Cecil College: IRB Expedited Application Form

The Cecil College IRB reviews all requests to conduct research involving human subjects. No data collection may take place before the PI receives written notice of the project approval from the IRB.

Prior to starting the application, the following is helpful:

- A copy of the research proposal.
- A copy of PI and Co-I up to date (within past 5 years) certificate of completion for CITI training.
    - If students are acting as research assistants in any research capacity, they must complete XXXX. It is the PIs' responsibility to ensure and document that students have annually completed training.

As the application form is written:

- Present information on the application in non-technical terms understandable to IRB members.
- Give information about research procedures that may entail risk, but not express judgment about the risk.

Part I: Research Staff

Cecil IRB Project # (To be Assigned, leave Blank): ASSIGNED BY IRB	
Date of submission:	
Principal Investigator Name (This must be full time faculty/approved staff):	
Email:	Phone:
Department/Division:	
If this submission involves another faculty member, a student or an outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Co-I Email: Co-I Phone: Co-I Affiliation (Cecil College, Other Institution, Outside Entity):	

Yes	No	
		Are students used as research assistants in the research?
		Do you accept responsibility for documentation of training, in accordance with the requirements of the IRB, and supervision of student research assistants?

		Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have any financial or other conflicts of interest related to this study? If "Yes", please explain.

Part II: Subjects and Procedures

What is the project title?
Who will be the subjects?
How will the subjects be recruited? If subjects are completing this as a part of a class activity or assignment provide the course name/section(s).
Describe where data will be collected (specify on or off campus, location, agency/organization). Describe in detail how researcher(s) will store the data and any identifiable information.
If subjects are not members of the Cecil College community AND/OR researcher(s) will not be collecting data on-campus identify by what means, and from whom, authorization to conduct your research was obtained. Include proof of permission from relevant parties.
Please attach a copy of the research proposal (when available) or describe the general purpose of the research below. If any materials are provided to subjects, please include a copy here.
Describe, in order, what researcher(s) and the subjects will do during data collection (e.g., when and how are instructions given, format of instructions, how the subjects will participate in the research, etc.). If subjects are provided with instructions include a copy of the exact instructions.

Part III: Risks and Benefits

The IRB retains final authority for determining risk status of a project.

Yes	No	
		In your opinion, does the research involve more than a minimal risk? Please see: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests." Please note that deception is considered more than a minimal risk.
		Are any emergencies or adverse reactions (physical, psychological, social, legal, or emotional) probable as a result of the research?

		Does the research include sexually explicit materials?
		Does the research ask subjects questions about drug or alcohol use, sexual behavior (sexual orientation, abuse or behavior), or current/previous criminal activity?
		Does your research systemically exclude groups of people?
		Do subjects leave the study or experiment in approximately the same emotional state as they began?
		Does the study involve any vulnerable subjects (e.g., children under 18 years old, adults older than 65 years of age, pregnant individuals, prisoners, economically disadvantaged individuals, individuals in nursing homes, physically or cognitively disabled individuals)?

If any of the above questions are answered "Yes" a Full Application Form is required. Please see the website for more information.

Yes	No	Does the research involve:
		Procedures that include behavioral intervention.
		Procedures that require collection of data from voice, video, digital,or image recordings (this excludes recordings of public observation).
		Procedures that include observation of public behaviors.
		Procedures that use educational tests (cognitive, diagnostic, aptitude, achievement).
		Procedures that use survey or interviews that collect information about mental health.
		Procedures that require collection of data with individual identifiers (i.e., subject name, subject id. (includes using retrospective data that does not have identifiers).
		If such identification is possible, could the disclosure of subjects' responses outside the research place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Part IV: Informed Consent

It is vital that subjects understand what will be asked of them and for what purpose their information will be used. The Informed Consent Template is designed to ensure that subjects' rights are maintained.

Answer the following questions about the informed consent procedures.

Yes	No	
		Will researcher(s) seek consent from all relevant parties? (e.g. subjects, parents, site supervisors)

		If “No”, explain why.
		Will a written informed consent form be used? If “Yes”, please include a copy in the templated form provided. If “No”, explain why and describe how consent will be obtaine
		If a subject is under 18 years old will assent be obtained? If “Yes”, include a copy of the assent script and/or written assent form. If “No”, explain why.
		If the Informed Consent Template is being used, have researcher(s) made any changes beyond replacing the bracketed sections with information appropriate to the project? If ‘Yes’ explain the reasons for making the changes.
		Will the anonymity of subjects be preserved? Anonymity is maintained when it is impossible for any person to connect the data provided by the research subject to said subject. If "No," explain why and describe how researcher(s) will protect the identity of subjects.
		Will subjects be debriefed in regard to the purposes, consequences, and benefits of the research? If "No," explain why.
		Is there deception involved in the research? Yes or No If “Yes”, will subjects be debriefed if there is deception involved in the research? Provide a copy of the debriefing script and/or written debriefing materials provided to subjects.

Assurance by Principal Investigator:

By electronically signing the PI and Co-I(s) agree to:

- Indicate any conflict of interest on the application form.
- Document required training for all PIs, Co-Is, and research assistants
- Submit a Change Form describing and providing rationale for any proposed changes to the research protocol.
- Refrain from implementing changes in the research project until IRB approval is received.
- Submit a yearly Annual Review Form a month prior to the annual review date to update the IRB on study progress.

- Hold all completed informed consent forms for XXX number of years and submit to the IRB upon request.
- Acknowledge that members of the IRB may interview investigators, research subjects, or research assistants to verify that the approved project is being followed.
- Complete an Adverse Event Form and submit in 24 hours if any adverse event concerning a subject enrolled in the research occurs, even if the event does not seem directly related to the research.