



University of Colorado
Denver | Anschutz Medical Campus

Colorado Multiple Institutional Review Board (COMIRB)

13001 E. 17th Place, Rm N3214
Mail Stop F490
Aurora, CO 80045
Main Office: 303-724-1055
Main Fax: 303-724-0990

March 5, 2021

Re: 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) is committed to ensuring that all research will be conducted following strict ethical standards, and will comply with all applicable federal and state laws, regulations and requirements.

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

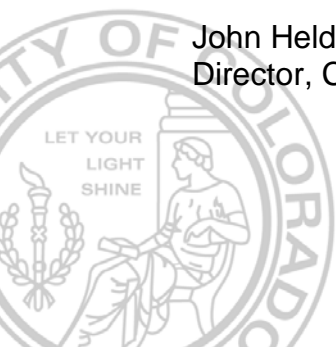
COMIRB's IRB Organization number is IORG0000433, and our federal-wide assurance is FWA# 00005070. COMIRB has five registered IRBs and meets the DHHS 45 CFR 46 Subpart E and FDA 21 CFR 56 regulation requirements for IRB registration. IRB rosters are available on the [COMIRB website](#). If an IRB member has a conflict of interest, he or she will not participate in the deliberation and voting of that protocol. Additional information about IRB member conflicts of interest can be found in Section 5.6 of the [COMIRB Policies and Procedures](#).

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,

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



Downtown Campus
Denver, Colorado

Anschutz Medical Campus
Aurora, Colorado