



February 28, 2018

To whom it may concern,

This letter confirms that the Institutional Review Board (IRB) at the University of Maryland Baltimore (UMB) is duly constituted according to the federal guidelines at 45 CFR 46, complies with FDA regulations at 21 CFR 56 and 21 CFR 50, and complies with International Conference on Harmonization Good Clinical Practice Guidelines. This letter also confirms that the University of Maryland Baltimore IRB is an IRB of record for the Veterans Affairs Maryland Health Care System (VAMHCS).

Specifically, the UMB IRB is comprised of clinicians, researchers, ethicists, scientists, non-scientists, and research subject advocates both internal and external to the 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 00007145. The FWA expiration date can be found at <https://ohrp.cit.nih.gov/search/FwaDtl.aspx>.

Dr. Robert Rosenthal is the UMB IRB Chairman. It is the IRB's policy not to distribute a roster of all 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 21 CFR 11. All copies of paper materials issues to 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 IRB office leadership. 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,

A handwritten signature in black ink that reads "Bruce E. Jarrell".

Bruce E. Jarrell, MD
Executive Vice President & Provost
Institutional Official
University of Maryland Baltimore