

To Whom It May Concern:

This letter is to confirm that the Western Institutional Review Board (WIRB) is the University of Rochester's IRB of record for FDA-regulated, industry-sponsored, industry-initiated drug and device trials involving greater than minimal risk.

Should you have any questions, you may contact me at 585-275-3050.

Sincerely,

Tiffany Gommel, MS, CIM, CIP

Executive Director

Research Subjects Review Board