# Millersville University of Pennsylvania Institutional Review Board for the Protection of Human Subjects

## Human Subjects Review Protocol

## **NOTE:** <u>Download and save this form to your desktop before adding information</u>.

1.	Princ	cipal Investigator:	
	Name:		
			_ Department:
	Offic	ce Phone:	E-Mail Address:
	Addr	ress:	
	Posit	tion:	_
	<b>If stu</b> gradu	udent researcher: Are you a gra	duate or undergraduate student; expected date of
	Revi	iewed by: (if student)Department C	ommitteeFaculty Advisor Date
2.	Co-ii	nvestigator (or thesis committee chair, ac	lvisor; use of a second sheet for any additional names):
	Nam	ne:	_ Department:
	Offic	ce Phone:	E-Mail Address:
	Addr	ress:	
	Posit	tion:	_
3.	Proje	ect Title:	
	Dates	during which project will be conducte	d (MM/DD/YYYY): To:
4.	А.	Project Funding Source: Check as r	nany as apply:
		Extramural Grant: Agency n MU Grant Non-funded Other (describe):	ame:
	В.	If grant funded, application deadlin	e or date of transmittal
		Please submit one copy of grant pro	oposal as soon as it is available.

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

Minors	Pregnant Women	Test subjects for new
Fetuses	Illegal behavior	drugs or clinical
Abortuses	Mentally disabled	devices
Incarcerated	Educationally or economical	lly disadvantaged persons

6. <u>Nature of Risk</u>. In your judgment, 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

7. 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.

By typing my name below, 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.

I have completed CITI Training.

I have NOT COMPLETED CITI Training. As of January 1, 2015, this is a mandatory requirement. If you have not completed training, please go to www.citiprogram.org, login with your Millersville username and password, and complete the on-line program.

Name of Principal Investigator/Program Director

8. Approval by Faculty Sponsor (required for **all** students): By typing my name below, I affirm the completeness and accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by law.

Faculty Sponsor Name

The following pages include directions for completing your IRB protocol. Please include information addressing each of the points below, including informed consent. Once you have completed the protocol, please using the buttons at the bottom of this form submit your document. If you need assistance, please contact Rene Munoz by email or by phone at ext. 4457.

Date

Date

### A. Project Purpose and Background

<u>Purpose of the study</u> – Please state what the study will accomplish. 3,000 character limit.

B. <u>Background</u> - Briefly state the background of the study, including references when appropriate, and identify the main questions the current study is intended to address. 3,000 character limit.

- C. <u>Characteristics of the Subject Population</u> Please provide the following information:
  - a. Vulnerable Subjects If vulnerable subjects will be included (children, pregnant women, prisoners, mentally ill) provide justification of the need to use these subjects in research. Enter N/A if no vulnerable subjects will be included.

b. <u>Exclusion Criteria</u> - 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.

c. <u>Inclusion Criteria</u>-What are the specific inclusion criteria?

d. <u>Number</u> – What is the estimated number of subjects?

e. <u>Gender</u> – What is the gender of the subjects? If there is a restriction, provide the rationale.

f. <u>Age Range</u> – What is the age range and why was it chosen?

#### D. INFORMED CONSENT

Please include a copy of the informed consent you will distribute to study participants with this protocol.

a. <u>Potential Risk</u> – Identify the potential risks of the study. Specify types and levels of risk.

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

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

#### E. <u>METHODS AND PROCEDURES</u>

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

b. Study Site – State the location(s) where the study will be conducted. <u>Include</u> <u>letters of approval to conduct the study from all non-MU sites.</u> c. <u>Methods and Procedures Applied to Human Subjects</u> - Describe in detail the study design and all procedures (sequentially) to be applied to subjects. <u>Attach copies of any instruments to be used, such as surveys, rating scales, or questionnaires.</u>

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

e. <u>Alternatives to Participation</u> - 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.

f. <u>Information Withheld</u> - Identify the nature of any information to be purposely withheld from subjects, and provide justification for the nondisclosure.

g. <u>Debriefing</u> - Describe the procedure for post-study debriefing of subjects.

h. <u>Confidentiality of Data</u> - 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.

## Checklist

**NOTE FOR EDUCATION RESEARCHERS:** Due to the volume of Millersville education students undertaking research in local public schools, principles and school district administrators require the MU IRB provide a full review of all protocols involving public school students. Furthermore, all protocols for school-based research **require** a letter of support from the school principal or relevant administrator. This letter **must** accompany the protocol and must be printed on school letterhead.

Is the Protocol form complete? Please fill in all blanks, marking NA if items are not applicable

Have you included a copy of informed consent and/or assent forms, if required?

Have you included a letter of support from a principal or other administrator if you are conducting research in a public school?

Have you included a letters of support or permission from relevant organizations?

Have you included copies of surveys, ratings scales or ther instruments?

Have you completed CITI training?

Have you saved and renamed your protocol in the proper format?

**ALL** IRB protocols must be submitted as a **SINGLE PDF**. Protocols submitted as multiple PDF documents or as combinations of PDF and Word/Pages documents will be returned without review. If you need help please contact the help desk at ext. 7777

Rename and save your protocol using the following format - SemesterYear **PI** Last Name "IRB Protocol", eg. SP2015 Smith IRB Protocol. Protocols not following this convention will be returned without review.

The MU IRB committee is no longer accepting protocols emailed from student accounts. ALL submitted protocols must be submitted by the student's faculty coinvestigator or advisor. This is being done to ensure that the faculty responsible for overseeing the research have had an opportunity to review the protocol prior to submission. PROTOCOLS SUBMITTED FROM STUDENT EMAIL ACCOUNTS WILL BE RETURNED WITHOUT REVIEW.

Email complete protocols to **sponsored.programs@millersville.edu**. Please type the name of your protocol, e.g. SP2015 Smith IRB Protocol, in the subject line of the email message.

### **Informed Consent Form**

**Description of Experiment:** You will be participating in a Psychology experiment that requires you to take a math test formatted similar to a placement test, as well as two visual acuity tests. Participation in this research is voluntary.

**Risks and Benefits:** There are no foreseen risks in the current research greater than that of a classroom setting. This is considered a minimal risk study. However, participants in this study will be eligible to receive extra credit from their professors that are willing to comply. Neither the researcher nor the university is responsible for any accidents that occur during the time of the study.

By signing this consent form, you are signifying that you understand the nature of the research and your agreement to participate in the study. Please consider the following points before signing:

- I understand that I am participating in Psychological research.
- I understand that my personal information and data will be kept confidential between the researchers.
- I will receive a debriefing letter providing an explanation of the research in which I participated, with the name and telephone number of a researcher to contact if I have any questions about the study.
- I understand that my participation in the research voluntary, and that I may decide to terminate my participation any time after the study begins without penalty.

For more information, you may contact:



Shawn P. Gallagher Shawn.Gallagher@millersville.edu (717) 871-7271 PO Box 1002 (South George Street) Millersville, PA 17551

By signing this form I am stating that I understand the above information and consent to participate in this study conducted at Millersville University.

Patient Name (Printed)	Signature	Date
Researcher Name (Printed)	Signature	Date

This research has been approved by the Millersville University Institutional Review Board.

## Survey Forms to be used – Comparison to non-STEM Majors

Imagine you are at the library studying with four friends, all in different majors. Their majors include English, History, Music, and Psychology. You are taking an algebra class, and would like help on a few homework problems. You do not know anything about your friends' mathematical abilities.

1. What is the likelihood that you would ask your English major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

2. What is the likelihood that you would ask your History major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

3. What is the likelihood that you would ask your Music major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

4. What is the likelihood that you would ask your Psychology major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

### Survey Forms to be used – Comparison to STEM Majors

Imagine you are at the library studying with four friends, all in different majors. Their majors include Biology, Chemistry, Physics, and Psychology. You are taking an algebra class, and would like help on a few homework problems. You do not know anything about your friends' mathematical abilities.

1. What is the likelihood that you would ask your Biology major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely	
1	2	3	4	5	

2 3 4 5
What is the likelihood that you would ask your Chemistry major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

3. What is the likelihood that you would ask your Physics major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5

4. What is the likelihood that you would ask your Psychology major friend for help with your algebra?

Not at all likely	Unlikely	Possibly	Likely	Very Likely
1	2	3	4	5