

April 28, 2014

To Whom It May Concern:

The University of Utah Institutional Review Board (IRB), through its Federal-wide Assurance and registered IRBs with the Office of Human Research Protections (OHRP), fulfills all federal requirements as a duly constituted IRB. The University of Utah IRB complies with all U.S. regulatory requirements related to the protection of human research participants as follows.

The University of Utah Human Research Protection Program (HRPP) subscribes to ethical principles set forth in The Belmont Report, which include respect for persons, beneficence, and justice.

The University of Utah has an active Federal-wide Assurance (FWA00003745) and agrees to apply 45 CFR Part 46 whenever the University "becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance."

The University HRPP adheres to 21 CFR Parts 50 and 56 as well as other parts of 21 CFR as appropriate for clinical investigations regulated by the Food and Drug Administration (FDA). The University HRPP applies the principles of the International Conference on Harmonization's Good Clinical Practices (ICH-GCP) to clinical investigations, as adopted by the FDA and insofar as the standards and requirements are consistent with 21 CFR.

The University HRPP applies the standards of the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) to research that involves the use of protected health information (PHI).

The University of Utah IRB has written policies and procedures available online at <http://irb.utah.edu/>.

Sincerely,



John Stillman
Director
IRB, University of Utah