Frederick Community College

Institutional Review Board

APPLICATION FOR USE OF HUMAN PARTICIPANTS

This application must be completed, reviewed and approved by the Institutional Research Board (IRB) before any research is conducted at Frederick Community College (FCC). The review process will not be initiated until a completed application is on file with the IRB Chair. The IRB accepts only electronic submission.

Application Date:	
Project/Research Title:	
Principal Investigator:	
Phone Number:	
Email Address:	
What is the reason for conducting this research? (MA, Ph.D., Publishing, or etc.)	
Name Institution Affiliated with the Research:	
Department:	
Faculty Advisor's Name:	
Faculty Advisor's Phone:	
Faculty Advisor's Email:	
Anticipated Starting Date of Research	
Anticipated End Date of Research	
Funding Agency (If Applicable)	

Federal government defines risk as: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

What is the level of risk for your project/research?

Level of Risk	
No Risk Involved	
Minimal risk	
More than minimal risk*	

Frederick Community College

By signing, the investigator will abide by all Frederick Community College policies and procedures and understand that no research activities will be conducted with human participants prior to obtaining the required approvals. The investigator will inform the IRB Chair at the earliest possible date of (1) any significant changes in the project with respect to human subject participation, (2) any adverse reactions or unexpected responses observed involving human subjects, and (3) any need for continuation of the project activities beyond the approval date.

I understand and agree any changes in approved research methodology must be submitted to the IRB for reconsideration. The IRB will revoke the investigator's research privilege at FCC if the investigator violates or deviates from the approved application. The IRB reserve the right to request a periodic reviews on the progress of the research.

Investigator's Signature: _____ Date: _____

Investigator's Full Name: _____

Faculty Advisor's Signature: _____ Date: _____

Faculty Advisor's Full Name: _____

Email completed application to:
Interim AVP, Institutional Research and Effectiveness/IRB Chair
Dr. Joseph H Wycoff
gwycoff@frederick.edu

IRB Use: ☐Approved ☐Not Approved

Reason(s) for not approving the research/project:

IRB Chair Signature: _____ **Date:** _____

Please complete all items.

Provide an abstract of your research (250 words):

1. **Purpose of the Study:**
   What are the specific objectives (aims) of the research?

2. **Investigator experience:**
   Briefly describe the research investigator's level of experience. Attach an abridged vita highlighting expertise as it relates to this study.

3. **Background:** If your project falls within the **"More than Minimal Risk"** category:

   a. Provide an evaluative summary of relevant literature on the topic. **IF** adverse affects occurred, indicate how your research is addressing or attempting to prevent such affects. Include full citations for included research. If possible, also include a copy of relevant articles.

   b. For **More than Minimal Risk** studies that also include invasive procedures, indicate which databases have been consulted (e.g., Medline). Summarize findings, including findings of adverse affects and steps taken by you to prevent this from occurring in your project. You may reference your response in 3a, as appropriate.

4. **Subject selection:**
   Who will be the subjects? How and from where will they be obtained? What are the criteria for inclusion and exclusion? How will eligibility be determined, and by whom? Will the subjects be selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, any social or economic qualifications, or from vulnerable populations include children, pregnant women, or people with intellectual disability?

5. **Procedures:**
   Describe the study design and all procedures to which human participants will be subjected.

6. **Data Collection, Storage, and Confidentiality:**
   How will data be collected and recorded? Will it be associated with personal identifiers or coded to protect personal privacy? Where will the data be stored during the study and how will it be secured? Who will have access to the data and/or to the codes? If data with subject identifiers will be released, specify the person(s) or agency to whom this information will be released. What will happen to the data when the research has been completed?

7. **Risks/Benefits:**
   What potential benefits may participants receive as a result of their participation in the research? What are the potential risks/discomforts associated with each intervention or research procedure? What procedures(s) will be utilized to prevent/minimize any potential risks or discomfort?

8. **Process of Consent:**
   How and where will the consent process take place? What steps will be taken to avoid coercion or undue influence? Also, enclose the informed consent form, waivers of consent, and the child assent process.

9. **Location:**
   Where will the study be conducted? If not on campus, what is the nature of your cooperative arrangement with those in charge of the research site? Provide approval documentation from the cooperating institution.

10. **Independent reviewers:**
    If your protocol is **More than Minimal Risk**, please list the names and contact information (telephone, e-mail, address) of three experts in your field who can independently evaluate your proposal and assist the IRB at Frederick Community College in the review process.

Frederick Community College

Please use the content of this table as a guideline for preparing the Consent Form for your research.

Project Title	
Purpose of the Study	*This research is being conducted by **[Principal Investigator]** at Frederick Community College. We are inviting you to participate in this research project because you_____. The purpose of this research project is_____.*
Procedures	*The procedures involve .*
Potential Risks and Discomforts	*There may be some risks from participating in this research study.*
Potential Benefits	*There are no direct benefits from participating in this research. However, possible benefits include_____. **OR** The benefits to you include_____. We hope that, in the future, other people might benefit from this study through improved understanding of____.*
Confidentiality	*Any potential loss of confidentiality will be minimized by_____. **[storing data in a secure location such as: locked office, locked cabinet, password protected computer, etc].*** *If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the Frederick Community College or governmental authorities if you or someone else is in danger or if we are required to do so by law.*
Compensation [*If Necessary]	*You will receive_____. You will be responsible for any taxes assessed on the compensation.* *If you expect to earn over $100 as a research participant in this study, you must provide your name, address and SSN to receive compensation.* *If you do not earn over $100 only your name and address will be collected to receive compensation.*
Right to Withdraw and Questions	*Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.* *If you decide to stop taking part in the study, if you have questions,*

	concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator: ***[Principal Investigator]*** ***[Address, telephone number, and e-mail address of Principal Investigator. Co-Investigator information may be listed as well]***	
Participant Rights	*If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:* **Frederick Community College** **Dr. Joseph H Wycoff** **Interim AVP** **Institutional Research and Effectiveness/IRB Chair** **7932 Opposomtown Pike** **Frederick, MD 21702** **E-mail:** gwycoff@frederick.edu **Telephone: 301-846-2451** *This research has been reviewed according to Frederick Community College IRB procedures for research involving human subjects.*	
Statement of Consent	*Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will receive a copy of this signed consentform.* *If you agree to participate, please sign your name below.*	
Signature and Date	**NAME OF PARTICIPANT** **[Please Print]**	
	SIGNATURE OF PARTICIPANT	
	DATE	