

MU IRB

What Researchers Need to Know

The Millersville Institutional Review Board (IRB) Protocol submission process is electronic. MU IRB provides this information to help researchers format their Research Proposal to prepare their information for the electronic submission. The expectation for protocol review is that the background, methodology, and analysis processes are fully developed by the researcher before submission of the protocol to IRB for review.

For more information on Human Subject research please visit the Millersville IRB website at www.millersville.edu/spra/irb/index.php.

Students: this document is designed to ensure you write about your research and research design in meaningful ways, informed by existing research to protect human subjects. Paying careful attention to wording, and necessary information in each section will help you work through IRB approval more quickly and efficiently. Additionally, paying careful attention to language will help you with future essays/reports you create for this project.

You should create the IRB together with your Faculty Mentor/Advisor – this document is designed to facilitate that collaboration.

This document includes the sections available in the online Protocol form in bold. MU IRB provides further information about each heading to support researchers in completing the protocol.

Principal Investigator Information

I am a*:

This menu allows researchers to select affiliation (Undergraduate Student, Graduate Student, Faculty Member, Administrator)

Principal Investigator Name

Include your full first and last name

Email (where are most likely to contact you)

Include your email address. After submission, this is the method that IRB will contact you

Phone

Include the phone number that you answer regularly – if there are questions an IRB representative may call you

Based on the response to “I am a” researchers will need to complete the fields that appear:

***Undergraduate Students**

Major

Select your major from the drop-down menu provided

Year

Select your year (Freshman, Sophomore, Junior, Senior) from the drop-down menu provided

Graduate Students*Field of Study**

Select your field of study from the drop-down menu provided

Faculty Member*Department**

Select your field of study from the drop-down menu provided

Do you have a co-Investigator?

Student researchers should select “Yes” and include their Faculty Mentor/Co-investigator in the Faculty mentor fields

Researchers with Co-investigators should also report “yes”

Has the research been approved by an institution other than Millersville?

Select “Yes” if the research has been approved. If researcher selects “Yes” the approval of the non-MU IRB needs to be included in the IRB protocol submission. This may include IRB approval from another Institution/University/College, a Hospital IRB, or other IRB approval as appropriate for the research discussed.

If the research has not been approved, select “No”

Faculty Mentor/Co-investigator Information

This field is required for graduate and undergraduate students. If this section is not complete, your protocol will be returned without review.

Faculty Mentor/Co-Investigator

Include the full first and last name of the Faculty Mentor/Co-investigator

This is required for all graduate and undergraduate student researchers

Email

Include the email address of the Faculty Mentor/Co-investigator

Phone

Include the phone number of the Faculty Mentor/Co-investigator

Faculty Department (please pick the closest match)

Select the appropriate department for the Faculty member/Co-Investigator working on the research

Institution

Provide the Institution of the Faculty Mentor/Co-Investigator

Project Information

Project Title

Descriptive title of the project the protocol submission will discuss. This title should succinctly and clearly communicate meaningful information about your research goals. The title should be approximately 1 sentence long.

Project Starts Date

Select the start date from the calendar provided. The research should begin after MU IRB approval. Please note, MU IRB protocol requires approximately 30 days for approval.

Project End Date

Select the end date from the calendar provided.

Project Funding

Select from the available options:

- None
- MU Grant (e.g. faculty grant, Noonan Award)
- External Grant
- Other

Will your study use data drawn (this is a dynamic list – you won't see ALL these options at once, this list is provided as a resource):

This question determines the type of IRB approval necessary for the research methods discussed within this protocol.

- Only from human subjects, e.g. from interview or surveys you conduct
- Only from publicly available sources such as the U.S. census
 - This requires an additional selection from
 - Will the data be de-identified?
 - YES – all of the data be deidentified when I receive it
 - NO – none of the data be deidentified when you receive it
 - Only some of the data will be deidentified when I receive it
- Only from Privately-owned sources, e.g. hospital records
 - This requires an additional selection from
 - Will the data be de-identified?
 - YES – all of the data be deidentified when I receive it
 - NO – none of the data be deidentified when you receive it
 - Only some of the data will be deidentified when I receive it
- From both public and private sources
 - This requires an additional selection from
 - Will the data be de-identified?
 - YES – all of the data be deidentified when I receive it

- NO – none of the data be deidentified when you receive it
 - Only some of the data will be deidentified when I receive it
- From public/private sources and human subjects, e.g. from census data and from interviews or surveys you conduct
 - This requires an additional selection from
 - Will the data be de-identified?
 - YES – all of the data be deidentified when I receive it
 - NO – none of the data be deidentified when you receive it
 - Only some of the data will be deidentified when I receive it

Nature of Risk

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.

Select “Yes” or “No” from the list as appropriate. Again, this helps determine the type of IRB approval necessary for the research submitted in this protocol.

If your research methods are not a routine activity in daily life, for the subjects, then indicate yes and explain why.

Protected Populations and Sensitive Subjects

Will your research have as its primary focus any protected populations or deal with illegal, potentially illegal or otherwise sensitive subjects?

Select “Yes” or “No” from the list as appropriate. Again, this helps determine the type of IRB approval necessary for the research submitted in this protocol.

If “Yes” selected:

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.

- Minors
- Fetuses
- Abortuses
- Incarcerated
- Pregnant women
- Developmentally Disables
- Test subjects for new drugs or clinical devices
- Educationally and/or Economically disadvantaged persons
- Illegal behavior (e.g. drug use, underage drinking)

This question provides more information on the humans you’re working with in the study included in the research submitted in this protocol.

Project Purpose and Background

Background

Briefly state the background of the study, including references when appropriate. Identify the main questions this study is intended to address and methods to be used. 5,000 character limit.

In addition to the in-text citations included in this Background, include the full reference information at the end of the section.

This section should identify the *previous or ongoing conversation(s) in your field of study* that influences your research question, and provides the background studies, theories, discussion that support the need for your research. These background ideas should be properly cited based on your field (APA, etc.) to demonstrate your familiarity with the existing research forming the basis of your research. Show the IRB readers what influenced the development of your research and your research question. This background information will also provide evidence for the hypothesis you're forming for your research questions.

This section resembles the literature review genre of articles published in academic fields. Use a current journal article as an example for how to briefly overview the existing research to demonstrate what discussions are influencing your ideas.

Purpose of the Study

Please state what the study will accomplish. This should read as an abstract describing the general reason and method of the study. (limit 1200 characters)

This section identifies your *research question and hypothesis*, and discusses what your research study *adds to the ongoing conversation*. You identified the conversation that influenced your research question in the Background section, use this section to describe what your study adds to the field.

What is the estimated no. of participants?

Provide the estimated number of participants you expect to recruit and include in this study. The exact number of participants may vary slightly.

Example: I am expecting roughly 20 students per course section, resulting in a total sample size $n=60$.

List participant inclusion criteria

Provide very specific inclusion criteria for the participants of this study. Who will be included and why?

Example: Any participant over the age of 18 who is enrolled in or auditing the three sections of ENGL 110 included in this study will have the opportunity to become a participant.

List any participant exclusion criteria

Provide very specific exclusion criteria for the participants of this study. Who will be excluded and why?

Example: I will be excluding participants under the age of 18. There is a possibility that a high school student may be enrolled in the course chosen for participant selection, but they will be excluded for the reason that this study will not be using minors as subjects.

Will sex or gender be used as an exclusion criteria?

Select from the button menu. Clear rationale for exclusion required if you answer “Yes”

What is the subject's age range and why was it chosen?

This should include the age range and WHY it was chosen. This should include the broadest possible age range based on the population included in the study design.

Example: Participants must be over the age of 18 as this study will not be using minors as participants.

Please list any potential risks. Specify types and levels of risk.

This should provide detailed information on any possible risks to the participants of the study. The five major types of risk are: physical risk, psychological risk, social risk, legal risk, and economic risk (see the website for details: <https://www.millersville.edu/spra/irb/institutional-review-board-guidelines.php>).

Example: This study poses no risk to subjects that would not occur in daily life. This study poses minimal risk.

Example2: This study could expose participants to political ideas in contradiction to their own.

Protection Against Risks - specify the procedures for preventing or minimizing any potential risks.

If more than minimal risk may occur, *how will you protect the subjects?* What are the procedures for supplying participants necessary information to help them work through the risk?

This is an example connected to Example2 above:

Example2: Students will be repeatedly reminded they can speak with the instructor inside or outside the classroom if they become uncomfortable with the political content. The project includes skills building to support students working through uncomfortable political content, in addition to listening to the student and their background, the learning connections will be reemphasized.

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

All research has potential benefits to a population. Be sure to work through what the potential benefits are from your study.

Example: The benefit to society is to further scientific knowledge. This research can potentially provide more information on ways that academic performance is affected by perceptions of writing, particularly as they are communicated by educators.

Please attach a copy of your informed consent.

The Informed Consent Template: General (<https://www.millersville.edu/spra/files/informed-consent-template.pdf>). The IRB provides Informed Consent samples that include all the required parts. Use the provided Informed Consent as a guide.

Be sure to include who to contact with questions (researchers AND IRB's Rene Munoz, Director of the IRB, and contact information).

For more information on the required elements see <https://www.millersville.edu/spra/files/elements-of-informed-consent.pdf>.

Please attach a copy of your parental assent, if necessary.

Again, use the template to help guide you with creating this form, if the form is necessary. There are Federal mandated elements that the template includes, follow the template closely.

Methods and Procedures

Describe the method(s) for identifying and recruiting prospective subjects.

Provide a complete picture of the method(s) used to identify and recruit prospective subjects.

Example: The current study will be focusing specifically on the college population. To do so, the researcher will work with Millersville University professors and use the students in one of their courses (the same course across all professors) as participants. The course being taught must be a general education course for the purpose of obtaining a variety of students across departments, and it should be taught in a large lecture hall for the purpose of obtaining a large sample size. Also, the course must have at least 3 sections to accommodate having three groups in the study.

Will you publicly advertise to recruit participants?

Include copies of any advertisements you will use to identify and recruit prospective subjects.

State the location(s) where the study will be conducted.

For most researchers, this will be Millersville University. For K-12 teachers, note classroom research requires additional approval from your Principal.

Will your research take place outside of Millersville?

This can be answered simply with “yes” or “no”. A yes indicates the study will occur at Millersville, a no indicates the study will occur outside Millersville University.

Describe in detail the study design and all procedures (sequentially) to be applied to subjects.

Provide a complete outline of the method(s) used in this study. This should be step-by-step, should include references where and when appropriate. The IRB committee should be able to replicate the procedure after reading your detailed description of the study design and procedures here.

Will you use any instruments such as surveys, rating scales, or questionnaires?

Upload copies of all instruments such as surveys, rating scales, or questionnaires that will be used as part of the study.

It is very important that the complete instruments are uploaded at the time of IRB submission so the IRB committee can see what participants will be asked to complete. The IRB carefully considers the questions and approaches to working with human participants to ensure participants remain protected.

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.

While participation can be incentivized, non-participation cannot be penalized. You need to clearly state how you are recruiting participants, what incentives you’re offering, and what alternatives exist for individuals who choose not to participate.

Example: Students who choose not to participate will be asked to leave the lecture hall at the end of their class period, prior to the start of the study.

Will the participants receive monetary or other forms of compensation for their participation?

In some cases, researchers incentivize study participation. If your research study will do that, clearly indicate how the research will be incentivized. Note: participants who withdraw cannot be penalized by having their chance at the incentive revoked.

Example: Participants will be entered into a random drawing to win one of two \$50 gift cards. Those who choose to terminate their participation prior to the conclusion of the study will still have their name entered into the drawing.

Will any information be withheld from the participants?

The answer to this question is often no. However, depending on the research methodology, a researcher may need to withhold some information. Revisit the CITI Training to fully understand what can and cannot be withheld from participants during research studies and why. If anything is

withheld, the IRB needs significant discussion on why information is being withheld. Note in the example below that participants **MUST** be debriefed on the true nature of studies by the end.

Example: The true purpose of the study will be initially withheld from participants. Social psychologists have found that in persuasion research, demand characteristics can cause participants to alter their behavior to fit what they believe the purpose of the study to be (Schul & Knapp, 1984). For example, if participants believe the purpose of the study to be about mental illness stigma, they may assume the researcher “wants” them to have reduced stigma, and will respond to the measures how they believe reflects the researchers supposed wishes, rather than how they actually feel. In order to address these issues, this study will use deception to hide the true purpose of the study. Participants will be told that the purpose of this study is to explore students’ reactions to various videos. At the conclusion of the study, all participants will be debriefed on the true nature of the study and why the information was initially withheld.

Describe the procedure for post-study debriefing of subjects

Researchers should discuss their research with participants. This debriefing will help participants when sensitive information is discussed. Debriefing plans and forms must be included at the time of IRB submission to demonstrate the careful care the researcher will take toward the participants in the study.

Example: At the conclusion of Day 2, the researcher will verbally explain the true nature of the study, and why the deception was necessary. The researcher will encourage anyone with questions, comments, or concerns to talk to directly or e-mail [researcher] or [faculty mentor] (faculty mentor). A debriefing form (Appendix D) will also be distributed to all participants.

Describe in detail how confidentiality and privacy will be maintained

As research progresses, it is important for researchers to continue to protect the individuals participating. Federal regulations specify all records must be kept for 3 (three) years and then destroyed.

Be sure to clearly identify how you will protect the data collected, how you will store the data collected, and how those measures will protect your participants.

Example: The confidentiality of all participant information will be maintained throughout the study. Participants will use the last 4 numbers of their Millersville ID as their participant number, rather than using identifying information such as their name or full ID. No information with subject identifiers will be released. Participant questionnaires will be stored in a locked filing cabinet in a locked room in Byerly Hall to ensure no one who is not part of the study has access to these documents. All questionnaires will be kept for three years to comply with federal law. All documents containing participant information will be destroyed at the end of the three years.

CITI Training is required for anyone submitting an IRB protocol. (check that you have completed)

Upload CITI Completion Certificate

This certificate can be found after you've successfully completed the required modules with an acceptable pass rate.

By signing 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.