Applications must be in Time New Roman or Arial font, 10 or 12 pitch, be left-justified, and paginated (including supporting material).

E-mailed submissions are encouraged; however, an original or facsimile of the signed Signature Assurance Sheet must be submitted.

**FROSTBURG STATE UNIVERSITY**
**Institutional Review Board (IRB)**

# APPLICATION FOR INITIAL REVIEW OF RESEARCH USING HUMAN PARTICIPANTS

Name of Principal Investigator:
*The PI is the corresponding investigator, who will remain in contact with the IRB and address any concerns raised by the IRB or participants.*

Department:

Tel.:

Names of Co-PIs:
*The Co-PIs are other researchers who will interact with participants and/or have access to identifiable data.*

Department:

Tel.:

Project Title:

Funding Agency (if applicable):

Project Duration (mo/yr – mo/yr):

**Human subjects training certificates are required for the PI and Co-PIs.**

**Please e-mail the completed application to irb@frostburg.edu, or submit it to the Sponsored Programs Office, 229 Hitchens.**

**A. Research:**
***"A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."***

Is this project more than an FSU course assignment? Yes ☐ No ☐
If so, what is its purpose?

Will the results ever lead to a publication or presentation? Yes ☐ No ☐
If so, where (i.e., will the results contribute to generalizable knowledge)?

*If you answered "no" to both of these questions, stop. Your project does not need to be reviewed by the IRB because it is not considered to be research. Thus, you should not submit an application to the IRB for this project. If you have questions please contact irb@frostburg.edu.*

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**B. Human Participants:**
***"A living individual about whom an investigator a) obtains data through intervention or interaction, or b) obtains, uses, studies, analyzes or generates identifiable private information"***

Will you collect data about living individuals? Yes ☐ No ☐
If so, who are the participants (check all that might apply)?

College Students ☐ General Public ☐ (Adults) Prisoners ☐
Pregnant Women ☐
Other ☐ _____ Children or Minors ☐

Will you interact/intervene with participants in any way? Yes ☐ No ☐
"*Interaction* includes communication or interpersonal contact between investigator and subject." All communications, including -- but not limited to -- online, mailed or phone, are considered *interaction*.
*"Intervention* includes physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes."

Will you collect private information that could identify individuals? Yes ☐ No ☐
"*Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information"

*If you answered "no" to two or more questions, stop. Your project does not need to be reviewed by the IRB because it is not considered to involve human participants. Thus, you should not submit an application to the IRB for this project. If you have questions please contact irb@frostburg.edu.*

**If the project does not need to be reviewed by the IRB, then the instructor or faculty advisor is responsible and liable for the appropriateness of the activities.**

## C. Information for Review

Please provide the following information, taking care to communicate in a manner that will be intelligible to educated persons who are not specialists in your field.

**1. Abstract:** Provide an abstract of the research proposed (maximum 200 words).

**2. Participant selection:** Who will be the participants? On what basis will the participants be selected? How will you enlist their participation? If you plan to advertise for participants, please include a copy of the advertisement in a separate document.

**3. Procedures:** What precisely will be done to the participants? Explain in detail your methods and procedures in terms of what will be done to participants. If you are using a questionnaire or handout, please include a copy in a separate document.

**4. Risks and Benefits:** What are the potential risks to the participants? How do you propose to minimize these risks? What potential benefits will accrue to justify taking such risks?

**5. Confidentiality:** Adequate provisions must be made to protect the privacy of participants and to maintain confidentiality of identifiable information. Explain how your procedures accomplish this objective, such as means of data storage, data location and duration, description of persons with access to the data, and method of destroying the data when completed. Also, explain in this section that the data will be kept for 3 years or for as long as required by external agencies or funding sources. At the conclusion of that time period, all data must be destroyed.

**6. Obtaining Consent:** FSU faculty, staff, and students must obtain the informed consent of any potential human participant before involving that person in research. Typically, you do this by providing the participants with an informed consent document written in simple, lay language, giving them sufficient opportunity to discuss and consider whether to participate. State how the participants' informed consent will be obtained.

**7. Consent Forms and Information to Include:** Submit a final copy of the Consent Form in a separate document, as it will be provided to participants.
*Please see https://www.frostburg.edu/osp/elements-of-the-informed-consent-document.php for other important required elements that pertain to specific situations.*

*When using children or minors in research*, the Consent Form should be addressed to and signed exclusively by the parent/guardian to gain their consent for their child to participate. A separate Assent Form should also be created, containing the same general information as the consent form, which should be addressed to (at an age appropriate reading level) and signed exclusively by the child participant.

The Consent Form must include the information that a reasonable person would want to have in order to make an informed decision about whether to participate, including the following:

General Language: The informed consent form should be written in simple, lay language. Consent documents are more understandable if they are written just as the clinical investigator would give an oral explanation to the subject, that is, the subject is addressed as 'you' and the clinical investigator as 'I/we.' It should not just be a list of isolated facts about the research.

Purpose and Description: The opening paragraph should state that it is a research study and give sufficient details for participants to be informed of the purpose of the study along with such details as where the study will be conducted, its duration and dates, the nature of participant's participation, and the number of participants in the study.

Procedures: Describe the procedures to be followed, including any that are experimental, and any discomforts and risks. Specify the amount of time participation will take. Also, if applicable, describe any alternative course of treatments that might be advantageous for the subjects.

Participant Benefits: Describe any benefits, if any, to the person participating and, if significant, any available alternatives to obtaining these benefits. If there are not any benefits for participation, indicate this also. (Do not include benefits to society or benefits to the researcher.) Explain whether clinically relevant results will be disclosed to the participants.

Confidential or Anonymous: State if the study is confidential or anonymous. Note that it is impossible for it to be both. "Confidential" means that the information provided by the participants may be connected to the participants, but that identities will be protected. "Anonymous" means that the information provided cannot be connected to the participant. For confidential research, explain how you will maintain confidentiality of records and data (e.g. by using coded responses or secure storage).

Participant Risks: Describe any risks--psychological, emotional, physical, etc.--however slight. Include a statement, if appropriate, that a particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable. Also describe any costs to the participants for being part of the research. Note that simply saying, "There are no risks associated with this study" is not acceptable, but it may be appropriate to describe the risks as being no greater than the risks associated with performing that type of activity under normal circumstances (e.g., for an online questionnaire: "The risks are no greater than those associated with typical computer use").

If the procedures involve more than minimal risk, explain whether any compensation will be given or whether any medical treatments will be made available if injury occurs, and if so where information about this procedure can be obtained.

Voluntary Participation and Withdrawal: Include a statement that participation is voluntary and that participants can withdraw from the study at any time. Clearly state the consequences of withdrawing. For instance, if applicable, state that withdrawing from the study will or will not affect such things as medical treatment, employment, benefits, grades, payment, course credit, etc. If there will be no such consequences, say so.

Collection of Private Information: If you are collecting private information that could identify participants, you must state a) that once their identities are removed, their information could be used for future research studies or distributed to another investigator for future research studies without their additional consent, or b) that their information will not be used or distributed for future research studies.

When Child Abuse May Be Uncovered: In all non-anonymous situations (that is, whenever personal identifying information is collected, regardless of whether it is kept confidential or not), the following statement must be included verbatim: "*In accordance with legal requirements and/or professional standards, we will disclose to the appropriate individuals and/or authorities information that comes to our attention concerning (past or present) child abuse or neglect or potential harm to you or others.*"

Contact Information: Include your name, address, and telephone number, as well as the following statement: "This research study has been reviewed by the Institutional Review Board (IRB) of Frostburg State University. For research-related problems or questions regarding participants' rights, contact the IRB Chair, Dr. Christopher Masciocchi, at cmmasciocchi@frostburg.edu or (240) 527-2746."

Final Statement: The following should be the final statements of the informed consent form verbatim: "I have read and understand the explanation provided to me and have been given a copy of this consent form. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate in this study."

Signatures: The informed consent must be signed and dated by both the participant and the principal investigator or authorized representative.

Page Numbering: Consent forms with more than one page should be initialed and dated by the participant on each page and the pages should be numbered like this: "page 2 of 3"

**8. Supporting Documents:** Include all relevant supporting documents, interview questions, surveys, letters sent to recruit participants, questionnaires completed by participants, and any other material germane to human subjects review *in separate documents*.

**SIGNATURE ASSURANCE SHEET**

**Principal Investigator/Student Assurance Statement**

I understand Frostburg State University's policy concerning research involving human participants and I agree:

1. To obtain prior approval from the Institutional Review Board before beginning this research study;
2. To accept responsibility for the scientific and ethical conduct of this research study:
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent form:
4. To immediately report to the IRB any adverse reactions and/or unanticipated effects on participants which may occur as a result of this study;
5. To complete, on request by the IRB, the Continuation/Final Review Forms.

SIGNATURE: _____DATE: _____

TYPED NAME: _____

**Faculty/Research Advisor's Assurance Statement:**

I certify that I have read and agree with this proposal, that the P.I. has received adequate training to perform this research and will receive adequate supervision while performing this research.

SIGNATURE: _____DATE: _____

TYPED NAME: _____

***If the Principal Investigator is completing this project to meet the requirements of Frostburg State University academic program the student's faculty/research advisor must also sign the Signature Assurance Sheet.**