GREATER SAN DIEGO SCIENCE & ENGINEERING FAIR (GSDSEF)

CERTIFICATION OF COMPLIANCE OF RESEARCH INVOLVING HUMAN PARTICIPANTS FORM

The SRC Pre-Approval Form and this form must be completed, signed, and approved by the GSDSEF Scientific Review Committee (SRC) BEFORE experimentation begins. If there are any questions or concerns about a student's project, contact Steve Rodecker, stevegsdsef@gmail.com. Save a copy or take a picture of this completed and signed form. The completed and signed Form must then be given to your teacher who will file it for quick reference if needed. Remember that this form MUST BE COMPLETED, SIGNED, attached to the SRC Pre-Approval Form, SUBMITTED through your GSDSEF account, and APPROVED by the GSDSEF SRC before experimentation can begin.

Student 1 Name (last, first, middle initial)

Student 2 Name (If applicable)

School Grade(s) /

Teacher/Advisor email address:

Project Title

The student(s), and all who sign this form, MUST be able to confirm that the project complies with the requirements for research involving human participants as outlined in the:

1. California State Educational Code 51513
2. Code of Federal Regulations 45 (§) 46.102
3. HIPAA Regulations
4. Public Health Service Act, 42 U.S.C., 241(d).
5. Rules and Guidelines of the International Science and Engineering Fair (ISEF) involving Human Participants- ISEF Rules and Guidelines.

Rules, Regulations, and Guidelines for Research Involving Humans

1. The rules, regulations, and guidelines of the California State Education Code 51513 and ISEF Human Participants in regard to projects with human participants will be followed. Such projects include, but are not limited to, surveys; professional tests; psychological, educational, and opinion questionnaires; physical tests; testing of inventions/computer applications; behavioral studies with modified environments; and studies in which the researcher is the subject of his/her own research.
2. No human participant or interviewee will be embarrassed, harmed or endangered in any way, or exposed to the possibility of injury, including physical, psychological or social injury; all subjects and interviewees will be treated with courtesy and consideration at all times.
   A) The Code of Federal Regulations 45 (§) 46.102 defines a human participant as a person from whom an investigator obtains:
      1) data through intervention or interactions with the person, or
      2) identifiable personal information.
3. (California State Education Code 51513) Parents/guardians have the right to deny participation of any minor child in any study involving tests or questionnaires which may be deemed overly personal/intrusive.
4. No identifiable private personal information (including medical data) will be included or distributed.
5. A signed and dated Human Informed Consent Form will be obtained from each subject (or if the subject is a minor, from her/his parent or guardian) or, in the case of testing done in a school classroom, from the teacher in charge. Information which must be included on the Human Informed Consent Form is found in the link.
6. ALL original signed and dated Human Informed Consent Forms should be held, in a sealed envelope, and kept by the teacher for possible future use (i.e. questions by GSDSEF staff or judges and use in applying to other Science Fairs, etc.).
7. No medical diagnoses of disease, administering of medications (including over-the-counter), or medical procedures will be performed.
8. It is illegal to publish information identifying human participants (Public Health Service Act, 42 U.S.C., 241(d). No photographs or any descriptors revealing identity of human participants will be shared or displayed physically or digitally.
9. Student researchers must indicate in their Research Plan risks to human participants and their plan to mitigate risks. Examples of unacceptable risks include: a) ingestion or physical contact with any potentially hazardous materials including toxic chemicals; known or suspected allergens, pathogens, or carcinogens; or exposure to ionizing radiation. b) intentionally inducing emotional stress resulting from invasion of privacy c) physical stress to pregnant women or anyone suffering debilitating physical illness c) exercise of a strenuous nature for a subject with medical problems. d) psychological stress to the mentally handicapped or those suffering psychiatric disorders. This list is for examples and is not complete/exhaustive.

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Human Research Plan

1. Describe the procedure which will be followed for the human participants. Provide specific information about:
   a. how the human participants will be recruited, i.e., age, gender, specific health issues, schoolmates, family, friends, random, etc.
   b. which procedures will be followed during the experiment: questionnaire, physical testing, consuming food or drink, etc.
   c. which personal data will be collected, i.e. name, phone number, address, email address, etc. and how confidentiality will be maintained.
   d. describing how you will ensure no individual public pieces of data can be pieced together to identify a person.

2. Describe the potential risks to your human participants as a consequence of participation in your project. Include possible risks such as physical risks--injury or discomfort-- psychological risks such as anxiety or frustration, social risks such as embarrassment, and financial/privacy risks. **There are inherent risks in all human participant research; stating there are no risks is not allowable, and the project will be declined.**

3. Which precautions will you take to protect your test participants from possible risks listed in item #2?

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***Before experimentation can begin*, you must:**

1) attach this completed, signed form and any other necessary forms to the SRC Pre-Approval Form in your GSDSEF account.
   - 1a) A pdf copy of the Human Informed Consent Form used in the experiment.
   - 1b) A pdf copy of the questionnaire/survey/ test (if this a part of your experiment)
   - 1c) Regulated Research Institutions (RRI)- For other circumstances, see GSDSEF Rules.
     - a. A pdf copy of ISEF Form 2 (Qualified Scientist)
     - b. A pdf copy of the signed approval from the Institutional Review Board (IRB) of the RRI.
2) submit the SRC Pre-Approval Form, this pdf form, and necessary, additional form(s) to the SRC of the GSDSEF.
3) receive approval from the SRC of the GSDSEF.

Student(s) Certification

I certify that I will follow all rules listed on page 1 of this form and that my project involves no/minimal physical, social, psychological, or financial risk to the human participants.

Student 1 Name

Student 1 Signature Date

Student 2 Name

Student 2 Signature Date

Teacher/Advisor Certification

I certify that I have reviewed and approved the Human Research Plan and agree to sponsor and assume responsibility for compliance with the Rules, Regulations, and Guidelines listed on page 1 of this form regarding research involving humans.

Teacher/Advisor Name

Teacher/Advisor Signature Date

Parent/Guardian Certification

I know my son/daughter will be working with human beings during his/her project and must follow all rules listed on page 1 of this form.

Parent/Guardian 1 Name

Parent/Guardian 1 Signature Date

Parent Guardian 2 Name

Parent/Guardian 2 Signature Date

Designated Supervisor/Adult Sponsor Certification (if necessary, see GSDSEF Rules)

I certify that I have reviewed and approved the Research Plan for this project and I will supervise and accept primary responsibility for the human research done in this project. I certify I have been trained in the techniques to be used by this/these students and I will provide direct supervision of the research. I assume responsibility for compliance with existing rules and regulations list on page 1 of this form in regard to experiments with human participants.

Adult Supervisor's Name email

Adult Supervisor's Signature Date

Qualified Scientist Certification (if necessary, see GSDSEF Rules)

I certify that I have reviewed and approved the Research Plan of this project before experimentation began. If experimentation is to be done at a Regulated Research Institution, or I provide direct supervision or training elsewhere, I have filled out and signed Qualified Scientist Form 2. I will ensure that all rules and guidelines of ISEF, and other agencies pertaining to human participants listed on page 1 of this form are adhered to. I will ensure IRB approval from my RRI. I will provide personal supervision, advice, or any necessary training of a Designated Supervisor.

Qualified Scientist Name Degree

Signature Date

Institution Telephone

Address email