



Institutional Review Board Policy

Policy Number:	AA 09-010 <i>Formerly AS 574</i>
Policy Administrator:	Provost and Vice President Academic Affairs
Policy Initiator:	Associate Vice President Academic Affairs
Authority:	National Research Act (1974); Code of Federal Regulations Title 21
Effective Date:	February 14, 2010
Revised Date:	May 7, 2018
Approved:	President Thomas A. Cropper
Approval Signature:	/s/

Purpose:

California State University Maritime Academy (Cal Maritime) encourages research within the institution and in collaboration with other educational institutions, agencies, and organizations. While respecting the right of faculty to full academic freedom in research, Cal Maritime is committed to adhering to basic ethical principles underlying the acceptable conduct of research involving human subjects.

Scope:

The scope of the policy is any research involving human subjects conducted by Cal Maritime faculty, staff or students, regardless of whether or not the project is funded.

Accountability:

The Provost, or Provost's designee, is responsible for administering this policy and ensuring compliance.

Policy:

It is the policy of Cal Maritime that any research that involves human subjects conducted by Cal Maritime faculty, staff or students, whether funded or unfunded and whether subject to federal regulations or not, shall be under the jurisdiction of the Institutional Review Board (IRB).

Procedure:

A. Duties and responsibilities of the Institutional Review Board (IRB)

The National Research Act (1974) created a commission that identified the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. The recommendations of this commission are codified in 45 CFR part 46 and 21 CFR Parts 50 and 56, which are the foundation of all Institutional Review Board procedures.

“It is the responsibility of the Chief Research Officer to ensure that the IRB is registered with the U.S. Department of Health and Human Services, signifying Cal Maritime is in compliance with federal regulations, and to submit and maintain a Statement of Assurance.”

The Cal Maritime IRB shall be responsible for assuring that:

1. Cal Maritime has an IRB Procedure Manual that is compliant with all regulations and available to the Cal Maritime community in a useable format and is available online;
2. the procedures as set forth in the manual are followed;
3. human subjects are not placed in unreasonable physical, mental, or emotional risk as a result of the research (see attached Research Participant’s Bill of Rights);
4. the necessity and importance of the research outweighs the risks to the subjects;
5. the researcher(s) is/are qualified to conduct research involving human subjects; and that
6. records of all applications are maintained in a secure environment.

B. Membership

The Cal Maritime IRB shall consist of at least six members. At least one member must be a faculty member from a scientific area and one faculty member from a non-scientific area. One member shall be drawn from Student Health Services. One member shall be from the Office of Risk Management. One member must be drawn from outside the institution. The sixth member will be an at-large member, drawn from the faculty or staff of Cal Maritime. The chair of the IRB shall be selected from among these members – by acclamation if possible, by vote if necessary.

The Cal Maritime faculty members of the IRB (scientific, nonscientific, and at-large member) shall be appointed by the Provost in consultation with the Senate Executive Committee and the Chief Research Officer. The external IRB member shall be designated by the Provost in consultation with the Chief Research Officer.

These membership rules fall within the parameters and guidelines set by the Code of Federal Regulations. And in accordance with the CFR, membership must adhere to the following principles and policies:

1. “Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped

or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

2. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
3. Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.
4. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
5. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.”

Members of the IRB must participate in initial and continuous training regarding human subject research. This training shall ensure that IRB members have a basic understanding of the federal regulations that protect the rights of human subjects. Members should be familiar with the Office of Human Research Protections – Human Subject Assurance Training and the Code of Federal Regulations (45 CFR Part 46).

C. Protocols and Procedures

1. Actions by the IRB:

Actions taken by the IRB shall be in accordance with the policy under which the applications before them were brought. IRB findings/recommendations shall be communicated in accordance with the policy under which the charge before them was brought as well as to the Provost and the Executive Committee of the Senate for their information. Actions of the IRB will be governed by the CSU Maritime Academy IRB Manual. The Chair will work with the CRO to ensure currency of the manual and compliance with all local and federal regulatory mandates and with communicating regularly with the Chief Research Officer.

2. Training:

All members of the IRB must be trained per Federal Regulations. Recertification is required as necessary to maintain currency with continuous changes in federal policy.

3. Meetings:

IRB meetings will be held as needed, as determined by the Chair of the Board. If, in the judgment of the Chair, a sufficient number of research proposals exist, a meeting may be scheduled to review such proposals in a timely manner. Note, however, that a proposal will not be held longer than one month before being reviewed by the IRB, except insofar as summer recess may impact timeliness

4. Archives:

It shall be the responsibility of the Chief Research Officer to maintain a confidential archive of the Board's activities for five years from the date of the initial request for hearing. The archive shall include:

- a. all documents generated during the review process or any matter coming before the committee; and
- b. a list of trained faculty

5. Reporting:
In a manner ensuring both the integrity and confidentiality of the Board's procedures, at appropriate intervals, the Chair of the IRB will forward summary reports of the activities of the Board to the Chief Research Officer, the Vice-Chair of the Academic Senate and to the Provost.
6. Appointment of sub-committees:
The Chair of the IRB shall be empowered to appoint ad hoc committees to facilitate the Board's efforts. All sub-committees of the Board shall adhere to the same standards of procedures and confidentiality imposed upon the parent Board.
7. Practices of this IRB will be governed by the specific policy governing the issue before them. A submission of a proposal to the IRB shall follow the processes as outlined in the flow chart contained in the IRB Manual.
8. Review Categories:
 - a. Exempt Review:
This designation means the research is exempt from federal human subject's regulations; however, that designation can only be made by the IRB, and therefore requires submission of application materials.
 - b. Expedited Review:
The expedited designation means that the project involves no more than minimal risk to human subjects and only involves procedures listed in one of the nine federally designated categories (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>).
 - c. Full Review:
The project is required to undergo a full board review, which represents the most rigorous level of review.

Appendix A: Research Participants Bill of Rights
Appendix B: CSU Maritime Academy IRB Manual.

Appendix A

Research Participant's Bill of Rights¹

Any person who is requested to consent to participate as a subject in an experiment, or who is requested to consent on behalf of another, has the following rights:

1. To be told what the study is attempting to discover.
2. To be told what will happen in the study and whether any of the procedures, drugs or devices are different from what would be used in standard practice.
3. To be told about the risks, side effects or discomforts of the things that may happen to him/her.
4. To be told if he/she can expect any benefit from participating and, if so, what the benefits might be.
5. To be told what other choices he/she has and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.
7. To be told what kind of treatment will be available if any complications arise.
8. To refuse to participate at all before or after the study is started without any adverse effects.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressures when considering whether he/she wishes to agree to be in the study. If at any time you have questions regarding a research study, you should ask the researchers to answer them.

¹ Adapted from Brandman University IRB, 2013