Copernicus Group IRB
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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 in compliance with local regulations and the regulations of the United States Food and Drug Administration as described in 21 CFR Parts 50 and 56, the International Conference on Harmonisation (ICH) E6, and the United States Department of Health and Human Services 45 CFR Part 46.

Copernicus Group IRB was inspected by the FDA in 1999, 2005, 2010, 2013 and again in 2014 with no Form FDA 483 issued.

In 2004, Copernicus Group IRB was awarded full accreditation of thehuman research protection program by AAHRPP®, The Association for the Accreditation of Human Research Protection Programs, Inc, and was awarded full reaccreditation in 2007 and 2011.

CGIRB is registered with the Office for Human Research Protections (OHRP)and FDA as IRB00001313.

In addition, CGIRB utilizes electronic signatures compliant with 21 CFR Part 11.

Glenn Veit, JD, CIP
IRB Chair
Copernicus Group IRB