

June 21, 2022

RE: BRANY IRB Institutional Review Board Compliance

To Whom it May Concern:

The Biomedical Research Alliance of New York (BRANY) Institutional Review Board (IRB#00000080) operates in compliance with regulations concerning the protection of human subjects enumerated at 45 CFR 46, as well as 21 CFR parts 11, 50, 54. 56, 312, and 812. The Institutional Review Board also complies with the FDA's Good Clinical Practice (GCP) Guidelines.

Investigators who are also members of the BRANY Institutional Review Board do not participate in discussion of or voting for projects in which they are involved.

If you have any questions or require any additional information, please contact the IRB staff at 516-470-6900. Thank you.

Sincerely,

Mark J. Sinnett, PharmD

Co Chairperson, BRANY IRB

Ira Leviton, MD Co-Chairperson, BRANY IRB