



POLICY AND ASSURANCE OF COMPLIANCE WITH FEDERAL REGULATIONS ON PROTECTION OF HUMAN SUBJECTS

History:

80-81 BEC 2; President approved 12/8/80

Amended 2/9/83;

Amended 4/9/91;

Amended 6/2/98;

07-08 CR 5; President approved June 08

20-21 CR 15; President approved 5/25/21

Purpose: The purpose of this policy is to provide assurance that this Institution and all of its activities related to human subjects research, regardless of the source of support, will be guided by the statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report), and to ensure the protection of and promote the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. Furthermore, this Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the [Terms of the Federalwide Assurance](#) of the Office for Human Research Protections (OHRP).

Policy Statement: Cal State East Bay (officially, the California State University, East Bay, abbreviated as CSUEB) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. In the review and conduct of research, actions by Cal State East Bay follow California State University policy and will be guided by the principles of respect for persons, beneficence, and justice set forth in the Belmont Report , and will be performed in accordance with the Department of Health and Human Services (DHHS) policy, Food and Drug Administration (FDA) policy, federal, state, and local laws and regulations regarding the conduct of research with human subjects as defined by the regulations and as applicable.

Policy Scope: To conduct the responsibilities of ensuring human protections in research effectively, the University maintains an Institutional Review Board (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the Cal State East Bay IRB to 1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth in the revised federal regulation known widely as “The Common Rule” regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) to assist the investigator in complying with federal and state regulations

The Cal State East Bay Institutional Review Board will comply with the applicable federal regulations when reviewing research subject to those regulations (e.g., research funded or directed by the Department of Health and Human Services (HHS), Food and Drug Administration (FDA), or other federal agencies). As stated in the regulations at 45 CFR §46.103(b)(4) and (5) and 21 CFR §56.108(a) and (b) the CSUEB IRB will follow written procedures for the following functions and operations:

- Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution. Board reviews will be conducted objectively and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from review of projects or activities in which they have an active role or conflict of interest.
- Reviewing proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (except when an expedited review procedure is used (see §56.110)). In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
- Maintaining appropriate and informative records of the Board's review of applications and activities, of documentation of informed consent, and of other documentation that may pertain to selection, participation, and protection of subjects and to the review of circumstances that adversely affect the rights or welfare of individual subjects.
- Ensuring that continuing constructive communication between the Board and Principal Investigator is encouraged as a means of safeguarding the rights and welfare of the subjects.
- Ensuring that investigators complete training and understand they are responsible for referring human subjects to appropriate professionals for treatment of physical, psychological, or other injury suffered as a result of participation in an activity.
- Determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review.

- Ensuring prompt reporting to the IRB of proposed changes in a research activity and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i.e., OHRP) for research conducted or supported by HHS, and FDA for FDA-regulated research of any:
 - Unanticipated problems involving risks to human subjects or others;
 - Instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;
 - Suspension or termination of IRB approval.

This institution will comply with the decisions of the Cal State East Bay Institutional Review Board, to which the employees of this institution will submit all research activities involving human subjects for review and approval.

The Board shall determine the following for each activity as planned and conducted:

- Whether subjects will be placed at risk;
- and if risk is involved, whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
- that the rights and welfare of any such subjects will be adequately protected;
- that legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulation;
- and that the conduct of the activity will be reviewed at timely intervals.

This institution acknowledges that it will bear responsibility for the proper performance of all work and services including the use of human subjects under each grant or contract covered by this assurance including continuing compliance with pertinent state or local laws, particularly those concerned with informed consent.

This institution will at least annually reassure itself through appropriate administrative overview that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are consistent with the regulations and with the implementation of this assurance as accepted by the Department of Health and Human Services.

Exclusions: None.

Definitions:

Human Subject — A living individual about whom an investigator (whether professional or student) conducting research: (a) Obtains information or biospecimens through intervention or interaction with the individual, and, uses studies, or analyzes the information or biospecimens; or (b) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research — As defined by the federal regulations for human subject protection, “research” means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Procedures: The Cal State East Bay Institutional Review Board shall establish and maintain publically available procedures, subject to approval of the Committee on Research Chair and the Institutional Official. The procedures shall be written in accordance and compliance with the Committee on Research Policies and Procedures, the Constitution and Bylaws of the University Faculty, the Department of Health and Human Services (DHHS) policy, Food and Drug Administration (FDA) policy, and any other relevant federal, state, and local policies, laws, statutes, and regulations.

The Institutional Official is appointed by the President. In addition to their other duties and responsibilities, as determined by the President and as specified in any relevant federal, state, and local policies, laws, statutes, and regulations, the Institutional Official shall report on matters related to human subjects research to the Committee on Research, as specified in the Committee on Research Policies and Procedures.

Enforcement: In the event that “the Common Rule” is violated in the conduct of research involving human subjects, there are various responses that can affect both investigators and federally-funded grantee institutions, such as withdrawal or restriction of an institution's or project's assurance and, with that action, of research funding and suspension or termination of IRB approval of the research. An IRB is authorized by the Common Rule to suspend or terminate its approval of research that fails to comply with the IRB's requirements or when a research subject suffers an adverse event.

Related Information: N/A

Policy Review: The IRB and Institutional Official will review at least annually.

Authority: The federal regulation followed by most federal agencies is known as “The Revised Common Rule,” Code of Federal Regulations (CFR) Title 45 Part 46 Protection of Human Subjects as published in the Federal Register on January 19, 2017 (82 FR 7149), and further amended by an interim final rule published on January 22, 2018 (83 FR 2885) and a final rule published on June 19, 2018 (83 FR 28497). The FDA also follows (CFR) Title 21 Food and Drugs Parts 50 and 56.

Shared Governance: The IRB is a regular subcommittee of the Committee on Research, and is subject to the Committee on Research Policies and Procedures, as well as the Constitution and Bylaws of the University Faculty.