



Office of Research

Committee on Human Research
Quality Improvement Unit

Human Research
Protection Program
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Dear Principal Investigator:

RE: Letter to Sponsor about IRB Membership

This information is being provided in response to requests from study sponsors for information about the membership of the Institutional Review Board (IRB) at the University of California, San Francisco (UCSF). The IRB at UCSF is called the Committee on Human Research (CHR).

The UCSF holds Federalwide Assurance (FWA) number 00000068. This Assurance remains in effect unless the University is otherwise notified. In this legally binding document, the University assures the federal government that it will meet all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human subject research. The UCSF HRPP is in compliance with both DHHS 46 CFR 46 Subpart E and FDA 21 CFR 56 regulations, which require IRB registration with DHHS. Section 45 CFR 46.107 is identical to Section 21 CFR 56.107 in its discussion of the IRB membership requirements; therefore, UCSF's IRB also meets FDA requirements for IRB membership. In addition, UCSF is fully accredited by the Association for Accreditation for Human Research Protection Programs (AAHRPP) which carefully reviews for compliance with federal requirements for IRB membership. Please see the current [member rosters](#) at on the UCSF Human Research Protection Program (HRPP) website.

As an additional point of information, Paragraph (e) of both sets of DHHS regulations states that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." The IRB is in compliance with this regulation. Nor, by extension, will any investigator participate in convened discussions of the IRB except, in very rare occasions, by invited attendance to provide information to the IRB before its deliberations. Neither deliberations nor voting about the approval or disapproval of a study occurs with an investigator present. If an investigator is also a committee member, the investigator/member is asked to leave the room during the review process. Please refer to the [Investigator Conflict of Interest and CHR Review](#) guidance on the HRPP website at for additional information about avoidance of CHR member conflict of interest.

If you have any other questions about the Committee membership, please call the office at (415) 476-1814 and ask to speak with the Director of the HRPP.

Thank you

John Heldens, CIP
Director, Human Research Protection Program