❖ Human Subjects ❖

The following rules were developed to help pre-college student researchers follow federal guidelines (Code of Federal Regulations 45 CFR 46) designed to protect the human research subjects and the student researcher. When students conduct research with human subjects, the rights and welfare of the participants must be protected. Most human subject studies require preapproval from an Institutional Review Board (IRB) and informed consent/assent from the research subject.

Exempt Studies

(Do Not Require IRB Preapproval or Human Subjects Paperwork)

Some studies involving humans are exempt from IRB pre-approval or additional human subjects forms. Examples of exempt projects for ISEF and affiliated fairs include the following:

- Testing of a student designed invention, program, concept, etc. where the feedback received is a direct reference to the product, where personal data is not collected and where the testing does not pose a health hazard. It is recommended that Risk Assessment Form (3) be completed.
- Data/record review studies (e.g., baseball statistics, crime statistics) in which the data are taken from preexisting data sets that are publicly available or published and do not involve any interaction with human subjects or the collection of any data from a human subject for the purpose of the student's research project.
- 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.
- Projects in which the student receives the data in a **de-identified/anonymous** format which complies with both conditions below:
  a) the professional providing the data must certify in writing that the data have been appropriately de-identified and are in compliance with all privacy and HIPAA laws and
  b) during the final SRC review and approval process, the SRC must ensure that the data were appropriately de-identified by review of the written documentation provided by the supervising professional.

Rules

1) The use of human subjects 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 subject** 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 subjects 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
   - Behavioral observations
     a) that involve any interaction with the observed individual(s) or where the researcher has modified the environment (e.g., post a sign, place an object).
     b) that occur in non-public or restricted access settings (e.g., day care setting, doctor's office)
     c) that involve the recording of personally identifiable information
   - 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.)
2) Student researchers must complete ALL elements of the Human Subjects portion of the Research Plan Instructions on p. 31, #1 and evaluate and minimize the physical, psychological and privacy risks to their human subjects. See risk assessment below and the online Risk Assessment Guide for additional guidance.
3) The research study should be in compliance with all privacy and HIPAA laws when they apply to the project (e.g. the project involves medical information.)
4) All research projects involving human subjects, 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 subjects. After initial IRB approval, a student with any proposed changes in the **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.
5) The research subjects must voluntarily give informed consent/assent (in some cases with parental permission) before participating in the study. Adult research subjects give their consent. Research subjects under 18 years of age or individuals not able to give consent (e.g. mentally disabled) give their assent, with their parents/guardians

giving parental 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 online Risk Assessment Guide for further explanation of informed consent.

- As part of the process of obtaining informed consent, the researcher will provide information to the subject (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study which then allows the subject, parents or guardians to make an educated decision about whether or not to participate.
- Participants will also be informed that their participation is voluntary (i.e., they may decide whether or not to participate) 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 on a page.

6) Research conducted by a pre-college student at federally regulated research institutions (e.g., universities, medical centers, NIH, correctional institutions, etc.) 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) or an official letter from the IRB attesting to this approval is required. A letter from the mentor is not sufficient documentation of IRB review and approval.

7) A student may observe and collect data for analysis of medical procedures and medication administration only under the direct supervision of a qualified professional. The qualified professional must be named in the research protocol approved by the IRB. Students are prohibited from administering medications and performing invasive medical procedures on human subjects. The IRB must confirm that the student is not violating the medical practice act of the particular state or nation in which he/she is conducting the research.

8) Student researchers may NOT publish or display information in a report that identifies the human subjects directly or through identifiers linked to the subjects, (including photographs), without written consent. (Public Health Service Act, 42, USC 241 (d)).

9) All standardized tests 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 will 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 Risk Assessment Guide for more detailed procedures.

11) After experimentation and shortly before fair competition, the SRC reviews and approves previously approved projects to make sure that students followed the approved **Research Plan** and the rules.

12) The following forms are required:
    - **a. Checklist for Adult Sponsor (1)**
    - **b. Student Checklist (1A)**
    - **c. Research Plan**
    - **d. Approval Form (1B)**
    - **e. Human Subjects Form (4)**
    - **f. Regulated Research Institution Form (1C)** - when applicable
    - **g. Qualified Scientist Form (2)** - when applicable

IRB Waiver of Written Informed Consent

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**:

a) Research involving normal educational practices

b) Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the subjects' behavior and the study does not involve more than minimal risk.

c) Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.

d) 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.

Risk Assessment

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 DAILY 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. These studies should require documented informed consent/minor assent/parental permission (as applicable).

1) Physical Risks

a. **Exercise** other than ordinarily encountered in DAILY LIFE would be considered more than minimal risk
b. **Ingestion, tasting, smelling, or application of a substance** would typically be considered more than minimal risk. However, ingestion or tasting projects that involve commonly available food or drink will be evaluated by the IRB who will determine risk level based upon the nature of the study and local norms.
c. **Exposure to any potentially hazardous material** would be considered more than minimal risk.

2) Psychological Risks

A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress would be considered more than minimal risk. For example, answering questions related to personal experiences such as sexual, physical or child 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) Invasion of Privacy

The student researcher and IRB must consider whether any activity could potentially result in negative consequences for the subject due to invasion of privacy or breach of confidentiality. Protecting confidentiality involves taking measures to ensure that identifiable research data are not disclosed to the public or unauthorized individuals.

Risk level can be reduced by protecting confidentiality or collecting data that is truly anonymous. Anonymity involves collecting 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 subjects 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, mentally 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 covered by federal regulations. (e.g. children/minors, prisoners, pregnant women, students receiving services under the Individuals with Disabilities Education Act).

See the online Risk Assessment Guide for a more detailed discussion of Risk Assessment.
www.societyforscience.org/isef/primer/rules.asp

Sources of Information

1) *Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*
http://ohsr.od.nih.gov/guidelines/45cfr46.html

2) Dunn, C. M. and Chadwick, G. L., *Protecting Study Volunteers in Research: A Manual for Investigative Sites (*2002). Boston, MA: Thomson Centerwatch. ISBN 1-930624-36-0.

Can be purchased from:
http://www.amazon.com

NIH tutorial also provides similar information:
http://www.cancer.gov/clinicaltrials/learning/page2

3) Penslar, R.L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

4) *Belmont Report*, April 18, 1979
http://ohsr.od.nih.gov/guidelines/belmont.html

5) *Standards for Educational and Psychological Testing.* (1999). Washington, DC: AERA, APA, NCME.
To order call: (800) 628-4094. If outside US, call (717) 632-3535, Ext. 8087
http://www.apa.org/science/standards.html

6) American Psychological Association
750 First Street, NE
Washington, DC 20002-4242
phone: 202-336-5500; 1-800-374-2721
http://www.apa.org

Information for students:
http://www.apa.org/science/infostu.html

Information regarding publications:
http://www.apa.org/publications/

7) Educational and Psychological Testing
Testing Office for the APA Science Directorate
phone: 202-336-6000
email: testing@apa.org
http://www.apa.org/science/testing.html

Many of the documents above are also available by contacting:

Office for Human Research Protections
Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
phone: 240-453-6900; toll free in U.S. 866-447-4777
email: ohrp@osophs.dhhs.gov