**Stony Brook University**

**Institutional Review Board**

**HIPAA Waiver of Authorization Form**

**(Health Insurance Portability and Accountability Act)**

Principal Investigator:

Project Title:

**All SBU investigators who conduct research where individually identifiable health information (Protected Health Information, PHI) is used, generated, or disclosed are required, by law, to protect their research subject’s right to privacy of their health information. Use or disclosure of PHI requires subject authorization unless the use or disclosure is determined by the IRB to qualify for a waiver.**

***\*\* NOTE \*\* All text boxes will expand with user input***

1. Describe, in detail, the health information that is to be collected for the research activity. Explain why this health information is the minimum necessary to meet the research objectives.

|  |
| --- |
| The Study Team will use the TriNetX data system during the accrual period to identify potential study subjects defined by the essential eligibility criteria of the study protocol. We will not collect more than what is described in these criteria. Following IRB approval, subjects meeting essential eligibility criteria, per the TriNetX query and verified per the current study protocol, may be approached for study participation. In order to re-identify patients, the institutional Honest Broker will plan to “Export Patient IDs” via TriNetX and map them back to PHI for patient identification purposes. Patients may be identified to staff belonging to the Schools of Health, Medicine, Dentistry, Nursing, or Social Work for the purpose of subject recruitment, within these guidelines: A. Patients with a “Yes” answer logged in their EMR to being contacted about research may be identified to a Study Team Member from any department, regardless of that patient’s Treatment provider. B. Patients with a “No” answer logged in their EMR to being contacted about research may only be identified to their treatment provider about a study. Study Team may be given the name of the patient’s treatment provider only.C. Patients with an “Unable to Obtain” or Blank answer may be identified to• the Study Team’s department IF the patient has been seen by anyone in that department OR• another department in which the patient has been seen, if that other department has agreed to assist in recruitment for the Study Team. Study Team may be given the name of the patient’s treatment provider only.Subjects interested in participating may move forward with study-specific procedures as outlined in the IRB-approved study protocol after providing informed consent/assent, per 45 CRF 46, 116 &117. The subject will be considered enrolled at the time informed consent is obtained. |

1. Identify the source of the health information (e.g., medical record, healthcare provider). Note that the department or source (‘entity’) supplying the records must be able to account for disclosures made under this waiver.

|  |
| --- |
| TriNetX platform includes clinical facts obtained through Stony Brook Electronic Medical Records. |

1. The IRB can waive the requirement to obtain authorization for use or disclosure of IIHI if all of the following criteria are addressed and met in this form:

1. The use or disclosure of PHI for this research activity must involve no more than **minimal risk** **to the privacy of individuals**, based on at least the presence of:

* 1. An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan, in the text box below, and indicate where the PHI will be stored and who will have access to it. This list must be inclusive (i.e., sponsor, IRB, OHRP, FDA, data safety monitoring boards, research team) as listed on the associated IRB application.

|  |
| --- |
| Only those patients identified for pre-screening will be contacted for recruitment, according to the guidelines in Section A. Thus: A. Patients with a “Yes” answer logged in their EMR to being contacted about research may be contacted by a Study Team Member from any department, regardless of that patient’s Treatment Provider. Study team members will be asked to remind the patient that they indicated that they would be willing to be contacted for a research study.B. Patients with a “No” answer logged in their EMR to being contacted about research may only be contacted by their Treatment Provider about a study. Study Team may be given the name of the patient’s Treatment Provider, and request the provider to make contact on their behalf.C. Patients with an “Unable to Obtain” or Blank answer may be contacted by:- the Study Team Members' departments IF the patient has been seen by anyone in their department. These staff will reference the patient’s Treatment Provider when making contact.OR - staff in a department NOT included on the Study Team may contact their OWN patients about the study. These staff will reference the patient’s Treatment Provider when making contact. The Study Team may assist with the contact process, only as requested by the patient’s Treatment Provider.All identifiable data (PHI) will be kept behind the confines of our Healthcare Organization, securely stored on a UHMC share drive with limited access to study staff only. |

* 1. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health, research, or legal justification for retaining the identifiers. Describe this plan, in the text box below, and include HOW the identifiers will be destroyed (e.g., shredding documents).

|  |
| --- |
| At the end of the study all identifiers collected via TrinetX will be destroyed. |

* 1. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for other research which would be specifically approved by the IRB would qualify for a waiver of authorization. *The* *Principal Investigator’s submission of this form in myResearch signifies assurance of compliance with this requirement.*

2. The research cannot practicably be carried out without the waiver.Explain why:

|  |
| --- |
| Patients eligible for this study may not be seen in the clinical practice of the investigators, or finding eligible patients may be overly burdensome without this tool. |

3.The research could not practicably be conducted without access to, and use of, the PHI. Explain why:

|  |
| --- |
| **This is a request for Partial Waiver of HIPAA Authorization for the purposes of allowing a researcher to obtain protected health information as necessary to recruit potential research subjects. Subjects interested in participating, may move forward with study-specific procedures as outlined in the IRB-approved study protocol after providing informed consent/assent, per 45 CRF 46, 116 &117. The subject will be considered enrolled at the time informed consent is obtained.** |

**Principal Investigator Certification**

**Submission of this form and the accompanying myResearch submission constitutes the Principal Investigator’s certification that the PHI obtained as above will not be reused or disclosed to any other person or entity, except as required by law, or for other research specifically approved by the IRB (and again, qualifying for a waiver of authorization).**