California State University Monterey Bay

100 Campus Center · Seaside, CA 93955-8001

Human Subjects in Research Policy

1.00 Purpose

It is the policy of this University that all CSUMB researchers undertaking studies involving living individuals as research subjects [1] shall take all necessary steps to ensure their protection and well being throughout the study, honoring the values of respect for persons, beneficence, and justice described in the Declaration of Helsinki [2], as well as complying with all applicable local, state, federal, tribal and foreign laws, policies, regulations, and standards of professional conduct and practice [3]. As such, CSUMB researchers must complete training in the protections of human subjects and document knowledge of other applicable laws, policies, regulations and standards.

In compliance with such regulations, this policy establishes the University's Institutional Review Board (IRB), hereafter called the Committee for the Protection of Human Subjects (CPHS). The CPHS responsibility is to facilitate University researchers' compliance with all applicable values, regulations and laws governing the protection of human subjects in research, and to assist the University to comply with regulatory governing requirements herein [4].

This policy is intended to reflect the University's commitment to the principles, goals, and ideals described in the Founding CSUMB Vision Statement and its core values.

2.00 Definitions

Refer to Code of Federal Regulations, 45 CFR 46 and 21 CFR 50 for a complete list of the U.S. Department of Health and Human Services, Office of Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulatory definitions [1] covered by this policy. Definitions shall not supersede any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that are applicable and provide additional protections for human subjects.

2.10 Additional Regulatory Definitions

Additional regulatory definitions pertaining to Human Subjects Research and personally identifiable private information are promulgated by other local, state federal, tribal and foreign agencies such as: National Institutes of Health Office of Extramural Research, U.S. Department of Veterans Affairs, U.S. Food and Drug Administration [5], U.S. Department of Education, State of California, and the European Union [6]. It is the responsibility of the researcher to understand all applicable regulatory definitions.

2.20 Additional Institutional Definitions

Institutional definitions and definitional elaborations pertaining to Human Subjects Research and personally identifiable private information as determined by the CPHS, are documented on the CPHS Guidelines for Conducting Human Subjects Research [7].

3.00 Role and Function of the Committee for the Protection of Human Subjects

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

1. Have access to meeting space and sufficient staff to support the CPHS' review and recordkeeping duties;
2. Prepare and maintain a current list of members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to CPHS deliberations; and any employment or other relationship between each member and the institution for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;
3. Establish and follow written procedures for:
    i. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
    ii. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous CPHS review; and
    iii. Ensuring prompt reporting to the CPHS of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the CPHS approval until any proposed changes have been reviewed and approved by the CPHS, except when necessary to eliminate apparent immediate hazards to the subject.
4. Establish and follow written procedures for ensuring prompt reporting to the CPHS, appropriate institutional officials, the department or agency head, and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of:
    i. Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the CPHS; and
    ii. Any suspension or termination of CPHS approval.
5. Except when an Exempt or Expedited review procedure is used, the CPHS must review proposed research at convened meetings at which a majority of the members of the CPHS are present, including at least one member whose primary concerns are in the 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.

3.20 Composition of the CPHS

Per §46.107 IRB Membership, the CPHS shall:

1. Have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution.
2. Be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and 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.
3. Be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The CPHS shall therefore include persons knowledgeable in these areas. Consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with subjects that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
5. 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.
6. Not permit any member to participate in the initial or continuing review of any project in which the member has conflicting interest, except to provide information requested by the CPHS.
7. At its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the CPHS. These individuals may not vote with the CPHS. "

4.00 Review and Approval

4.10 Protocol Review

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

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CPHS should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The CPHS should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the CPHS should take into account the purposes of the research and the setting in which the research will be conducted. The CPHS should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented or appropriately waived by CPHS in accordance with, §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. The CPHS shall interpret and determine the "vulnerability" of all proposed human subjects populations on a case-by-case basis.

4.20 Research Not Requiring CPHS Review

Per §46.118 Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects and §46.102 Definitions for Purposes of this Policy, the CPHS shall interpret applicability of the regulatory definitions of "human subject" and "research" to all protocols submitted for CPHS review. As such, when the CPHS determines the proposed procedures do not meet the regulatory definition of "human subject" or "research" the activity is not subject to CPHS oversight.

4.30 Other Institutional Approvals

Per §46.112 Review by Institution, research covered by this policy that has been approved by the CPHS 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 CPHS. Conversely, protocols reviewed by the CPHS and found not to require CPHS oversight may still require other institutional approvals. It is the researcher's responsibility to understand and obtain all required institutional approvals for proposed research activities.

4.40 Retroactive Approval

There are no regulatory provisions for retroactive approval of research involving humans as subjects. If Human Subjects Research is begun without prior CPHS approval, upon discovery of the error, the researcher shall stop the research and notify the CPHS immediately. The researcher shall then submit a protocol to the CPHS 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 CPHS. Human Subjects Research data collected without CPHS approval is invalid and cannot be used in any way.

4.50 Suspension or Termination

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

4.60 Cooperative Research

Per §46.114 Cooperative Research, for projects covered by this policy that involve more than one institution, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45CFR46. The CPHS shall have authority to approve cooperative research as the reviewing institution or the relying institution (relying on an external IRB review and approval).

4.70 International Research

Per §46.101(h) To what does this policy apply?, when research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, this policy shall not supersede any local, state, federal, tribal and foreign laws, policies, regulations, and standards (including tribal law passed by the official governing body of an indigenous tribe) that are applicable and provide additional protections for human subjects. It is the researcher's responsibility to understand and comply with all applicable foreign policies and procedures. To this end, the CPHS may refer CSUMB researchers to consultation services provided by OHRP's International Activities program [8]

5.00 Procedures, Guidelines and Training

Procedures are documents issued by the CPHS that identify the processes and steps by which the CPHS and support staff conduct protocol reviews, day-to-day operations, and other regulatory matters. Guidelines are documents issued by the CPHS that describe the standards for what is required and recommended practices for researchers developing Human Subjects Research protocols for review by the CPHS. It is the responsibility of the researcher to understand and follow all applicable guidelines. Procedures and guidelines are posted on the CPHS website for Human Subjects Research [9]

5.10 CPHS Procedures

Per §46.115 IRB Records, the CPHS shall prepare and maintain adequate documentation of written procedures. CPHS procedures shall not supersede any local, state, federal, tribal and foreign laws, policies, regulations, and standards (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that are applicable and provide additional protections for human subjects.

5.20 CPHS Guidelines

Per §46.115 IRB Records, the CPHS should prepare and maintain adequate guidelines [7] to facilitate researchers' understanding and compliance with 45 CFR 46 and 21 CFR 50. CPHS guidelines should be maintained in accordance with changes to regulations, regulatory guidelines, or research practices as well as the policies and procedures of the University. CPHS guidelines shall not supersede any local, state, federal, tribal and foreign laws, policies, regulations, and standards (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that are applicable and provide additional protections for human subjects.

5.30 Training in the Protections of Human Subjects

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 human subjects [10]. As such, all researchers who "interact with" or "intervene with" human subjects or who have access to "personally identifiable private information" of human subjects must complete training in the protections of human subjects and provide proof of validity with every submission to the CPHS. Training options are posted on the CPHS website for Human Subjects Research [9].

6.00 Faculty and Staff Responsibilities

6.10 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 CPHS oversight, it is the responsibility of the advisor/supervisor to assist in preparing the student/staff application materials for the CPHS and to ensure that the research is conducted in accordance with this policy.

6.20 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 humans as subjects prior to submitting their protocol for CPHS review. It is the PI's responsibility to understand and comply with the sponsor's certification requirements [10].

6.30 Applicants with Potential Conflicts of Interest

Researchers submitting protocols when they have an interest (paid consultant or board member), regardless of grant-funding source, are required to disclose financial interest conflicts prior to the submission of a CPHS 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 submission of the protocol to the CPHS.

7.00 Authorized Institutional Official

The Authorized Institutional Official for all human subject matters shall be the University Provost/Vice President for Academic Affairs or his/her designee.

8.00 Continuous Renewal

This policy shall remain in effect for ten years from its effective date to determine its effectiveness and appropriateness. The policy may be revised as needed.

President Eduardo M. Ochoa

Effective Date: 2/22/2019

Certification of Process

Reviewed by: The Committee for the Protection of Human Subjects, Policy Facilitation Team, Associated Students, Academic Affairs Council, ASEC, Academic Senate Committee on Postgraduate Studies and Research, Academic Senate, Academic Personnel, and Provost.

END NOTES

1. Federal Code of Regulations, U.S. Department of Health and Human Services, Office for Human Research Protections, 45 CFR §46.102 Definitions for Purposes of this Policy: https://www.ecfr.gov/cgi-bin/text-idx?SID=cea9c13774a449c0d4fe2cc384d6fc21&pitd=20180719&node=se45.1.46_1102&rgn=div8. Federal Code of Regulations, U.S. Food and Drug Administration, 21 CFR §50.3 Definitions: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3.
2. Declaration of Helsinki as amended 2013: http://www.wma.net/en/30publications/10policies/b3
3. Federal Code of Regulations, U.S. Department of Health and Human Services, Office for Human Research Protections, 45 CFR §46.101 To What Does this Policy Apply: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c09d1e4edd0cbb485147644a92f6aae1&mc=true&n=sp45.1.46.a&r=SUBPART&ty=HTML#se45.1.46_1101, and §46.107 Protection of Human Subjects, IRB Membership (see endnote [4]). Federal Code of Regulations, U.S. Food and Drug Administration, 21 CFR §50.1 Scope: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.1.
4. Federal Code of Regulations, U.S. Department of Health and Human Services, Office for Human Research Protections, 45 CFR §46.107 IRB Membership: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c09d1e4edd0cbb485147644a92f6aae1&mc=true&n=sp45.1.46.a&r=SUBPART&ty=HTML#se45.1.46_1107.
5. U.S. National Institutes of Health, Human Subjects Glossary: http://grants.nih.gov/grants/policy/hs/glossary.htm. U.S. Department of Veterans Affairs, "VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research": http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052. U.S. Food and Drug Administration, Clinical Trials and Human Subject Protection: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm.
6. 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/. European Union: https://eugdpr.org/.
7. CPHS Guidelines for Conducting Human Subjects Research: https://sites.google.com/csumb.edu/cphs-guidelines-hsr-rev-rule.
8. OHRP International Program: http://www.hhs.gov/ohrp/international/index.html.
9. CSUMB's website for the Committee for the Protection of Human Subjects (CPHS): https://csumb.edu/compliance/human-subjects-research.
10. OHRP's Investigator Responsibilities FAQ "Must investigators obtain training in the protection of human subjects?" https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html.

Memorandum from Policy Facilitation Team

To: **President Eduardo M. Ochoa**

Date: **February 22, 2019**

Subject: **Policy Recommendation**

From: **Provost Bonnie Irwin**

Policy: **Human Subjects in Research Policy**

This existing campus policy has been revised and updated to reflect changes to federal regulations that became effective January 2019. Due to the fact that all changes to this policy are strictly limited in scope to align with federal regulations, this update did not undergo full campus vetting.

Provost Bonnie D. Irwin

2-22-19
Date