Roles and Responsibilities of Students & Adults

1) The Student Researcher(s)

The student researcher is responsible for all aspects of the research project including enlisting the aid of any needed supervisory adults (Adult Sponsor, Qualified Scientist, etc.), obtaining necessary approvals (SRC, IRB, etc.), following the Rules & Guidelines of the ISEF, and doing the experimentation, engineering, data analysis, etc. involved in the project.

Scientific fraud and misconduct are not condoned at any level of research or competition. Such practices include plagiarism, forgery, use or presentation of other researcher's work as one's own and fabrication of data. Fraudulent projects will fail to qualify for competition in affiliated fairs or the Intel ISEF.

2) The Adult Sponsor

An Adult Sponsor may be a teacher, parent, university professor, or scientist in whose lab the student is working. This individual must have a solid background in science and should have close contact with the student during the course of the project.

The Adult Sponsor is responsible for working with the student to evaluate any possible risks involved in order to ensure the health and safety of the student conducting the research and the humans or animals involved in the study. The Adult Sponsor must review the student's **Student Checklist (1A)** and **Research Plan** to make sure that: a) experimentation is done within local, state, and federal laws and these International Rules; b) that forms are completed by other adults involved in approving or supervising any part of the experiment; and c) that criteria for the Qualified Scientist adhere to those set forth below.

The Adult Sponsor must be familiar with the regulations that govern potentially dangerous research as they apply to a specific student project. These may include chemical and equipment usage, experimental techniques, research involving human or vertebrate animals, and cell cultures, microorganisms, or animal tissues. The issues must be discussed with the student when completing the **Research Plan**. Some experiments involve procedures or materials that are regulated by state and federal laws. If not thoroughly familiar with the regulations, the Adult Sponsor should help the student enlist the aid of a Qualified Scientist.

The Adult Sponsor is responsible for ensuring the student's research is eligible for entry in the Intel ISEF.

3) The Qualified Scientist

A Qualified Scientist should possess an earned doctoral/ professional degree in the biological or medical sciences as it relates to the student's area of research. However, a master's degree with equivalent experience and/or expertise in the student's area of research is acceptable when approved by a Scientific Review Committee (SRC). The Qualified Scientist must be thoroughly familiar with the local, state, and federal regulations that govern the student's area of research. The Qualified Scientist and the Adult Sponsor may be the same person, if that person is qualified as outlined above. A student may work with a Qualified Scientist in another city or state. In this case, the student must work locally with a Designated Supervisor (see below) who has been trained in the techniques the student will use.

4) The Designated Supervisor

The Designated Supervisor is an adult who is directly responsible for overseeing student experimentation. The Designated Supervisor need not have an advanced degree, but should be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Adult Sponsor may act as the Designated Supervisor.

If a student is experimenting with live vertebrates and the animals are in a situation where their behavior or habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals.

5) 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 human subjects. 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 an IRB should be established at the school level to evaluate human research projects. An IRB at the school or ISEF Affiliated Fair level must consist of a <u>minimum</u> of three members.

An IRB must include:

- a) an educator
- b) a school administrator (preferably, a principal or vice principal),
- and one of the following who is knowledgeable and capable of evaluating the physical and/or psychological risk involved in a given study: a medical doctor, physician's assistant, registered nurse, a psychiatrist, psychologist, licensed social worker or licensed clinical professional counselor.

Additional Expertise: If the IRB needs an expert as one of its members and one is not in the immediate area, then documented contact with an external expert is appropriate and encouraged. A copy of the correspondence (e.g. email, fax, etc.) should be attached to Form 4 and can be used as the signature of that expert.

In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor who oversee a specific project must not serve on the IRB reviewing that project. Additional members are recommended to help avoid this conflict of interest and to increase the expertise of the committee. IRBs exist at federally regulated institutions (e.g., universities, medical centers, NIH, correctional facilities). Prisoner advocates must be included on the IRB when research subjects are at a correctional facility. 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 ISEF rules.

An IRB generally makes the final determination of risk. However, in reviewing projects just prior to a fair, if an SRC judges an IRB's decision as inappropriate, thereby placing human subjects in jeopardy, the SRC may override the IRB's decision and the project may fail to qualify for competition.

6) The Affiliated Fair Scientific Review Committee

A Scientific Review Committee (SRC) is a group of qualified individuals that is responsible for evaluation of student research, certifications, research plans and exhibits for compliance with the Rules and pertinent laws and regulations. Local SRCs may be formed to assist the ISEF Affiliated Fair SRC in reviewing and approving projects. The operation and composition of the local and ISEF-Affiliated Fair SRCs must fully comply with the International Rules.

Any proposed research in the following areas must be reviewed and approved BEFORE experimentation: projects involving vertebrates and potentially hazardous biological agents. (Human studies reviewed and approved by a properly constituted IRB do not have to be reviewed by the SRC until the Fair competition.)

ALL projects must be reviewed and approved by the SRC after experimentation and shortly before competition in an ISEFaffiliated Fair competition. (Projects requiring preapproval which were conducted at a regulated research institution (not home or high school, etc.) and which were reviewed and approved by the proper institutional board before experimentation must also be reviewed by the Fair SRC for rules compliance.)

An SRC must consist of a minimum of three persons. The SRC must include:

- a) a biomedical scientist (Ph.D., M.D., D.V.M., D.D.S., or D.O.)b) an educator
- c) at least one other member

Additional Expertise: Many projects will require additional expertise to properly evaluate (for instance, extended knowledge of biosafety or of human risk groups.) If animal research is involved, at least one member must be familiar with proper animal care procedures. If the SRC needs an expert as one of its members and one is not in the immediate area, then documented contact with an external expert is appropriate and encouraged.

In order to eliminate conflict of interest, the Adult Sponsor, parents, the Qualified Scientist, and the Designated Supervisor must not serve on the SRC reviewing that project. Additional members are recommended to help avoid this conflict of interest and to increase the expertise of the committee. A Scientific Review Committee (SRC) examines projects for the following:

- a) evidence of literature search
- b) evidence of proper supervision
- c) use of accepted and appropriate research techniques
- d) completed forms, signatures and dates showing maximum of one year duration of research and appropriate preapproval dates (when needed)
- e) evidence of search for alternatives to animal use
- f) humane treatment of animals
- g) compliance with rules and laws governing human, animal research and those involving potentially hazardous biological agents
- i) documentation of substantial expansion for continuation projects
- j) compliance with the ISEF ethics statement

7) Other Review Committees

Certain areas of research conducted in a regulated research institution require review and approval by federally mandated committees that have been established at that institution. These committees include:

- a) Institutional Animal Care and Use Committee (IACUC)
- b) Institutional Review Board (IRB)
- c) Institutional Biosafety Committee (IBC)
- d) Embryonic Stem Cell Research Oversight Committee (ESCRO)

8) The ISEF Scientific Review Committee (ISEF SRC)

A Scientific Review Committee exists at the Intel ISEF level. The ISEF SRC reviews the forms and the research plan for all projects to ensure that students have followed all applicable Rules.

The ISEF SRC, like an ISEF Affiliated Fair SRC, is made up of a group of adults knowledgeable about research regulations. The ISEF SRC reviews the **Checklist for Adult Sponsor (1)**, **Abstract, Student Checklist (1A)**, **Research Plan** and **Approval Form (1B)** in addition to all other required forms for students who enter the Intel ISEF. They also identify problems local fairs may be having and work with fair directors and teachers to resolve them.

A fair director or ISEF Affiliated Fair SRC member with any questions regarding the process, should contact the Society for Science & the Public or a member of the ISEF SRC. (See page 3.)

The ISEF SRC is the final authority on projects that are qualified to compete in the Intel ISEF. In some cases, the ISEF SRC may have questions about particular projects. Usually, after students explain their procedures and research to the ISEF SRC, a simple corrective measure is prescribed (*e.g.*, contacting the Designated Supervisor to confirm a detail, or rewriting an abstract for purposes of clarification).

It is important that students retain all original signed forms. Do not send original forms to the Society for Science & the Public.