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HUMAN RESEARCH PROTECTIONS PROGRAM

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To whom it may concern:

The five Institutional Review Boards of the University of California, San Diego (UCSD) are duly constituted to conform to all federal regulation requirements of the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) that govern research involving human subjects. They are composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at this institution. The Institutional Review Boards include at least one member whose primary concerns are in the scientific areas and at least one member whose concerns are in nonscientific areas. Each also includes one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. IRB members are of both genders, and fulfill federal requirements for diversity. No member of the Institutional Review Board may participate in the review, or vote on any project in which the member has a conflicting interest, except to provide information requested by the IRB. A list of the Institutional Review Board members, by profession, and gender is on file with DHHS.

The UCSD Human Research Protections Program (HRPP) has written procedures for initial and continuing review, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. IRB committee operations are compliant with requirements defined in 21 CFR (Code of Federal Regulations) Parts 50 and 56, and 45 CFR 46, as well as ICII (International Conference on Harmonization) guidance relating to Good Clinical Practice. UCSD has an approved Federal Wide Assurance of Compliance on file with the Department of Health and Human Services (DHHS). The identification number of this Assurance is FWA00004495. This Assurance is effective through April 6, 2012.

This Federal Wide Assurance of Compliance applies to all research conducted under the aegis of the University of California, San Diego, which includes research conducted at all UCSD medical facilities, including the UCSD Medical Center, the Thornton Hospital, and the San Diego Veterans Affairs Healthcare System.

Questions regarding the program and its federal assurances may be directed to (858) 455-5050.

A handwritten signature in black ink, appearing to read "M Caligiuri".

Michael Caligiuri, Ph.D., Director
Human Research Protections Program