# HUMAN INFORMED CONSENT PROCESS

**Written informed consent must be collected (or waived by the OCSEF SRC) BEFORE the project is begun. In addition, students must submit their research plan & certification for research involving human subjects form to the OCSEF Scientific Review Committee (SRC) for review BEFORE starting experiments or risk not being accepted to the OCSEF.**

**Purpose of Informed Consent:**

An informed consent/assent form to be signed by adult subjects or parent/guardian of minor research subjects should be developed in consultation with the Adult Sponsor, Designated Supervisor or Qualified Scientist. The attached Form is a sample that contains elements required by ISEF (International Science and Engineering Fair) that are also required by Federal regulations for the Protection of Human Subjects in Research 45 CFR 46.

It is the expectation that a truly informed consent should also contain any additional information that affects risks to your subjects. **A "Permission Slip" required by the school that does not contain these elements does not satisfy the requirements of informed consent.** Written Informed consent will be required when the OCSEF Scientific Review Committee finds your project to be greater than minimal risk for subjects and/or when identifiable personal health information is being used or collected from subjects.

**Instructions to the Student Researcher(s):**

To obtain written informed consent, you may use the attached Form below or create your own document that **must include** the same elements as the included form. You must:

1. Complete the grey boxes on the attached Form as follows:
    a. **Purpose:** Describe the scientific goal of your project or the problem you are studying and how your hypothesis addresses that problem.
    b. **Procedure:** Please describe and be specific about the activities you will ask your subjects to complete.
    c. **Time:** Describe how long participation will last? Include the length (e.g. hours or minute) of each session involve and how many sessions or trials will you require.
    d. **Potential Risks to Subjects:** Please anticipate and describe risks to your specific test subject population and prepare a plan to respond to them if an adverse event occurs.
    e. **Benefits to subjects:** Most often there is no direct benefit to subjects who chose to participate in research. In clinical/medical research, subjects should not be induced to enroll in a study by the amount of money they are provided for their expenses. Please explain any potential direct benefits from your science fair experiment, or that there may be no direct benefit to subjects, other than their helping you complete your research project.
    f. **Confidentiality:** If you are collecting personal identifiers, describe which ones they are and how you will keep them secure. For example: *All personal identifiers, (e.g. names, addresses, phone numbers, that the researcher collected for this experiment will not be shared with others, kept in a secure place, and destroyed at the end of the project.*
2. Print and copy the form and give each adult subject or parent/guardian of minor research subjects a copy of the form (alternately, you may email this form and obtain electronic signatures).
3. Collect the signed forms.
4. Begin your experiment.

After written informed consent is obtained, you must:

- Keep the original signed forms in a secure place and do not bring them or any identifying information (e.g. names, addresses, phone numbers) about your subjects to the local Fair.
- On any report or board displayed at the fair, identify your test subjects with a number, letter, or ID
- Destroy any personal identifiers included in your data at the completion of the study. You can and should keep the remaining data.
- If parental/guardian consent is being sought for a project involving a survey or questionnaire, copies of these surveys or questionnaires must be attached to your informed consent when provided to the parent/guardian.

# HUMAN INFORMED CONSENT TEMPLATE

**Grey boxes must be completed by the researcher(s).**

PLEASE TYPE OR PRINT

| Name of all Researchers (include First and Last Name) | School Name |
|---|---|
| Project Title | |

*Dear Participant:*

*I am asking for your **voluntary participation** in my science fair project. If you would like to participate, please sign in the appropriate area below. If you are younger than 18 years old, your parent/guardian is also being asked to provide written consent for you. You can withdraw at any time without any consequences (e.g. this will not affect your school record as your participation is not a school requirement). You can decide not to answer any specific question or perform any task.*

| **Purpose:** |
|---|
| **Procedures:** If you chose to participate, these are the activities you will be asked to do. |
| **Time required for participation**: |

| |
|---|
| **Potential risks to subjects**: All research requiring written informed consent has some potential risks. |
| **Benefits to subjects**: |
| **Confidentiality:** |

If you have any questions about this project, please contact:

| Adult Sponsor/Qualified Scientist/Designated Adult Supervisor (print) | Phone/email |
|---|---|
| | |

**By Signing this Form , I am attesting that I have had the opportunity to ask questions, read and understand the information above, and freely give my consent (if an adult or parent/guardian of the research participant) or assent (if I am a subject less than18 years old) to participate in this project.**

## Adult Informed Consent

| Research Participant Name (Print) | Signature of Research Participant | Date Signed |
|---|---|---|
| | | |

**OR**

## Minor Assent

| Research Participant Name (Print) | Signature of Research Participant | Date Signed |
|---|---|---|
| | | |

**If this form is serving to document parental consent for a minor, a copy of any survey or questionnaire used in the project must be provided to the parent (attached).**

## Parental/Guardian Consent for a Minor.

| Parent/Guardian Name (Print) | Signature of Parent/Guardian of Research Participant | Date Signed |
|---|---|---|
| | | |