December 6, 2016

Re: University of Colorado Denver Assurance - Human Research Protection Program

To Whom It May Concern:

The Colorado Multiple Institutional Review Board (COMIRB) at the University of Colorado Denver (UC Denver) has an on-going commitment to ensure that all research will be conducted following strict ethical standards, as well as complying with the applicable federal and state laws, regulations and requirements.

To that end, I serve as the Director of COMIRB and can affirm that COMIRB has the requisite registration and assurances with the DHHS Office of Human Research Protections. Our IRB registration is #IORG0000433 and our federal-wide assurance is FWA# 00005070.

Additionally, COMIRB has a full accreditation for our human research protection program by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

Further, COMIRB (also acting as the COMIRB Privacy Board) complies with the privacy and security standards set forth by Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA) and its applicable regulations set forth in 45 CFR Parts 160, 162, 164 and the standards for human subjects protections set forth by DHHS Office of Human Research Protections in 45 CFR 46, the DHHS Food and Drug Administration in 21 CFR Parts 50, 56, and the Veterans Health Administration in 38 CFR 16. COMIRB also complies with the Good Clinical Practice standards set forth by the Food and Drug Administration and the International Conference on Harmonization (to the extent that the regulations align).

If you need additional information, please contact the COMIRB office at 303-724-1055 or COMIRB@ucdenver.edu.

Sincerely,

[Signature]

John Heldens, CIP, CCRP, RAC
Director, Colorado Multiple Institutional Review Board