

Office of the Vice President for Research

Human Subjects Office / IRB University of Iowa 600 Newton Road 105A HLHS Iowa City, Iowa 52242-1098 319-335-6564 irb@uiowa.edu https://hso.research.uiowa.edu/

STATEMENT OF COMPLIANCE

The University of Iowa has a federalwide assurance (FWA) of compliance with the Office of Human Research Protections under FWA000003007. The University of Iowa assured that activities related to human subjects research, regardless of the source of support, will be guided by the Belmont Report as its statement of principles governing the institution for protecting the rights and welfare of human subjects.

The University of Iowa FWA includes three registered internal Institutional Review Boards (IRB) under IORG# IORG0000070:

IRB-01(Biomedical) IRB00000099 IRB-02(Social Science\Behavioral) IRB00000100 IRB-03(Biomedical\VA Review only) IRB00006022

The University of Iowa Institutional Review Boards are duly constituted with written procedures for initial and continuing review of human subjects research; written minutes of convened IRB meetings, an electronic research application system to adhere to records retention requirements for the review and approval process. All documented processes are compliant with the requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP) as adopted by the FDA, as applicable.

The University of Iowa IRB reviews are also in compliance with other applicable federal and state laws and regulations governing IRBs and human subjects research. The <u>UI IRB Standard Operating Procedures and Researcher Guide</u> is available via institutional log in (<u>https://hso.research.uiowa.edu/standard-operating-procedures-and-researcher-guide</u>).

The University of Iowa has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2003.