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IRB-HSR Compliance Statement

To Whom It May Concern:

The University of Virginia IRB for Health Sciences Research (IRB-HSR) is duly constituted, fulfilling all the applicable requirements for diversity and qualification of its members, allowing only those IRB members who are independent of the investigation and the sponsor of the protocol to participate in the approval of human research studies under IRB-HSR consideration. Further, the IRB-HSR has enacted written procedures for initial and continuing review of human research studies including the preparation of written minutes of all convened meetings and retention of records pertaining to the review and approval process. The IRB-HSR complies with all applicable federal and state legal requirements for human subject research protections, including those of the FDA, OHRP, the ICH GCP (International Conference on Harmonization Good Clinical Practice) to the extent they are compatible with FDA and DHHS regulations.

The IRB-HSR is registered with OHRP and the FDA.

The Federalwide Assurance number is 00006183

The parent organization registration number is ORG# 0000264

The registration # for IRB-HSR #1 is 00000447

The registration # for IRB-HSR #3 is 00010459