Statement of Liability for End Users of SBM Research Information Systems

This document defines responsibilities of users of Stony Brook University Research Information Systems to collect, store, review, and extract data (both Protected Health Information = PHI and de-identified information) for research. Such systems include, but are not limited to, REDCap, TriNetX, OnCore, and BOX.

User agrees to use all data outputs from these systems in compliance with all applicable laws, rules and regulations, all professional standards applicable to research. User assures that SBM institutional policies, including but not limited to the completion of any IRB review or approval that may be required, have been followed. User understands that such data is for research purposes only, and is not to be used for one's own personal benefit.

☐ My login credentials are created for me and me alone. I will safeguard these credentials and will not share them with anyone else, nor will I attempt to log in using credentials belonging to someone else.

☐ I have completed a Human Research Protections training (CITI course) within the last three years.

☐ Any PHI I receive or have access to as a researcher will be pursuant to SBU IRB approval or an IRB waiver OR another IRB's Approval and SBU IRB registration.

☐ I will not engage in any other research uses not outlined in IRB or Human Research Protections approved documentation, unless I have consulted with the IRB and acquired the appropriate waivers or protocol modification prior to proceeding.

☐ I agree to use each resource for its intended purpose and according to the policies governing its use, where available. Contact Research Services IT if unsure of a resource use policy at sbmit_research_services@stonybrookmedicine.edu.

☐ I will comply with all applicable SBU policies pertaining to patient confidentiality and information security, including but not limited to:

- **IM0079** Research Data – Storage and Collaboration

- **RC0033** Disclosure of De-identified Information: To ensure that information considered individually identifiable health information is appropriately de-identified to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its accompanying regulations, for reasons other than treatment, payment or operations.

- **RC0034** Limited Data Set/Data Use Agreement: Protected Health Information (PHI) that is not fully de-identified is permitted for research, public health, and health care operations purposes providing specific data elements have been removed and SBUH (SBUH) enters into a Data Use Agreement (DUA) for the use and/or disclosure of the limited data set.

- **RC0064** Use and Disclosure of Decedent's PHI: The protected health information of a decedent will be treated the same as if the patient were alive but, unable to agree or object. The patient's personal representative or other person authorized by law to act on behalf of the decedent may exercise the rights of the decedent.

- **RC0081** Uses and Disclosures of Protected Health Information: Stony Brook University Hospital (SBUH) workforce members use and disclose protected health information (PHI) only as permitted by law including the Health Information Portability and Accountability Act ("HIPAA").

- **Research Data Ownership, Retention and Access Policy** University Data is information collected or created through a function of the University. Stony Brook University owns University Data. Research Data is a subset of University Data and is subject to additional policies and requirements. This policy governs Research Data.

Statement of Liability for Principal Investigators

- ☐ If I am a Principal Investigator on any study (contract, grant, and/or IRB application), in addition to the responsibilities delineated above, I understand that I am also accountable and liable for all Clinical Informatics systems users associated with my study adhering to the data use and security policies outlined in this attestation agreement. If I become aware of a breach of the policies outlined in this agreement, I will report the breach to the info off to the Stony Brook Privacy Office or the Stony Brook Information Security Office as soon as reasonably possible.