

Individual Investigator Agreement (IIA)

**(Commitment to follow SUNY Downstate Health Sciences University Policies & Procedures
and be under the oversight of the SUNY Downstate IRB & Privacy Board)**

Submit an executed agreement with each IRB Application.

The Individual Investigator attests that all information on this form is true and accurate to the best of my knowledge.

- The Individual Investigator will comply with Downstate Policy IRB-01 and other relevant Downstate Policy that applies to the research.
- When protected health information is involved in a study, the Individual Investigator is responsible for complying with the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule") and the Standards for Security of Electronic Protected Health Information (the "Security Rule") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") including the 2013 HIPAA Omnibus Rule and complying with the applicable requirements under SUNY Downstate's HIPAA policies and procedures located at www.downstate.edu/hipaa.
- The Individual Investigator agrees to complete all training modules required by SUNY Downstate as described on the most current IRB Guidance, as applicable to a study under review by the Downstate IRB.
- The Individual Investigator understands that the State of New York does not purchase insurance against liability arising out of the negligent acts of the State, the State University or their respective officers or employees. In lieu of such insurance, the State certifies that it self-retains for insurance purposes and hereby makes the following certifications: The State shall be responsible for any and all damage (including death) which may arise out of the negligent acts of the State, its officers and employees, acting within the scope of their authority. The State's obligations with respect to claims for such damage or injury are limited only to the availability of lawful appropriations as required by Section 41 of the State Finance Law, and further subject to a determination of liability pursuant to the provisions of the New York Court of Claims Act.
- SUNY Downstate and Individual Investigator will be responsible for their own negligence in connection with their respective performance of this Agreement.
- The Individual Investigator shall indemnify, defend and hold harmless SUNY Downstate Health Sciences University and the SUNY Research Foundation and its and its affiliates' directors, officers, employees, and agents (each, including the SUNY Downstate IRB and Privacy Board, an "Indemnitee") from and against any and all costs, damages, liabilities, or expenses (including reasonable attorneys' fees and court costs) or other losses incurred by the Indemnitee, or brought by a third party against an Indemnitee, arising from Individual Investigator's negligence, intentional misconduct, breach of this Agreement, or failure to comply with applicable laws, rules, and regulations.
- The Downstate Financial Conflict of Interest Committee cannot review COI determinations of those who are not employed by Downstate; therefore, an Investigator who is also an "Investigator for the Purposes of COI" and not an employee of Downstate must provide a COI adjudication letter and documentation that they have completed their required COI training from their employer with a statement that the employer follows NIH COI policies. If their employer does not have jurisdiction or follow NIH COI policies, the investigator should indicate this in the IRB application seek these requirements from an external COI Committee, Attorney, or Consultant who confirms they follow NIH policies.

- The Individual Investigator is responsible for the acts or omissions in connection with this Agreement. This representation is based upon and limited to the obligation of the Individual Investigator to defend, indemnify and hold harmless Downstate, its officers, employees, agents and contracted affiliates from any and all liability and damages arising from or in connection with the research.
- This Agreement may not be assigned or transferred, in whole or in part, by either party without prior written consent of the other party. Any attempt to do so shall be void.
- The e-mail address for the Individual Investigator may be used for other communications from SUNY Downstate.
- The Individual Investigator understands that upon execution of this agreement, the Downstate IRB will send a copy of this executed form to SUNY Downstate's Office of Compliance and Audit Services (OCAS) to activate HIPAA training request. Approval for Enrollment in SUNY Downstate training is contingent upon OCAS and IRB review and approval of the enrollment request.

Individual Investigator's Name:

Degree:

Address:

Phone #:

E-mail:

Individual Investigator MM/DD of birth: Month / Day:

NPI Number, if applicable:

Signature of Individual Investigator

Date: _____

Signature of Designated Official
SUNY Downstate Health Sciences University

Kevin Nellis, MS

Executive Director, Human Research Protections Program and Quality Assurance

For: Heidi Aronin, MPA, Senior VP and Chief Administrative Officer, Institutional Official

Date: _____

CC: Downstate IRB, Downstate OCAS