CERTIFICATION OF HUMAN SUBJECTS RESEARCH

This form must be completed and reviewed by the OCSEF Scientific Review Committee (SRC) for all projects involving humans BEFORE the project is begun. The SRC will determine if you must use the informed consent template to obtain written informed consent from your subjects.

PLEASE TYPE OR PRINT

Name of Student Investigator 1 (include First and Last Name)	School Name
Name of Student Investigator 2 (for team projects only)	School Name (leave blank if same as above)
Name of Student Investigator 3 (for team projects only)	School Name (leave blank if same as above)
Project Title	

1. The regulations of the OCSEF are intended to protect human subjects, both physically, psychologically, and socially. The regulations supplement, and do not supplant, relevant State and Federal regulations dealing with such protection .

2. The Code of Federal Regulations 45 CFR §46 .102 defines human subject as a person from whom an investigator obtains:
   (1) data through intervention or interactions with the person; or
   (2) identifiable private information.

3. Orange County Science and Engineering Fair requires that ALL research projects involving human subjects (including, but not limited to, surveys, professional tests, questionnaires, and studies in which the investigator is the only subject of his/her own research) comply with the regulations for experiments with human subjects.

4. Students are **prohibited** from independently diagnosing disease, administering medication, or performing medical procedures.

5. According to Public Health Service Act, 42 U.S.C., 241/dl, it is illegal to publish information in a report that identifies the human subjects directly or through identifiers linked to the subjects, including photographs. **Names or photographs of human subjects may not be displayed or brought to the fair.**

6. Student investigators must list the risks to their human subjects on this form. Risks include the possibility of physical, psychological, or social injury or discomfort as a consequence of participation.

   Examples of unacceptable risk include, but are not limited to:
   a) ingestion or physical contact with any potentially hazardous materials including toxic chemicals; known or suspected allergens, pathogens, or carcinogens; or exposure to ionizing radiation;
   b) intentionally inducing emotional stress resulting from invasion of privacy - see Privacy Act of 1974 45 CFR 5B:
   c) physical stress to pregnant women or anyone suffering debilitating physical illness;
   d) exercise of a strenuous nature for a subject with medical problems; and
   e) psychological stress to the mentally handicapped or those suffering psychiatric disorders.

   This list is intended to be illustrative, not exhaustive.

WRITTEN INFORMED CONSENT must be collected (or waived by the OCSEF SRC) before the project is begun.

1. An informed consent/assent form to be signed by adult subjects or parent/guardian of minor research subjects should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist.

2. It is the expectation that a truly informed consent should contain information that affects risks to your subjects. **A "Permission Slip" required by the school that does not contain these elements does not satisfy the requirements of informed consent.**

3. If the SRC approves your project and requires you to obtain written informed consent from your subjects you may use the Informed Consent Template. Make copies of the Informed Consent Template for each of your subjects and obtain the appropriate signatures from each of your subjects.

4. According to California State Education Code 51513, parents/guardians have the right to deny participation of any minor child in any study including those involving tests or questionnaires. Questions on sexual activities or preferences, AIDS testing and results, suicide attitudes, divorce and its effects on psychological well-being, religion and religious opinion, and other sensitive societal issues, may be overly invasive. **Such questionnaires must be provided to parents/guardians. Parents must provide written informed consent.**

After written informed consent is obtained, you must:

- Keep the original signed forms in a secure place and do not bring them or any identifying information (e.g. names, addresses, phone numbers) about your subjects to the local Fair.
- On any report or board displayed at the fair, identify your test subjects with a number, letter, or ID
- Destroy any personal identifiers included in your data at the completion of the study. You can and should keep the remaining data.

CERTIFICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS SIGNATURE PAGE

CERTIFICATION BY STUDENT INVESTIGATOR(S)

I certify the information on this form is correct and that:

- D **I understand that this form must be signed and approved by all parties BEFORE the project can begin.**
- D I have completed the Informed Human Consent used in my project.
- D I understand that I will use the completed Informed Consent Template to obtain written consent from my subjects if required by the OCSEF SRC after review of this document
- D I have attached the questionnaire/survey/test (if this is a part of your experiment).
- D An element of deception is employed in the study design and I wish to withhold some procedures/information from the informed consent document. I am providing this information and a justification in a separate document to the SRC.

Student Investigator 1 Name (Print)	Student Investigator 1 Signature
Student Investigator 2 Name (Print) •	Student Investigator 2 Signature•
Student Investigator 3 Name (Print) •	Student Investigator 3 Signature•

CERTIFICATION BY TEACHER/ADVISOR

I certify that I have reviewed and approved the Informed Consent Template and agree to sponsor the above named student investigator(s) and assume responsibility for compliance with the existing rules and regulations pertaining to experiments with human subjects cited above.

Teacher/ Advisor Name (Print)	Signature ofT eacher / Advisor	
School Name	Position	Date Signed
School Address		School Phone

CERTIFICATION BY DESIGNATED ADULT SUPERVISOR

I certify that I have reviewed and approved the Informed Consent Template and agree to supervise the above named student investigator(s) and assume primary responsibility for compliance with the existing rules and regulations pertaining to experiments with human subjects cited above.

Adult Supervisor Name (Print)	Signature of Adult Supervisor
Home Address (Leave blank if parent)	Home Phone (Leave blank if parent)

HUMAN INFORMED CONSENT TEMPLATE

Grey boxes must be completed by the student investigator(s).

PLEASE TYPE OR PRINT

Name of Student Investigator 1 (include First and Last Name}	School Name
Name of Student Investigator 2 (for team projects only}	School Name (leave blank if same as above}
Name of Student Investigator 3 (for team projects only}	School Name (leave blank if same as above}
Project Title	

Dear Participant:

*I am asking for your **voluntary participation** in my science fair project. If you would like to participate, please sign in the appropriate area below. If you are younger than 18 years old, your parent/guardian is also being asked to provide written consent for you. You can withdraw at any time without any consequences (e.g. this will not affect your school record as your participation is not a school requirement). You can decide not to answer any specific question or perform any task.*

Purpose: The scientific goal of the project or the problem being studied.

1. **Procedures:** These are the specific procedures and steps that test subjects will be asked to follow. It should include the following:
    a. How were test subjects recruited (age, gender, specific health issues, etc., convenience sample of schoolmates, family, friends, or random recruitment, etc.).
    b. A description or example of the questionnaire/testing, physical activity, consumption of food or liquid, etc.
    c. The personal identifiers and information to be collected (name, phone number, address, etc.).

Potential risks to subjects: All research requiring written informed consent has some potential risks. Possible risks could include physical risks such as injury or discomfort, psychological risks such as anxiety or frustration, social risks such as embarrassment, and financial/ privacy risks. This consent should consider how the experiment might adversely affect test subjects. There is always risk. To say there are none is not acceptable.

Confidentiality: This is how personal identifiers and information will keep them secure.

Questions about this project should be directed to:

Adult Sponsor/Qualified Scientist/Designated Adult Supervisor (print)	Phone/email

By Signing this Form I am attesting that I have had the opportunity to ask questions, read and understand the information above, and freely give my consent (if an adult or parent/guardian of the research participant) or assent (if I am a subject less than 18 years old) to participate in this project.

Adult Informed Consent

Research Participant Name (Print)	Signature of Research Participant	Date Signed

OR

Minor Assent

Research Participant Name (Print)	Signature of Research Participant	Date Signed

If this form is serving to document parental consent for a minor, a copy of any survey or questionnaire used in the project must be provided to the parent (attached).

Parental/Guardian Consent for a Minor.

Parent/Guardian Name (Print)	Signature of Parent/Guardian of Research Participant	Date Signed