Los Angeles County Science & Engineering Fair
Inspiring Student Discovery & Innovation

1107 Fair Oaks Ave. # 94, South Pasadena, CA 91030 www.lascifair.org

*This is a **fillable PDF**. Please **download** this document to your device and enter your responses in the given boxes. You do not need to complete the form in one sitting. Choose Save to save your progress. Once you complete the form, get it approved by your adult supervisor and site coordinator BEFORE you go online to complete the online pre-approval form. You can then copy and paste your responses in the appropriate sections of the online form.*

Research Plan for Experiments with Human Subjects and Safety Precautions

GUIDELINES FOR RESEARCH USING HUMAN SUBJECTS AND SAFETY PRECAUTIONS

Students planning research involving the use of human subjects must complete and obtain LACSEF Scientific Review Committee (SRC) approval of certification before starting experiments. Projects will not be accepted in the annual science and engineering fair without approval.

The Science Review Committee (SRC) of the Los Angeles County Science Fair does not allow experimentation or surveys using human subjects prior to the approval of this Research Plan. There are federal regulations that must protect the rights and welfare of human subjects. Therefore, students must plan carefully before undertaking research that involves the use of human subjects in either behavioral or biomedical studies. This will protect subjects from unnecessary exposure to physical or psychological complications.

1. All Research Plans/Questionnaires involving human subjects must be received and approved by the Los Angeles County Science Fair Science Review Committee (SRC) before research begins. These pages must be attached to the project logbook when brought to the Fair.
2. Human subjects research includes projects involving: (a) Human Subjects participating in physical activities (physical exertion, ingestion of any substance, any medical procedure), (b) Psychological and opinion studies (surveys, questionnaires, tests of any kind), (c) Behavioral observations, (d) Studies in which the researcher is the subject of the research.
3. Confidentiality: When research activities involve collection of personal information (history of abuse, opinions, fingerprints, test scores, survey answers) or health related data (genetic material, blood, tissue), the student must consider risks related to invasion of privacy and possible breach of confidentiality.
4. Student researchers may NOT publish or display information in a report that identifies the human subject directly or through identifiers linked to the subjects (including photographs), without written consent.
5. The use of the Internet to obtain data for human subjects research is permissible. The Student Researcher and the Adult Sponsor must take additional care to ensure that survey responses remain confidential and informed consent is documented.

6. A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional must be named in the Research Plan. Students are prohibited from administering medications and performing medical procedures on human subjects.
7. The Research Plan shall list objectives of the project and describe fully the methods and techniques involved (including planned use of anesthetics, drugs, thermal procedures, physical stress, organisms pathogenic to humans or other vertebrates, radiation, carcinogens or surgical procedures). When the use of electrical current, laser beams, sound stimuli or other artificial stimuli are an integral part of the project, it must not exceed the normal tissue tolerances for the species concerned, as indicated in the Biosafety in Microbiological and Biomedical Laboratories, 6th Edition
8. Written consent is required for all projects. Children/Minors (under 18 years old) participating in research will require consent of the parent/guardian.
9. Once a study population is chosen, the student researcher must consider any potential physical and/or psychological risks when developing the Research Plan. The federal definition of minimal risk is as follows: No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical or psychological examinations or tests. Student researchers must be aware of the following:
    a. Risk Groups: Naturally at-risk groups include pregnant women, individuals with diseases such as cancer, asthma, diabetes, AIDS, cardiac disorders, psychiatric disorders, etc. Special vulnerable at-risk groups include: children/minors, prisoners or mentally disabled persons.
    b. Risk Activities:
        i. Physical:
            1. Exercise other than ordinarily encountered in daily life by that subject.
        ii. Eating or drinking of any potentially hazardous substance or exposure to any potentially hazardous materials.
        iii. Psychological:
            1. Any activity (survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress.
10. Covid 19 Risk Mitigation: Due to the special circumstances brought on by the COVID-19 pandemic, it is strongly recommended that ALL students include in their risk assessment how they will mitigate the spread of the disease while conducting their experiment. Such mitigations may be found at: https://www.societyforscience.org/isef/human-participant-research-with-covid-19-precautions/
11. Students under the age of 21 are prohibited by federal and state law from using controlled substances in their research project. These substances include all forms of alcohol, explosive materials, tobacco and firearms. Any proposed changes in the Research Plan and Written Consent by the student after initial SRC approval must have

subsequent SRC approval before such changes are made and before experimentation resumes.

12. Arrangements must be made to assure that any proposed procedure is safe before any project proposal is approved. Whenever specialized safety equipment and/or facilities are necessary for a procedure, arrangements must be made in advance. Please contact the LACSEF SRC for questions or assistance at Pre-approval@lascifair.org

Student Name	
School	
Email (non-school)	

☐ I certify that I have read and understand the guidelines for human subject research and s safety precautions.as outlined in the LACSEF Rules and Regulations (check box)

In addition to this plan, I have also completed the following research plan(s) for this project (check all that apply).

☐ Hazardous Material

☐ Tissue, Cell Lines, Organs or Organ Parts

☐ Microbes

☐ Vertebrates

☐ No other research plan was submitted

Project Title:

- Title must be limited to 150 characters (including spaces)

Problem

- State in the form of a question

Objective(s)

- State what the goal for the project is
- Explain why is it important

Hypothesis

Number of Project Team Members

- This refers to the number of students conducting the project, not the number of test subjects.
- There are a maximum number of three students allowed on a project team.

Age range, gender, and number of human subjects to be tested;

- Identify the age range, gender, and number of human subjects
- Identify how old the participants will be (ex: 13 - 18 years old).
- Identify how many participants will there be in the project; and if applicable, how many males, females,

Risk Assessment

- Describe any potential risks to your human participants as a consequence of participation in your project. Identify all possible physical, psychological, allergy reactions, social, and financial/privacy risks.
    - Naturally at-risk groups include pregnant women, individuals with diseases such as cancer, asthma, diabetes, AIDS, cardiac disorders, psychiatric disorders, etc. Special vulnerable at-risk groups include: children/minors, prisoners, or mentally disabled persons.
    - Physical risks include exercise other than ordinarily encountered in daily life by that subject, eating or drinking of any potentially hazardous substance or exposure to any potentially hazardous materials.
    - Psychological Risks include any activity (survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress.
    - Allergies/Food Intolerances: Environmental and/or food allergies/intolerances need to be addressed in the survey. Food allergy symptoms usually develop within a few minutes to two hours after eating the offending food and may include tingling or itching in the mouth; hives, itching or eczema; swelling of the lips, face, tongue and throat; nasal congestion or trouble breathing; abdominal pain, diarrhea, nausea or vomiting; dizziness, lightheadedness or fainting or even life-threatening anaphylaxis.
- Identify what you will do to mitigate each risk and how you will make sure no humans will be harmed (physically or emotionally) by your experiment.
- You MUST state that minors require written parental/guardian consent in order to participate.
- **There are inherent risks in all human participant research; stating there are no risks is not allowable, and the project will be declined**.

COVID-19 Risks

Due to the special circumstances brought on by the COVID-19 pandemic, it is strongly recommended that ALL students include in their risk assessment how they will mitigate the spread of the disease while conducting their experiment. Such mitigations may be found at: https://www.societyforscience.org/isef/covid-policy/

Experimental Location

- Identify the exact location where the majority of the project will take place: both surveying and experimentation.
- The use of the internet to obtain data for human subjects is permissible.

Procedures/Research Techniques

- Provide a clear and detailed description of your proposed procedure, including equipment to be used .
- Students are prohibited from administering medications and performing medical procedures on human subjects. A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional must be named in the Research Plan.
- Describe fully the methods and techniques involved (including planned use of anesthetics, drugs, thermal procedures, physical stress, organisms pathogenic to humans, radiation, carcinogens or surgical procedures).
- When the use of electrical current, laser beams, sound stimuli, or artificial stimuli are an integral part of the project, it must not exceed the normal tissue tolerances for humans, as indicated in the Biological Data Handbook, 2nd Edition; Editors, P.O. Altman and D.S. Dittner, Publisher: Federation of American Societies for Experiment Biology.

Survey Form

Studies that involve the use of a survey or questionnaire require submission for review.

- Provide a link to the survey or questionnaire that you will be using.
- Make sure to provide appropriate viewing rights.
- If you are not using a survey, write “not-applicable”

Bibliographic References

- Provide bibliographic references for your project.
- References should be written in APA format
- At least one reference must be from a source other than the internet.
- Junior Division projects require at least three references.
- Senior Division projects require five references.

Reference 1

Reference 2

Reference 3

Reference 4

Reference 5

Certification References

Please provide the email addresses for the people who will be serving in the following roles in your experiment. An email will be sent to each address with a link for the person to certify your project. You can see what qualifications each person needs on our website.

Teacher/Advisor	
Name	
Email Address	
Qualifications	

Biomedical Scientist	
Name	
Email Address	
Qualifications	

Designated Adult Supervisor	
Name	
Email Address	
Qualifications	

☐ By checking this box, I certify that the experimental procedures used in this project follow the rules and regulations of the LACSEF. I also certify that the procedure followed will ensure that neither the procedures nor the materials constitute any known danger and that all microorganisms, pathogenic or non-pathogenic, will be handled and disposed of as if pathogenic. I understand that this form must be approved and signed by all parties BEFORE the project can begin, and I will comply with all regulations.

Since your project involves humans, you need to complete the Human Consent Form on the following page.

A Human Consent Form needs to be developed in consultation with your Site Coordinator, Designated Supervisor, or Qualified Scientist. This form will provide information to your research subject (or parent/guardian) about your project and will document written

informed consent, and/or parental permission. For project approval, we need to approve the main sections of the form here.

- Every participant and parent/guardian needs to receive this form and sign his or her consent at the bottom, both before starting the research project.
- You MUST identify that minors require written parental/guardian consent in order to participate.
- Human consent forms need to be completed even if the test subject is yourself or a family member.
- You are responsible for printing the consent form, collecting the necessary signatures, and attaching the forms to your logbook.

LIST THE INFORMATION FOR YOUR PROPOSED FORM IN EACH BOX, FOR APPROVAL

In addition, **Senior Division** students need to complete the ISEF Human Consent forms found **HERE** and bring them to the fair.

Human Consent Form

Purpose of the Project

- Identify the goal of the project and why conducting the project is important.

If you participate, you will be asked to: ('You' refers to your subjects, not yourself)

- Explain in detail exactly what your participants will be doing.

Time required for participation:

- Identify the participant's total time commitment, how many trials will be done and how much time there will be between trials.

Your participation in this study is voluntary:

- You need to inform participants that their participation in this study is completely voluntary and that there will be NO negative consequences if they choose not to participate.
- You need to inform participants that if they decide to participate, that they may stop participating at any time and may decide not to answer any specific question.

Risks to you ('You' refers to your subjects, not yourself)

- Explain what MIGHT happen, both psychologically and/or physically to the participant and how you will reduce the risk to keep your participants safe.

Benefits to you ('You' refers to your subjects, not yourself)

- Describe what the participant gets for participating. Financial compensation is not allowed. Think REAL benefits - there is always something.

Confidentiality of your name and any photos will be maintained by ('You' refers to your subjects, not yourself)

- STATE EXACTLY HOW CONFIDENTIALITY WILL BE MAINTAINED. (Example: use #'s or letters to refer to subjects in reports or display - only the researcher will know real names; no recognizable photos on board. etc.)

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

Name of Adult Supervisor, Site Coordinator, or Designated Adult Supervisor	
Phone Number	
Email Address	

Adult Informed Consent

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.

Research Participant Signature:

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

Research Participant Printed Name:

Minor Assent

Parental/Guardian Permission (if applicable)

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.

Parent Guardian Signature:

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

Parent/Guardian Printed Name: