

CALIFORNIA STATE SCIENCE FAIR
2011 REGULATIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS,
TISSUE SAMPLE SOURCES (INCLUDING DNA SOURCE MATERIALS),
AND HUMANE TREATMENT OF LIVE VERTEBRATE ANIMALS

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 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.



CALIFORNIA STATE SCIENCE FAIR
2011 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 |
|----------------------|-------------|

PROJECT ADVISOR

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