

GREATER SAN DIEGO SCIENCE & ENGINEERING FAIR

**Certification of Compliance of Research Involving Humans —
(GSDSEF-3, 2009)**

Student Research involving human subjects, helpers or interviewees MUST COMPLY with the requirements of the *California Civil Code* - and the *Intel International Science and Engineering Fair (Intel ISEF)*.

This form MUST:

- **Be Completed and Signed Prior to Starting the Project**
- **Be in the Front of the Project Notebook at Screening Fair**
- **If the student is invited to apply to the *Greater San Diego Science and Engineering Fair (GSDSEF)*, be included with the Application for Entrance.**

Box 1 — Basic Information

1. STUDENT'S NAME (Last, First, M.) _____

A. Phone _____

B. Address _____

C. School _____

D. Teacher _____

E. Grade _____

(Question 2 for Senior Division, 2-Person Projects ONLY)

2. PARTNER'S NAME (Last, First, M.) _____

A. Phone _____

B. Address _____

C. School _____

D. Teacher _____

E. Grade _____

3. PROJECT TITLE _____

GO TO PAGE 2

GSDSEF Human Subject Form — Page 2

BOX 2 — Statement of Compliance and Signatures

With the understanding that failure to comply will result in disqualification, we CERTIFY THAT:

- **The rules/regulations of the *GSDSEF*, *Intel ISEF* and the *California Civil Code*, will be followed in all particulars.**
- **No subject, helper or interviewee will be embarrassed, harmed or endangered in any way or exposed to the possibility of physical, psychological or social injury (See **Note 3** and "**Subject at Risk**" on page 4). All will be treated with courtesy and consideration.**
- **No identifiable private information (including medical data or photos) will be included in the project report.**
- **A signed and dated consent form will be obtained from each subject (or if a minor, from his/her parent/guardian) or, in the case of testing done in a school classroom, from the teacher in charge. A photocopy of a blank consent form must be submitted with the *Application for Entrance* if the student is invited to apply to the *GSDSEF*. All originals should be with the display in an unsealed envelope at screening and kept by the student for future reference by the *GSDSEF* or other affiliated groups**
- **No copyrighted/other restricted test (or other) materials will be used without written permission of the author/owner.**

In addition we AGREE THAT:

GO TO PAGE 3

GSDSEF Human Subject Form — Page 3

- Should this student (**9th – 12th grade only**) be selected to compete at the *2009 Intel International Science and Engineering Fair (Intel ISEF)*, each person signing below will complete, pre-date to the date on this form and sign any *Intel ISEF* forms required for this project. *Intel ISEF* forms can be viewed on the *GSDSEF* website at www.gsdsef.org.

Student's Signature

Date

2nd Student's Signature (Senior Division 2-person projects only)

Date

Parent/Guardian's Signature

Date

2nd Student's Parent/Guardian's Signature

Date

Teacher's Signature

Date

Biomedical Scientist's Signature
(if required—see Note 3 on Page 4)

Date

GO TO PAGE 4

GSDSEF Human Subject Form — Page 4

SPECIAL CONSIDERATIONS FOR HUMAN SUBJECTS, HELPERS OR INTERVIEWEES

Because federal regulations have become increasingly rigid, students must plan carefully before undertaking either behavioral or biomedical studies involving human subjects. This will protect subjects from unnecessary exposure to physical or psychological risks and experimenters and schools from legal complications. For example, the law is very clear about disclosure of medical information: "This information may be disclosed to...accredited public or private non-profit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way which would permit identification of the patient." (*California Civil Code, Section 56.10, (c), (7)*).

Furthermore, the *HIPAA Regulations* regarding patient records and confidentiality may well affect whether a project is suitable for student development. No identifiable personal information may appear in your records or project notebook or on your display. All subjects must sign consent form allowing the student to use data collected and these slips must be kept in a sealed envelope and made available to screeners. A blank sample consent form should be included in the project notebook. If any question exists as to the propriety of the proposed project, the student/teacher must contact Phil Gay at phil@gsdsef.org.

A human subject is defined as "a person about whom an investigator (professional or student) conducting scientific research obtains (1) data through intervention or interaction with the person, or (2) identifiable private information."

A subject at risk is defined as "any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research."

Students using humans as subjects must comply with all regulations reflecting the will of society and plan methodology to protect those subjects. They must be alert to humane concerns at all times.

The teacher reviews the forms and determines if any potential psychological, social, or physical risk (including possibility of injury or health hazards) is involved. If none is apparent, the teacher signs the certification (approval subject to confirmation by the *GSDSEF* Scientific Review Committee at screening and/or application to the *GSDSEF*). If any question of risk exists, the student must redesign the experimental study or plan a different study.

NOTES

Any project involving human subjects that is developed with the advice and assistance of personnel at a medical/scientific organization must comply with any regulations of that organization requiring approval of its institutional review board and informed consent certification.

Projects involving exercise or other strenuous activity or in which subjects are given caffeine – soft drinks, coffee, etc. -- or over-the-counter products or food supplements must have protocols analyzed by and/or be supervised by a medical doctor. Ingestion of other substances – e.g. nuts (possible allergen) or sugar (hazard for diabetics) -- may also require medical supervision (to be determined on a case by case basis).

Questions or Concerns? Contact Philip D. Gay – (619) 697-2024 or phil@gsdsef.org or src@gsdsef.org.

GSDSEF USE: SRC APPROVAL