



September 6, 2023

Re: SLHS IRB Compliance Statement

From: Melissa Nowicki, MS, CCRP, IRB Manager

Saint Luke's Health System (SLHS) Institutional Review Board (IRB) holds a Federal Wide Assurance, number FWA00024002, 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 SLHS IRB and updated per regulatory requirements. The status of SLHS IRB FWA is also located in the [DHHS database](#). In this document, SLHS IRB 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, SLHS IRB also meets FDA requirements for IRB membership.

Per regulation, no IRB member may participate in review of any IRB submission in which the member has a conflicting interest, except to provide information requested by the IRB. SLHS IRB is in compliance with this regulation.

IRB#00000749 (Board I) and IRB#00011523 (Board II), IORG0000439, is registered with OHRP and FDA.

IRB rosters, with initials of IRB members, are located on the [SLHS IRB website](#). These are publicly available and can be provided to sponsors or regulatory agencies.

In addition, the SLHS IRB operates in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Rule applicable to research, as described in 45 CFR Parts 160 and 164.

If you have any questions about IRB membership, please contact the IRB office at irb@saintlukes.org.