

MONTEREY COUNTY SCIENCE & ENGINEERING FAIR
CERTIFICATION OF COMPLIANCE FOR RESEARCH
INVOLVING HUMAN SUBJECTS, TISSUE SAMPLE SOURCES,
AND HUMANE TREATMENT OF LIVE VERTEBRATE ANIMALS

NAME OF APPLICANT (LAST NAME, FIRST NAME)	NAME OF SCHOOL
PROJECT TITLE	

This form is for:

- Compliance for Research Involving Human Subjects _____
- Tissue Sample Source Verification _____
- Humane Treatment of Animals _____

We certify that the experimental procedure used in this science fair project complies with State and Federal regulations including but not limited to 45 CFR 46 46.102 and California Education Code 51540:

SIGNATURE OF STUDENT	DATE SIGNED
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PROJECT ADVISOR

PRINT NAME:	TITLE
NAME OF INSTITUTION	TELEPHONE NUMBER
ADDRESS OF INSTITUTION	
SIGNATURE OF PROJECT ADVISOR	DATE SIGNED

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The following codes apply to all student research projects. Project advisors must acknowledge on the certification forms that the student has complied with all research regulations.

FOR ALL PROJECTS INVOLVING HUMANS AS THE SUBJECT OF RESEARCH

The Code of Federal Regulations 45 CFR 46 §46.102 defines

“Human Subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. In order for the obtaining of private information to constitute research involving human subjects, the identity of the subject must be readily associated with the information.

- **“Minimal Risk”** means that the risks of harm 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: (1) ingestion or physical contact with any potentially hazardous materials including toxic chemicals, known or suspected pathogens or carcinogens, or exposure to ionizing radiation; (2) intentionally inducing emotional stress through questioning or invasion of privacy; (3) physical stress to pregnant women or anyone suffering debilitating physical illness; and (4) psychological stress to the mentally handicapped or those suffering psychiatric disorders. This list is intended to be illustrative, not exhaustive.

The American Psychological Association’s Code of Ethics for Human Subject Research Indicates the Following in Regards to Dispensing With Informed Consent for Research:

Psychologists may dispense with informed consent only (1) where research would not reasonably be assumed to create distress or harm and involves (a) the study of normal educational practices, curricula, or classroom management methods conducted in educational settings; (b) only anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected; or (c) the study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected or (2) where otherwise permitted by law or federal or institutional regulations

The regulations of the Fair 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.

FOR ALL PROJECTS INVOLVING TISSUE SAMPLES:

Live tissue samples must be taken either from a continuously maintained tissue culture line already available to institutional researchers, or from animals already being used in an on-going institutional research project.

Students may not be involved in the direct acquisition of these samples from living human or vertebrate animals.

FOR ALL PROJECTS USING ANY LIVE VERTEBRATE ANIMAL, EXCLUDING HUMANS:

The State of California Education Code §51540: *In the public elementary and high schools or in public elementary and high school school-sponsored activities and classes held elsewhere than on school premises, live vertebrate animals shall not, as part of a scientific experiment or any purpose whatever:*

- a. Be experimentally medicated or drugged in a manner to cause painful reactions or induce painful or lethal pathological conditions.*
- b. Be injured through any other treatments, including, but not limited to, anesthetization or electric shock.*

Live animals on the premises of a public elementary or high school shall be housed and cared for in a humane and safe manner. The provisions of this section are not intended to prohibit or constrain vocational instruction in the normal practices of animal husbandry.