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

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.

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