DukeHealth

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 (ICH) as adopted by the U.S. Food and Drug Administration.

Sharon Ellison, Pharm.D.

*Signature of Sharon Ellison, Pharm.D.*
*Executive Director, DUHS IRB*

02/26/2025

*Date*

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