



February 8, 2012

To Whom It May Concern:

This letter confirms that the Institutional Review Board (IRB) for the University of Maryland, Baltimore (UMB) is duly constituted according to the federal guidelines in 45CFR46, complies with FDA guidelines in 21CFR56, 21CFR50, and complies with International Conference on Harmonization Good Clinical Practice Guidelines. This letter also confirms that the University of Maryland, Baltimore IRB is the Institutional Review Board of Record for the Veterans Administration Maryland Health Care Medical System.

Specifically, the UMB IRB is comprised of clinicians, researchers, ethicists, scientists, non-scientists and research subject advocates both internal and external to University of Maryland, Baltimore. The UMB IRB operates within the federal guidelines with respect to the review and approval of research protocols involving human subjects. Any individual with a conflicting interest in the research does not deliberate or vote on those protocols under review.

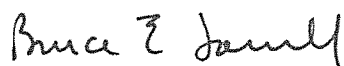
The U of Maryland, Baltimore, Professional Schools Federal Wide Assurance (FWA) number is FWA00007145. The FWA expiration date can be found on the Office of Human Research Protections' (OHRP's) website at - <http://ohrp.cit.nih.gov/search/fasurdtl.asp?ASURIDENT=FWA00007145&Submit=SEARCH>

Dr. Robert Rosenthal is the Chairman of the IRB. It is the IRB's policy not to distribute a roster of all of the IRB members.

Due to the sensitive nature of the materials being reviewed by the IRB, all materials are maintained in a strictly confidential manner. The University of Maryland, Baltimore IRB utilizes an electronic protocol management system called CICERO. The CICERO system is compliant with FDA 21 CFR 11. All copies of paper materials issued to UMB IRB members for review are returned and all copies are destroyed by the IRB office staff. Original paper documents are kept in a secure facility where access is limited to the IRB office staff. Electronic IRB records are maintained in the IRB with the appropriate role security.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Bruce E. Jarrell, MD, FACS
University of Maryland, Baltimore Institutional Official