

## **Institutional Review Board Policy**

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

**Purpose:**

California State University Maritime Academy

## **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



5. Reporting:

In a manner ensuring both the integrity of procedures, 0.44

# Appendix A