission
• Students must may use the sample informed consent form in Appendix 3

Common SRC problems with Human Participant Studies include the following:

• Approval was not submitted prior to start of experiment
• Data was identifiable - data set includes name, birth date, phone number or other identifying variables
• Project paperwork was missing one or more of the following forms:
  o Form 4 (Human Participant Form)
  o Informed Consent – Only one sample is needed
  o Form 2 (Qualified Scientist)
• Sample survey or questionnaire was not included
• Form 4 (Human Participant Form) did not include all required signatures or signature dates were after the project start date on Form 1A

Hazardous Chemicals, Activities or Devices
As a rule, these studies do not require prior SRC review and approval; however, depending upon the specifics of the project prior review may be requested and is strongly suggested to avoid problems. All hazardous chemical, activities and device studies require a Risk Assessment documented on Form 3. If in doubt, fill it out and submit it.

Projects which involve hazardous substances that are DEA - controlled require a Qualified Scientist. All other studies require a Designated Supervisor

Examples of hazards include:

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

In addition to the forms required for all projects, the paperwork for these projects must include:
- Form 3 — Risk Assessment

If applicable, the paperwork must also include
- Form 2 — Qualified Scientist
- Form 1C — Regulated Research Institution/Industrial Setting Form (if conducted in a Regulated Research Institution)

**Common SRC problems with Hazardous chemicals, activities and devices projects include:**
- Risk Assessment was not documented on Form 3
- Form 3 was not signed and dated properly
- Form 2 (Qualified Scientist) was not submitted when required
- Form 2 (Qualified Scientist) was not signed and dated properly
- Adult Sponsor accurately identify risk involved

Learn more about all hazardous chemicals, activities and devices at https://student.societyforscience.org/hazardous-chemicals-activities-or-devices.

**Vertebrate Animals**
For research purposes as indicated by the ISEF rules, vertebrate animals are:
- Live, nonhuman vertebrate mammalian embryos or fetuses
- Tadpoles
- Bird and reptile eggs within 3 days of hatching
- All other nonhuman vertebrates (including fish) at hatching or birth
- Zebrafish embryos 7 days (168 hours) post fertilization

In addition to the forms required for all projects, the paperwork for these projects must include:
- Form 2 — Qualified Scientist
- Form 5A — Vertebrate Animal Form (if conducted in a school, home or field research site), OR
- Form 5B — Vertebrate Animal Form (if conducted in a Regulated Research Institution)

If applicable, the paperwork must also include
- Form 1C — Regulated Research Institution/Industrial Setting Form (if conducted in a Regulated Research Institution)

**Common SRC problems with Vertebrate Animals studies include:**
- Form 5A or 5B (Vertebrate Animal Form) was not completed, was missing signatures or was dated incorrectly
- Form 2 (Qualified Scientist) was not submitted when required
- Form 2 (Qualified Scientist) was not signed and dated properly
• Bibliography missing animal care reference
  o At least one of these references must be an animal care reference
• Lack of alternatives for the use of vertebrate animals for research are not explored or discussed in the research plan

For additional information about vertebrate animal studies, visit
https://student.societyforscience.org/vertebrate-animals. Here you can:

• Learn when approval prior to experimentation is required
• Learn when behavioral observations require approval prior to experimentation or are exempt
• Learn what types of studies can be conducted in the home/school/field versus studies that must be conducted in a Regulated Research Institution
Summary

- Visit [www.pittsburghsciencefair.org](http://www.pittsburghsciencefair.org) or [Covestro PRSEF](https://www.covestro.com) for complete rules and guidelines
- Visit [Covestro PRSEF](https://www.covestro.com) Forms for required forms

Top issues to be aware of when submitting paperwork to the SRC:

- All students must submit a complete research plan
  - This includes at least 5 reputable citations referenced in a recognized format (APA, MLA etc.) URLs alone are not acceptable references.
- Dates must be in order
  - Form 1B dates must be before Form 1
  - Experimentation dates (Form 1A) must be AFTER Form 1 and 1B
- Bacteria are considered Potentially Hazardous Biological Agents (PHBA) – All PHBA projects must be approved by Covestro PRSEF prior to experimentation (before the project is started)
  - Most bacteria projects CANNOT be conducted at home
  - BSL1 or BSL2 are required with proper supervision and safety equipment
  - Mold projects can be conducted at home but must be terminated at the first evidence of mold unless conducted in an appropriate lab
  - Hair, teeth, hooves, nails, and feathers do not need to be considered PHBA
    - Teeth must be sterilized
- Informed consent forms are required for all human participants studies. A sample form is acceptable for pre-approval.
- All human participant studies must be approved by Covestro PRSEF’s and the School’s IRB prior to experimentation.
- Hazardous Chemicals, Activities and Devices studies must include Form 3 on which all risks involved are addressed.
- All studies on vertebrate animals must be pre-approved.
Appendix 1 Form 1A Student Checklist

Student Checklist (1A)
This form is required for ALL projects.

1. a. Student/Team Leader: ______________________ Grade: ______________________
   Email: ______________________ Phone: ______________________
   b. Team Member: ______________________
   c. Team Member: ______________________

2. Title of Project: ______________________

3. School: ______________________
   School Phone: ______________________
   School Address: ______________________

4. Adult Sponsor: ______________________

5. Does this project need SRC/IRB/IACUC or other pre-approval? □ Yes □ No
   Tentative start date: ______________________

6. Is this a continuation/progression from a previous year? □ Yes □ No
   If Yes:
   a. Attach the previous year’s □ Abstract and □ Research Plan/Project Summary
   b. Explain how this project is new and different from previous years on
      □ Continuation/Research Progression Form (7)

7. This year’s laboratory experiment/data collection:
   Actual Start Date: (mm/dd/yy) End Date: (mm/dd/yy)

8. Where will you conduct your experimentation? (check all that apply)
   □ Research Institution □ School □ Field □ Home □ Other: ______________________

9. List name and address of all non-home and non-school work site(s):
   Name: ______________________
   Address: ______________________
   Phone/Email: ______________________

10. Complete a Research Plan/Project Summary following the Research Plan/Project Summary instructions and attach to this form.

11. An abstract is required for all projects after experimentation.
Research Plan/Project Summary Instructions
A complete Research Plan/Project Summary is required for ALL projects and must accompany Student Checklist (1A).

1. All projects must have a Research Plan/Project Summary
   a. Written prior to experimentation following the instructions below to detail the rationale, research question(s), methodology, and risk assessment of the proposed research.
   b. If changes are made during the research, such changes can be added to the original research plan as an addendum, recognizing that some changes may require returning to the IRB or SRC for appropriate review and approvals. If no additional approvals are required, this addendum serves as a project summary to explain research that was conducted.
   c. If no changes are made from the original research plan, no project summary is required.

2. Some studies, such as an engineering design or mathematics projects, will be less detailed in the initial project plan and will change through the course of research. If such changes occur, a project summary that explains what was done is required and can be appended to the original research plan.

3. The Research Plan/Project Summary should include the following:
   a. RATIONALE: Include a brief synopsis of the background that supports your research problem and explain why this research is important and if applicable, explain any societal impact of your research.
   b. RESEARCH QUESTION(S), HYPOTHESIS(ES), ENGINEERING GOAL(S), EXPECTED OUTCOMES: How is this based on the rationale described above?
   c. Describe the following in detail:
      - Procedures: Detail all procedures and experimental design including methods for data collection. Describe only your project. Do not include work done by mentor or others.
      - Risk and Safety: Identify any potential risks and safety precautions needed.
      - Data Analysis: Describe the procedures you will use to analyze the data/results.
   d. BIBLIOGRAPHY: List major references (e.g. science journal articles, books, internet sites) from your literature review. If you plan to use vertebrate animals, one of these references must be an animal care reference.

Items 1–4 below are subject-specific guidelines for additional items to be included in your research plan/project summary as applicable.

1. Human participants research:
   a. Participants: Describe age range, gender, racial/ethnic composition of participants. Identify vulnerable populations (minors, pregnant women, prisoners, mentally disabled or economically disadvantaged).
   b. Recruitment: Where will you find your participants? How will they be invited to participate?
   c. Methods: What will participants be asked to do? Will you use any surveys, questionnaires or tests? If yes and not your own, how did you obtain? Did it require permissions? If so, explain. What is the frequency and length of time involved for each subject?
   d. Risk Assessment: What are the risks or potential discomforts (physical, psychological, time involved, social, legal, etc.) to participants? How will you minimize risks? List any benefits to society or participants.
   e. Protection of Privacy: Will identifiable information (e.g., names, telephone numbers, birth dates, email addresses) be collected? Will data be confidential/anonymous? If anonymous, describe how the data will be collected. If not anonymous, what procedures are in place for safeguarding confidentiality? Where will data be stored? Who will have access to the data? What will you do with the data after the study?
   f. Informed Consent Process: Describe how you will inform participants about the purpose of the study, what they will be asked to do, that their participation is voluntary and they have the right to stop at any time.

2. Vertebrate animal research:
   a. Discuss potential ALTERNATIVES to vertebrate animal use and present justification for use of vertebrates.
   b. Explain potential impact or contribution of this research.
   c. Detail all procedures to be used, including methods used to minimize potential discomfort, distress, pain and injury to the animals and detailed chemical concentrations and drug dosages.
   d. Detail animal numbers, species, strain, sex, age, source, etc., include justification of the numbers planned.
   e. Describe housing and oversight of daily care.
   f. Discuss disposition of the animals at the end of the study.

3. Potentially hazardous biological agents research:
   a. Give source of the organism and describe BSL assessment process and BSL determination.
   b. Detail safety precautions and discuss methods of disposal.

4. Hazardous chemicals, activities & devices:
   - Describe Risk Assessment process, supervision, safety precautions and methods of disposal.
   - Material Safety Data Sheets are not necessary to submit with paperwork.
Appendix 2 Bibliography Help

Students are required to list at least 5 (five) major references (e.g. science journals, books, articles, internet sites will be checked and must be well documented) in their research plans. Referencing sources correctly is crucial for purposes of academic integrity and of students’ future success in higher educational pursuits. A reference must take the reader to a specific book or article.

NOT A REPUTABLE SOURCE: A library, Google, Wikipedia or any search engine

A REPUTABLE SOURCE: A specific book, a specific Journal article, a specific article resulting from a successful search using a search engine. Visit sites such as How to Write a Research Paper for further help.

Below are examples of what types of information to include in references, descriptions of what that information entails and how to find it, and formatting requirements for those references.

Basic Reference Structure:

Author(s), title, journal name, journal identifying information (year date, volume, issue, page(s)), web address (if any), date accessed (if web based)

Anatomy of a reference:

Author: The names of the people who wrote the reference. If this is an anonymous publication, such as a report from a government agency, you would list the government agency.

Title: the name of the article. If this was a report from a government agency, the name of the report. If this was a news item, even from web source, this is the headline. If this is a web item, it’s the title at the beginning.

Journal name and identifying information should be obvious. If this was a news item, it would be the newspaper, or the web-based news site, with the date.

Web address: If the source was obtained from the web, then this is the exact URL which would bring up the content cited. If this is a print journal or a print newspaper which you are viewing on-line, then you don’t need to reference the web address, because this exists on paper.

Date accessed: This is the date on which you viewed the material you are citing.

Examples of different types of sources:


Journal Article: Ormerod, R. J. (1998). Beyond internal OR groups. *Journal of Operational Research Society, 49*(4), 420-429. N.B., If an article is from a print journal, you don’t need to add a URL, even if you read the article on line.


Appendix 3 Sample Human Consent Form

### Human Informed Consent Form

**Instructions to the Student Researcher(s):** An informed consent/assent/permission form should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist. This form is used to provide information to the research participant (or parent/guardian) and to document written informed consent, minor assent, and/or parental permission.

- When written documentation is required, the researcher keeps the original, signed form.
- Students may use this sample form or may copy ALL elements of it into a new document.

If the form is serving to document parental permission, a copy of any survey or questionnaire must be attached.

#### Student Researcher(s):

#### Title of Project:

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate area below.

**Purpose of the project:**

**If you participate, you will be asked to:**

**Time required for participation:**

**Potential Risks of Study:**

**Benefits:**

**How confidentiality will be maintained:**

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

**Adult Sponsor/QS/DS:** [Name]  **Phone/email:** [Contact Information]

**Voluntary Participation:**

Participation in this study is completely voluntary. If you decide not to participate there will not be negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

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

<table>
<thead>
<tr>
<th><strong>Adult Informed Consent or Minor Assent</strong></th>
<th><strong>Date Reviewed &amp; Signed:</strong> (mm/dd/yy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Participant Printed Name:</strong></td>
<td><strong>Signature:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Parental/Guardian Permission (If applicable)</strong></th>
<th><strong>Date Reviewed &amp; Signed:</strong> (mm/dd/yy)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parent/Guardian Printed Name:</strong></td>
<td><strong>Signature:</strong></td>
</tr>
</tbody>
</table>