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
   - Testing of student designed invention or concept by human participants other than student researcher
   - 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.)
   - 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

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 a federally Regulated Research institution (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