Title: Institutional Review Board (IRB) Policy:

- ❒ **Initial Action:** September 2020
- ❒ **Board Resolution:** 20-061
- ❒ **Last Revised**
  - **Policy:** New - September 2020
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- ❒ **Last Reviewed:**
- ❒ **Effective:** October 28, 2020
- ❒ **Next Review:** September 2026
- ❒ **Responsibility** Academic Programs

POLICY:

All human subjects research at Cecil College, as defined by federal regulations and included in the attached IRB Mission and Operating Procedures document, will be approved by the Institutional Review Board.

PROCEDURE:

See the IRB Mission and Operating Procedures document included below, or visit the IRB online. (reviewed 9.2023)

Mission and Operating Procedures

IRB Committee

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INTRODUCTION TO CECIL COLLEGE'S IRB

The history surrounding human protection in research is riddled with examples of studies conducted where the rights of human subjects, especially those of vulnerable populations, were violated. Following World War II, atrocities committed by members of the Nazi regime highlighted the importance of protection for human subjects. Out of this specific example principles to evaluate the impact of such standards were set forth in The Nuremburg Code. One of the main components of this document highlighted the importance of having the informed consent of subjects and put the onus of securing the informed consent in the hands of the investigators. Following this document, other principles, including the importance of approval and ongoing review by an independent ethical committee in research, were discussed in the World Medical Association's Declaration of Helsinki. (World Medical Association, 1989)

Despite calls for ethical guidelines in research, it was not until 1974 that the National Research Act established clear standards to regulate research involving human subjects. One of the most relevant documents used in IRBs today remains The Belmont Report which, following concerns about the lack of ethical practices during the longitudinal U.S. Public Health Service Syphilis Study at Tuskegee, was written in 1979. The Belmont Report outlines three important ethical principles that should guide the development and practice of research, including respect for persons, beneficence, and justice. (Department of Health, Education and Welfare, 1979)

The importance of IRBs was emphasized within the state of Maryland in 2002, when the Maryland General Assembly passed House Bill 917, "Human Subjects Research – Institutional Review Boards". The law, which took effect in October of 2002, indicated that research conducted in the state of Maryland, that involves the presence of human subjects, must follow federal regulations to ensure human subject protection. (Maryland Office of the Attorney General, 2018)

Institutional Review Boards (IRBs) must determine if a proposed research project meets the following criteria to be approved:

- There are minimal risks to human subjects.
- The benefits of the anticipated research are reasonable in the face of the risk to human subjects.
- The selection of human subjects, especially those that represent vulnerable populations (children, prisoners, those with developmental delays) is equitable, and research on vulnerable populations is safe.
- Informed consent is sought and documented.
- The research contains adequate situations to protect the privacy and confidentiality of human subjects and the data collected.
- The researchers do not coerce participation in the research; participation is voluntary and anonymity is preserved.

As delineated in the Strategic Plan 2015-2020, Cecil College aspires to following the values of excellence, integrity, innovation, and collaboration. Broadly, the IRB upholds the ethical guidelines surrounding research, which encourages integrity around projects conducted on Cecil College's campus. Additionally, awareness of research

ethics promotes academic excellence within the designated field, fosters collaboration between investigators within the institution, and encourages innovation. The inclusion of an IRB on campus also educates students on proper research ethics, which will aid them as they progress forward in their academic careers.

The Cecil College IRB reviews proposed research projects and other activities that involve the use of human subjects to assure that projects conducted meet state and federal regulations. The purpose of the IRB is not to evaluate the merit of research, but instead to ensure that the rights and welfare of human subjects are protected; that the risks involved in the study are considered, minimized and weighed against the benefit of the research; that all human subjects engaged in research activities have volunteered and have undergone informed consent; and that all research is conducted in compliance with ethical standards. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects.

It is not the role of the IRB to evaluate or provide rulings on methodological approach of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. It is, however, the responsibility of the IRB to evaluate each project in terms of the ethical standards with regard to issues such as informed consent, confidentiality, and risk to human subjects.

The following guidelines clearly define the operating procedures for the IRB and provide definitions of the types of research/evaluation that must be submitted to the IRB for review.

I. INSTITUTIONAL AUTHORITY

This document establishes and empowers the Cecil College Institutional Review Board (IRB) to make decisions regarding research that involves human subjects. IRB approval of a research study does not constitute or imply Cecil College's endorsement or sponsorship of the study.

II. BASIC PRINCIPLES

A. The IRB is based on the principles set forth in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm].

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at Cecil College to ensure that adequate safeguards are provided:
   1. Human subjects' legal rights will be respected; their rights to privacy, dignity, and safety will also be considered in approving proposed research.
   2. Risks to human subjects must be reasonable in relation to any

anticipated benefits to subjects and to the importance of the knowledge that may reasonably be expected to result.

3. Adequate provisions must be made for all facilities, procedures, and professional resources necessary for the protection of the individual as a research subject.
4. Adequate provisions should be made for recruiting a human subject population that is representative of the Cecil College population base in terms of gender and minority representation, unless scientifically justified.
5. The rights of human subjects from vulnerable populations must be protected through additional safeguards.
6. The selection of human subjects must be equitable.
7. Informed consent must be obtained from all human subjects (or legal representative) and documented.
8. Data collected from human subjects must be protected to ensure the human subjects' privacy and confidentiality.
9. Research involving human subjects must be supervised by qualified persons, including qualified clinicians or faculty for all study-related healthcare decisions.
10. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided during the informed consent process. Information provided to gain human subject consent must be adequate, appropriate, and presented in clear language appropriate to the human subject population.
11. All research programs that involve human subjects must be reviewed by the IRB and must receive approval of a formally constituted review *prior* to their initiation or *prior* to initiating any changes to the project. Continuing research programs are subject to annual review, in addition to project change and adverse event reviews.

III. SCOPE OF AUTHORITY

While Cecil College has not currently undergone application for Federalwide Assurance (FWA) through OHRP, the following procedures have been written in anticipation of approval of FWA. Therefore, Cecil College IRB agrees to consider *all* research involving the use of humans, or data maintained by the college, as being subject to federal regulations regardless of the source of funding.

It is not the role of the IRB to evaluate or provide rulings on methodological approach of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. It is, however, the responsibility of the IRB to evaluate each project in terms of the ethical standards with regard to issues such as informed consent, confidentiality, and any risk to the subjects.

IV. TERMINOLOGY

A. Research – Means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research may include surveys, interviews, focus groups or other projects that involve data gathering.

B. Private information – Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

C. Intervention – Includes both physical procedures by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes.

D. Minimum risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

E. Principal Investigator (PI)– Is the primary contact for research; students must have a faculty or staff advisor who serves as the PI for the IRB process. While, students may serve as a co-PI all correspondence with the IRB will go through the primary PI (faculty/staff) and all research materials must be housed with the primary PI.

V. MEMBERSHIP AND ADMINISTRATIVE REPORTING

A. The Division of Academic Programs (AP) will be responsible for managing all administrative requirements of the IRB. Administrative personnel from AP will be assigned to coordinate the logistical operations of the IRB.

B. The IRB is administratively responsible for reporting to the Vice President for Academic Programs and the President of the College.

C. The Chair of the IRB will be voted by the IRB committee and must be a member of the faculty body.

D. The Chair will appoint the Vice Chair of the IRB with the concurrence of

the IRB. The Vice Chair presides over all convened IRB meetings in the absence of the Chair, and has authority to sign all IRB action items in the absence of the Chair. The Vice Chair must be a voting member of the IRB.

E. The IRB shall be composed of six to seven members. Two of these members will be a Representative from Institutional Research and the Associate Dean of Academic Assessment and Development. Three of the other members will be faculty from different disciplines. Two of the faculty members will be voted upon by the faculty body. One faculty member will be appointed by the Vice President of Academic Programs. From the faculty group, one person will be voted on as the chair of the IRB by the IRB committee. Additionally, one member will be appointed from Student Services by the Vice President of Student Services and Enrollment Management. There may be an outside community member added to the IRB. All appointments to the IRB will be communicated by the Chairperson of the IRB to appropriate administration. In the case of a tie, the Vice President of Academic Programs will vote.

F. The composition of members on the IRB will reflect the diversity of the campus and bring expertise that will assure adequate review of the research brought before the IRB.

G. Members of the IRB shall be serve a tenure of three (3) years. However, the term may be terminated by notice of the committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapacity to serve the committee adequately. In either event, the Chair, in consultation with the Vice-President of Academic Programs, will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member, the Chair and the Vice-President of Academic Programs. For the first three-year cycle of the IRB, all positions will be appointed by the Vice President of Academic Programs.

H. All members must complete formal training at the time of their initial appointment and every 3 years from initial date of completion if they remain on the IRB. Training that satisfies this requirement is Human Subjects Research modules for Biomedical Basic and Social-Behavioral-Educational Basic through the Citi program (https://about.citiprogram.org/en/series/human-subjects-research-hsr/).

I. Academic Programs must maintain a log of training completion dates for IRB members.

J. IRB members do not receive compensation for their service, however the IRB is considered fulfillment of committee requirements for faculty on their annual contract.

K. Liability coverage for IRB members is provided through Cecil College's liability insurance coverage, whether or not the IRB member is an employee of Cecil College.

L. No person shall be excluded from serving on the IRB based on sex, race, color or national origin, disability, religion, marital status, sexual orientation, gender identity, or any other characteristic protected by federal, state, or local law.

VI. OPERATIONS OF THE IRB

A. Meetings

1. IRB meetings are scheduled monthly during the academic term. Timeline for projects submitted over the summer months will be determined by the IRB chair.
2. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least ten (10) business days prior to the meeting. AP administrative personnel will be responsible for checking completion of submitted materials. An IRB member will be responsible for meeting minutes, which are kept confidential.

B. Voting requirements

1. At all IRB meetings convened to review proposal(s), a quorum of the IRB, must be present. At minimum the membership in attendance must include at least one member whose primary concerns are in nonscientific areas.
2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting.
3. Principal Investigators, including those who are also IRB members, may offer information and answer questions about their projects at a convened meeting, but may not be present during voting.
4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of projects, and individual votes are considered confidential and should not be discussed outside of the meeting context. If, during an IRB meeting, the Chair moves the meeting to executive session, then any visitors will be asked to leave the room until the executive session has ended.

C. Documentation

1. All procedures, policies, applications and sample forms are available on the college portal.
2. Completed applications and required materials should be emailed the IRB at irb@cecil.edu prior to review as delineated in the submission process. Following review, PIs will be sent electronic copies of all submission approvals.
3. The following information is managed by the IRB through a secure server.
    i. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
    ii. Copies of all correspondence between the IRB and the investigators.
    iii. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.
    iv. Detailed minutes of IRB meetings, showing:
        i. Members present (any consultants/ guests/others shown separately).
        ii. Results of discussions on debated issues and record of IRB decisions.
        iii. Record of voting (showing votes for, against and abstentions).
    v. Other correspondence or documents generated by the IRB.

VII. TRAINING

A. Training and support to the campus: Given that many are unfamiliar with IRB procedures, an additional responsibility of the IRB at Cecil will be to provide ongoing professional development to faculty, staff, and students that provides education around the purpose, processes and procedures of the IRB in coordination with other required training.

B. PIs and research teams that seek IRB approval will need to complete mandatory training through the CITI program. A copy of up-to-date (within past 5 years) certificate of completion for CITI Training for the PI and any Co-Is is required with submission of IRB documents and will be kept on file within the Academic Programs office. PIs and outside entity personnel that are co-PIs must complete the Human Subjects Research Course (HSR). Depending on the nature of the research the PIs must complete either the Biomedical Basic course or the Social-Behavioral-Educational Basic course. Students

must complete the Responsible Conduct of Research (RCR) Basic protocol.

VIII. SCOPE OF IRB

A. All individuals, affiliated or not with the college, who conduct research involving human subjects on Cecil College campus or primarily with Cecil College faculty, staff, or students (if, for example, the research is done online, but targets Cecil College) must apply for IRB approval.

1. Research is defined as a systematic investigation, including but not limited to research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

2. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

B. Exceptions: The following projects do not require IRB review.

1. Research that relies on summary statistics involved in mandatory reporting.

2. Classroom Data Gathering: When engaging in classroom or assignment-based activities that involve data gathering, faculty should be aware of concerns that present related to consent, type of data gathered, and confidentiality. Faculty are asked to review and sign the Classroom Data Gathering document as a part of annual training.

- In instances where students may be involved in course activities such as conducting surveys of Cecil students, staff or faculty, or members of the community, or obtaining data via oral history, the course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval.
    - Class projects that are designed solely with the objective of providing students with training about experience with research methods are not considered research and do not require IRB approval. In these cases, data cannot be used out outside of the classroom context and data must be destroyed upon completion of the project.
    - STEM posters presented outside of the Cecil College STEM night require completion of an Exempt Application Form (Retrospective data use) prior to the presentation.

- At minimum, if the instructor has any doubt concerning the classification of these activities, he/she is encouraged to contact the IRB chair or complete an Exempt Application Form for approval and submit it along with the project and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities

IX. IRB APPLICATION PROCESS

A. Process

1. It is the responsibility of all employees of the College to be familiar with the IRB Procedures and to submit applications for review as indicated. The application process is determined by the level of IRB review indicated. Application to the IRB must be made prior to soliciting human subject participation or data collection. If data collection is retrospective, IRB approval is required before data is utilized. It is also the responsibility of all employees of the College to inform other individuals, students or outside entities about the IRB processes when appropriate.

B. Level of IRB Submission

1. Federal guidance describes three levels of IRB review, including exempt, expedited and full. Please note that all three of these levels require approval of the IRB and simply refer to the level of review that the project will receive. Exempt research still requires submission of an application. The determination of the level of review is dependent on the purpose of research, the human subjects under review, the type of intervention to be studied, and the data to be collected and analyzed. The IRB also has a process in place for research that has prior IRB approval from an outside institution.
2. Individuals gathering data on human subjects at Cecil College should consult the provided tables that highlight levels of IRB review prior to completing the IRB application. Once the Primary Investigator has identified the level of IRB review required, they should submit the appropriate application to the IRB. Upon submission of a new application, the chair of the Cecil College Institutional Review Board (IRB) assigns an application number (YYYYMMDD#) and the project is placed on the IRB agenda. If the incorrect application materials are supplied, the IRB will reach out to the Primary Investigator. If there are questions about level of IRB review or if a project does not need to be reviewed, the Primary Investigator should contact the IRB chair for clarification.

Exempt research projects do not put the subjects at risk and do not gather data that:

- Asks about criminal or civil liability such as illicit drug use, underage drinking or criminal behavior.

- Causes increased distress (i.e., asking questions about past sexual abuse/assault; prior traumatic experiences; history of STDs, HIV, abortions, schizophrenia, mental health disorders, child abuse or neglect, elder abuse or neglect, incest, suicidal or homicidal thoughts or behaviors, sexual experiences with a faculty member).

- Damages the subjects' financial standing, employability, educational advancement, or reputation.

- Uses deception.

- Includes a behavioral intervention.

- Requires collection of data from voice, video, digital, or image recordings (this excludes recordings of public observation).

- Requires collection of data from minors or vulnerable populations.

Additionally, exempt research includes:

- Research that gathers data on customer satisfaction for a single office or event if the information gathered will not be presented externally. Information that may be presented in forums outside of the college, for example grant applications, publications, or conferences, should be approved by the IRB through the expedited submission process.
- Research that is conducted annually, and that has previously received IRB approval.

Expedited research projects do not present more than a minimal risk to human subjects and involve either of the following:

- data that is gathered with the purpose of sharing externally, or

- data that is not anonymous, where the subject can be linked back to his/her/their response through subject id number or other means.

Full research projects meet all the criteria for expedited and involve any of the following:

- conducting human subjects research on campus or with Cecil College employees or students by an outside entity,

- gathering data for grant-based research,
- exposing subjects to risks greater than those normally encountered in daily life or in routine medical, dental, or psychological examinations, and/or
- gathering data on vulnerable populations.

The following chart is provided to help clarify the types of projects that will require IRB review and the appropriate application process.

Examples of Level of IRB Review		
Example of Project	Considerations	Submission Type
Summary statistics regarding completion in developmental course series is collected and reported in a Middle States document.	Data is summary in nature and being used for mandated reporting.	Exception
A student is gathering data on bacteria she is observing in her Biology course.	Research does not involve human subjects.	Exception
A professor is gathering large amount of demographic data on students to use in class, but no identifiers are used, the faculty is sensitive to the types of data being collected, and it is not being used outside of the course.	Research is for class-based learning only. No identifiers are used. Sensitive information is not being collected.	Exception: Classroom data gathering form is completed by faculty.
A staff member was involved with collection of data a number of years ago. The data set no longer contains student names or ID numbers and the staff member would like to use the data to present on a topic at a local conference.	Retrospective data use. No identifying information included. Being used for outside use.	Exempt
A student would like to survey other students as a part of a class project about their eating habits. The information will be presented at a conference.	Identifying information is present. Questions pose minimal risk. Research is being presented outside of the classroom.	Expedited
Two professors create a new course that evaluates the effectiveness of a new learning strategy. A control group is being used in the study. Data will be used to inform changes to the course in the future, but will not be used outside of the college environment.	Research that evaluates a new teaching methodology where a control group is involved. Data is not being used outside of the college.	Expedited

A professor in history is collecting student accounts of racism in a publication. Projects initiated where results may be published in professional journals or presented at a	Research involves potentially vulnerable populations. Identifying information is linked to the data. Will be published.	Full
An outside mental health organization requests permission to gather data about the sexual health practices of Cecil College students by surveying them on campus. Identifying information will be collected in the study.	Research involves identifiers and sensitive information. Research is being conducted by an outside organization.	Full

C. Submission
   a. Detailed instructions about how to submit application materials and application forms can be found on the college portal. Forms are to be completed, and then emailed to irb@cecil.edu.
   b. Informed consent means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Sample forms are also available with the IRB application materials. The basic elements of information necessary to such consent are found at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116
      i. Given that the research conducted on campus may involve minors, informed consent for participation is of concern to the IRB. See addendum for additional information on requirements for informed consent (Consent Form Addendum). The IRB will review the content of the informed consent, and the method for assuring the informed consent is adequate and appropriate. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects.
   c. Conflict of Interest:
      i. It is the responsibility of the PI and Co-I's to identify and avoid any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest. All PIs and co-PIs will be asked to complete the Cecil College COI form.
      ii. It is the responsibility of all IRB members to identify and avoid any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. It is the responsibility of the IRB members to inform the IRB Chair should they have a conflict of interest during review of any proposal.

D. Application Review – Exempt/Expedited/Full
    1. Research that is categorized as exempt, expedited or full is reviewed by the IRB.
    2. Complete applications must be submitted ten (10) business days prior to the IRB meeting.
    3. IRB members will be asked to review all applications prior to the upcoming meeting. If concerns arise, the PI may be contacted to provide further clarification or may be asked to attend the meeting to answer questions.
    4. If an IRB member has a conflict of interest, they will be excused from the review of the application in question.
    5. If following review of the application by the IRB the research is approved, the IRB chair will draft a letter of approval that is sent to the Primary Investigator within ten (10) days of the review deadline. Both the letter, a conflict of interest (COI) form, and a compliance statement, to be completed by the Primary Investigator, are sent through electronic mail (when an address is provided) and through campus or U.S. mail depending upon the address given on the application. The compliance statement and COI must be received by the IRB prior to data collection. The IRB will acknowledge that they received the compliance statement and will indicate that data collection may begin via an email to the PI.
    6. If the IRB requests alterations or corrections before approving the application, then the IRB chair drafts a memo detailing the concerns and sends it via electronic and campus or U.S. mail to the investigator(s). Depending upon the extent of the revisions requested, the investigator may be asked to resubmit an entire application or just the documents that are revised or added.

E. Timeline in Summer
    a. Review of applications received during the summer months may be delayed until the end of the second week of the fall semester depending on urgency.

X. COMPLIANCE

A. When an application is approved, the PI must return a COI and a Compliance Statement, which describes the requirements for maintaining IRB approval. Specifically, the statement requires PIs to agree to the following:
    1. “If I wish to make any changes in the conduct of my research as stated in my proposal approved by the IRB, I will promptly submit a change form to the IRB describing the proposed changes and the rationale for them. No material changes can be made to the conduct of this research without prior IRB approval.
    2. “I will complete a yearly annual review form to update the IRB on study progress.”
    3. “I will submit all completed informed consent forms to the IRB chair for seven years.”
    4. “I am aware that members of the IRB may interview me, research subjects, or research assistants to verify that the approved project is being followed."

5. "If, at any time, it is brought to my attention that there is an adverse event concerning a subject enrolled in the research, even if the event does not seem directly related to the research, I will complete an adverse event form and submit it within 24 hours of my awareness of the event."

XI. APPEAL

A. The Primary Investigator (PI) of any proposal may appeal the decision of the IRB, within ten (10) business days, when a project has been disapproved or approved with recommendations and mutual agreement cannot be reached as to an acceptable alternative. Within ten (10) business days of the written notification of appeal from the PI, the IRB, in consultation with the Vice President of Academic Programs, shall name an *ad hoc* committee of three or more faculty and/or consultants to review the project a second time and materials will be redistributed. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The project will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The *ad hoc* committee will meet within ten (10) business days following the formation of the committee. The PI will be promptly notified of actions of the *ad hoc* committee and final action by the IRB within ten (10) business days of the meeting. Final disapproval of the IRB cannot be overridden by any institutional official.

XII. OTHER TYPES OF REVIEW

A. Approval by outside IRB
   a. When an outside organization or institution has approved a research project through their IRB, PIs will be asked to complete the appropriate application form and submit documentation as required on the form for review.

B. Annual review
   a. All projects will submit annual review forms to help keep the IRB apprised of progress. These should be submitted to the IRB 45 days prior to the date of the IRB meeting when the initial application was approved.
   b. The IRB research database is reviewed monthly to identify projects needing continuing review for that month. A request for a status report on each qualifying project is sent to the PI in the form of an email. The PI is responsible for completing the annual review form. This is true of all research that is under the IRB purview, including research approved by an outside IRB.

C. Change to project
   a. If the PI feels it is necessary to make changes to the research project, the PI must complete the change form and submit it to the IRB. No changes or modifications can be made until the IRB has approved them. This is true of all research that is under the IRB purview, including research approved by an outside IRB.

D. Closure

a. When a project is complete, the PI should submit a closure form to the IRB indicating that the project has closed. This should be done within 30 days of the last point of data collection. This is true of all research that is under the IRB purview, including research approved by an outside IRB.

XIII. INVESTIGATION AND ADVERSE EVENTS

A. Projects may be investigated further at the discretion of the IRB when the risk to human subjects warrants additional consideration, when a PI or member of the research team identifies an adverse event, or when a subject reports an adverse event. Verification that no material changes have been made since previous IRB review and that risks to subjects remain at or below the level indicated in the approved project is sought. Moreover, regardless of the study, investigation is always conducted should a significant material complaint made by research subject come to the attention of the IRB. Evidence may be sought from the PI, research assistants, the project advisor, or in exceptional cases, from research subjects themselves.

B. Projects with special populations or risks

1. Upon the IRB's identifying such a population or risk, the IRB chair will include a schedule for verification, which will constitute an added section to the usual Compliance Statement (below). Although the exact schedule will be tailored to the particular project, the PI must inform the IRB chair of the actual start of data collection, so that at a minimum a first stage of verification can occur during the first ten(10) days of data collection.
2. The IRB chair or his / her designee will interview the PI, focusing on the following matters
    i. Joint review of actual written materials and procedures used, to be compared against the approved research design
    ii. PI's oral review of objective evidence of research subjects' experiences in the study (statistics for research subjects to that date, including how many pointed questions or expressed concerns are raised; rate of withdrawal from the study before data collection is complete; any visual evidence of anxious behavior, physical discomfort, or adverse reactions to substances administered within data collection; results of debriefing)
    iii. PI answers any questions from IRB chair or designee, and affirms verbally that no material changes have been made to the research design and materials, and that no concerns have arisen that might indicate changes to IRB approval.
    iv. IRB chair or designee writes a report of the findings within ten (10) business days of the meeting, and both parties approve the report, which goes into the PI's file for the research study. This document constitutes permission to continue data collection

under the approved procedures until the next scheduled stage, or until data collection is complete if no further verification stage was deemed necessary.

v. After final data collection, PI drafts a brief final report summarizing how the research met IRB verification requirements.

C. Projects where a PI or member of the research team identify an adverse event.

a. Principal investigators and research staff should be monitoring any potential adverse events that occur as a result of their research. If an adverse event occurs, an adverse event form must be submitted to the IRB within 24 hours of awareness of the event.

b. Adverse events are categorized into two categories

i. Category A: Serious Adverse Event

- A serious adverse event occurs within 48 hours of participation in research, and
- incorporates a serious adverse event (death, a life-threatening experience, hospitalization, or extended hospitalization, persistent or significant disability or capacity, congenital anomaly or birth defect).

ii. Category B: All three of the following statements are true

- Event has caused harm to the subject, has impacted the subject detrimentally, has worsened the result of their participation, or has resulted in increased risk to the subjects or others (even if the risk has not resulted in harm). Examples: Misplacing a subject's record, mild distress after completing the research, etc.
- Event or outcomes were not described or disclosed as a risk for participation in the research, or they have occurred with increased frequency after completing the research.
- Event or outcomes were possibly, probably or definitely linked to the research.

c. Following receipt of the adverse event form the IRB chair or designee will contact the PI and arrange an interview within ten (10) business days. In the interim, data collection is temporarily discontinued.

i. The interview will focus on the following matters

i. Joint review of actual written materials and procedures used will be compared between the approved research design and the adverse event form

ii. Joint assessment of the context and possible causes of the expressed concern, reassessment of the study's potential risks, and either (a) a plan to eliminate or further minimize such concerns in the future, or (b) an explanation of how the adverse event does not in fact go beyond the level of minimal risk and therefore have been addressed

iii. As soon as possible following this interview, the IRB chair or

designee will report to the full IRB. The Academic Programs Vice-President will also be informed. Procedures and their attendant risks again will be reassessed to determine whether more than minimal risks are present.

d. Final decision

i. If no unacceptable risks are found, the PI is notified via electronic correspondence and will be informed that data collection may continue under the previously agreed-upon research design.

ii. If unacceptable risks are found, the PI must submit change forms to the IRB addressing the risks and making adaptations to the research project to be reviewed at the next IRB meeting.

iii. In either case, the IRB chair or designee drafts a report for the PI's IRB file for that research study summarizing the results of verification and action taken.

D. Projects where a research subject expresses concern.

1. Upon the IRB chair or his / her designee receiving notification that a research subject has expressed concern about risks or experimental procedures, he or she will contact the PI and arrange an interview within ten (10) business days. In the interim, data collection is temporarily discontinued.
2. The interview will focus on the following matters

ii. The IRB chair or designee will relay the concerns of the research subject

iii. Joint review of actual written materials and procedures used, to be compared against the approved research design

iv. Joint assessment of the context and possible causes of the expressed concern, reassessment of the study's potential risks, and either (a) a plan to eliminate or further minimize such concerns in the future, or (b) an explanation of how the subject's concerns do not in fact go beyond the level of minimal risk and therefore have been addressed

3. As soon as possible following this interview, the IRB chair or designee will report to the full IRB. The Academic Programs Vice-President will also be informed. Procedures and their attendant risks again will be reassessed to determine whether more than minimal risks are present.
4. Final decision

iv. If no unacceptable risks are found, the research subject who expressed concerns to the IRB is contacted within five (5) business days and thanked for his or her intervention. He or she should receive an oral report of the findings (at the time of contact), along with reassurance that even though no evidence for changing the research design was found, important issues were raised that are of prime importance to the PI and the IRB, that the research subject's concerns remain personally valid, and that it remains the subject's prerogative to have his or her data included in the study or eliminated from consideration if they are not anonymous, and

therefore can be identified. After this communication, within two (2) business days, the PI is notified of the conversation and informed that data collection may continue under the previously agreed-upon research design.

v. If unacceptable risks are found, the research subject who expressed concerns to the IRB is contacted within five (5) business days and thanked for his or her intervention. He or she should receive an oral report of the findings (at the time of contact), including reassurance that important issues were raised that are of prime importance to the PI and the IRB, and be informed that the research study's temporary hold on data collection will be continued so that the PI may reapply for IRB approval. After this communication, within two (2) business days, the PI is notified of the conversation and informed that data collection may not continue until the project is resubmitted to the IRB and approved.

vi. In either case, the IRB chair or designee drafts a report for the PI's IRB file for that research study summarizing the results of verification and action taken.

E. Document Retention

1. These documents and records shall be retained according to requirements of the funding agency, but at minimum for three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.
2. In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments.
3. All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave Cecil College, signed consent forms are to be transferred to the IRB Chair. If this is a student led project, all materials must be maintained by the Advising PI on campus. These items should be protected to ensure confidentiality.

Appendix A:
Classroom Data Gathering

Courses often require students to participate in data gathering activities within, as well as outside of, class. While many of these activities do not require IRB approval, it is important for faculty and students to understand how basic research ethics guide data collection. Below are a few items to consider when data is collected as a part of a course:

1. Teaching students about basic research ethics, including the role of the IRB, the purpose of informed consent, and the importance of confidentiality is fundamental to academic and research integrity.

2. Some classes gather data on students enrolled in the course to help demonstrate theoretical concepts, research methodology, or as a part of a class activity. When gathering data it is essential for faculty to consider the importance of confidentiality.
    a. If the data collected could be sensitive in nature (i.e., political beliefs; social beliefs; personal experiences) it is important that data is collected in a way that protects the confidentiality of the student. This includes, but is not limited to, not tying demographic data to responses on the questions posed. In small institutions, like Cecil College, it is often easy to identify a student's data by demographic information collected. Faculty should be aware of these concerns and make efforts during data collection to maintain privacy.
    b. Additionally various types of questions may cause student distress. Asking these questions as a part of a data gathering measure, not just for personal reflection during class, should be carefully considered. For example, questions about prior criminal, sexual, substance use, mental health status, or traumatic experience should be carefully handled. If faculty feel that these questions are necessary, IRB consultation should be sought.

3. Courses may also collect data, via surveys, observation or oral history, on individuals outside of the classroom environment. Some of these activities may qualify for IRB review. A few important considerations are below:
    a. Faculty should be aware that if data is collected, with the intention to be used outside of Cecil College, IRB approval is required. If data was initially a STEM poster and then presented in the future at an outside conference, IRB approval is also required.
    b. If students collect data from outside sources, subjects should be aware of informed consent.
    c. Individual identifying information should be left out of the student report on the data. For example, if a student obtains an oral history from a family member, identifying information should not be included in the report write up. All data should be destroyed after the project is completed.
    d. Students should be made aware of how the types of information they are collecting could be sensitive in nature and the proper use of confidentiality, as well as data storage.

4. Faculty should be aware that data that is used by student's in assignments, and submitted via LMS,may be housed and available to other faculty via SafeAssign. It is important that data is not identifiable.

By signing this document I acknowledge that I have read the above information.

_____ _____

Faculty signature Date

References

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PROCESS CHECKLISTS

Steps to Submission

The following provides information to help researchers determine if they need to apply for IRB approval and how to apply to the IRB if approval is necessary.

The IRB reviews all proposals for human subjects' research before the research is conducted to ensure that the research plan adequately protects human subjects.
To apply for IRB approval, researchers must complete the following:

1. Determine if your research requires IRB review.
   - Not all projects require IRB review/approval. If your project meets both of the qualifications below then move to question number 2.
   - First, you must be conducting research.
     - Research is defined as a systematic investigation, including but not limited to research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.
     - Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
   - Second, you must be using human subjects in your research
   - If your research does not meet the two qualifications above, you do not need to continue the IRB process.

2. Identify the Principal Investigator (PI) for the study.
   - If you are a fulltime faculty or staff member, please go directly to #3.
   - If you are a student or someone who is looking to do research on Cecil College's campus, but you do not work for Cecil College, you need a primary PI who is an approved faculty or staff member at Cecil College.
     - If you are a student, you should identify a faculty member who will serve as the PI for your project.
     - If you are an outside entity or a staff member, you must approach the Associate Dean of Academic Assessment and Development at irb@cecil.edu, who will consult with administration about an appropriate PI. If you have someone you have approached to be the PI at Cecil College, please specify that person in your correspondence with the Associate Dean.

3. Determine the type of IRB review.
   - Decide if the project requires Exempt, Expedited or Full review. LINK HERE FOR FORM TO USE

4. Complete the application form.
    - Complete the appropriate application form. LINK EXEMPT, EXPEDITED AND FULL APPLICATION FORMS
    - Submit electronically the application form, with all supporting documents to irb@cecil.edu 10 business days prior to the next IRB meeting. LINK TO IRB MEETING SCHEDULE

5. Complete Training. Please note that all investigators who are directly involved with human subjects and data collection/analysis must complete training. Please be mindful of who is considered a co-investigator and is directly involved with human subjects and data collection/analysis. If you have completed the appropriate training in the past 5 years, you do not need to retake the modules, just attach the previous certificate of completion. All certificates of completion must be attached to the initial application form. LINK HERE TO CITI
    - Primary PI Human Subjects Research HSR – Basic module
    - Student co-PI –Responsibility C RCR
    - Outside entity HSR – Basic module if not approved by an outside IRB

APPLICATION FORMS

The Cecil College IRB reviews all requests to conduct research involving human subjects.

Prior to submitting, investigators should:

- Consult the checklist for submission to make sure that they are filling out the correct application form. Please see this link: LINK TO "STEPS TO DETERMINE WHAT FORM TO SUBMIT"
- 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.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed application, which includes this application form, your proposal, and any relevant attachments. Documents that will be presented to subjects should be in their final form. (i.e., as subjects will see them). Incomplete applications will be returned without review.

No data collection may take place before the researcher receives written notice of the project approval from the IRB.

Cecil College: IRB Exempt Application Form

Part I: Contact Information

Cecil IRB Project #(To be Assigned, leave Blank): ASSIGNED BY IRB	
Date of submission: Click or tap here to enter text.	
Principal Investigator Name (This must be full time faculty/approved staff): Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Department/Division: Click or tap here to enter text.	
If this submission involves a student or outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Click or tap here to enter text. Co-I Email: Click or tap here to enter text. Co-I Phone: Click or tap here to enter text. Co-I Affiliation (Cecil College, Other Institution, Outside Entity): Click or tap here to enter text.	
Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study? Yes or No If you answered "yes" Please explain: Click or tap here to enter text.	

Part II: Project Information

Project Title: Click or tap here to enter text.
If this is a class project, provide Course Name/Section: Click or tap here to enter text.
Where will data be collected (specify on or off campus, location, agency/organization): Click or tap here to enter text.

Part III: Purpose and Procedures

Please attach a copy of the research proposal (when available) or describe the general purpose of the research below. Click or tap here to enter text.
Describe, in order, what researcher(s) and the subjects will do during data collection (e.g., when and how are instructions given, will subjects be participating alone or in groups, etc.): Click or tap here to enter text.

Part IV: Project Information Checklist

This form may only be submitted when the following criteria are met. Please check all boxes to confirm that this is an Exempt submission.

If all of these criteria are not met, then the *Expedited or Full* form must be filed instead. Link to EXPEDITED AND FULL IRB FORM

Research involves:

☐ Questions or procedures that do not put the subject at risk for criminal or civil liability, such as illicit drug use, underage drinking, or criminal behavior, etc.

☐ Questions or procedures that could not cause the subject distress (i.e., asking questions about past sexual abuse/assault, prior traumatic experiences, etc.).

☐ Questions or procedures that do not involve the collection of sensitive medical or mental health information (i.e., asking questions about history of STDs, HIV, abortions, schizophrenia, mental health disorders etc.).

☐ Questions or procedures that do not collect reportable information (i.e., child abuse or neglect, elder abuse or neglect, incest, suicidal or homicidal thoughts or behaviors, sexual experiences with a faculty member).

☐ Questions or procedures that do not collect information that could damage the subjects financial standing, employability, educational advancement, or reputation.

☐ Questions or procedures that do not use deception.

☐ Procedures that do not include a behavioral intervention.

☐ Procedures that do not require collection of data from voice, video, digital, or image recordings (this excludes recordings of public observation).

☐ Procedures that do not require collection of data with individual identifiers (i.e., subject name, subject id. (includes using retrospective data that does not have identifiers)

☐ Procedures that do not require collection of data from minors.

Before Submitting please consult the checklist below to make sure the application is completed:

☐ A complete application form.

☐ A copy of your research proposal (if applicable)

☐ A copy of up-to-date (within past 5 years) certificate of completion for CITI Training for the PI and any Co-Is.

- ☐ PI and outside entity personnel that are co-PIs must complete the Human Subjects Research (https://about.citiprogram.org/en/series/human-subjects-research-hsr/).
  Depending on the nature of the research the PIs must complete either the Biomedical Basic course or the Social-Behavioral-Educational Basic course.
- ☐ Students must complete the Responsible Conduct of Research (RCR) Basic protocol (https://about.citiprogram.org/en/series/responsible-conduct-of-research-rcr/)

The application should be submitted to IRB committee by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

Cecil College: IRB Expedited Application Form

The Cecil College IRB reviews all requests to conduct research involving human subjects.

Prior to submitting, investigators should:
Consult the checklist for submission to make sure that they are filling out the correct application form. Please see this link: LINK TO "STEPS TO DETERMINE WHAT FORM TO SUBMIT"
Understand that individuals reviewing this form may or may not be familiar with the field of study involved.
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.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed application, which includes this application form, your proposal, and any relevant attachments. Documents that will be presented to subjects should be in their final form. (i.e., as subjects will see them). Incomplete applications will be returned without review.

No data collection may take place before the researcher receives written notice of the project approval from the IRB.

Part I: Contact Information

Cecil IRB Project #(To be Assigned, leave Blank): ASSIGNED BY IRB	
Date of submission: Click or tap here to enter text.	
Principal Investigator Name (This must be full time faculty/approved staff): Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Department/Division: Click or tap here to enter text.	
If this submission involves a student or outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Click or tap here to enter text. Co-I Email: Click or tap here to enter text. Co-I Phone: Click or tap here to enter text. Co-I Affiliation (Cecil College, Other Institution, Outside Entity): Click or tap here to enter text.	
Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study? Yes or No If you answered "yes" Please explain: Click or tap here to enter text.	

Part II: Project Information

Project Title: Click or tap here to enter text.
If this is a class project, provide Course Name/Section: Click or tap here to enter text.
Where will data be collected (specify on or off campus, location, agency/organization): Click or tap here to enter text.

Part III: Purpose and Procedures

Please attach a copy of the research proposal (when available) or describe the general purpose of the research below. Click or tap here to enter text.
Describe, in order, what researcher(s) and the subjects will do during data collection (e.g., when and how are instructions given, will subjects be participating alone or in groups, etc.): Click or tap here to enter text.
Describe in detail how researcher(s) will store the data and any identifiable information: Click or tap here to enter text.

Part IV: Project Information Checklist

This form may only be submitted when the following criteria are met. Please check all boxes to confirm that this is an Expedited submission.

If all of these criteria are not met, then the Full *form must be filed instead.* *Link to FULL IRB FORM*

Research involves:

☐ Use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviors.

AND

☐ Information is not recorded in such a manner that human subjects can be identified directly, or through identifiers linked to the subjects. (The IRB recommends this option unless identifying information is needed in order to address the research question.)

OR

☐ If such identification is possible, then disclosure of subjects' responses outside the research will not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Procedures. Research does not ask or involve:

☐ Deception of subjects

☐ Sexually explicit materials or questions

☐ Questions about drug and/or alcohol use

☐ Questions about sexual orientation, sexual experience, or sexual abuse

☐ Questions about subject's criminal activity

☐ Change subject's emotional state

Subjects. Research does not:

☐ Systematically exclude any group, particularly those of minority status

☐ Includes subjects younger than age of 18 and/or older than age 65

☐ Targets subjects that are physically, emotionally, or cognitively challenged individuals

☐ Targets subjects that are economically or educationally disadvantaged individuals

☐ Targets subjects that are pregnant females

☐ Targets subjects that are victims or residents in prisons, nursing homes, or halfway houses

Informed Consent. Subjects:

☐ Are informed that the researcher(s) will preserve their anonymity (Anonymity is maintained when it is impossible for any person to connect the data provided by the research subject to said subject). When anonymity is not possible, subjects are informed that researcher(s) will maintain strict standards of confidentiality.

☐ Are told that they are participating in research

☐ Are given an explanation of the general purposes of the research and told that they may receive a more thorough explanation once the project has been completed

☐ Are told how long their participation is expected to take

☐ Are provided a description of the procedures to be followed

☐ Receive contact information to allow them to seek answers to pertinent questions about the research and research subjects' rights. Contact information for the PI and IRB chair should be included.

☐ Are told that their participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

☐ Are told the approximate number of subjects involved in the study

☐ Are offered an explanation of the research project in more detail upon completion. Subjects should be told what the expected findings are and be allowed to ask questions about the research. To maintain the validity of the research, researcher(s) may ask subjects to please not discuss the details of the research with people who may participate in the future.

Before Submitting please consult the checklist below to make sure the application is completed:

☐ A complete application form.

☐ A copy of your research proposal (if applicable)

☐ A description or copy of all materials given or presented to subjects.

☐ A copy of any instructions to subjects. Indicate whether they will be given orally or in writing.

☐ A copy of the informed consent form and/or other procedures used to assure informed consent. If standard informed consent procedures are not followed, explain why.

☐ A copy of up-to-date (within past 5 years) certificate of completion for CITI Training for the PI and any Co-Is.

☐ PI and outside entity personnel that are co-PIs must complete the Human Subjects Research (https://about.citiprogram.org/en/series/human-subjects-research-hsr/). **Depending on the nature of the research the PIs must complete either the Biomedical Basic course or the Social-Behavioral-Educational Basic course.**

☐ Students must complete the Responsible Conduct of Research (RCR) Basic protocol (https://about.citiprogram.org/en/series/responsible-conduct-of-research-rcr/)

The application should be submitted to IRB committee by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I

certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

Cecil College: IRB Full Application Form

The Cecil College IRB reviews all requests to conduct research involving human subjects.

Prior to submitting, investigators should:

- Consult the checklist for submission to make sure that they are filling out the correct application form. Please see this link: XXX
- 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.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed application, which includes this application form, your proposal, and any relevant attachments. Documents that will be presented to subjects should be in their final form. (i.e., as subjects will see them). Incomplete applications will be returned without review.

No data collection may take place before the researcher receives written notice of the project approval from the IRB.

Part I: Contact Information

Cecil IRB Project #(To be Assigned, leave Blank): Click or tap here to enter text.	
Date of submission: Click or tap here to enter text.	
Principal Investigator Name(This must be full time faculty/staff): Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Department/Division: Click or tap here to enter text.	
If this submission involves a student or outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Click or tap here to enter text. Co-I Email: Click or tap here to enter text. Co-I Phone: Click or tap here to enter text. Co-I Affiliation (Cecil College, Other Institution, Outside Entity): Click or tap here to enter text.	
Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study? Yes or No If you answered "yes" Please explain: Click or tap here to enter text.	

Project Title: Click or tap here to enter text.
If this is a class project, provide Course Name/Section: Click or tap here to enter text.
Where will data be collected (specify on or off campus, location, agency/organization): Click or tap here to enter text.

Part II: Project Information

Part III: Subjects

Who will be the subjects? Click or tap here to enter text.
How will the subjects be recruited? Click or tap here to enter text.
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: Click or tap here to enter text.

Part IV: Purpose and Procedures

Please attach a copy of the research proposal (when available) or describe the general purpose of the research below. Click or tap here to enter text.
Describe, in order, what researcher(s) and the subjects will do during data collection (e.g., when and how are instructions given, will subjects be participating alone or in groups, etc.): Click or tap here to enter text.
Describe in detail how researcher(s) will store the data and any identifiable information: Click or tap here to enter text.

Part V: Project Information

Yes	No	
☐	☐	Will research be conducted in established or commonly accepted educational settings involving normal educational practices such as research on regular and special instructional strategies, or research on the effectiveness or the comparison of instructional techniques, curricula, or classroom management methods?
☐	☐	Will research involve use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviors?
☐	☐	Will information be recorded in such a manner that subjects can be identified directly, or through identifiers linked to the subjects (e.g. will there be a list of subject names with subject numbers)?

If 'yes', could disclosure of the subjects' responses outside the research reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

☐ ☐ Will research involve collecting or studying of existing data, documents, records, pathological specimens, or diagnostic specimens that are publicly available?

☐ ☐ Will research involve conducting a taste or food quality evaluation or consumer acceptance study with materials previously deemed safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety Inspection Service of the U.S. Department of Agriculture?

If the response to any of the following is "yes," provide an explanation at the end of the section.

Yes No Does the research involve:

☐ ☐ Deception of subjects
☐ ☐ Shock or other forms of punishment
☐ ☐ Sexually explicit materials or questions
☐ ☐ Handling of money or other valuable commodities
☐ ☐ Extraction of blood or other bodily fluids
☐ ☐ Questions about drug and/or alcohol use
☐ ☐ Questions about sexual orientation, sexual experience, or sexual abuse
☐ ☐ Purposeful creation of anxiety
☐ ☐ Any procedure that might be viewed as an invasion of privacy
☐ ☐ Physical exercise or stress
☐ ☐ Administration of substances (food, drugs, etc.) to subjects
☐ ☐ Any procedure that might place subjects at risk (e.g., disclosure of criminal activity). Specify here:
☐ ☐ Systematic exclusion of any group, particularly those of minority status. Explain rationale for exclusion

Explanation to any items checked "Yes": Click or tap here to enter text.

Subject Information: If the response to any of the following is "yes," provide an explanation at the end of the section.

Yes No Does the research target subjects from any of the following categories?

☐ ☐ Under 18 years of age
☐ ☐ Over 65 years of age
☐ ☐ Physically, emotionally, or cognitively challenged

☐	☐	Economically or educationally disadvantaged
☐	☐	Pregnant females
☐	☐	Victims of sexual or physical assault
☐	☐	Individuals in institutions (e.g., prisons, nursing homes, halfway houses)

Explanation to any items checked "Yes": Click or tap here to enter text.

Risks and Benefits: If the response to any of the following is "yes," provide an explanation at the end of the section. (Note: the IRB retains final authority for determining risk status of a project)

Yes	No	Answer the following questions about the research.
☐	☐	In your opinion, does the research involve more than minimal risk to subjects? "Minimal risk" (need to hyperlink to https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102) means that "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." If the answer is "yes," explain on continuation pages and attach an explanation of the benefits of the research to the subjects and to the discipline or profession.
☐	☐	Are any emergencies or adverse reactions (physical, psychological, social, legal, or emotional) probable as a result of the research? (If "yes," then explain how they will be handled.)
☐	☐	Do subjects leave the study or experiment in approximately the same emotional state as they began? (If "no," then explain how distress will be handled)

Explanation to any items above: Click or tap here to enter text.

Part VI: 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

Explanation if "No": Click or tap here to enter text.

☐ ☐ Will a written informed consent form be used? (If "yes," include a copy. If "no," explain why and describe how consent will be obtained.)

Yes No

☐ ☐ 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.)

Explanation if "No": Click or tap here to enter text.

Yes No

☐ ☐ Will subjects be debriefed in regard to the purposes, consequences, and benefits of the research? (If "no," explain why.)

Explanation if "No": Click or tap here to enter text.

Yes No

☐ ☐ 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.)

Explanation if "Yes": Click or tap here to enter text.

Yes No

☐ ☐ Will researcher(s) seek consent from all relevant parties? (e.g. subjects, parents, site supervisors)

☐ ☐ Have researcher(s) deleted the general instructions box that was included in the template from the top of the informed consent sheet?

Before Submitting please consult the checklist below to make sure your application is completed:

☐ A complete application form.

☐ A copy of the research proposal (if applicable)

☐ A description or copy of all materials given or presented to subjects.

☐ A copy of any instructions to subject, indicating if instructions will be given orally or in writing.

☐ A copy of the informed consent form and/or other procedures used to assure informed consent. If standard informed consent procedures are not followed, explain why.

☐ A copy of the debriefing statement. Indicate whether it will be given orally or in writing. If subjects are not debriefed, explain why.

☐ A copy of up-to-date (within past 5 years) certificate of completion for CITI Training for the PI and any Co-Is.

- ☐ PI and outside entity personnel that are co-PIs must complete the Human Subjects Research (https://about.citiprogram.org/en/series/human-subjects-research-hsr/).
  - **Depending on the nature of the research the PIs must complete either the Biomedical Basic course or the Social-Behavioral-Educational Basic course.**
- ☐ Students must complete the Responsible Conduct of Research (RCR) Basic protocol (https://about.citiprogram.org/en/series/responsible-conduct-of-research-rcr/)

The application should be submitted to IRB committee by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

Cecil College: Outside IRB APPROVAL Application Form

The Cecil College IRB reviews all requests to conduct research involving human subjects, but understands that some research projects have already been approved by outside IRBs at other institutions.

Prior to submitting, investigators should:

- Consult the checklist for submission to make sure that they are filling out the correct application form. Please see this link: LINK TO FORM TO USE
- 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.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed application, which includes this application form, your proposal, and any relevant attachments. Documents that will be presented to subjects should be in their final form. (i.e., as subjects will see them). Incomplete applications will be returned without review.

No data collection may take place before the researcher receives written notice of the project approval from the IRB.

Part I: Contact Information

Cecil IRB Project #(To be Assigned, leave Blank): ASSIGNED BY IRB	
Date of submission: Click or tap here to enter text.	
Principal Investigator Name (This must be full time faculty/approved staff): Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Department/Division: Click or tap here to enter text.	
If this submission involves a student or outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Click or tap here to enter text. Co-I Email: Click or tap here to enter text. Co-I Phone: Click or tap here to enter text. Co-I Affiliation (Cecil College, Other Institution, Outside Entity): Click or tap here to enter text.	
Do you [the PI] or any other responsible personnel (or the spouse, registered domestic partner and/or dependent children thereof) have financial interests related to this study? Yes or No If you answered "yes" Please explain: Click or tap here to enter text.	

Part II: Project Information

Please attach the following:

☐ A complete application form.

☐ A copy of the outside institution's IRB approval letter.

☐ A copy of the application form sent to the outside IRB, including approved consent forms.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

ADDITIONAL FORMS

The Cecil College IRB reviews all changes.

Principal investigators should notify the IRB of changes to the research project.

Minor changes:

- Do not alter the risk-benefit assessment of the research
    - Examples include but are not limited to: changes in PI or an additional location for subject participation; grammatical changes in the language of the consent form or measures used; length of participation or recruitment

Major changes:

- Engage subjects in activities not previously approved
- Increase risk to the physical, emotional, or psychological well-being of the subjects
- Decrease benefit of the subject
    - Examples include but are not limited to: additions of a new measure that is significantly different from the others previously approved, changes in the informed consent process, changes in procedures that alter subject confidentiality

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) with all relevant attachments.

No changes in the research protocol may take place until the PI has received documentation of IRB approval for the changes

Cecil College Change Form

Part I: Contact Information

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

Part II: Change information

Which category of change best describes the alterations to the protocol: ☐ Minor ☐ Major ☐ Unsure
Describe the requested changes: Click or tap here to enter text.
Describe the rationale for the requested changes: Click or tap here to enter text.
Do these changes impact the risk-benefit ratio of participating in the study? ☐ Yes ☐ No ☐ Unsure

Before submitting please consult the checklist below to make sure your submission is completed:

☐ The change form is complete.

☐ For changes to currently approved procedures or to add new procedures, resubmit the protocol application incorporating the revisions throughout. PIs may also modify consent/assent forms, recruitment materials, measures, etc. Ensure that all new and revised documents are attached with this amendment.

☐ All changes should be highlighted in the appropriate documents.

The completed forms and other documentation should be submitted to IRB committee by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. The signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

Cecil College: IRB Annual Review Form

The Cecil College IRB reviews all IRB approved projects 45 days prior to the annual expiration date.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed Annual Review form, the progress report, and a current version of the consent form. Incomplete applications will be returned without review.

No data collection may take place after 1 year from the last IRB approved date without further approval via the annual review process.

Part I: Contact Information

Cecil IRB Project #: Click or tap here to enter text.	
Project Title: Click or tap here to enter text.	
Principal Investigator Name: Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Last IRB Approval Date: Click or tap here to enter text.	

Part II: Progress Report

A progress report including how much progress has been made in the research, the projected timetable for completion of the research, and documentation of subject enrollment/withdrawal must be submitted with this form. Researchers should specifically note the number of subjects enrolled during the previous year and the number accrued since the project began. Principal Investigators are required to assure the confidentiality of all data and any breach of confidentiality must be reported to the IRB.

Yes	No	
☐	☐	Does the evidence from your experience to date or from recent literature indicate the existence of risks different from those previously described?
☐	☐	Has the study has been active for three years?
☐	☐	Has there been any withdrawal of subjects from the research?
☐	☐	Have there been any complaints about the research?

If any of the above questions are answered "yes", please explain:

Part III: Project Status (Check all items that apply):

Yes	No	
☐	☐	Project remains active and contact with human subjects is ongoing.
☐	☐	Subject interviews are still required.
☐	☐	Data are still being collected from records or other sources.

☐ ☐ Data are still being analyzed.

☐ ☐ Original procedures for protecting human subjects are still in effect.

If the answer to all above questions is "no" and no further contact with human subjects or records is required, the study can be closed. Researchers should complete the IRB closure form. LINK TO IRB CLOSURE FORM

Before submitting, please consult the checklist below to make sure your complete application contains:

☐ A complete annual review form;

☐ A copy of the research progress report;

☐ A copy of any instructions to subject, indicating if instructions will be given orally or in writing if changed from the original application form;

☐ A copy of the informed consent form and/or other procedures used to assure informed consent, if changed from the original application form; and,

☐ A copy of up-to-date (within past 5 years) certificate of completion for CITI training for the PI and any Co-Is, if training expired during past year.

PI and outside entity personnel that are co-PIs must complete the Human Subjects Research (https://about.citiprogram.org/en/series/human-subjects-research-hsr/). **Depending on the nature of the research the PIs must complete either the Biomedical Basic course or the Social-Behavioral-Educational Basic course.**

Students must complete the Responsible Conduct of Research (RCR) Basic protocol (https://about.citiprogram.org/en/series/responsible-conduct-of-research-rcr/)

The annual renewal form should be submitted to IRB committee by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

The Cecil College IRB reviews all adverse events during research involving human subjects.

Principal investigators should be monitoring any potential adverse events that occur as a result of their research. If an adverse event occurs (either Category A or B), this form must be submitted to the IRB. The IRB requires that the event be reported even if it does not seem to be connected to the research project. IRB office should be notified within 24 hours from when the PI is aware of the adverse event by submitting this form to irb@cecil.edu.

Category A: Serious Adverse Event

- A serious adverse event occurs within 48 hours of participation in research, and
- incorporates a serious adverse event (death, a life-threatening experience, hospitalization, or extended hospitalization, persistent or significant disability or capacity, congenital anomaly or birth defect).

Category B: All three of the following statements are true

- Event has caused harm to the subject, has impacted the subject detrimentally, has worsened the result of their participation, or has resulted in increased risk to the subjects or others (even if the risk has not resulted in harm).
  Examples: Misplacing a subject's record, mild distress after completing the research, etc.
- Event or outcomes were not described or disclosed as a risk for participation in the research, or they have occurred with increased frequency after completing the research.
- Event or outcomes were possibly, probably or definitely linked to the research.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) within 24 hours of the research team's awareness of the event.

No data collection may take place until the adverse event form is reviewed by the IRB and the PI has received documentation of how to proceed.

Cecil College: IRB Adverse Event Form

Part I: Contact Information

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

Part II: Adverse Event Timing, Location, and Type

Date of event: Click or tap here to enter text.
Date when research team or PI was notified/aware of event: Click or tap here to enter text.
Location research participation occurred: Click or tap here to enter text.
Location adverse event occurred: Click or tap here to enter text.
Person(s) present during adverse event or when adverse event was discovered: Click or tap here to enter text.
Type of adverse event: ☐ Category A—Serious Adverse Event ☐ Category B—Other Unanticipated Event Adversely Affecting Subject or Others

Part III: Subjects

Subject ID of the individual who experienced the adverse event: Click or tap here to enter text.
Subject's age: Click or tap here to enter text.

Subject's gender: Click or tap here to enter text.
Any pre-existing conditions of the subject: Click or tap here to enter text.

Part IV: Adverse Event

This event (check all that apply):

- ☐ caused psychological harm or injury.
- ☐ caused physical harm or injury.
- ☐ caused congenital anomaly/birth defect.
- ☐ caused social harm or injury.
- ☐ caused economic harm.
- ☐ caused a breach of confidentiality.
- ☐ increased risk of psychological, social, or economic harm or injury.
- ☐ increased risk of breach of confidentiality.
- ☐ was a life threatening experience.
- ☐ required emergency treatment.
- ☐ required transport to hospital.
- ☐ required hospitalization.
- ☐ prolonged a current hospital stay.
- ☐ death occurred due to an underlying or progressive disease, not related to research.
- ☐ death occurred related to research.
- ☐ was related to this study drug and/or biologic: Click or tap here to enter text.
- ☐ was related to this study device: Click or tap here to enter text.
- ☐ Other: Click or tap here to enter text.

Provide a description of the event here: Click or tap here to enter text.
Subject's participation level: ☐ stopped research participation. ☐ withdrew from further participation. ☐ withdrawn by principal investigator from further participation. ☐ was completed. ☐ is actively continuing. ☐ is continuing with follow-up only. ☐ Other: Click or tap here to enter text.
Describe any steps taken by the research team in response to the event in an attempt to resolve the issue: Click or tap here to enter text.

Has any previous research produced this type of event? ☐ Yes ☐ No ☐ Unsure

If yes, describe previous research results: Click or tap here to enter text.

In the PI's judgement, the event is:
☐ expected
☐ unexpected

In the PI's judgement, the event is:
☐ serious
☐ not serious

In the PI's judgment, was there a relationship between the event and the research?
☐ Definitely: clearly related to the research
☐ Probably: likely related to the research
☐ Possibly: may be related to the research but not enough information is available to assess this
☐ Probably not: doubtfully related to the research
☐ Definitely not: clearly not related to the research

Was the event related to the risks as presented in the research proposal and/or consent documents?
☐ Yes
☐ No

If yes, include a copy of the proposal and consent document with relevant sections highlighted.

Does the PI feel that the research project or consent form need revision?
☐ Yes
☐ No

If yes, please include all revised materials with the appropriate LINK to IRB Change Form .

Does the PI feel that other research subjects should be notified?
☐ New subjects
☐ Currently enrolled subjects
☐ Subjects that have completed the research
☐ None

If any of the above (other than "none") are marked, the PI must submit a Change form (LINK) with revised consent forms attached.

Does the PI feel that research should:
☐ Continue as planned with no changes to the research project or consent process.
☐ Continue with changes to the research project or consent process, as previously noted on this form.
☐ Suspend new subject enrollment until the event is assessed further.
☐ Be terminated (stopped completely), with all subjects removed from research.

Have any of the following organizations or regulatory bodies been notified of the event: Check all that apply
☐ Research sponsor/coordinating site/other IRB
☐ Other (like funding source)

Part V: Adverse Event in Relation to Research

Before Submitting please consult the checklist below to make sure your form is completed:

☐ A complete form.

☐ A copy any revisions of the project or consent forms (if applicable)

The form should be submitted to IRB committee within 5 days of notification of the event by sending all forms to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I agree to conduct this research project in accordance with rules and regulations established by the Institutional Review Board. No changes in my research project will be implemented without the prior review and approval of the Institutional Review Board. I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature: _____
Date_____

Co-I Signature: _____
Date_____

Co-I Signature: _____
Date_____

Cecil College: IRB Project Closure Form

A final report summarizing the research findings will need to be submitted along with this form. The report should include final subject enrollment and withdrawal numbers, changes to the research proposal, and adverse events that occurred over the course of the study.

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) of your complete, typed closure form, along with a project summary when an approved human subjects research project has concluded or been cancelled.

Part I: Contact Information

Cecil IRB Project #: Click or tap here to enter text.	
Principal Investigator: Click or tap here to enter text.	
Project Title: Click or tap here to enter text.	
Email: Click or tap here to enter text.	Phone: Click or tap here to enter text.
Co-I Name: Click or tap here to enter text. Co-I Email: Click or tap here to enter text. Co-I Phone: Click or tap here to enter text. Co-I Affiliation (Cecil College, Other Institution, Outside Entity): Click or tap here to enter text.	
Original IRB Approval Date: Click or tap here to enter	

Part II: Research Summary

Reasons for project closure:

☐ No further contact with human subjects or records is required. No follow-up planned with subjects and data no longer contain subject identifiers.
☐ Project is no longer funded.
☐ Principal investigator is no longer at Cecil College.
☐ Original data and/or research materials have been destroyed.
☐ Other. Please explain: Click or tap here to enter text.

Before submitting, please consult the checklist below to make sure your completed application contains:

☐ a complete closure form, and
☐ a copy of the research summary.

The closure form should be submitted to IRB committee by sending all materials to irb@cecil.edu in PDF format.

Assurance by Principal Investigator:
I certify that the information provided is complete and accurate to the best of my knowledge. Signatures below are originals.

PI Signature:

_____

Date_____

Co-I Signature:

_____

Date_____

Co-I Signature:

_____

Date_____

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

General instructions: This template is for research with adult participants. Please note that there are specific items that need to be removed or added based on the type of research (survey versus oral history). Replace bracketed text with information specific to your project. You may modify the sample text to fit your project. Participants should be given 2 copies of the Informed Consent document, one to complete and return to you and one to keep for their own records. Please remember to use lay language (6th to 8th grade reading level throughout the document).

Informed Consent Document for *[Title of Project]*

Researchers: *[Names of PI and any Co-Is; Contact information of PI including email and phone number should be provided]*

Affiliation: Cecil College *[and/or other affiliation if appropriate]*

You are being asked to participate in a research study of *[insert general statement about the purpose of the project]* at Cecil College. We are asking you to take part because *[insert reasoning as to why subjects were chosen]*. Please read this form and ask any questions you may have before agreeing to participate in the study.

What the study is about:
The purpose of the research project is to *[insert explanation of the research question and purpose]*. Approximately *[fill in approximate number of subjects needed]* people from *[insert list of all locations]* will be participating in this project.

What we will ask you to do:
During the course of this research project, you will be asked to *[detail what the subject will be asked to do as a part of the project e.g., complete a survey, participate in an interview. If, the project includes a survey describe what kinds of questions participants will be asked. Describe what else they will be asked to do e.g. return the survey in the provided envelope. Include the duration of the study, specifically noting the duration of the participants involvement. If this is an oral history project indicate the length of time in hours/minutes that the participation will be interviewed.]*

Risks and benefits of being in the study:
[If there are potential benefits to the subject, e.g. extra credit, describe them and delete the following sentence]. There may be no direct benefits for you; however, information from this research project may benefit other people now or in the future by *[explain the potential benefits to others]*.

By taking part in this study, you may experience the following risks *[describe any potential risks, including changes in emotional state, or indicate that the researchers foresee no potential risks to participation.]* There may also be risks involved in taking part in this study that are not known to researchers at this time.

If this is an intervention based study that has alternative courses of action include the following statement. At the current time alternative procedures or courses of treatment,

including *[insert options here]*, may be proposed. *If there are no alternatives include the statement.* At the current time there are no alternative procedures or courses of treatment. *[remove this paragraph if this is not an intervention based study].*

Compensation:
[Describe any costs that will be incurred by the subject or any compensation that will be given to the subject. Please note that extra credit is considered compensation. If no compensation is offered, include the statement "No monetary or other compensation is offered for your participation in the study."]

Your answers will be confidential:
Your answers will be confidential. The records of the study will be kept private. In any sort of report that is made public we will not include any information that will make it possible to identify you. Paper research records will be kept in a locked file on campus; electronic data will be stored on a password-protected secure server.

If you are conducting an oral history project, please use the following two (2) paragraphs [*if not delete this section*].

The interview will be recorded and you may be identified by your name, subject to your consent. You also may be identified by name in any transcript (whether verbatim or edited) of the interview, subject to your consent. Please indicated your choices below:

_____ I may be identified by name in any transcript or reference to any information contained in this interview.

_____ I wish to remain anonymous in any transcript or reference to any information contained in this interview. I recognize that the interviewer and the transcriber will have knowledge of my identity, but they will maintain the confidentiality of that information.

Recordings and transcripts of the interview will be used for this project as described above. You have the right to review the recording and/or transcript of the interview and impose any restrictions as to use of portions of the recording. Those portions will be edited out of the final copy of the transcript. Recordings will be stored in a locked file for [*indicate how long records will be kept*]. Personally identifying information will not be shared with third parties.

If a professor is awarding extra credit, the [*insert primary investigator's name*] will be providing that professor with a list of the students in the class who participated *[delete this sentence if it is not accurate].* In addition to the researchers, the Cecil College Institutional Review Board, or federal agencies with appropriate regulatory oversight, may review your records and they may be released in response to an order from a court of law.

Taking part is voluntary:
Taking part in this study is completely voluntary. You may skip any questions you do not want to answer. If you decide to not take part, end your involvement in the study or

skip some of the questions, it will not affect your current or future relationship with Cecil College or your professor. If you decide to take part, you can withdraw at any time. If this is an oral history project insert this statement [*If you choose to withdraw at any time, recordings made of the interview will be either given to you or destroyed. No transcript will be made of the interview*].

If you have any questions:
If you have any questions now or in the future, you may contact *[insert name of principal investigator]* at *[insert telephone number and email address]*. If you have questions or concerns about rights and treatment of research subjects you may contact the Chair of the Cecil College Institutional Review Board, *[name of current IRB Chair]*, at irb@cecil.edu.

Consent to Participate in *[title of study]:*
By signing below, I grant my consent to participate in the research project *[title of project]* being conducted by *[insert names of researchers]*. The procedures have been explained to me and my questions have been answered to my satisfaction. I understand that I may withdraw from this research project at any time without penalty or loss of benefits. A copy of this form was provided to me. I understand that this study will be [if applicable] recorded and consent to the use of the information and images created during this study as described above.

_____ _____
Signature of Subject/ Legally Authorized Representative Date

_____
Printed Name of Subject/ Authorized Representative

_____ _____
Signature of Witness (When applicable)** Date**

_____
Printed Name of Witness**

** Use when subject has had the consent form read to them (i.e., illiterate, legally blind, translated into foreign language).**

If you are under the age of 16 your parent or legal guardian must sign the consent form in order for you to participate in the research.