



Sponsor Request for IRB Membership Information

Dear Principal Investigator/Sponsor:

This letter is in response to requests from study sponsors for information regarding the membership of the Research Subjects Review Board (RSRB), the IRB of record for the University of Rochester.

The University of Rochester has a Federalwide Assurance (#9386) with the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS). The Federalwide Assurance is a binding agreement between DHHS and the University of Rochester that assures the federal government that the University will meet all requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human subject research, regardless of sponsorship. As a requirement of the FWA, the RSRB meets both DHHS and FDA requirements for IRB membership as specified in Sections 45 CFR 46.107 and Section 21 CFR 56.107, respectively.

The Research Subjects Review Board complies with DHHS regulations regarding board member conflict of interest. Investigators do not participate in RSRB board meetings except by invitation, and then only to provide information requested by the board.

Additionally, RSRB board members leave the board room prior to discussion or voting on any study in which they may have a real or perceived conflict of interest.

By University policy, the RSRB membership list is not disclosed to sponsors or other external parties. Membership lists are filed as part of the University's FWA.

If you have any other questions about board membership, please contact the RSRB at 585-275-2398.

A handwritten signature in black ink that reads "Kelley O'Donoghue".

Kelley O'Donoghue, MPH, CIP
Associate Vice President for Human Subject Protection
Office for Human Subject Protections