

May 9, 2018

Assurance of Compliance

The Metro Health Institutional Review Board (IRB) is compliant with all applicable federal and state laws and regulations governing the conduct of IRBs and research with human subjects. The Metro Health IRB has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46 and its subparts, and as applicable, ICH Good Clinical Practice (GCP). The Metro Health IRB has a federal wide assurance and is registered in compliance with both the FDA and OHRP. The following federal identification numbers are specific to Metro Health:

FWA00003875

IORG0002456

IRB00003013

This information can be verified by visiting the OHRP website found at:

<http://ohrp.cit.nih.gov/search/IrbDtl.aspx>).

If you have questions or need further information, please do not hesitate to contact the Office of the Metro Health IRB at 616-252-5026.