Human Participants Rules
Rules involving human participants

Student researchers must follow federal guidelines (Code of Federal Regulations 45 CFR 46) to protect the human research participant and the student researcher. When students conduct research with humans, the rights and welfare of the participants must be protected. Most human participant studies require preapproval from an Institutional Review Board (IRB)/Human Subjects Participant Program (HSPPP) and informed consent/assent from the research participant.

Exempt Studies (Do Not Require IRB Preapproval or Human Participants Paperwork)
Some studies involving humans are exempt from IRB pre-approval or additional human participant forms. Exempt projects for the Intel ISEF and affiliated fairs are:

1. Student-designed Invention, Prototype, Computer Applications or Engineering/Design Project in which the student is the only person testing the invention, prototype or computer application and the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed. The use of human participants (other than the student researcher him/herself) for this testing requires IRB review and approval (see page 10).

2. Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from pre-existing data sets that are publicly available and/or published and do not involve any interaction with humans or the collection of any data from a human participant for the purpose of the student's research project.

3. Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which all of the following apply:
   a. the researcher has no interaction with the individuals being observed
   b. the researcher does not manipulate the environment in any way and
   c. the researcher does not record any personally identifiable data.

4. Projects in which the student receives pre-existing/retrospective data in a de-identified/anonymous format which complies with both of the following conditions:
   a. the professional providing the data certifies in writing that the data have been appropriately de-identified before being given to the student researcher and are in compliance with all privacy and HIPAA laws, and
   b. the affiliated fair SRC ensures that the data were appropriately de-identified by review of the written documentation provided by the supervising adult(s).

Rules
1. The use of human participants in science projects is allowable under the conditions and rules in the following sections. Based upon the U.S. Code of Federal Regulations (45 CFR 46), the definition of a human participant is a living individual about whom an investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information. These projects require IRB review and preapproval and may also require documentation of written informed consent/assent/parental permission. Examples of studies that are considered “human participant research” requiring IRB preapproval include:
   a. Participants in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
   b. Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
   c. Studies in which the researcher is the subject of the research (Expedited Review may be used, see page 9)
   d. Testing of student designed invention, prototype or computer application by human participants other than student researcher (Expedited Review may be used, see page 9)
   e. Testing of student designed invention or concept by human participants other than student researcher
   f. Data/record review projects that include data that are not de-identified/anonymous (e.g., data set that includes name, birth date, phone number or other identifying variables).
   g. Behavioral observations that
      1) involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
      2) occur in non-public or restricted access settings (e.g., day care setting, doctor’s office)
      3) involve the recording of personally identifiable information

2. Student researchers must complete ALL elements of the Human Participants portion of the Research Plan/Project Summary Instructions and evaluate and minimize the physical, psychological and privacy risks to the human participants. See Risk Assessment information on page 11 and the online Risk Assessment Guide (https://student.societyforscience.org/human-participants#riskass) for additional guidance.

3. The research study should be in compliance with all privacy laws (e.g., U.S. Family Educational Rights and Privacy Act (FERPA) and U.S. Health Insurance Portability and Accountability Act (HIPAA)) laws when they apply to the project (e.g. the project involves medical information).

4. All research projects involving human participants, including any revisions, must be reviewed and approved by an Institutional Review Board (IRB) before the student may begin recruiting and/or interacting with human participants. The IRB must assess the risk and document its determination of risk on Form 4. After initial IRB approval, a student with any proposed changes in the Research Plan/Project Summary must repeat the approval process and regain approval before laboratory experimentation/data collection resumes.

5. Research conducted by a pre-college student at a Regulated Research Institution (e.g., university, college, medical center, government lab, correctional institution) must be reviewed and approved by that institution's IRB. A copy of the IRB approval for the entire project (which must include the research procedures/measures the student is using) and/or an official letter from the IRB attesting to approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.

6. Research participants must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research participants may give their own consent. Research participants under
11. After experimentation and before Intel ISEF competition, the Intel ISEF SRC reviews and approves previously-approved projects to ensure that students followed the approved Research Plan/Project Summary and all of the Intel ISEF rules.

12. The following forms are required for studies involving human participants:
   a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan/Project Summary, and Approval Form (1B)
   b. Human Participants Form (4) with applicable consents and survey(s)
   c. Regulated Research Institution Form (1C), when applicable
   d. Qualified Scientist Form (2), when applicable
   e. Risk Assessment Form (3) when applicable

**IRB Waiver of Written Informed Consent/Parental Permission**

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involves only minimal risk and anonymous data collection and if it is one of the following:

- Research involving normal educational practices
- Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the participants' behavior and the study does not involve more than minimal risk.
- Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory, etc. and that do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
- Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

**Expedited Review**

An expedited review by only one member of the IRB may be conducted for projects that meet one of the criteria listed below. The IRB member reviewing the project will determine whether appropriate safety precautions will be employed and whether the project meets criteria for expedited review. If a project submitted for expedited review does not meet the criteria specified below, the project must undergo full IRB review. The IRB member reviewing the project must have the expertise necessary to make such a decision and/or receive advisement from an appropriate expert.
Human Participant Involvement in Student-designed Invention, Prototype, Computer Application & Engineering/Design Projects

Student-designed invention, prototype, computer application and engineering/design projects that involve testing of the invention by any human participant require attention to the potential risks to the individual(s) testing or trying out the invention/prototype. To be considered for Exempt Status or Expedited Review, the data collected/feedback received must be a direct reference to the invention/prototype (i.e., personal data cannot be collected) and the testing may not pose a health or safety risk.

- Exempt Status can be used when the student researcher is the only person testing the invention/prototype. It is recommended that a Risk Assessment Form be completed.
- Expedited Review process may only be used for projects that involve human participants to test a student designed intervention or prototype in which the feedback obtained is only related to the invention.
- Full IRB Review is necessary if the activities involved in testing of the invention or prototype are more than minimal risk or involve collection of personal information from participants.
- Full IRB Review is necessary if the testing of the invention, prototype or project involves a medical intervention (as defined by the FDA or Medical Practices Act) and should be conducted in a Registered Research Institution with IRB approval from the institution.