



DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board

Statement of Compliance

To Whom It May Concern:

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), FWA 00009025, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45 CFR 46, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 45 CFR 164.508-514. In addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U. S. Food and Drug Administration.

Signature of Chair/Vice Chair/Designee

Date