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Policy for the Protection of Human Research Participants

1.00 Purpose

This policy sets forth Cal State Monterey Bay's compliance with the University's Federal-Wide Assurance on file with the Department of Health and Human Services (DHHS) Office of Human Research Protections (FWA No. 00004739). In compliance with such regulations, this policy establishes the University's Institutional Review Board (IRB). The IRB's responsibility is to facilitate University researchers' compliance with all applicable values, regulations and laws governing the protection of research participants. The responsibility and authority for implementing and administering policies and procedures that will protect the dignity, rights and welfare of research participants shall be delegated to the IRB. Per federal regulations, the IRB at CSUMB reports directly to the U.S. Department of Health & Human Services (HSS) and Office for Human Research Protections (OHRP).

This policy conforms to the Code of Federal Regulations, 45 CFR 46, Subparts A, B, C and D established by the U.S. Department of Health and Human Services, Office of Research Protections (OHRP), the National Institutes of Health Office of Extramural Research, the U.S. Department of Veterans Affairs, the U.S. Food and Drug Administration, as well as federal and state laws.

This policy is deemed to be consistent with the University's commitment to the principles, goals, and ideals described in the California State University, Monterey Bay Founding Vision and to its core values.

2.00 Scope and Responsibility

Cal State Monterey Bay has a responsibility to protect the rights and welfare of research participants which includes obtaining informed consent from potential research participants in research prior to their participation in studies conducted by all CSUMB researchers. The University agrees to comply with both its Federal-Wide Assurance and the federal policy which governs human subjects research (HSR). The Authorized Institutional Official for all human subjects research (HSR) matters shall be the University Provost/Vice President for Academic Affairs or designee.

All CSUMB researchers must complete training in the protections of research participants as well as comply with all applicable federal, state, and local regulations pertaining to the involvement of research participants. CSUMB researchers are reminded to strictly adhere to the guidelines for human subject research (HSR) as described in their research protocols. Any change in protocol or consent must be approved by resubmission to the IRB prior to implementation. Additionally, all CSUMB researchers are reminded to report promptly (no later than five calendar days), in writing, any unanticipated or adverse events causing risks to research participants or others.

2.10 Responsibility of Advisors of Inexperienced Researcher-led Projects

It is the responsibility of faculty advisors to ensure that student-led research activities are conducted according to the standards set forth in this policy. Likewise, when inexperienced staff-led research is proposed, adequate supervision is required. When such activities are subject to IRB oversight, it is the responsibility of the advisor/supervisor to assist in preparing the student/staff application materials for the IRB and to ensure that the research is conducted in accordance with this policy.

2.20 External Funding (Grant) Applicants

Principal Investigators (PI) applying for grants or contracts shall complete all additional training and/or certifications required by the sponsor for funding of research with human subjects prior to submitting their protocol for IRB review. It is the PI's responsibility to understand and comply with the sponsor's certification requirements.

Principal Investigators (PI) are required to disclose any real or perceived financial interests, regardless of grant-funding source, prior to the submission of an IRB protocol for review. If a financial conflict of interest is identified related to a specific project, it must be reviewed and managed prior to the approval of the protocol by the IRB.

3.00 Definitions

Additional regulatory definitions pertaining to Human Subjects Research are promulgated by agencies such as the National Institutes of Health Office of Extramural Research, the U.S. Department of Veterans Affairs, the U.S. Food and Drug Administration, as well as federal and state laws. It is the responsibility of the researcher to understand all applicable regulatory definitions.

Institutional definitions pertaining to Human Subjects Research, determined by the IRB, are documented on the IRB website under Human Subjects Research: Teaching & Learning, "Definitions" section.

Refer to Code of Federal Regulations, 45 CFR 46, Subparts A, B, C and D for a complete list of the U.S. Department of Health and Human Services, Office of Research Protections (OHRP) regulatory definitions covered by this policy. OHRP definitions of particular import to this policy are as follows:

Human Subject: Per §46.102 Definitions, human subject means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains data through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 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. Interaction includes communication or interpersonal contact between investigator and subject. 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. NOTE: Beyond specifying this regulatory definition, this policy and IRB documents will henceforth refer to as research participant.

Minimal Risk: Per §46.102 Definitions, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Protected and Vulnerable Populations: Per §46.111 Criteria for IRB Approval of Research, when some or all of the participants are likely to be vulnerable to coercion or undue influence, the IRB shall ensure additional safeguards have been included in the study to protect the rights and welfare of these participants.

Research: Per §46.102 Definitions, 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.

4.00 Institutional Review Board (IRB) Committee

Per §46.108 IRB Functions and Operations, the IRB shall:

A. Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).
B. When research procedures meet Minimal Risk criteria (see 2.30 Minimal Risk): Review proposed research by at least one (1) IRB member.
C. When research procedures exceed Minimal Risk criteria: Review proposed research at convened meetings in which a majority of the members of the IRB are present, including at least one (1) member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting in accordance with §46.109.
D. Review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
E. Require that information given to participants as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants.
F. Require documentation of informed consent or may waive documentation in accordance with §46.117.
G. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
H. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

Per §46.107 IRB Membership, the IRB will:

A. Have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
B. Make every nondiscriminatory effort to ensure that the membership is diverse in regards to identity (e.g. gender, race/ethnicity, age);
C. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
D. 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; and
E. Not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB;
F. Reflect the following additional criteria when research involving prisoners as research participants is "commonly conducted by the institution:"
G. A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

H. At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement.

5.00 IRB Review and Approval

5.10 Protocol Review

Per §46.111, in order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

A. Risks to participants are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
C. Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
D. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by §46.116.
E. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
F. The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
G. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
H. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

5.20 Research Not Requiring IRB Review

In keeping with §46.118 Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects, as the designated IRB of CSUMB the IRB shall interpret applicability of the regulatory definitions of "human subject" and "research" to all protocols submitted for IRB review. As such, when the IRB determines the proposed procedures do not meet the regulatory definition of "human subject" or "research" the activity is not subject to IRB oversight.

5.30 Other Institutional Approvals

Per §46.112 Review by Institution, research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB. Conversely, protocols reviewed by the IRB and found not to require IRB oversight (per 4.20 Research

Not Requiring IRB Review) may still require other institutional approvals. It is the researcher's responsibility to understand and obtain all required institutional approvals for proposed research activities.

5.40 Retroactive Approval

There are no regulatory provisions for retroactive approval of research involving humans as subjects. If Human Subjects Research is begun without prior IRB approval, upon discovery of the error, the researcher shall stop the research and notify the IRB immediately. The researcher shall then submit a protocol to the IRB along with a detailed explanation as to why the protocol was not submitted in advance of commencing research. If the researcher is a student, a detailed letter from his or her faculty advisor shall accompany the materials submitted to the IRB. Human Subjects Research data collected without IRB approval is invalid and cannot be used in any way.

5.50 Suspension or Termination

Per §46.113 Suspension or Termination of IRB Approval of Research, the IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with this policy's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB action and shall be reported promptly to the lead researcher and applicant researcher, appropriate institutional officials, and the department chair.

5.60 Cooperative Research

Per §46.114 Cooperative Research, the IRB shall have authority to approve cooperative research. Cooperative research projects are those covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of research participants and for complying with this policy. With the approval of the department or agency head, the IRB may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements to avoid duplication of effort.

5.70 International Research

In keeping with §46.101(h), when research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect research participants may differ from those set forth in this policy. In these circumstances, if the IRB determines that the human subjects research (HSR) norms of the foreign country afford protections that are at least equivalent to those provided in this policy, the IRB may approve the substitution of the foreign procedures in lieu of the procedural requirements referenced in this policy. It is the researcher's responsibility to understand and comply with all applicable foreign policies and procedures. To this end, the IRB may refer CSUMB researchers to consultation services provided by OHRP's International Activities program.

6.00 IRB Procedures, Guidelines, and Training

Procedures are documents issued by the IRB that identify the processes and steps by which the IRB and support staff conduct protocol reviews, day-to-day operations, and other particular matters. Guidelines are documents issued by the IRB that describe recommended practices and instructions for researchers developing Human Subjects Research protocols for review by the IRB. It is the responsibility of the researcher to understand and follow all applicable procedures and guidelines. Procedures and guidelines are posted on the IRB website at Human Subjects Research: Teaching & Learning "Procedures" and "Guidelines" sections.

6.10 IRB Procedures

Per §46.115 IRB Records (6), the IRB shall prepare and maintain adequate documentation of written procedures as described in §46.103(b)(4) and §46.103(b)(5). IRB procedures shall be maintained in accordance with changes to regulations, regulatory guidelines, or research practices as well as the policies and procedures of the University.

6.20 IRB Guidelines

In keeping with §46.115 IRB Records, the IRB shall prepare and maintain adequate guidelines to facilitate researchers' understanding and compliance with all applicable policies and procedures. IRB guidelines shall be maintained in accordance with changes to regulations, regulatory guidelines, or research practices as well as the policies and procedures of the University.

6.30 Training in Human Subjects Research (HSR)

In keeping with §46.115 IRB Records, all researchers including faculty or staff advising students or supervising inexperienced staff researchers, have the responsibility to be knowledgeable about the protections of research participants. As such, all researchers who "interact with" or "intervene with" research participants or who have access to "personally identifiable private information" of research participants must complete training in the protections of research participants and provide proof of validity with every submission to the IRB. Training is provided by the University through CITI Program.

7.00 References and Related Policy Information

Where there are substantive differences between the policy and the referenced or related documents below, the regulations shall take precedence.

- Federal Code of Regulations 45 CFR 46: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46
- Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- Declaration of Helsinki as amended 2024: https://www.wma.net/policies-post/wma-declaration-of-helsinki/
- U.S. National Institutes of Health, Human Subjects Glossary: http://grants.nih.gov/grants/policy/hs/glossary.htm
- U.S. Federal Drug Administration 21 CFR 50: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
- U.S. Health Insurance Portability and Accountability (HIPPA) Act: https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html
- U.S. Family Educational Rights and Privacy Act (FERPA): http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
- State of California, Privacy Laws: https://oag.ca.gov/privacy/privacy-laws
- State of California, Education Laws & Codes: http://www.cde.ca.gov/re/lr/cl/
- OHRP's International Activities program: http://www.hhs.gov/ohrp/international/index.html
- CITI Program: https://about.citiprogram.org/

8.00 Continuous Renewal

This policy shall be reviewed ten years from its effective date to determine its utility and appropriateness. This policy may be reviewed before that time as necessary.

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President Vanya Quiñones

Effective Date: 05/22/2025

Certification of Process

Reviewed by: IRB, Policy Facilitation Team, Academic Leadership Team, Academic Senate Executive Committee, Committee on Research, Scholarship, and Creative Activity, Sponsored Programs Office, Enrollment Management & Student Affairs, Administration & Finance, and University Advancement, Academic Senate, Provost.

Memorandum from Policy Facilitation Team

To: **VP Andrew Lawson**

Subject: **Policy for final Presidential approval**

From: **Policy Facilitation Team**

Date: **May 15, 2025**

Policy: **Policy for the Protection of Human Research Participants**

This policy has been updated to comply with updates to federal regulations and to align with CSUMB processes and organization.

05/16/2025

Andrew Lawson, Provost JH

Date