Copernicus Group IRB
One Triangle Drive
Suite 100
PO Box 110605
Research Triangle Park, NC 27709
http://www.cgirb.com

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Copernicus Group IRB Statement of Compliance

Copernicus Group IRB (CGIRB) was established in 1996, and consists of an independent institutional review board (CGIRB Board) and support staff. CGIRB provides ethical review and support services to principal investigators (PIs), institutions, contract research organizations (CROs), and sponsors of human subjects research.

CGIRB is organized and operates in compliance with the International Conference on Harmonisation (ICH) E6 Consolidated Guidelines for Good Clinical Practice and all applicable federal and local regulations. FDA-regulated studies are reviewed in accordance with the applicable regulations outlined in Title 21 of the Code of Federal Regulations (eg, Parts 50, 56, 312, 812). Non-FDA regulated studies are reviewed under the provisions of Title 45 of the Code of Federal Regulations, Part 46.

Copernicus Group IRB was inspected by the FDA in 1999 and again in 2005 with no objectionable findings and no Forms FDA 483 issued. In 2004, Copernicus Group IRB was awarded full accreditation of the human research protection program by AAHRPP®, The Association for the Accreditation of Human Research Protection Programs, Inc, and was awarded full reaccreditation in 2007.

In accordance with 21 CFR 56.106 and 45 CFR 46.106, CGIRB is registered with FDA and the Office for Human Research Protections (OHRP) as IORG0000942 (IRB00001313). CGIRB's registration currently expires on 24 July 2012. FDA and OHRP do not issue certificates of registration; however, the registration may be verified through OHRP's web site at http://ohrp.cit.nih.gov/search/search.aspx.

Glenn Veit, JD, CIP
Chairperson
Copernicus Group IRB