

CERTIFICATION OF PROTECTION FOR HUMAN SUBJECTS RESEARCH

This form must be completed and signed for all projects involving humans BEFORE the project is begun. In addition, students must submit their research plan & certification form to the OCSEF [Scientific Review Committee \(SRC\)](#) for review BEFORE starting experiments or risk not being accepted to the OCSEF.

PLEASE TYPE OR PRINT

Name of Entrant (Last Name, First Name)	School Name
Project Title	

1. The [Code of Federal Regulations 45 CFR §46.102](#) defines human subject as a person about whom an investigator (whether professional or student) conducting scientific research obtains:
 - (1) data through intervention or interactions with the person; or
 - (2) identifiable private information.
2. Orange County Science and Engineering Fair require that ALL research projects involving human subjects (including, but not limited to, surveys, professional tests, questionnaires, and studies in which the researcher is the subject of his/her own research) comply with the regulations for experiments with human subjects.
3. Student researchers must list the risks to their human subjects when developing research plans. Risks are the possibility of injury or discomfort, including physical, psychological, or social, as a consequence of participation as a subject in any research.

Minimal risk means that the risks of harm or discomfort anticipated in the research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Examples of unacceptable risk include, but are not limited to:

- (1) ingestion or physical contact with any potentially hazardous materials including toxic chemicals, chemicals, known or suspected pathogens or carcinogens, or exposure to ionizing radiation;
 - (2) intentionally inducing emotional stress resulting from invasion of privacy - see [Privacy Act of 1974 45 CFR 5B](#);
 - (3) physical stress to pregnant women or anyone suffering debilitating physical illness;
 - (4) exercise of a strenuous nature for a subject with medical problems; and
 - (5) psychological stress to the mentally handicapped or those suffering psychiatric disorders.
- This list is intended to be illustrative, not exhaustive.
4. According to [Public Health Service Act, 42 U.S.C., 241\(d\)](#), 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 with a project without informed consent.**
 5. Parents 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 with consent forms when requested.

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

HUMAN RESEARCH PLAN

1. Describe the procedures and steps which will be used when dealing with human subjects in your project. Please be specific about the following information:
 - a. Who will be recruited (age, gender, specific health issues, etc.)?
 - b. Will a physical human consent form, including a statement explaining that participation is voluntary and may be withdrawn at any time, be provided and collected from each potential subject?
 - c. How will human subjects be recruited (convenience sample of schoolmates, family, friends, or random recruitment, etc.)?
 - d. What procedures will be followed during the experiment (questionnaire/testing, physical activity, consuming food or liquid, etc.)?
 - e. What personal data will be collected (name, phone number, address, etc.)?

2. Describe the potential risks to your human subjects as a consequence of participation in your research. Possible risks 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 certification is for you to consider how your experiment might adversely affect your test subjects. It will then be up to the reviewer to determine if the benefits of the knowledge gained in the experiment are worth the risk you are putting the test subjects through. There is always risk, so say that there are none is not acceptable.

3. What precautions will you take to protect your test subjects from the risks described in question 2?

CERTIFICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS

CERTIFICATION BY STUDENT

I certify that the experimental procedures used in this science fair project involve no physical, social, or psychological risk, or minimal risk to any involved human subject as defined in the [Code of Federal Regulations 45 CFR §46](#).

I understand that this form must be approved and signed by all parties BEFORE the project can begin, and I will comply with this regulation.

Student Name (Print)	Student Signature
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CERTIFICATION BY TEACHER/ADVISOR

I certify that I have reviewed and approved the Human Research Plan and agree to sponsor the above named student and assume responsibility for compliance with the existing rules and regulations pertaining to experiments with human subjects cited above.

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

CERTIFICATION BY DESIGNATED ADULT SUPERVISOR

I certify that I have reviewed and approved the Human Research Plan and agree to supervise the above named student 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 home parent)