❖ Human Subjects ❖

When students conduct research with human subjects, the rights and welfare of those participating in the study must be protected. There are federal regulations protecting human subjects that require the prior review of human subjects research by an Institutional Review Board and, in most cases, the informed consent of research subjects. The following rules were developed to help student researchers adhere to the Federal regulations and to, therefore, protect the rights and welfare of both the research subjects and the student researcher.

Rules

1) All research projects involving human subjects, including any revisions, must be reviewed and approved by an **Institutional Review Board (IRB)** before the research begins.

2) 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 a investigator conducting research obtains (1) data or samples through intervention or interaction with individual(s), or (2) identifiable private information.
   A) Examples of studies that are considered "human subjects research" and require IRB approval 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
     - o 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).
     - o that occur in a non public or restricted access settings (e.g., day care setting, doctor's office)
     - o that involve the recording of personally identifiable information
   - Data/record review projects that include identifiable data (see #3)

   B) Examples of projects that are **NOT** considered human subjects research and do not require IRB pre-approval include:
   - Product testing of a student invention that does not pose a health hazard, personal data is not collected and feedback received is a direct reference to the product. 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 pre-existing data sets that are publicly available or published (see #3-c)
   - Behavioral observations of unrestricted, public settings (e.g., shopping mall, public park) in which **all** of the following apply:
     - o The researcher has no interaction with the individuals being observed,
     - o The researcher does not manipulate the environment in any way **and**
     - o The researcher does not record any personally identifiable data.

3) Projects involving pre-existing data sets or data obtained through record review fall into one of three categories (a, b, and c below) and must adhere to the regulations detailed below. Pre-existing data set/review projects are projects that 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. These projects may involve the student analyzing data given to the student researcher in paper or electronic form.
   a) Projects in which the data are **not de-identified/ anonymous** (e.g., data set that includes patient name, birth date, phone number or other identifying variables; student gathers data from patient files that include identifiers) are considered human subjects projects. These projects require prior IRB review and pre-approval and may require informed consent. Student researchers and adult mentors (Designated Supervisor or Qualified Scientist) should be familiar with and in compliance with all privacy and HIPAA laws.
   b) Projects in which the student receives the data in a **de-identified/anonymous** format will not require IRB pre-approval, but must comply with BOTH conditions below:
      i) 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.
      ii) 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.
   c) Projects in which the records/data are **publicly available** (print, electronic or internet) do not require IRB review or approval. Examples of such projects include examination of sports teams or individual athlete statistics or crime statistics.

4) When developing the Research Plan, student researchers must evaluate and minimize the physical and/or psychological risks to their human subjects.

5) The documentation of written **Informed Consent** is required for most projects. **Children/Minors participating in most research will require special consent procedures including assent of the child/minor and consent of the parent/guardian.** Children/Minors are persons who have not attained the legal age for consent; in most jurisdictions the legal age is 18 and in some jurisdictions this may include all students still in secondary school.

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 to be specifically 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 collect data via use of the internet (e.g., email, web based surveys) require special consideration from the IRB which should have at least one member with professional expertise in conducting human subjects research. The use of the internet and email for data collection 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. The research plan and Form 4 must explicitly address how these challenges were evaluated and addressed.

    It is permissible to develop a process of obtaining informed consent that is conducive to internet research. Researchers will want to provide information to potential participants about the purpose of the study and nature of their participation, potential risks, the voluntary nature of the study and the participant's right to withdrawal from the study at any time. A sample informed consent statement for adult participants is available on the web at www.societyforscience.org/isef/document/index.asp.

    Recruiting and utilizing participants who are under the age of 18 for a research study conducted on the internet is permissible under the two following conditions.
    a. If the IRB has determined that informed consent is required, the parent/legal guardian must give consent through a traditional Form 4 and informed consent procedures. In this situation, parents/guardians review and sign a Form 4 before the minor participant completes the online or email survey.
    b. If the IRB determines that informed (parental) consent is not necessary for a study that poses very minimal risk, the student researcher can use an assent procedure similar to the sample consent form available on the web. The researcher should provide information to potential participants describing the nature of the study and what the participant will be asked to do, informing the participant of his/her right to withdrawal at any time and indicating that by typing I AGREE or checking a box on the survey and completing the survey, he/she has agreed to participate in the study.

11) After initial IRB/SRC approval, a student with any proposed changes in the **Student Checklist (1A)** and **Research Plan** of the project must repeat the approval process before laboratory experimentation/data collection resumes.

Risk Assessment

Once a study population is chosen, the student researcher must consider any potential physical and/or psychological risks when developing the research plan. In evaluating risk, students and IRBs must use the following federal definition of minimal risk as a guide: **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.**

Risk Groups: The following risk groups require additional safeguards because they have been judged as vulnerable to coercion or undue influence:

1) 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, cardiac disorders, psychiatric disorders, dyslexia, AIDS, etc.)
2) Special vulnerable groups that are covered by federal regulations (*e.g.* children/minors, prisoners, pregnant women).

Risk Activities: The following are examples of activities that contain **more than minimal risk:**

1) **Physical**
   a. **Exercise** other than ordinarily encountered in DAILY LIFE by that subject.
   b. **Ingestion, tasting, smelling, application of a substance** or exposure to any potentially hazardous materials.
2) **Psychological**
   a. Any activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in **emotional stress**. For example, answering

questions related to personal experiences such as sexual, physical or child abuse, divorce and/or psychological well-being (e.g. depression, anxiety, suicide) must be considered more than minimal risk. Additionally, research activities that involve exposing subjects to stimuli or experimental conditions that could potentially result in emotional stress must also be considered more than minimal risk. Examples include violent or distressing video images, distressing written materials or activities that could potentially result in feelings of depression, anxiety, or low self-esteem in subjects.

b. Any activity that could potentially result in negative consequences for the subject due to **invasion of privacy or breech of confidentiality**. Confidentiality involves taking careful measures to ensure that the research data and/or responses are not disclosed to the public or unauthorized individuals with identifiable information. When research activities involve collection of personal information (e.g. history of abuse, drug use, opinions, fingerprints) or health-related data (genetic material, blood, tissue) the researcher must consider risks related to invasion of privacy and possible breech of confidentiality. Ways to reduce these risks include collecting data anonymously or developing data collection procedures that make it impossible to link any identifying information (e.g. subject's name) with his/her responses or data. Anonymity involves collecting research data in such a way that it is impossible to connect research data (e.g. responses, questionnaires) with the individual who provided the data. That is, personal identifiers (e.g. names, birthdates, social security numbers) are not collected or linked with the data.

Informed Consent

The process of obtaining informed consent provides information to the subject (and where applicable, parents or guardians) about the risks and benefits associated with participation in the research study and allows the subject (and where applicable, parents or guardians) to make an educated decision about whether or not to participate. Informed consent is an on-going process, not a single event that ends with a signature on a page. It must incorporate procedures that do not involve coercion or deception.

Section A. Informed Consent Required

Documentation of informed consent is required for the following as long as the study does not meet any of the criteria for a waiver as described in Section B.:

1) When the IRB determines that a research study involves physical or psychological activities with more than minimal risk.
2) When the IRB determines that the project could *potentially* result in emotional stress to a research subject.
3) When the IRB determines that the research subjects belong to a risk group and the study does not meet any of the criteria below for a waiver.

Section B. Informed Consent May Be Waived

The IRB may waive the requirement for documentation of written informed consent 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 and questionnaires 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. If there is any uncertainty regarding the appropriateness of waiving informed consent, it is strongly recommended that informed consent be obtained.

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 the documentation of informed consent is not required or obtained, all subjects must still give their consent/assent to participate in the study. Research subjects under 18 years of age or other individuals not able to give consent (e.g. mentally disabled) give their assent, whereas adults give their consent. The researcher must inform potential subjects about the purpose of the study and what they will be asked to do. The potential subjects must also be informed that their participation is voluntary and that they may withdraw from the study at any time. This information and the consent/assent can be either verbal or written. The procedure for obtaining consent/assent should be included in the research plan.

If a research subject is under 18 years of age, it is recommended that informed consent be obtained. Both the parent/legal guardian and the school age research subject must sign **Human Subjects Form (4)**. However, an IRB may decide that informed consent is not required because of the allowable exceptions listed above. **When the IRB waives informed consent of research subjects under the age of 18 for studies involving surveys or questionnaires, justification of this waiver must be stated on Human Subjects Form (4).**

Review Process

1) A student interested in doing a human subjects research project must first **review the rules**, choose a study group and consider the risks of their proposed research. The student must work with their Adult Sponsor who can guide them to a Qualified Scientist, if necessary, to help in the development of their research plan.

2) The student must complete the **Student Checklist (1A)**, **Research Plan**, and **Human Subjects Form (4)** and submit this information along with a copy of any questionnaire, survey or instrument used to collect human data to the Institutional Review Board (IRB). Submission of the appropriate forms does not give the student permission to begin the research. The IRB must **sign the Approval Form (1B) and Human Subjects Form (4)**, approving the project, before the research can begin.

3) To complete the IRB review process, the IRB must designate the risk-status of the project and other requirements by checking the appropriate box(es) on **Human Subjects Form (4).** The IRB may require one or more of the following:

a. Documentation of written Informed Consent on the **Human Subjects Form (4).** When the IRB waives informed consent of research subjects under the age of 18 for studies involving surveys or questionnaires, justification of this waiver must be stated on Form 4.

b. **Qualified Scientist Form (2)** – The IRB will require the project to be overseen by a Qualified Scientist when there is more than minimal risk involved. If the Qualified Scientist is unable to directly supervise the project, a trained **Designated Supervisor** will also be required.

c. Changes to the **Research Plan** – If the IRB requires changes or modifications of the Research Plan, the student must incorporate those changes into the written **Research Plan** before the IRB approves the project.

4) After the IRB has approved the project and **all committee members have signed the Human Subjects Form (4),** the student may begin recruiting and/or interacting with human subjects.

5) 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.

6) 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)** - if applicable
   - **g. Qualified Scientist Form (2)** - if applicable

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/page3

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