University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 1.5
UCSD Institutional Policies

Policy

There are a number of local institutional policies that complement federal and state regulations regarding research involving human volunteers. In general UCSD may institute or amend policies as needed that relate to human subjects as long as they do not violate Federal or State regulations, or contravene University of California policy.

It is the policy of UCSD that only Principal Investigator-qualified faculty, as defined by UCSD policy PPM-15-10, can serve as the Principal Investigator (PI) on a study unless a PI exemption has obtained from the Office of Academic Affairs for funded studies. This policy, however, does not prohibit salaried faculty from submitting an application to the IRB with the non-salaried faculty as a co-investigator. Individuals who are non-faculty may be permitted to serve as a PI only for non-funded studies on a case-by-case basis. Circumstances under which this may be permitted include that the PI is affiliated with UCSD as a student or has a salaried appointment. The proposed PI must have appropriate training, resources, and qualifications to ensure the protection of the rights and welfare of individuals associated with the study. Student PIs will require a faculty supervisor to be a co-investigator on the study.

All clinical trials and other human subject activity that is not exempt from IRB review involving University faculty, staff, and students must be reviewed by a UCSD IRB unless UCSD has entered into an agreement with an "outside" IRB to provide review such as a Review/Rely agreement. The HRPP program recognizes that, on occasion a research sponsor may require use of a common IRB; such practices are permitted only if the outside IRB review and oversight is in addition to that provided by the UCSD HRPP.

All clinical trial activity sponsored, in whole or part, by commercial and not-for-profit entities must be negotiated by one of the following offices: UCSD Office of Grants and Contracts, or UCSD Office of Clinical Trials Administration.

All sponsored clinical trials must have a clinical trial agreement in place, signed by one of the officials authorized to execute UCSD contracts and grants, before initiation of the clinical trial activity.

A copy of all FDA, NIH, Departmental, Divisional, Organizational Research Units, or Center audits and/or letters of warning must be forwarded to the HRPP Office within ten working days after receipt. Failure to comply with this policy may result in suspension of human subjects approval for project(s). Additionally, a copy of all responses to audits and/or letters of warning

must be sent to the HRPP Office prior to or immediately following being sent to the regulatory agencies.

As a result of the Moore v. Regents court decision, informed patient consent requires "…that (a) a physician must disclose personal interest unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (b) a physicians' failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of confidentiality."

General Counsel of the Regents of the University of California has stated that: "If a principal investigator conducts an activity involving human subjects, but does not obtain the approval of the campus Human Subjects Committee, the Regents would not be obligated to defend or indemnify the principal investigator if legal action were instituted by the subject."

This institutional has policies and procedures for the review of the safe use of hazardous biological materials and organisms, the use of radioactive materials or radiation-producing equipment that results in exposure to human subjects, and for the identification and management of conflict of interest issues of all investigators.

This institution has policies and procedures for the identification and management of conflict of interest issues of not only IRB members, but of all investigators. These conflicts are reviewed and managed by a separate committee, the Independent Review Committee. When appropriate, conflict of interest information is included in informed consent documents.

Procedures

1. IRB Chair, IRB members and Chair Designees review Research Plan and consent documents for compliance with local institutional policy.

Applicable Regulations

Moore v. Regents of University of California, 51 Cal.3d 120, Supreme Court of California, July 9, 1990

PPM 150-10 Policy — Eligibility To Submit Proposals For Extramural Support

UCSD HRPP Standard Operating Policies and Procedures, section 3.19, Collaboration with UCSD Committees