



Institutional Review Board Standard Operating Procedures

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Dr. Melanie Osterhouse, FY19-21 IRB Chair

**College of Southern Maryland
Institutional Review Board
Standard Operating Procedures**

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Special thanks to Sinclair College for permission to use their document as a model to create CSM’s IRB Charter in 2007. <https://www.sinclair.edu/about/offices/grants-development/compliance/>

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INTRODUCTION

The College of Southern Maryland encourages and supports the scholarly endeavors of students, faculty, staff of the College, and community members. Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. The College of Southern Maryland's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the College of Southern Maryland Institutional Review Board.

Some research projects involving human subjects are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices such as work undertaken as a part of a course; educational tests when the subjects are not identified; and course evaluations.

The Institutional Review Board (IRB) for Human Subjects Research at the College of Southern Maryland has responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The role of the IRB is to review proposed research projects that involve the use of human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study; and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using human subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. IRB approval does not encumber any CSM member to help with the research, such as in subject recruitment, data collection, etc. *Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.*

I. INSTITUTIONAL AUTHORITY.

This Standard Operating Procedures establishes and empowers the College of Southern Maryland (CSM) human subject's protection committee. Currently CSM has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board. This committee is hereinafter referred to as "the IRB."

II. PURPOSE.

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

III. BASIC PRINCIPLES.

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained 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 <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>]

B. Therefore, the following principles apply to all research, including student projects, involving human subjects at the College of Southern Maryland to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified. Such representation breakdown can be found in the U.S. Census data for the region or at the Maryland Department of Planning website [see <https://www.census.gov/> or <https://planning.maryland.gov/MSDC/Pages/census/censusdata.aspx>].
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7. All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review *prior* to their initiation or *prior* to initiating any changes to the protocol. Continuing research programs must submit the CSM Continuing Review Questionnaire to the IRB Chair 365 days from approval and every 365 days thereafter for the duration of the research.

IV. THE AUTHORITY OF THE IRB.

A. College of Southern Maryland holds a Federalwide Assurance (FWA) through the Office for Human Research Protection (OHRP). As part of this Assurance, CSM agrees to consider *all* research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which CSM has an “IRB Authorization Agreement” as specified in CSM’s FWA), or
2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which CSM has an “IRB Authorization Agreement” as specified in CSM’s FWA), or
3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4. The research involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require Institutional Review Board (IRB) approval. If an instructor has any doubt concerning the classification of these activities, they are encouraged to complete an Exempt Protocol Summary Form for approval and submit it along with the protocol 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.

B. The IRB reviews all projects and programs involving human subjects in accordance with this Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.

D. The IRB has approval authority of human subject protocols, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the AVP of PIER. However, the AVP of PIER may not approve the non-exempt research if it has not been approved by the IRB.

E. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.

F. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

G. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.

H. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

I. IRB decisions about research are final. The IRB is autonomous.

V. THE IRB'S FUNCTIONAL RELATIONSHIPS.

A. The IRB functions administratively through the Chair of the IRB. This structure provides for administrative coordination for the IRB with the various academic and administrative units at CSM.

B. The IRB advises and makes recommendations to the President, to policy and administrative bodies, and to any member of the CSM community on all matters, including, but not limited to, processes and procedures, related to the use of human subjects in research.

VI. THE MEMBERSHIP OF THE IRB.

A. The IRB is composed of at least five voting members. Decisions by the IRB are made by a majority vote of the voting members in attendance at the meeting and five members must be present for a vote to ensue.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of CSM regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB may not consist of members of only one gender, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with the College of Southern Maryland. The full complement of members to the IRB would include two members from the social sciences, two members from the health sciences, two members from the natural sciences, two members from nonscientific areas, two members not affiliated with the College of Southern Maryland, one staff member from the Planning, Institutional Effectiveness, and Research Department (PIER), and the Associate Vice-President of PIER (the only permanent and non-voting member of the IRB).

D. The AVP of PIER will be responsible for electronically housing all historical information, such as IRB meeting minutes, correspondence letters with Principal Investigators, copies of the proposals, etc. All such records and minutes shall be retained for at least three years after completion of the research, and the records shall be accessible for inspection and copying by authorized persons, including representatives of the Department of Health and Human Services, at a reasonable time, place and manner.

E. No person shall be excluded from serving on the IRB based on sex, race, color, or national origin.

VII. MANAGEMENT OF THE IRB.

A. The IRB Chair has authority to sign all IRB action items and is appointed by majority vote of the IRB membership. The duties of the Chair are to: Nominate new members to serve on the IRB to be approved by the majority of the IRB membership; Serve as the liaison to internal and external stakeholders; Establish meeting agendas; Maintain meeting minutes or documentation; Communicate with applicants and IRB members; Ensure that IRB member expectations are followed; Ensure that procedures are followed; Seek assistance for research projects on vulnerable populations from expert staff; and Review IRB procedures annually and update as necessary.

B. Members, including the IRB Chair, serve a three-year term and may opt to serve an additional three-years for a maximum of six consecutive years of service. An IRB member may return to serve after a three-year absence.

C. Members are appointed by the Division Chairs or an IRB member and must be approved unanimously by the IRB membership. However, the term of appointment may be terminated by notice of any Committee member to the Chair or by notice from the Chair. If a member finds oneself unable to attend meetings for an extended period, 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 incapability to serve the committee adequately. Members will rotate out of committee service so that no more than half of the membership exits in a given year. Member duties include the following: Attend all scheduled meetings or participate in the research approval process; Maintain the confidentiality of all proceedings; Keep abreast of trends in research in higher education; Complete periodic training as determined by the IRB; Disclose potential conflicts of interest and recuse themselves when appropriate; Maintain extensive knowledge of FERPA (Family Educational Rights Privacy Act of 1974); and Review applications.

D. All IRB members are required to undergo formal training at the time of their initial appointment. Training that satisfies this requirement is the on-line tutorial entitled Protecting Human Research Participants Online Training. The IRB Chair will maintain a log of training completion dates. IRB members must complete the Training Verification Form once every three years. This training is paid for by the institution.

E. IRB members do not receive compensation for their service.

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

G. Consultants with competence in special areas may be used when deemed appropriate.

H. Conflict of interest policy and procedure

1. Principle investigators (PI) shall not be involved in the selection of IRB members.

2. Investigators will be asked in CSM's Conflict of Interest form and The Report Form for Financial Disclosure whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

3. Investigators and IRB members who are CSM employees and who apply for federal grants and contracts are subject to the CSM Conflict of Interest, Proprietary Information, and Political Activity Policy, HR 4025 [see <https://www.csmd.edu/faculty-staff/administrative-manual/>]

4. Standard Operating Procedures will entail a verbal question by the IRB Chair at the beginning of each proposal consideration asking, "Does any IRB member have a conflict of interest that would require the member to recuse oneself from reviewing this proposal?"

5. Other conflict of interest guidelines specifically for IRB members are found in section XIII of the Standard Operating Procedures.

VIII. PROCEDURES OF THE IRB.

A. Initial Review.

1. No or Minimal Risk:

Under the auspices of the IRB, the IRB Chair will review Exempt Protocol Summary Forms eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise [see <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>]. Exempt types of research include:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as those that are part of the course and are not used outside of the class. Data collection conducted by an instructor, in a classroom setting, as part of a course curriculum does not need to be

presented to the IRB in any form. These activities include those designed for demonstration purposes as part of the educational experience for students. If the instructor plans to disseminate research, findings beyond the classroom, they should submit the appropriate proposal (EXEMPT, EXPEDITED, FULL). The IRB abides by the code of Federal Regulations which states:

46.104 Exempt Research d.12.i.ii.iii

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy: (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. [see https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104].

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study,

evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must Petition with an exemption request citing the specific exemption category and providing justification for the exemption.

Under federal regulations certain types of research qualify for an 'expedited' review [see <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>]. These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

(1) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight-week period and collection may not occur more frequently than two times per week.

(2) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(3) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(4) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

(5) Collection of data from voice, video, digital, or image recordings made for research purposes.

(6) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

(7) Continuing review of research previously approved by the convened IRB as follows:

- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- (b) where no subjects have been enrolled and no additional risks have been identified; or
- (c) where the remaining research activities are limited to data analysis.

(8) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit one original of the “Exempt Protocol Summary Form” or the “Expedited Review of Research Form” to the IRB Chair at least eight days prior to any proposal deadline in order to provide time for review and processing. Copies of the form are available via the CSM website: <https://www.csmd.edu/about/pier/institutional-review-board/> which has links to those categories of research that may qualify for exemption or expedited review.

The IRB Chair may recommend a protocol to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full board. The IRB Chair cannot “disapprove” of a protocol but may table action pending further information/clarifications. The IRB Chair will inform the PI of its actions. Any disagreement between the PI and the IRB Chair must be resolved by the IRB.

The PI will be notified of the IRB decision by the Chair.

If it is determined that one of these protocols require IRB review, it will be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the material from the PI, the IRB Chair will distribute copies to each IRB member.

2. More Than Minimal Risk

Protocols for full-board (IRB) review must be submitted three weeks prior to the proposal deadline. The prospective PI will submit to the IRB Chair one original and the required number of copies of the “Full IRB Review Protocol Summary Form.” Copies of the form are available via <https://www.csmd.edu/about/pier/institutional-review-board/>. In the petition, the investigator assures the IRB that they will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy.

The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

3. Actions of the IRB:

The IRB may take one of the following four actions in regard to the proposed protocol and consent form: *Approved, Approved with Contingency, Tabled, or Not Approved.*

Approved

When a protocol has been approved, the Chair completes a response letter, dates it, and distributes one copy of the letter to the principal investigator, and one copy to the AVP of PIER for archiving.

Approval of the protocol will be based on the following:

- a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.
- b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
- c. Assurances of acceptable debriefing, if appropriate.

It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if, in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time.

There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

- d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.
- e. Anticipated benefits, if any.
- f. The personal risk to the subject in relation to expected benefits.
- g. The adequacy of procedures for securing informed consent from the subject.

h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.

i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

Approved with Contingency

If the protocol is approved with contingency, the IRB Chair completes a response letter, dates it, and distributes one copy of the letter to the principal investigator, and one copy to the AVP of PIER for archiving stating that the protocol is approved with contingency. The PI then must respond to the restrictions as indicated by the IRB and submit the compliance changes in writing to the IRB Chair. Upon receipt and approval of the responses, the restrictions are removed and the protocol is then processed as an approved protocol and distributed as described above. The original response letter stating Approved with Contingency will have an addendum added to the end stating the date when the proposal has met the requirements to be Approved.

Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB and the additional information necessary for completion of the IRB review is requested.

Not Approved

If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit the protocol for one more review. If a proposal is Not Approved after the resubmission, the PI may not submit this research project again.

B. Continuing Review.

The IRB conducts continuing review of research once per year. PIs will be informed of the annual review by receipt of a Continuing Review Questionnaire. This Continuing Review Questionnaire is to be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.).

When a Continuing Review Request is submitted, the IRB Chair shall consider the following: changes to the research, protocol deviations and violations, since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project have been amended within the past year, the PI will be requested to submit a new protocol incorporating these amendments if such have not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

C. Procedures Pertaining to Both Initial and Continuing Review.

1. The IRB shall have authority to determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to subjects; (ii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
2. PIs shall be informed at the time of protocol approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects;
3. PIs shall be informed at the time of protocol approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.
4. Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the chair of the IRB so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

D. Adverse Event Reporting Guidance.

1. The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

IX. OPERATIONS OF THE IRB.

A. IRB meetings are scheduled monthly throughout the year.

B. The place and time of meeting, agenda, and study material to be reviewed are distributed by the IRB Chair to IRB members at least seven days prior to the meeting.

C. Voting requirements

1. Except when an expedited review procedure is used, five voting IRB members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas must be present to vote on the proposal. Presence is defined throughout this document as physical, via phone, Zoom or other technology but cannot be via proxy.

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. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. PIs, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).

4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, 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.

D. Appeals

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI to the Chair of the IRB, the IRB shall name an *ad hoc* committee of three or more CSM affiliated and non-IRB members to review the protocol a final time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established by this document and the OHRP herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

E. Proposal Amendments

1. Amendments are categorized into minor changes and significant changes and require the Continuing Review Request form submission.

Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Examples of minor changes to a research study include but are not limited to, the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to subjects;
- Addition of non-sensitive questions to unvalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of significant changes to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
- Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

2. Level of Review for Amendments

Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer the amendment to the full IRB.

Minor modifications/changes may be reviewed and approved using an “administrative approval” process. Administrative approval may be given by the IRB Chair. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

3. Sponsor Agency Modifications

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research protocol before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research protocol.

Sponsor agency generated modifications (or addenda) require review and approval by the IRB. The PI should provide all sponsor documentation and summarize how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of participants.

F. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested by the VP of DAA or legal counsel, the board will act in an advisory capacity.

G. Cooperative Activities

Cooperative activities relating to human subjects are those which involve College of Southern Maryland and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions have Federalwide Assurances (FWAs) approved by OHRP;
2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and
3. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

- I. A copy of the research final report should be sent to the IRB for archival purposes.

X. RECORD REQUIREMENTS.

A. The Chair of the IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
2. Detailed minutes of IRB meetings, showing:
 - a. Members present (any consultants/ guests/others shown separately).
 - b. Results of discussions on debated issues and record of IRB decisions.
 - c. Record of voting (showing votes for, against and abstentions).

3. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents are signed by the Chair to show IRB approval and date of approval expiration.
4. Copies of response letters from the IRB to the principal investigators.
5. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.
6. Adverse reactions reports and documentation that the IRB reviews such reports.
7. Emergency use reports.
8. General project information provided to subjects (e.g., fact sheets, brochures).
9. Copy of final research report supplied by the PI.

These documents and records shall be retained by the AVP of PIER for at least three 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.

In addition, the AVP of PIER maintains a permanent record of the list of current IRB members, and written procedures for the IRB.

B. All forms submitted or retained as evidence of informed consent must be preserved by the PI in a way that only the PI has access to protect subject anonymity. Should the PI leave CSM, signed consent forms are to be transferred to the IRB Chair who must also protect the forms from access.

XI. INFORMATION THE INVESTIGATOR PROVIDES TO THE IRB.

A. Professional qualifications to do the research (including a description of necessary support services and facilities);

B. Appropriate CSM review form including protocol summary.

C. Complete study protocol which includes/addresses:

1. Title of the study and summary of the research to be conducted,
2. Purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits),
3. Sponsor of the study,

4. Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research),
5. Justification for use of any special/vulnerable subject populations (such as children [under age 18], prisoners, or handicapped, economically/educationally disadvantaged, or mentally disabled persons),
6. Study design (including, as needed, a discussion of the appropriateness of research methods),
7. Description of procedures to be performed,
8. Provisions for managing adverse reactions,
9. Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations,
10. Procedures for documentation of informed consent, including any procedures for obtaining assent from minors ('minor' is defined in Ohio as an individual under the age of 18), using legally authorized representatives (see XII B and C of this Standard Operating Procedures), witnesses, translators and document storage,
11. Remuneration to subjects for their participation,
12. Any compensation for injured research subjects,
13. Provisions for protection of subject's privacy,
14. Extra costs to subjects for their participation in the study,
15. Inclusion/exclusion of women, minorities, and/or children.

D. Investigator's brochure (when one exists);

E. The case report form (when one exists);

F. The proposed informed consent document, including translated consent documents, as necessary, considering likely subject population(s); or request for waiver of the requirement to obtain informed consent;

G. Copies of advertisements and surveys, questionnaires, or other materials provided to subjects;

H. Copies of relevant grant applications (if any);

I. Requests for changes in study after initiation including changes to consent forms;

J. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports;

K. Progress/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XII. PRINCIPLES OF INFORMED CONSENT.

A. When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists, e.g., participation in a research project, the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving consent. A copy of the signed consent form must be given to the person signing the form and a signed copy must be kept on file with the investigator or CSM as indicated below.

B. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative (LAR). The LAR must be authorized either by a power of attorney or a court order.

C. "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. The basic elements of information necessary to such consent are found at <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>.

The IRB may approve a telephonic consent procedure under which the subject's LAR is sent an email or hand-carried version of the informed consent document, a consent interview is conducted by phone while the LAR has the document in hand, and the LAR signs and returns the signed document to the investigator by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an investigator, coordinator, etc.) should monitor the consent process.

D. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

E. For research involving more than minimal risk to subjects or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

F. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. For electronic surveys, using software tools such as Survey Monkey or Qualtrics, a signature is not required if the consent form clearly states that beginning the survey constitutes consent. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Exceptions to the confidentiality of data associated with individual human subjects are made only when disclosure is required by statutory or judicial authority or when the subject has given prior written approval for disclosure. Or when there is imminent danger to self or others and vulnerable populations. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written or electronic statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those

studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

XIII. CONFLICT OF INTEREST GUIDELINES FOR IRB MEMBERS.

A. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an investigator or sub-investigator on the protocol;
2. Has a “significant financial interest” in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest [see CSM Conflict of Interest, Proprietary Information, or Political Activity Policy, <https://www.csmd.edu/faculty-staff/administrative-manual/>]
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified themselves for any other reason as having a conflicting interest.

B. It is the responsibility of each IRB member to identify and avoid any situations in, either personally or by virtue of their position, the IRB member 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. If assigned as a reviewer for a matter with which the IRB member feels that there may be a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.

C. Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation and actions (including vote). In general, IRB member(s) who have a real, or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair, during the discussion of the matter, in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

D. Minutes of IRB meetings will reflect when a member leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.