Human Research Protections Program - HRPP
Supporting the work of the IRB and Providing HRPP Oversight

VANDERBILT

August 6, 2018

To Whom It May Concern;

The Vanderbilt University Medical Center (VUMC) Institutional Review Boards (IRBs) through its Federalwide Assurance and registered IRBs with the Office for Human Research Protections (OHRP) fulfills all federal requirements as duly constituted IRBs. The VUMC IRBs comply with all US regulatory requirements related to the protection of human subjects. Specifically, the VUMC IRBs comply with 45 CFR 46 Subparts A-E, 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 VUMC 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 VUMC IRB's written policies and procedures as well as Committee rosters are available on line at: www.vanderbiilt.edu/irb/.

Sincerely,

Julie Ozier, MHL, CIP
Director
Human Research Protections Program/IRB

3319 West End Ave., Suite 600
Nashville, TN 37203
www.vanderbilt.edu/irb