SLHS IRB Compliance Statement

Saint Luke’s Health System (SLHS) Institutional Review Board, FederalWide Assurance (FWA) #00024002, IRB#00000749 (Board One) and IRB#00011523 (Board Two), IORG0000439, is organized and operates in compliance with all relevant federal and local regulatory requirements related to the protection of human research participants. The IRB registration number’s applies for both FDA and OHRP registrations.

SLHS is in compliance with the regulations of the United States Food and Drug Administration (US FDA) as described in 21 CFR Parts 50 and 56, the International Conference on Harmonization Good Clinical Practice Guidelines E6 and the United States Department of Health and Human Services regulations 45 CFR Part 46, as applicable.

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.