

**Title: Institutional Federalwide Assurance of Compliance**

**SOP # 2**

**Department: Office of Research & Economic Development (ORED)**

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**Subject:** Institutional Federalwide Assurance of Compliance

**Policy:**

All of the human subjects research undertaken by this institution and all activities of the Institutional Review Board designated under its Federalwide Assurance of Compliance (FWA00005105), will be guided by the ethical principles of the Belmont Report which are the ethical principles and guidelines for the protection of human subjects in research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; and by the other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects.

The terms of the UC Merced Federalwide Assurance of Compliance will apply whenever this Institution becomes engaged in human subjects research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects. See Office of Research Policy "Activities Subject to UC Merced Human Research Protection Program." The terms of UC Merced's Federalwide Assurance of Compliance will apply to research regardless of the funding source or location of the study.

All research activities designated under UC Merced's Assurance will comply with the Common Rule (45 CFR 46). This includes all Subparts (A, B, C, and D) of the Common Rule. All federally supported research will also comply with any additional regulations and policies of the supporting federal department or agency. UC Merced's Assurance is based on the following principles:

- Safeguarding the rights and welfare of human participants in research is an institutional policy delegated by the Chancellor and the Provost through the Vice Chancellor for Research and Economic Development. It is their responsibility to exercise appropriate administrative oversight to assure that UC Merced's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance.
- UC Merced's faculty, students, and staff which comprise its schools, units, divisions, and facilities are subject to the Assurance and its underlying policies. This includes any research for which an Assurance or another formal agreement (e.g., MOU, IAA) identifies UC Merced's Institutional Review Board as the IRB of Record.
- UC Merced further agrees to apply additional federal regulations such as the U.S. Food and Drug Administration's Human Subjects Regulations (21 CFR 50, 56, 312 and 812); and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under IRB purview.

**Procedures:**

1. A copy of UC Merced's Federalwide Assurance of Compliance will be maintained in the Office of the Vice Chancellor for Research and Economic Development and available to the UC Merced community at any time.
2. The Vice Chancellor for Research and Economic Development will ensure, with the assistance of the staff of the ORED, that this Assurance is updated at least every 36 months, even if no changes have occurred, in order to maintain an active Assurance for UC Merced. Amendments to the Assurance are to be reported promptly to OHRP. This includes changes to the IRB committee membership.
3. The Office of the Vice Chancellor for Research and Economic Development will provide the IRB with resources and professional and support staff sufficient to effectively carry out their responsibilities under the Assurance.
4. Annually, the IRB budget will be reviewed by the Vice Chancellor for Research and Economic Development and modified as necessary to accommodate the volume and type of research reviewed, space, facilities, and staff.

**References:**

45 CFR 46  
21 CFR 50, 56, 312, 812  
HIPAA Regulations