Assurance of Compliance

October 23, 2019

The Spectrum Health IRB complies with applicable federal and state laws and regulations governing IRBs and research with human subjects. The Spectrum Health IRB has written procedures for initial and continuing review of research, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. These activities comply with the requirements of 21 CFR Parts 50 and 56, 45 CFR 46 and its subparts, and ICH Good Clinical Practice (GCP), as applicable. The Spectrum Health IRB has a Federalwide Assurance (FWA) and is registered with both the FDA and OHRP.

FWA0000058
IORG0000551
IRB0000083

This information as well as current status of the Spectrum Health FWA and IRB registration (e.g., expiration dates) may be verified on the HHS website: http://OHRP.cit.nih.gov/search/irbdl.aspx.

If you have any questions or need further information, please do not hesitate to contact the Spectrum Health Office of Research Oversight at 616.486.2031.

Signed,

[Signature]
Brenda Hoffman
Director, Office of Research Oversight