MEMORANDUM

Re: Information about IRB Composition at the University of Minnesota

From: Debra Dykhuis, Executive Director

Sponsors or regulatory agencies occasionally inquire about IRB composition and request a list of the membership of the University of Minnesota’s Institutional Review Board (IRB). This IRB does not provide a list of membership but prefers to provide a narrative description of our compliance with federal rules and regulations.

This IRB holds a Federal Wide Assurance, number FWA00000312 from the Office for Human Research Protection (OHRP) in the Department of Health and Human Services (DHHS). This FWA is a binding agreement between DHHS and the University of Minnesota and updated per regulatory requirements. The status of the University of Minnesota’s FWA can always be located in the DHHS database. In this document, the University assures the federal government that it will meet all 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 University of Minnesota’s IRB also meets FDA requirements for IRB membership.

As an additional point of information, Paragraph (e) of both of these sections of the regulations states that “No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.” The IRB is in compliance with this regulation. Nor, by extension, will any investigator participate in convened discussion or voting of the IRB except, to provide information to the IRB except, to provide information to the IRB upon request.

The Human Research Protection Program at the University of Minnesota is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP http://aahrpp.org/www.aspx).

This IRB is regularly inspected by the Food and Drug Administration (FDA). Our biomedical committee (IRB00000438) is registered with the FDA. The last inspection by the FDA was completed in October 2015. Additional committees registered with OHRP include the Faculty Social/Behavioral committee (IRB00000440) and the Student Social/Behavioral committee (00003398).

If you have any other questions about the IRB membership, please call (612) 626-5654.