



Institutional Review Board
Donald Guthrie Foundation
One Guthrie Square
Sayre, Pennsylvania 18840-1692
Tel (570) 887-4885

June 1, 2016

Re: Assurance of Compliance

The Institutional Review Board of the Guthrie Clinic (GC IRB) is compliant with all applicable federal and state laws and regulations governing IRBs and research with human subjects. The GC 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 regulation 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46 and ICH Good Clinical Practice E6, Section 3 (GCP E6). The GC IRB has a federalwide assurance and is registered with OHRP; the registration numbers are as follows:

OHRP
FWA 00000278
IORG 0000585
IRB 00000918

This information may be verified on the HHS website (<http://ohrp.cit.nih.gov/search/>).
If you have questions or need further information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael Georgetson".

Michael Georgetson, M.D., FACG
Chairman, Institutional Review Board

www.guthrie.org

