

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

Section 1.2
HRPP Program Organization

Policy

The Dean's Office, UCSD School of Medicine, supports the UCSD Human Research Protections Program (HRPP) and for personnel and fiscal purposes is an administrative unit of the School of Medicine. The San Diego Veterans Medical Research Foundation (VMRF), and general campus also provide support for the program. The UCSD HRPP has review and oversight responsibility for all research involving human subjects that is conducted by UCSD faculty, staff, or students regardless of the site of performance. Specifically, although the program is administratively located within the School of Medicine, its operations are not limited to School of Medicine researchers and includes UCSD "main campus" faculty in all undergraduate and graduate departments, centers, and programs, as well as VASDHS investigators.

For purposes of Veterans Administration programs, the Institutional Review Boards of the UCSD HRPP function as subcommittees of the VASDHS Research and Development (R&D) committee. This administrative relationship does not pre-empt or limit the HRPP responsibilities to OHRP, FDA, University of California, and other organizational entities. As noted elsewhere and in accordance with federal regulations, neither the VASDHS R&D committee nor any other institutional component may approve research involving human subjects if it has not received approval from a UCSD IRB. Within this document, references to VASDHS research apply to research administered by its associated research foundation, VMRF.

A Director who oversees program operations and also functions as the IRB Administrator of record leads the UCSD HRPP. The Director reports administratively to the Vice Chancellor for Health Sciences and Institutional Official for matters involving UCSD IRB policy and institutional compliance. There is an Assistant Director who has operational management responsibilities within the program and report to the Director. This Assistant Director has personnel management responsibilities for protocol analysts within the HRPP office, and administrative support staff.

Procedures

1. IRB Director
 - a) Program interactions with VASDHS, Vice Chancellor for Health Sciences, and Institutional Official.
 - b) Policy and procedure development consistent with federal and local organizational requirements.

- c) Oversight of program implementation and management
- 2. IRB Associate Directors
 - a) Policy and procedure development in collaboration with IRB Administrator
 - b) Overall program implementation and management
 - c) Office personnel management

Applicable Regulations

[21 CFR 56.101\(a\)](#)

[21 CFR 56.109](#)

[21 CFR 56.113](#)

[38 CFR 16.101](#)

[38 CFR 16.109\(a,e\)](#)

[38 CFR 16.113](#)

[45 CFR 46.101](#)

[45 CFR 46.109](#)

[45 CFR 46.113](#)