SUNY RF
The Research Foundation for
The State University of New York

Institutional Review Board
& Privacy Board

FWA#:3624 • IORG#:64 • IRB#:11521

SUNY DOWNSTATE
Medical Center

DATE: **October 3, 2018**

RE: **Statement of Research Compliance for SUNY Downstate Medical Center**

The SUNY Downstate Institutional Review Board & Privacy Board (IRB) is a committee established to review and approve human research or determine exemptions for such approval.

The IRB ensures ethical conduct of human research in compliance with applicable regulations and policy, while protecting the rights and welfare of research participants. The IRB ensures appropriate regulatory approval and compliance of clinical trials involving investigational or unlicensed test articles (drugs, biologics, and devices). The IRB approves each research protocol or plan according to criteria based on policy, applicable laws, regulations, codes, guidance, and best practices. The IRB may perform or request audits as necessary, serves as a Privacy Board, establishes policy, and provides guidance, education, and technical support to investigators and their collaborators.

The IRB maintains a membership in accordance with regulatory requirements; follows written procedures for initial and continuing review of human research and clinical trials; prepares written minutes of convened meetings; and retains records pertaining to the review and approval process.

The IRB and Investigators operate in compliance with applicable regulations pertaining to human research, including but not limited to the following:

- NY State Protection of Human Research Participants, NYS Article 24A,
- NY Codes, Rules and Regulations, Title 14, Department of Mental Hygiene, Part 527, Rights of Patients
- NY Mental Hygiene Law, Article 81,
- NY Family Health Care Decisions Act (FHCDA) - Health Care Decisions for Adult Patients by Surrogates (NY Article 29-CC-§2994-D),
- U.S. Department of Health and Human Services (HHS) regulations for the protection of human research participants 45 CFR Part 46, including subparts A-E,
- U.S. Food and Drug Administration (FDA) Regulations for Clinical Trials, 21 CFR Parts 11, 50, 56, 312, and 812,
- FDA Amendments Act of 2007 (FDAA)
- HHS Office for Civil Rights Health Insurance Portability and Accountability Act of 1996 (HIPAA) 45 CFR Parts 160, 162, and 164,
- HHS Confidentiality of Alcohol and Drug Abuse Patient Records (45 CFR 2)

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The IRB and Investigators follow the ethical principles set forth in The Belmont Report. When applicable, the Investigators and IRB adhere to the International Conference on Harmonization (ICH) Good Clinical Practices E6 (GCP), World Medical Association Declaration of Helsinki, the European Union General Data Protection Regulation (GDPR), and any relevant international human research regulations and customs.

The SUNY Downstate Medical Center's Conflict of Interest policy complies with federal regulations (42 CFR Part 50 & 94) effective August 24, 2012, for researchers who are applying for or have received research funding from the Public Health Service (PHS).

Regards,

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