## 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. Expedited review by one member is allowable a) for studies involving 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 hazard or b) for studies in which the student is the subject of their research and the research does not involve more than minimal risk.

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.