Policy:

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 a Data Use Agreement (DUA) is fully executed for the use and/or disclosure of the limited data set.

Definitions:

**Limited Data Set (LDS)**- is protected health information that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual including but not limited to name, address, telephone number, email address, social security number, facial photographs, medical record number, account number, health plan number, device identifiers, biometric identifiers, etc. Elements of dates and code numbers assigned for research purposes are permitted.

**Protected Health Information (PHI)** - Any information, including but not limited to, specimens, radiographs, photographs, any portion of the paper or electronic medical record or research data that contains patient identifiers; such as name, medical record number, social security number, date of birth, encounter number, test results, diagnoses, dates when services were provided, dates of admission, dates of discharge, date of death, etc., that relates to the past, present or future physical or mental health condition of an individual, the provision of health care to an individual, or payment for the provision of health care to an individual. This definition applies to information that is spoken, written or electronic in form and either directly identifies the individual or could
reasonably be used to identify the individual. Any form of information that can identify an individual who has received, is receiving or will be receiving health care.

**Procedures:**

A. SBUH may use Protected Health Information (PHI) to create a limited data set for disclosures; including but not limited to our business associates, for quality purposes, for regulatory reporting purposes, etc.

B. SBUH may disclose a limited data set (LDS), upon receipt of satisfactory assurances from the intended recipient in the form of a Data Use Agreement (DUA). The recipient is permitted to use and/or disclose the data for the specified, limited purposes as set forth in the DUA such as research, public health, etc. (Data Use Agreement can be obtained by contacting the Privacy Officer).

C. All research requests to use and/or disclose a LDS require SBU Institutional Review Boards/Privacy Board (Committee on Research Involving Human Subjects - CORIHS) approval.

D. When the request to use and/or disclose a LDS is approved by CORIHS and a DUA is required for the disclosure to a sponsor the agreement between the sponsor and the Research Foundation contains specific language to permit the disclosure of the LDS to the sponsor. CORIHS instructs the Principle Investigator (PI) to contact the SBUH Privacy Officer to initiate and implement the DUA.

E. When a requested DUA is denied by the SBUH Privacy Officer an appeal may be filed by the requestor for review by the HIPAA Privacy and Security Committee and a response to the appeal is sent to the requestor with the final determination.

F. Any known or suspected violations or a breach of the limitations defined in the DUA by the data recipient are reported without delay to the SBUH Privacy Officer. Reasonable steps are implemented to remediate the breach or mitigate the violation and if unsuccessful, the DUA is terminated and the incident reported to the Secretary to the Department of Health and Human Services. (refer to the HIPAA Privacy/Security Breach Notification policy IM 0067)
G. When SBUH is in receipt of a LDS the SBUH recipient(s) abide by the terms and conditions of the DUA executed with the entity disclosing the limited data set.

H. The SBUH Privacy Officer is contacted for questions or concerns related to this policy or the use and/or disclosure of a LDS.

**Forms:**  (Ctrl-Click form name to view)

Stony Brook University Hospital Data Use Agreement  (contact SBUH Privacy Officer)

**Policy Cross Reference:**  (Ctrl-Click policy name to view)

SBU Committee on Research Involving Human Subjects Standard Operating Procedures section

**Relevant Standards/ Codes/ Rules/ Regulations/ Statutes:**

Health Insurance Portability & Accountability Act (HIPAA) 45 CFR 164.514(e)

**References and Resources:**

None