

State Science and Engineering Fair of Florida
Fall SRC Meeting
Human Participant Studies

This an overview of the ISEF rules for Human Participant studies. For a more detailed review, please see the ISEF Rules for 2016, the ISEF online supplement (Human Participant Studies-Risk Assessment Guide), and Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).

IRB

The majority of Human Participant Research projects will require review by an Institutional Review Board (IRB). This board should be locally constituted and must have at least three members. There should be an educator, a school based administrator and a Medical or Mental Health Professional, depending on the type of project.

Exempt from IRB Pre-Approval

Those types of projects involving human participants that are exempt from IRB preapproval are:

- a. Student researcher testing his/her designed product only on his-self/herself **and** there is no health or safety issue.
- b. Data taken from preexisting data sets, publically available and no interaction with humans.
- c. Behavioral observations of unrestricted public settings where there is no human interaction, no manipulation of the environment and no personalized data is recorded.
- d. Student receives pre-existing, de-identified data along with written certification from the provider stating compliance with all laws and the SRC reviews the documentation.

IRB Pre-Approval

All other human participant studies will require IRB Review and Human Participant paperwork prior to the experiment starting or any involvement with human participants including recruitment.

Research conducted at a Research Institution must have IRB approval from the Research Institution's IRB.

Informed Consents

Research participants must give informed consent or assent, depending upon IRB requirements. There may be a requirement for parental or guardian consent.

Informed consent must include complete information to the participant, must be voluntary and can be revoked at any time. See the Human Informed Consent Form in the ISEF Forms section. Informed consent forms are protected by the Department of Health and Human Services and HIPAA laws and must be kept confidential. The only people who can have access to or view the forms are the individuals outlined in the study as it was approved by the IRB.

Informed consents:

- a. should be kept in a closed folder by the researcher. No one should have access to the forms.
- b. should be counted by the research teacher prior to the project's first competition. This is to verify that there are the same number of forms as data points.
- c. should be kept by the researcher in a secure area in a sealed, dated folder for three years.

Human subject projects that involve laboratory tests/procedures (e.g. blood tests, cultures, x-rays, etc.) must include information in the research plan about how the costs of the tests will be paid. If the costs will be paid by the human subject or their health insurance the risk section of the Human Subject Consent Form must include the following statement "Tests and/or procedures in this project may be billed to you or your health insurance."

One original signed and dated Informed Consent must be copied and then redacted and kept with the rest of the project protocol paperwork. No originals should travel to any competition at any time. The Verification of Informed Consent form needs to also be included with the protocol.

Other Rules

- a. Students are prohibited from administering medication and performing invasive medical procedures.
- b. All published testing instruments not in the public domain, must be scored and interpreted by a Qualified Scientist and use of the instrument must comply with the publisher's requirements.
- c. Collection of data via the Internet is complicated. Please see the ISEF on-line supplement Section D. It needs a disclosure statement and an affirmative act such as a button for the participant to select. IP addresses need to be deleted. If Parental Permission is required there are additional procedures to be followed.

Expedited IRB Review:

- a. If the student's project involves testing of a student designed invention or program and the human participants provide direct feedback to the researcher about the invention and there is no personal data collected or
- b. the student is the subject of their own research and there is no more than minimal risk; In either of the above situations, one knowledgeable member of the IRB may approve the project.

Previously Exempt Human Studies (Product testing)

1. Student Designed Invention
 - a. Testing of a student designed invention is exempt from IRB approval if it is tested only by the researcher and if the testing is not a health hazard.
 - b. Testing by anyone other than the researcher requires prior IRB approval.
 - c. Prior IRB approval is required for researcher testing of a potentially dangerous design.

Example: The student creates a new steering system for shells used by a competitive crew team. She wants to collect data from crew team practices comparing the current method with results achieved with her invention.

Example: A student designs a voice synthesizer for a cell phone. He wants to test the human qualities of the voice by having students listen to the voice and complete a survey rating the human characteristics that are present or absent.

Both of these examples would require prior IRB approval.