

For:

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## Human Subjects

When students conduct research with human subjects, they are responsible for protecting the rights and welfare of those participating in the study. There are federal regulations protecting human subjects that require the prior review of human subjects research by an Institutional Review Board and 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) Human subjects research includes projects involving:

- Subjects participating in physical activities (e.g., physical exertion, ingestion of any substance, any medical procedure),
- Psychological and opinion studies (e.g., survey, questionnaire, test of any kind),
- Behavioral observations,
- Studies in which the researcher is the subject of the research.

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

4) 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.

5) Research conducted by a pre-college student at federally registered 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.

6) 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 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.

7) 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)).

8) 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.

9) The use of the internet to obtain data for human subjects research is permissible. The Student Researcher, Adult Sponsor and IRB must take additional care to ensure that survey responses remain confidential and that, when required, informed consent is documented.

10) Any proposed changes to a previously approved research plan must be resubmitted to the IRB for another complete review. The proposed changes must not be implemented until the modified project is approved by the IRB.

## **Risk Evaluation**

Once a study population is chosen, the student researcher must assess 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, 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, mentally disabled persons, or economically or educationally disadvantaged persons)

**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 of any 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 and 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 breach of confidentiality**. 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 breach 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.

## **Informed Consent**

The process of obtaining informed consent provides information to the subject about the risks and benefits associated with participation in the research study and allows the subject 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.

Documentation of informed consent is required:

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.

Informed consent is required for most research projects. However, 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 the observation of legal public behavior
- b. Research involving collection or study of existing publicly available data or records
- c. Research involving normal educational practices
- d. 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.
- e. 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.
- f. 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 (in and of themselves) than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

**If a research subject is under 18 years of age, it is recommended that, in all cases, informed consent be obtained.** Both the parent/legal guardian and the school age research subject must sign Form 4 (Human Subjects and Informed Consent Form). 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, documentation justifying this waiver must accompany 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 assess 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 [Research Plan \(1A\) and Attachment, Human Subjects Approval and Informed Consent 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

- [Consent 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 and Informed Consent 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 Approval and Informed Consent Form \(4\)](#). Before approving the project, the IRB may require one or more of the following:
    - a. Documentation of written Informed Consent on the **Human Subjects Approval and Informed Consent Form (4)** – The IRB will require informed consent for projects that are more than minimal risk.
    - 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** (and the [Designated Supervisor Form \(3\)](#)) 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 signs for approval.
  - 4) After the IRB has approved the project and **all committee members have signed the Approval Form and Human Subjects Form**, 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 (1A) and the rules.**

<b>Required Forms</b>
<p><b>FOR ALL PROJECTS</b></p> <ul style="list-style-type: none"> <li>• <a href="#">Checklist for Adult Sponsor</a></li> <li>• <a href="#">Research Plan (1A)</a></li> <li>• <a href="#">Research Plan Attachment</a></li> <li>• <a href="#">Approval Form (1B)</a></li> <li>• <a href="#">Reg. Research Institutional/Industrial Setting Form (1C)</a> (If Applicable)</li> </ul> <p><b>IN ADDITION FOR PROJECTS INVOLVING HUMAN SUBJECTS:</b></p>

- [Human Subjects Form \(4\)](#)  
Must be submitted to an IRB for review and approval before experimentation is started.

***If the IRB determines that more than minimal risk is present the following additional forms are required:***

- [Qualified Scientist Form \(2\)](#) and/or
- [Designated Supervisor Form \(3\)](#)

**TIP:**

***Review the IRB section of the Roles and Responsibilities of Students and Adults on page 12 to better understand the IRB review process necessary for a project involving human subjects.***

**MUST HAVE APPROVAL and  
RISK ASSESSMENT by the IRB  
BEFORE You BEGIN  
EXPERIMENTATION.**

## Sources of Information

- 1) *Code of Federal Regulation (CFR), Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)*
- 2) Penslar, R. L., *Institutional Review Board (IRB) Guidebook*, (1993). Washington, DC: ORRP-NIH
- 3) *Bellmont Report*, April 18, 1979

Above documents available from:  
Office for Human Research Protections  
Department of Health and Human Services  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852  
phone: 301-496-7005  
email: [ohrp@osophs.dhhs.gov](mailto:ohrp@osophs.dhhs.gov)

website: <http://ohrp.osophs.dhhs.gov/polasur.htm>

Educational materials, IRB tutorials, etc. also available at the website above.

- 4) 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.

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Information for students:

<http://www.apa.org/science/infostu.html>

Information regarding publications:

<http://www.apa.org/science/pubs.html>

**Educational and Psychological Testing**

Testing Office for the APA Science Directorate

phone: 202-336-6000

website: <http://www.apa.org/science/testing.html>

*Standards for educational and psychological testing.* (1999).

Washington, DC: AERA, APA, NCME.

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