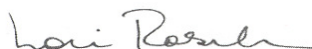


Memo

Date: 28 January 2010
To: Investigators, research staff, and sponsors
From: Lori Roesch, CIM, CIP, Manager, RSPP Office, Aurora IRB
C:
Re: Aurora IRB Statement of Compliance



Research Subject
Protection Program



This memo will serve as verification that the Aurora Health Care Institutional Review Boards (Aurora IRBs) comply with all applicable laws, guidelines, and federal regulations that oversee the operation of Institutional Review Boards, specifically 45 CFR part 46 and 21 CFR parts 50 and 56, as well as the International Conference of Harmonisation E6 Good Clinical Practice: Consolidated Guidance. The Aurora IRBs are duly constituted (fulfilling federal requirements for diversity), have written procedures for initial and continuing review of clinical trials, prepare written minutes of convened meetings, and retain records pertaining to the review and approval process. In accordance with these regulations [45CFR46.107(e) and 21CFR56.107(e)], the Aurora IRBs prohibit any member from participating in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to provide information requested by the IRB. Our policy is to require a voting member of the IRB to leave the room for final discussion and voting on a protocol in which the member is an investigator, or has any conflict of interest.

In addition, Aurora's Research Subject Protection Program has received FULL accreditation by AAHRPP (valid until 11 September 2011).

The Aurora IRBs are registered with the Office for Human Research Protection (OHRP) of the Department of Health and Human Services (DHHS) and this registration also meets FDA requirements. Aurora Health Care currently has two duly constituted IRBs registered with OHRP (see OHRP web site for current expiration dates):

Aurora Biomedical IRB #1: IRB00001266
Aurora Behavioral IRB #3: IRB00002754

Facilities of Aurora Health Care have approved Federalwide Assurances (FWA) with OHRP. If you would like to know the FWA number for a specific Aurora facility, please contact the RSPP office.

If there are additional questions, please feel free to contact me at 414.219.7744.