The Institutional Review Board (IRB)

An Institutional Review Board (IRB) is a committee that, according to federal regulations (45-CFR-46), must evaluate the potential physical and/or psychological risk of research involving humans. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes review of any surveys or questionnaires to be used in a project.

Federal regulations require local community involvement. Therefore, it is advisable that an IRB be established at the school level to evaluate human research projects. If necessary, the local or Intel ISEF-affiliated SRC can serve as an IRB as long as it has the required membership. An IRB must:

a. consist of a minimum of three members.
b. include an educator
c. include a school administrator (preferably principal or vice principal),
d. include an individual who is knowledgeable about and capable of evaluating the physical and/or psychological risk involved in a given study. This may be a medical doctor, physician's assistant, registered nurse, psychologist, licensed social worker or licensed clinical professional counselor.

Additional Expertise: If an expert is not available in the immediate area, documented contact with an external expert is recommended. A copy of all correspondence with the expert (e.g. emails) must be attached to Form 4 and can be used in lieu of the signature of that expert.

No Adult Sponsor, parent or other relative of the student, the Qualified Scientist, or Designated Supervisor who oversee the project may serve on the IRB reviewing that project. Additional members are recommended to help avoid a potential conflict of interest and to increase the expertise of the committee.

Most projects require review by the full three member IRB.

IRBs exist at federally Regulated Research Institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research participants are incarcerated. The institutional IRB must initially review and approve all proposed research conducted at or sponsored by that institution. The Adult Sponsor and the local IRB are responsible for ensuring that the project is appropriate for a pre-college student and adheres to the Intel ISEF rules.

An IRB is responsible for assessing risk and documenting the determination of risk level on Human Participant Form 4. However, in reviewing projects just prior to a fair, if the SRC serving at that level of competition judges an IRB's decision as inappropriate, thereby placing human participants in jeopardy, they may override the IRB's decision and the project may fail to qualify for competition. It is advised that IRBs consult with the local or affiliated fair SRCs and/or with the Intel ISEF SRC in questionable cases.

IRB Waiver of Written Informed Consent: The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involved 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 an 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 one member of the IRB may be conducted for the following types of projects. This person must have the expertise necessary to make such a decision and/or receive advisement from the appropriate expert.

- Projects that involve testing by anyone other than the student researcher of student-designed invention, program, concept, etc. where the feedback received is a direct reference to the design, where personal data is not collected, and where the testing does not pose a health or safety hazard.
- Projects in which the student is the subject of their research and the research does not involve more than minimal risk.