HOWARD
UNIVERSITY

Office of Regulatory Research Compliance

STATEMENT OF COMPLIANCE

February 11, 2016

FWA#: 00000891

FWA Expiration Date: 1/23/2020

The Howard University Institutional Review Boards (HUIRBs) operates under all applicable federal and state regulations, including Food and Drug Administration (FDA) and the Office of Human Research Protection (OHRP) guidance. Specifically, the IRB complies with regulations 45 CFR 46, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 45 CFR 164.508-514. In addition, the IRB complies with the International Conference on Harmonization (ICH) E6 and Good Clinical Practice (GCP) guidelines, to the extent required by the FDA. Additionally, the IRB complies with the ethical principles of the Belmont Report and other ethical standards recognized by federal departments and agencies that have adopted federal policies for the protection of human subjects.

The HUIRBs are duly constituted, and consist of members of the clinical and basic sciences, non-scientists, as well as members of the community as required by Federal regulations to assure a fair and thorough review process. The HUIRBs allow only those board members who are independent of the investigators and the sponsor of the research, to vote/provide opinion on the research, have written procedures for initial and continuing review of clinical trials, prepare written minutes of convened meetings, and retain records pertaining to the review and approval processes. These measures are to ensure compliance with all U.S. regulatory requirements related to the protection of human research participants.

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