



WIRB-Copernicus Group Companies

**Date:** October 4, 2018  
**To:** Sponsors, CROs and sites  
**From:** David Borasky, Vice President, IRB Compliance, WIRB-Copernicus Group  
**Re:** WIRB-Copernicus Group Panel 18 as IRB of record

This memo serves as clarification regarding the requirement in section five of FDA Form 1572 that the site / investigator provide the name and address of the institutional review board that is responsible for review and approval of the study.

Panel 18 is shared by Western IRB (WIRB) and Copernicus Group IRB (CGIRB), working in a single electronic system. The electronic system that is used to manage Panel 18 is fully validated and compliant with 21 CFR Part 11.

All actions by Panel 18 are applicable at both WIRB and CGIRB. Therefore, either WIRB or CGIRB may be listed on a 1572 for a site / investigator approved by Panel 18 and this will be compliant with FDA requirements.

You may keep this memo on file to document WCG's position on the 1572 question.

Addresses for section 5 of FDA Form 1572

Copernicus Group IRB  
5000 Centregreen Way, Suite 200  
Cary, NC 27513

Western Institutional Review Board  
1019 39th Avenue SE Suite 120  
Puyallup, WA 98374

Compliance statements for Western IRB and Copernicus Group IRB are available on their company websites.

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