Human Participants Rules

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) 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:

- Testing of a student-designed invention, program, concept, etc. where the feedback received is a direct reference to the product, where personal data is not collected, and where the testing does not pose a health or safety hazard. It is recommended that a Risk Assessment Form (3) be completed.

- Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting 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.

- 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.

- Projects in which the student receives the 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 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 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), and/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:
   - Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure)
   - Psychological, educational and opinion studies (e.g., surveys, questionnaires, tests)
   - Studies in which the researcher is the subject of the research
   - Behavioral observations that
     a) involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., posts a sign, places an object).
     b) occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
     c) involve the recording of personally identifiable information
   - Data/record review projects that include data that are not de-identified/anonymous (e.g., name, birth date, phone number and/or other identifying variables.)

2) Student researchers must complete ALL elements of the Human Participants portion of the Research Plan Instructions and evaluate and minimize the physical, psychological and privacy risks to their human participants. See Risk Assessment below and the Risk Assessment Guide for additional guidance.

3) The research study must be in compliance with all privacy and HIPAA laws as 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 must repeat the approval process and regain approval before laboratory experimentation/data collection resumes.

5) Research conducted by a student where human participants are at an institution with an IRB (e.g., university, 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 18 years of age and/or individuals not able to give consent (e.g. developmentally disabled individuals) give their assent, with the parent/guardian providing permission. The IRB will determine whether the consent/assent/parental permission may be verbal or must be written depending on the level of risk and the type of study, and will determine if a Qualified Scientist is required to oversee the project. See Risk Assessment below and the Risk Assessment Guide for further explanation of informed consent.
   - Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the nature of the study and risks and benefits associated with participation. This allows the participants and parents or guardians to make an informed decision about whether or not to participate.
   - Participants must be informed that their participation is voluntary (i.e., they may participate or decline to participate, with no adverse consequences of nonparticipation or aborted participation) and that they are free to stop participating at any time.
   - Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature.
   - When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.

7) A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a medical professional. This medical professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medication and/or performing invasive medical procedures on human participants. The IRB must also confirm that the student is not violating the medical practice act of the state or country in which he/she is conducting the research.

8) Student researchers may NOT publish or display information in a report that identifies the human participants directly or through identifiers linked to the participants (including photographs) without the written consent of the participant(s) (Public Health Service Act, 42, USC 241 (d)).

9) All published instruments that are not in the public domain must be administered, scored and interpreted by a Qualified Scientist as required by the instrument publisher. Any and all use and distribution of the test must be in accordance with the publisher's requirements, including procurement of legal copies of the instrument.

10) Studies that involve the collection of data via use of the internet (e.g., email, web-based surveys) are allowed, but researchers should be aware that they can pose challenges in a) collecting anonymous data, b) obtaining informed consent and c) ensuring that participants are of the appropriate age to give informed consent. See the Risk Assessment Guide and the Online Survey Consent Procedures.

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 and all of the Intel ISEF rules.

12) The following forms are required:
   a. Checklist for Adult Sponsor (1), Student Checklist (1A), Research Plan, 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

Sources of Information are available as a separate section at the end of this document.

IRB Waiver of Written Informed Consent

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:

a) Research involving normal educational practices
b) 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.
c) Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
d) 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.

Human Participant Risk Assessment

Projects involving no more than minimal risk and those with more than minimal risk are allowed under the following guidelines.

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater (in and of themselves) than those ordinarily encountered in everyday life or during performance of routine physical or psychological examinations or tests.

More than minimal risk exists when the possibility of physical or psychological harm or harm related to breach of confidentiality or invasion of privacy is greater than what is typically encountered in everyday life. Most of these studies require documented informed consent or minor assent with the permission of parent or guardian (as applicable).

1) Examples of Greater than Minimal Physical Risk

a. Exercise other than ordinarily encountered in everyday life
b. Ingestion, tasting, smelling, or application of a substance. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB which determines risk level based upon the nature of the study and local norms.
c. Exposure to any potentially hazardous material.

2) Examples of Greater than Minimal Psychological Risk

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress. Some examples include: answering questions related to personal experiences such as sexual or physical abuse, divorce, depression, anxiety; answering questions that could result in feelings of depression, anxiety, or low self esteem; or viewing violent or distressing video images.

3) Privacy Concerns

The student researcher and IRB must consider whether an activity could potentially result in negative consequences for the participant due to invasion of privacy or breach of confidentiality. Protecting confidentiality requires measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.
Risk level can be reduced by protecting confidentiality or collecting data that is strictly anonymous. This requires the collection of research in such a way that it is impossible to connect research data with the individual who provided the data.

4) Risk Groups

If the research study includes participants from any of the following groups (vulnerable populations), the IRB and student research must consider whether the nature of the study requires special protections or accommodations:

a. Any member of a group that is naturally at-risk (e.g. pregnant women, developmentally disabled persons, economically or educationally disadvantaged persons, individuals with diseases such as cancer, asthma, diabetes, AIDS, dyslexia, cardiac disorders, psychiatric disorders, learning disorders, etc.)
b. Special groups that are protected by federal regulations or guidelines (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act (IDEA).

See the online Risk Assessment Guide and Online Survey Consent Procedures for more information.