



Copernicus Group IRB
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CONFIDENTIAL

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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 regulations outlined in Title 21 of the Code of Federal Regulations (21 CFR). Non-FDA regulated studies are reviewed under the provisions of 45 CFR.

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. CGIRB is registered with the Office for Human Research Protections (OHRP) as IRB00001313, enabling the review of HHS-supported or -conducted human subjects research under the Federalwide Assurance (FWA) of a submitting body.

Glenn Veit, JD, CIP
Chairperson
Copernicus Group IRB