

Log Number _____

Date Received _____

Millersville University of Pennsylvania Institutional Review Board
For the Protection of Human Subjects

Human Subjects Review Protocol

1. Principal Investigator

Name: _____ Department: _____

Phone: _____ E-Mail Address: _____

Address: _____

Position: _____

If student: ___masters ___undergraduate; expected date of graduation _____

2. Co-investigator (or thesis committee chair, advisor; use of a second sheet for any additional names):

Name: _____ Department: _____

Position: _____ Office Phone: _____

Address: _____ E-Mail Address: _____

Reviewed by: (if student) ___Department Committee ___Faculty Advisor Date _____

3. Project Title: _____

Dates during which project will be conducted: From: _____ To: _____

4. A. Project Funding Source: Check as many as apply:

_____ Extramural Grant: Agency name: _____

_____ MU Grant

_____ Non-funded

_____ Other (describe):

B. If grant funded, application deadline or date of transmittal _____

Please submit one copy of grant proposal as soon as it is available.

5. Address each of the following separately. PLEASE NUMBER ALL PAGES!!!

A. PURPOSE, RESEARCH VARIABLES, AND POPULATION

Purpose of the study- State concisely and realistically what the study is intended to accomplish.

Background-Briefly state the background of the study, including references when appropriate, and identify the main questions the current study is intended to address.

Characteristics of the Subject Population-The following information should be provided:

- a. Age Range-What is the age range and why was it chosen?
- b. Gender-What is the gender of the subjects? If there is a restriction, provide the rationale.
- c. Number-What is the estimated number of subjects?
- d. Inclusion Criteria-What are the specific inclusion criteria?
- e. Exclusion Criteria-What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.
- f. Vulnerable Subjects-If vulnerable subjects will be included (children, pregnant women, fetuses, prisoners, mentally disabled persons), provide justification of the need to use these subjects in research.

B. METHODS AND PROCEDURES

Method of Subject Selection-Describe the study's method(s) of identification and recruitment of prospective subjects. Provide a copy of any planned advertisements.

Study Site-State the location(s) where the study will be conducted. Include letters of approval to conduct the study from all non-MU sites.

Methods and Procedures Applied to Human Subjects-Describe in detail the study design and all procedures (sequentially) to be applied to subjects. Attach copies of any instruments to be used, such as surveys, rating scales, or questionnaires.

C. INFORMED CONSENT

Potential Risks-Identify the potential risks of the study. Specify the types and levels of risk.

Protection Against Risks-For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

Potential Benefits-Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

Compensation for Participation-Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

Alternatives to Participation-Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

Information Withheld-Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

Debriefing-Describe the procedure for post-study debriefing of subjects.

Confidentiality-Describe explicitly how confidentiality of data will be maintained. If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations.

Copy of Consent Form-An informed consent form addresses five critical points:

1. Subject participation in the study is voluntary (provide a description of the procedure to be used if choosing not to participate)
2. A statement of the subject's right to withdraw at any time and a clear description of the procedures for withdrawal from the study without penalty
3. Subjects are informed of the level of risk (no known risk, minimal, moderate, or high) and the means of protecting the subjects from known risks or minimizing the risk
4. Confidentiality is ensured
5. The means by which confidentiality is to be ensured is explained fully

See the attached form, "Essentials of Informed Consent" for specific inclusion information. A copy of the Informed Consent Form should be given to each subject who participates in the study. Please note: The IRB will not accept "blanket waivers" of the right to privacy. Subjects or their legal agents must sign a consent form for each research study. If children are involved in the research, consent of a parent or guardian is required.

Mailed surveys ordinarily receive expedited reviews and do not need consent forms except when one of the following conditions prevail:

1. The researcher knows the person's name or other identifier.
2. The content of the survey puts the respondent at risk for emotional, physical, or other types of distress.

If an informed consent form is not required, the researcher should use a cover letter to potential subjects which addresses all the elements of informed consent previously described. Please include a copy of this cover letter with your protocol.

6. Protected Populations and Sensitive Subjects: If any Human Subjects from the following list would be involved in the proposed activity, place an X next to the category.

<input type="checkbox"/> Minors	<input type="checkbox"/> Pregnant Women	<input type="checkbox"/> Test subjects for new
<input type="checkbox"/> Fetuses	<input type="checkbox"/> Illegal behavior	drugs or clinical
<input type="checkbox"/> Abortuses	<input type="checkbox"/> Mentally disabled	devices
<input type="checkbox"/> Incarcerated	<input type="checkbox"/> Educationally or economically disadvantaged persons	

7. Nature of Risk. In your judgement, does your research involve more than minimal risk? “Minimal risk” means that the risk of harm anticipated in the proposed research is not more likely than those risks encountered in daily life, or during routine physical or psychological examinations/tests.

Yes No

8. Additions to or changes in procedures involving human subjects as well as any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.

I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any research with human subjects before I have received approval/or complied with all contingencies made in connection with the approval. I understand that as the principal investigator I am ultimately responsible for the welfare and protection of human subjects and will carry out the project as approved.

Signature of Principal Investigator/Program Director

Date

9. Approval by Faculty Sponsor (required for all students):

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by law.

Signature

Date

ESSENTIALS OF INFORMED CONSENT

Title: Show the heading of “informed consent form.” You may want to add the full title of the project.

Involvement: Identify the investigator, faculty sponsor (if relevant), and any funding or sponsoring organizations. Identify MU as the responsible institution or as one of the responsible institutions.

Overview: Invite subjects to participate and tell them the purposes of the study. Give a brief description of the procedures of the procedures to be used and the time required, providing enough detail to enable subjects to make an informed decision. It might be helpful to ask yourself what information you would need to have as a naïve potential subject in order to feel that you could make such an informed decision.

Risks and benefits: Describe any reasonable foreseeable risks or discomforts associated with the study. If there are no known risks, this should be stated. Also, give a description of the likely benefits to subjects or to others.

Compensation: Provide a statement of any compensation available to subjects, along with information on how it can be obtained.

Handling discomfort or injury: If appropriate, tell subjects what treatment will be available and how it can be obtained.

Confidentiality: Specify the procedure for maintaining the confidentiality of records that identify subjects.

For more information: Tell subjects how to obtain more information about the project.

Voluntary participation: Explicitly state that subjects may refuse to participate or may withdraw for any reason without penalty. Describe the procedures for both electing to participate and for declining, along with a statement regarding the disposition of data which may have already been collected from subjects who later elect to withdraw.

Signature: Provide a space for signatures indicating consent, and remember to include a second copy for the subject to keep when obtaining consent.

Miscellaneous: Include the following statement: “This project has been approved by the Millersville University of Pennsylvania Institutional Review Board for the Protection of Human Subjects.”