

December 3, 2013

To whom it may concern:

The Institutional Review Board (IRB) of Rady Children's Hospital –San Diego (RCHSD) is 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. The Board is composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at this Institution. It includes at least one member whose primary concerns are in the scientific areas and at least one member whose concerns are in nonscientific areas. The board 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 the Department of Health and Human Services (DHHS).

The Rady Children's Hospital Office for Human Subjects Protection 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 ICH (International Conference on Harmonization) guidance relating to Good Clinical Practice.

Rady Children's Hospital has an approved Federal Wide Assurance (FWA) of Compliance on file with DHHS. The identification number of this Assurance is FWA 00000021. This FWA was initially approved on January 23, 2001. The approval for FWA00000021 is valid through **December 03, 2018**. The IRB Organization number is IORG0000362. The approval for IORG0000362 is valid through **December 03, 2016**. The RCHSD IRB number is IRB00000617. The FWA also permits the IRB to defer to IRB Committees at other Institutions when an agreement is established.

Questions regarding the program and its federal assurance and registration may be directed to the Office for Human Subjects Protection at (858) 966-4008.



J. Ellen Looney  
IRB Coordinator  
Rady Children's Hospital – San Diego



*... because children are the future*