#### **CALIFORNIA SCIENCE & ENGINEERING FAIR**

### 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.

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### RESEARCH CERTIFICATION FORM Directions

All projects must submit either this form or the full set of required ISEF forms. The only difference is that students who wish to be ISEF-eligible *must* submit the ISEF forms. All other students (including all students in the Junior Division) should use this CSEF form.

#### **Team Projects Note:**

Only one copy of this form should be submitted for any team project. Submitting multiple copies may delay the processing of your applications. We recommend that the first member of the team to submit an application (who should be the only person entering the text of the Project Summary online) be the person who completes this form and passes it on to the research advisor who then emails the form to the fair.

#### **Identification:**

Print names of all team project members here. Use the Application Confirmation Code (the "E"-number) of the first member submitting an application. A shortened version of the project title may be used here.

#### **Issues:**

Check *every* box which applies to your project. Be careful not to omit any or the fair's SRC may require a replacement form, delaying the processing of your application.

#### **Explanation/ Accommodation:**

You are required to have considered all risks to the well-being of any human or vertebrate subjects from your research activity. Your research supervisor must have provided oversight and prior approval when needed.

**Research in which any human was the subject** (including yourself) must involve no more than "Minimal Risk" as defined in 45 CFR 46 (see page 16). Now that your research is completed, list any injury to any human subject, including yourself if you were a subject.

Research in which any vertebrate (non-human) animal was the subject must adhere to California Ed Code §51540 (see page 16). Specify how your research was expected to affect your subjects and what plans you made in order to avoid or minimize any risks. If you housed the animals, describe their condition. Now that your research is completed, identify any actual injury to any animal, including death, during the project, and the final disposition of all subject animals.

If your project involved any biological, chemical, or physical agents that posed a risk to any person, including yourself, specify what agents were involved, what risk they posed, and what precautions you took to avoid those risks. Now that your research is completed, identify any actual exposure to these agents and any actual injury to any person.

If you checked "None of the Above," explain why none of the considerations above apply.

#### **Signatures:**

The signature of only one student in a team is needed here, along with that of the research advisor.

When completed, scan the form and email it to CSEF.SRC@gmail.com. Do not send cell phone pictures.

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#### RESEARCH CERTIFICATION FORM

When complete, scan to PDF and email to CSEF.SRC@gmail.com
Do not send an image taken by cell phone.

STUDENT(S) – INCLUDE ALL MEMBERS IF TEAM PROJECT	APPLICATION CONFIRMATION CODE
PROJECT TITLE	
Check every box below which fits your project in any way  ☐ Human Subjects ☐ Vertebrate Animals ☐ Potentially Hazardous Biological Agents ☐ Potentially Hazardous Chemicals or Physical Agent ☐ None of the Above	
EXPLANATION/ ACCOMMODATION FOR ALL CHECKED ITEMS ABOVE. If "None of the Above," explain what your project did involve.	
We certify that the above accommodations and experimenta with all local, State, and Federal regulations.	procedure used in this science fair project comply
STUDENT SIGNATURE (ONLY ONE MEMBER OF A TEAM IS NEEDED)	DATE SIGNED
STODENT SIGNATURE (ONLY ONE MEMBER OF A TEAM IS NEEDED)	DATE SIGNED
PROJECT ADVISOR NAME (PRINTED)	ADVISOR'S TITLE
DDO IFOT ADVICED CIONATURE	DATE CIONED
PROJECT ADVISOR SIGNATURE	DATE SIGNED
NAME OF ADVISOR'S INSTITUTION	ADVISOR'S EMAIL ADDRESS