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 (HSPP) 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. The Expedited Review process (see page 9) may be used for projects that involve human subjects to test a student designed intervention or prototype.

2. 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.

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 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 their 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., Family Educational Rights and Privacy Act (FERPA) and 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 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. Risk Assessment information on page 11 and the online Risk Assessment Guide (https://student.societyforscience.org/human-participants#riskass) for further explanation of informed consent.
   a. Informed consent requires that the researcher provides complete information to the participant (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study, which then allows the participants and parents or guardians to make an informed decision about whether or not to participate.
   b. 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.
   c. Informed consent may not involve coercion and is an on-going process, not a single event that ends with a signature.
   d. When written parental permission is required and the study includes a survey, the survey must be attached to the consent form.
   e. The student researcher may request that the IRB waive the requirement for written informed consent/parental permission in his/her research plan if the project meets specific requirements. See section on IRB waivers for more information about situations in which written parental permission and/or written informed consent can be waived by the IRB.

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 Online Studies Section of the Risk Assessment Guide.

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 (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.

- Student-designed Invention, Prototype, Computer Application, or Engineering/Design Project: The data received in these types of projects must be in direct reference to the design. Personal data are not collected and the testing does not pose a health or safety hazard.

Or

- Projects in which the student is the subject of his/her own research study and the project does not involve more than minimal risk.

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 (3) be completed.
- Expedited Review can be used if the project includes participants other than the student researcher.
- Full IRB Review is necessary if the activities involved in testing of the invention or prototype are more than minimal risk and/or involve collection of personal information from participants.

Human Participant Risk Assessment

Use this information to help determine the level of risk involved in a study involving human participants.

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**
   a. 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.
   b. 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, 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 (https://student.societyforscience.org/human-participants#riskass) and Online Survey Consent Procedures (https://member.societyforscience.org/document.doc?id=40) for more detailed information on risk assessment.