November 18, 2014

To Whom it May Concern;

The Vanderbilt University (VU) Institutional Review Boards (IRBs) through its Federalwide Assurance and registered IRBs with the Office for Human Research Protections (OHRP) fulfills all federal requirements as a constituted IRB. The VU IRBs comply with all US regulatory requirements related to the protection of human subjects. Specifically, the VU IRBs comply with 45 CFR 46 Subparts A-D, 45 CFR 164.508-514, 21 CFR 50 and 56 and applicable portions of 21 CFR 54, 21 CFR 312, 32 CFR 812, and 21 CFR 814.

Although the VU IRBs have not officially adopted the ICH-GCP guidelines in their entirety, their policies and procedures are in accordance with ICH-GCP as adopted by the Food and Drug Administration (FDA) particularly as published in the Federal Register, May 9, 1997, regarding Institutional Review Board/Independent Ethics Committee (IRB/IEC) criteria 3.1 through 3.4 of E-6.

The VU IRB’s written policies and procedures as well as Committee rosters are available on line at: www.vanderbilt.edu/irb/.

Sincerely,

Julie Ozier, MHL, CIP
Director
Human Research Protection Program/IRB
Vanderbilt University