October 29, 2010

To Whom It May Concern:

The University of Utah 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 duly constituted IRB. The University of Utah IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the University of Utah IRB complies with the 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 University of Utah 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 University of Utah IRB’s written policies and procedures are available online at: http://www.research.utah.edu/irb/. Thank you for your consideration.

Yours truly,

John Stillman
Director
IRB – Institutional Review Board at
University of Utah