

June 5, 2006

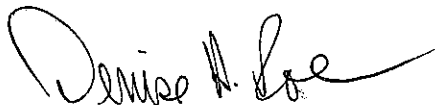
To Whom It May Concern:

The Vanderbilt University (VU) Institutional Review Board (IRB) 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 IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the VU IRB complies with 45 CFR 46 Subparts A-D, 45 CFR 164.508-514, 21 CFR 50, 21 CFR 56 and applicable portions of 21 CFR 54, 21 CFR 312, 21 CFR 812, and 21 CFR 814.

Although the VU IRB has not officially adopted the ICH-GCP guidelines, its policies and procedures are in accordance with the ICH-GCP guidelines 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 online at: <http://www.mc.vanderbilt.edu/irb/>.

Sincerely,



Denise A. Roe, MSM, CCRP, CIP
Director, Institutional Review Board
Vanderbilt University