



**SUNY
DOWNSTATE
Medical Center**

University Hospital of Brooklyn
College of Medicine
School of Graduate Studies
College of Nursing
College of Health Related Professions
School of Public Health

Institutional Review Board

Phyllis Supino, EdD, Chair
Stanley Friedman, MD, Vice-Chair
Daniel Cukor, PhD, Vice-Chair
Kevin L. Nellis, MS, CIP, Executive Director

DATE: October 23, 2015

RE: Statement of Compliance for SUNY Downstate Medical Center
Federal Wide Assurance Number (FWA) 00003624

The primary responsibility of the SUNY Downstate Medical Center IRB is to protect the the rights, privacy, safety and welfare of the human research participants.

The SUNY Downstate Medical Center Institutional Review Boards A, B, and E are duly constituted. The IRBs have 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 IRBs are organized and operate in compliance with NY State regulations pertaining to human research, including NYS 24A; the U.S. Department of Health and Human Services and U.S. Food and Drug Administration regulations for the protection of human subjects as described in 45 CFR Part 46 and 21 CFR Parts 50 and 56. The IRBs and Investigators follow the ethical principles of The Belmont Report. When applicable, the Investigators and IRB adhere to 21 CFR 312 and 812, 45 CFR Part 160, Part 162, and Part 164, the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), World Medical Association Declaration of Helsinki and any relevant International human research regulations and customs. The IRBs utilize electronic signatures compliant with 21 CFR Part 11. The SUNY Downstate Medical Center's Research Conflict of Interest policy complies with federal regulations, effective August 24, 2012, for researchers who are applying for or have received research funding from the Public Health Service (PHS).

The SUNY Downstate Medical Center Institutional Review Boards are registered with OHRP/FDA; our IRB registration numbers are IRB00000088, IRB00000089, IRB00000090 under IORG0000064. To learn more contact Kevin Nellis at 1-718-613-8461 or Kevin.Nellis@downstate.edu.

Thank You.


Phyllis G. Supino, EdD
IRB Chair