



U.S. Department of Veterans Affairs
Veterans Health Administration
Minneapolis VA Health Care System

One Veterans Drive
Minneapolis, MN 55417
www.minneapolis.va.gov

May 2022

Re: Federalwide Assurance, IRB registration, and Composition of the Institutional Review Board of Minneapolis VA Health Care System

From: Human Research Protection Program
Minneapolis VA Health Care System

Sponsors of research studies may inquire about IRB composition and request membership rosters for the Minneapolis Veterans Affairs Health Care System (MVAHCS) IRB. The IRB does not provide a list of members but rather a narrative description of our compliance with federal rules and regulations.

The MVAHCS IRB holds a Federalwide Assurance, **FWA 00001480**, from the Office for Human Research Protection (OHRP) in the U.S. Department of Health and Human Services (HHS). The FWA is a binding agreement between HHS and the MVAHCS and is updated at regular intervals.

In the FWA, the MVAHCS assures the federal government that it will meet all the requirements of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all human subjects research regardless of sponsorship. Section 45 CFR 46.107 is identical to Section 21 CFR 56.107 in its discussion of the IRB membership requirements. Therefore, the IRB at the MVAHCS also meets Food and Drug Administration (FDA) requirements for IRB membership.

In addition, the MVAHCS IRB complies with all the requirements of the Department of Veterans Affairs Protection of Human Subjects regulations in Title 38 Code of Federal Regulations Part 16 (38 CFR 16).

The federal regulations state "No IRB may have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." The MVAHCS IRB is in compliance with this regulation.

The FDA regularly conducts surveillance inspections of the MVAHCS IRB. At the most recent audit in September 2021 no deficiencies were noted in the membership composition of the IRB, nor was an FDA Form 483 issued.

If you have any questions about IRB membership, please contact the Human Research Protection Program at (612) 467-5655 or IRBMN@VA.gov.

FWA #00001480

IORG #0000128

IRB-A Registration: #00000211

These registration numbers can be found at <http://ohrp.cit.nih.gov/search/SrchMtch.aspx>.