

# Memo

Date: November 2022  
To: Investigators, research staff, and sponsors  
From: Michelle Maternowski, BS  
Director, RSPP Office, Aurora IRB  
C:  
Re: Advocate Aurora Health IRB Statement of Compliance



Research Subject  
Protection Program

This memo will serve as verification that the Advocate Aurora Health Institutional Review Board (AAH IRB) complies 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 (when applicable). The AAH IRB is 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 AAH IRB prohibits 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 recuse him/herself for final discussion and voting on a protocol in which the member is an investigator, or has any noted conflict of interest.

***In addition, the AAH Human Research Protection Program has received FULL accreditation by AAHRPP (valid through September 2026).***

The AAH IRB is 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. Advocate Aurora Health currently has one duly constituted IRB registered with OHRP (see OHRP web site for current expiration dates):

AAH IRB: IRB00001266

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

If there are additional questions, please feel free to contact me at 414.219.7744 or at IRBOffice@aah.org.