



March 13, 2018

RE: BRANY 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 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 he or she is involved.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Sinnett".

Mark J. Sinnett, PharmD
Co-Chairperson, BRANY IRB

MS/IL: rh

A handwritten signature in blue ink, appearing to read "Ira Leviton".

Ira Leviton, MD
Co-Chairperson, BRANY IRB