Are you using HUMAN SUBJECTS?

FORM 4 QuickSheet

Human Subject Projects Include Studies Involving...

- ➔ Interactions with humans or their identifiable private data.
- ➔ Physical activities (exertion, ingestion, or medical procedures)
- ➔ Psychological, educational, or opinion studies (surveys, questionnaires)
- ➔ the researcher as the subject
- ➔ testing of student-designed inventions other than on self
- ➔ Data analysis or records review projects that include personally identifiable information (such as names, phone numbers, addresses, etc)
- ➔ Behavioral observations that:
  - ◆ *involve any interactions with the participant*
  - ◆ *have modified the environment (with signs, objects, etc)*
  - ◆ *occur in non-public settings*
  - ◆ *involve recording personally identifiable information from the participant*

In your Research Plan...

- ➔ Complete ALL elements of the Human Participants portion of the Research Plan/Project Summary, as per instructions
- ➔ Evaluate and detail how physical, psychological, and privacy risks to Human Participants will be minimized or eliminated

ALWAYS Check Complete ISEF HUMAN SUBJECT Rules!

https://www.societyforscience.org/isef/international-rules/human-participants/

On Form 4...

- ➔ Completely fill in the top section
- ➔ Have an Institutional Review Board (IRB) review your Research Plan and complete the second section
- ➔ Ensure they mark all the checkboxes relevant to your project
- ➔ Ensure they sign and date the form BEFORE experimentation

EXEMPT Studies That Do Not Require IRB Review

- ➔ Student-designed inventions that are only tested by the researcher
- ➔ Analysis of de-identified human subject data, verified as anonymous by the data source
- ➔ Observational, non-interactive studies in public settings where the environment hasn't been altered in any way

Human Subject Studies MUST...

- ➔ Have an IRB approve and sign Form 4 before experimentation begins
- ➔ Get Informed Consent (using the Informed Consent Form, or a similar document) from participants prior to experimentation
- ➔ Disclose what participants will see, hear, and do as part of Informed Consent
- ➔ Inform participants that their participation is voluntary and they are free to discontinue participation at any time
- ➔ Get permission from Parents/Guardians before allowing minors to participate in the study
- ➔ Provide protection for at-risk groups (such as pregnant women, disabled persons, disadvantaged persons, or individuals with disease conditions)
- ➔ Protect the privacy and anonymity of all participants, as directed by State and Federal Privacy Laws
- ➔ Take steps to minimize risk to participants

It is PROHIBITED to...

- ➔ Diagnose disease (including the use of diagnostic apps), administer medication, or perform a medical procedure on a human participant
- ➔ Draw blood on anyone except on the student researcher themselves
- ➔ Display, publish, or reveal personally identifying information about human participants
- ➔ Use published instruments without the permission of the publisher
- ➔ Use human participants (other than the student researcher) to test inventions or prototypes without IRB approval and participant permission.

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