



December 1, 2018

Request for IRB Membership/Roster Information

Dear Principal Investigator/Sponsor:

This letter is in response to requests for information regarding the membership of the National Institutes of Health (NIH) Intramural Institutional Review Board (IRB).

The NIH IRB has a Federalwide Assurance (FWA00005897) with the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS). The Federalwide Assurance (FWA) is a binding agreement between DHHS and the NIH that assures the federal government that the NIH 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 NIH IRB 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 NIH IRB complies with DHHS regulations regarding board member conflict of interest. Investigators do not participate in NIH IRB meetings except by invitation, and then only to provide information requested by the board. Additionally, NIH IRB 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.

The NIH IRB membership list is not disclosed to sponsors or other external parties. Membership lists are filed as part of the NIH's FWA.

If you have any other questions about board membership, please contact the NIH IRB at 301-402-3713 or irb@od.nih.gov.

Respectfully,

A handwritten signature in cursive script that reads 'Tiffany Gommel'.

Tiffany Gommel, MS, CIP
Director
Office of IRB Operations (IRBO)
Office of Human Subjects Research Protections (OHSRP)
National Institutes of Health
Office of Intramural Research
Office of the Director