

Title: IRB Institutional Authority

SOP # 3

Department: Office of Research and Economic Development (ORED)

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Subject: Institutional Authority of the IRB

Policy:

In accordance with federal policy on the Protections of Human Subjects (DHHS Regulations 45 CFR Part 46, FDA Regulations 21 DFR Parts 50 and 56), the University of California, Merced (UCM) is responsible for the protection of the rights and welfare of human subjects in research conducted by, or under the supervision of, UCM faculty, staff, or students. To conduct this responsibility effectively, the University has delegated responsibility for the UCM human subjects protection program to the Vice Chancellor of Research (VCR). Under the authority of the VCR, an Institutional Review Board (IRB) has been established and empowered to oversee human subjects research.

45 CFR 46 Section 103(a) requires that each institution engaged in Federally sponsored human subjects research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution's commitment to protect human subjects participating in research. UCM, as part of its Federal-wide Assurance (FWA # 00005105), has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore the UCM IRB has oversight over all human subject research conducted at UCM, or by its faculty, students or staff.

The IRB shall have the authority to:

- Approve, require modifications, or disapprove all human subjects research activities conducted under the auspices of UCM.
- Suspend or terminate approval of any human subjects research studies.
- Observe or have an observer present during the consent process of human subjects research studies.
- Require progress reports from the investigators and oversee the conduct of any human subjects research studies.
- Place restrictions on any human subjects research study.

IRB committee members and IRB administrative staff shall not be unduly influenced. Any person attempting to unduly influence committee members or administrative staff will be reported to the office of the Vice Chancellor of Research.

References:

45 CFR 46 and 21 CFR 50, 56, 312, 812