



### Copernicus Group IRB

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Sharon Hill Price  
Founder and CEO

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#### Areas of Expertise:

- All Phases of Research
- All Therapeutic Areas
- Vulnerable Populations
- Specialized Training Available for Sponsors
- Streamlined Processes
- Expeditious Turnaround Time

## COPERNICUS GROUP IRB

### COMPANY PROFILE:

Copernicus Group IRB was established in July 1996 as an independent institutional review board (IRB or "Board") and operates in compliance with Federal Regulations governing institutional review boards set forth in 21 CFR, 45 CFR and ICH GCP Guidelines.

Composed of highly qualified individuals dedicated to ensuring that the safety and welfare of research study participants is protected, CGIRB reviews research protocols, investigators, and subject information & consent forms to ensure compliance with federal regulations and consideration of local concerns. CGIRB reviews studies for single investigators and serves as a central IRB for multi-center trials involving thousands of investigators. Additionally, Copernicus Group IRB functions as IRB of Record for studies conducted at hospitals and academic institutions.

In August 1999 and July 2005, Copernicus Group IRB underwent

successful FDA inspections (no FDA Form 483 issued). CGIRB's Human Research Protection Program was awarded full accreditation by AAHRPP®, The Association for the Accreditation of Human Research Protection Programs, Inc in July 2004, and received a full re-accreditation in September 2007. Special commendation was given on the quality of CGIRB's Board and their review. Copernicus Group IRB is also a Certified Women's Business Enterprise and can provide a certificate to assist clients in meeting supplier diversity initiatives.

In addition to comprehensive IRB review, CGIRB's proven ability to offer personalized service and training consistently results in streamlined startup timelines and increased process efficiency throughout the life of a project. CGIRB utilizes a special team specifically dedicated to study start-up. A central Project Management team provides a dedicated point of contact (POC) throughout the life of the study.



**Sharon Hill Price**  
Founder & CEO

*"With a proven track record of over 10 years in the research industry, a full AAHRPP Accreditation and an IRB and staff committed to the protection of human subjects while supporting our clients in the submission process, CGIRB is well positioned to meet the challenges of performing ethical review."*

## PRODUCTS AND SERVICES

- IRB Review of FDA and OHRP Regulated Studies
- IRB Review of Phase I-IV drug studies in all therapeutic areas
- IRB Review of Device, Biologic,

- Observational, Registry and Social Behavioral Studies
- Special Study Start-up Team dedicated to expeditious turnaround times
- Education and Training Resources

- Consulting Services
- Single Point of Contact for each study
- Translation services
- Educational Website
- Online Submission Capabilities