



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: July 15, 2009

Re: UCSD's FWA and IRB registration

The FDA and OHRP are adding a new regulations to their respective CFRs. These new regulations, 45 CFR 46, subpart E; and 21 CFR 56.106, become effective July 14, 2009. OHRP regulations require Institutional Review Boards (IRBs) that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance approved for federal-wide use to register with HHS. The registration information includes contact information, approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS, and staffing for the IRB.

FDA regulations include that IRBs that review clinical investigations that are regulated by FDA or review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register.

These registration requirements will make it easier for the FDA and OHRP to convey information to IRBs, inspect IRBs, and will support the current IRB registration system operated by OHRP.

As written in the final rule for OHRP, all IRBs must adhere to this new registration process within 90 days of the effective date or when IRB renews its registration. For the FDA, all IRBs must comply with the initial registration requirement, and if necessary, make required revisions to their registration by September 14, 2009.

This document serves to inform interested parties that the UCSD IRBs are currently compliant. The expiration date for UCSD's IORG is June 26, 2012. Under the new regulations, there is no need to update the UCSD IRB registration with OHRP at this time. UCSD will update its IRB registration information when it becomes necessary to revise its current FWA or IORG or prior to September 14, 2009.

For more information about the UCSD FWA, please visit the OHRP website: <http://ohrp.cit.nih.gov/search/IOrgDtl.aspx>. Please use the "Search OHRP Database (Current Data)" option and insert the number, 0000210, for the IORG number and click "Search."

Sincerely,

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