**Protocol Template for Exempt Research**

Please use this form to describe a research protocol that may qualify for an exemption. **Types of research that may meet the criteria for exempt review include: educational research, survey/interviews/observation of public behavior, benign behavioral interventions (brief, painless/harmless, non-invasive), and secondary research (involving data or biospecimens that were not/will not be collected for the purposes of this protocol). Note: Only secondary research for which consent is not required may be approved as exempt research.**

Keep an electronic copy to modify when making changes either as directed by the Human Research Protection Program, or for amendments/modifications.

Please use lay language, avoid professional jargon and define all abbreviations when they first appear.

**PROTOCOL TITLE:**

Response:

**PROTOCOL VERSION/AMENDMENT # AND DATE**

Response:

**PRINCIPAL INVESTIGATOR:**

Response:

**1.0 Objectives**

*1.1 Describe the purpose of this research. Explain why it is important to do the study. If there are hypothesis, please list them here.*

Response:

**2.0 Background**

*2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge. Include complete citations or references:*

Response:

**3.0 Study Design**

*3.1 Describe the study design (e.g., case-control, cross-sectional, ethnographic, longitudinal, and observational).*

Response: In efforts to better understand current disease, treatment and management trends, it is reasonable to examine prior years’ trends, on both an institutional and national level. TriNetX® is a research network combining Stony Brook’s anonymized Cerner Electronic Medical Record data with data from other national and global Health Institutions, and claims data from insurance groups for study. (www.stonybrookmedicine.edu/trinetx)(Topaloglu et al). The TriNetX software collects anonymized patient data pulled from electronic medical record systems, such as Cerner Millennium®, and organizes them into a user interface that allows researchers to use query criteria to complete their cohort selection and analysis. Utilizing this data resource, our study team aims to conduct a retrospective analysis of all \_\_\_\_\_\_\_\_\_patients ages \_\_\_\_\_ to \_\_\_\_\_ admitted with a diagnosis of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ during the period of time from \_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_during the years of \_\_\_\_\_\_\_\_\_ - \_\_\_\_\_\_\_\_\_\_\_\_\_\_. We will query results from TriNetX Stony Brook Research Network database {and the larger, national TriNetX research network database}. Once our study cohort is selected, we will request to download the Limited Dataset of our cohort. This dataset qualifies as a Limited Dataset because the only identifiers present of the 18 HIPAA Identifiers are Dates – e.g., admission, discharge, service, date of birth, and date of death.

**4.0 Local Number of Participants**

*4.1 Indicate the total number of participants who will be enrolled or records that will be reviewed.*

Response: N/A. TriNetX is a dynamic database with increasing numbers of patients included daily. The total number of subjects to be included in this study will only be known once a query is made within the TriNetX program at the time of study implementation.

*4.2 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below.*

[ ]  *Adults unable to consent*

[ ]  *Minors (under 18 years old*)

[ ]  *Pregnant women*

[ ]  *Prisoners*

*4.3 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion*

Response:

*4.4 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Following approval of the English versions, you must submit the translated materials (consent and assent forms, questionnaires, etc) with the translation attestation for approval.*

Response:

**5.0 Recruitment and Screening Methods**

*5.1 Describe source of participants: when, where, and how potential participants will be recruited. Include age range of participants as well as other inclusion/exclusion criteria. NOTE: Recruitment can include, but is not limited to: West Campus departmental pools, research participant groups/help groups, advertising companies, call centers, in person announcements / presentations. If you are using a recruitment or screening tool, upload the tool. These can include flyers, questionnaires, posters, letters or written material to be sent or emailed, pamphlets, posted advertisements, email invitations, etc.*

Response:

We will not be recruiting patients, but selecting a cohort using the TriNetX query tool according to the following criteria:

-patients seen at Stony Brook University Hospital and/or Clinics and/or Stony Brook Children's Hospital and/or within the TriNetX shared database

-with a diagnosis/procedure/lab code of {insert relevant terms} or related

-between {insert relevant dates}

*5.2 Describe how you will protect the privacy interests of prospective participants during the recruitment and screening process).*

Response: N/A

**6.0 Research Procedures**

*6.1 Provide a detailed description of all research procedures or activities being performed on/by the research participants (what will occur, where each activity will occur, etc.). This should include enough detail so that another investigator could pick up your protocol and replicate the research. If the study includes an intervention, please describe the intervention (e.g., subjects play an on-line game, solve puzzles under various noise conditions, etc.).*

Response: Patient data provided from the Stony Brook TriNetX database will be used in

analysis.

*6.2 Describe what data will be collected.* *List, and upload, any instruments or measurement tools used to collect data (e.g., surveys, scripts, questionnaires, interview guides, validated instruments, data collection forms).*

Response: Data provided in this downloaded Limited Dataset from TriNetX will include the following for the selected cohort:

* Demographics
* Diagnosis
* Medications
* Procedures
* Labs
* Vitals
* Visit Types
* Mortality
* Genomics
* Allergies

*6.3 Describe any source records that will be used to collect data about participants (e.g. school records, electronic medical records) and include the date range for records that will be accessed.*

Response: N/A

*6.4* *Indicate if subjects will be deceived regarding the nature or purpose of the research.*

[ ]  *No*

[ ]  *Yes*

**7.0 Study Timelines**

*7.1 Describe the duration of an individual participant’s participation in the study. Include length of study visits.*

Response: N/A

**8.0 Other Approvals**

*8.1 List approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agencies, laboratory, University Hospital, Cancer Center).*

Response: None

**9.0 Data Management and Analysis**

*9.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.*

Response:

**10.0 Confidentiality**

**Data**

*10.1 Where and how will all data and records be stored? If the research involves the access, use, or disclosure of Protected Health Information (PHI), please indicate. Include information about password protection, encryption, physical controls, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable for both paper and electronic files.*

Response: The Limited Dataset will be downloaded from TriNetX and stored on a secure Research IT server with access limited to those listed on the IRB for this project. The dataset will be accessed via a SBM PC. All work will be completed within {say location on campus}.

*10.2 Who will have access to the data?*

Response: {Contacts listed in the IRB for the study}

*10.3 How will the data be transported/transmitted?*

Response: Limited Dataset will be downloaded from the TriNetX platform and stored on a secure Research IT server and accessed via a SBM PC.

*10.4 Describe the procedures for maintenance of security and confidentiality of* ***patient records*** *that will be reviewed for data collection.*

Response: We will not be accessing patient records. The Limited Dataset will be stored on a secure Research IT server with access limited to those listed on the IRB for this project.

*10.5 Will a waiver, partial waiver, or alteration of HIPAA authorization be needed?*

Response: No. Only a Limited Dataset Form will be required.

*If requesting a waiver or alteration of HIPAA authorization, please confirm the following*

[ ]  *There is an adequate plan to protect the identifiers from improper use and disclosure*

[ ]  *There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.*

[ ]  *There is adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted*

[ ]  *The research could not practicably be conducted without the waiver or alteration*

[ ]  *The research could not practicably be conducts without access to and use of the PHI*

**Specimens**

[x]  **No specimens will be collected or analyzed in this research.**

*10.6 Where and how will all specimens be stored? Include information about physical controls, authorization of access, separation of identifiers and specimens and labeling of specimens, as applicable.*

Response: N/A

*10.7 How long will the specimens be stored?*

Response: N/A

*10.8 Who will have access to the specimens?*

Response: N/A

**11.0 Compensation for Participation**

*11.1 Describe the amount/nature and timing/scheduling of any compensation to participants, including monetary, course credit, or gift card compensation.*

Response: N/A

*11.2 Participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. List alternative activities and who to contact about completing alternative activities below and in the consent document.*

Response: N/A

**12.0 Informed Consent**

*12.1 Describe the consent process that will be conducted to ensure that participant is fully informed regarding study details and participant rights. Include where the consent process will take place with consideration of the need to protect the subject’s right to privacy.*

Response: N/A

*12.2 Describe how you will ensure that participants are provided with sufficient time to consider taking part in the research study. Detail if there is an expected time period between informing the prospective participant and obtaining the consent. If participants who do not speak English will be enrolled, describe the process to consent the participants, as well as the process to be used to ensure their understanding of the research*

Response: N/A

**13.0 Consent Waiver Request for Secondary Research**

***Note:*** *This section is not applicable if the secondary research plan involves only the collection of* ***retrospective*** *(already available as of the date of initial IRB submission) data and/or biospecimens.*

***For studies that involve collection of prospective data and/or biospecimens, please fully address each criterion below (ALL must be met for exemption of secondary research):***

[ ]  *The research involves no more than minimal risk.*

**Please explain:**

[ ]  *The waiver will not adversely affect the rights and welfare of the subjects.*

***Please explain:***

 [ ]  *The research could not practicably be carried out without the waiver.*

***Please explain:***

 [ ]  *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.*

***Please explain:***

 [ ]  *Whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

***Please explain:***

**14.0 Multi-Site Research (Multisite/Multicenter Only)**

*14.1 If this is a multi-site study where SBU is the lead site and/or the IRB of record, describe the processes to ensure communication among sites. Include:*

* *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
* *All required approvals have been obtained at each site (including approval by the site’s IRB of record).*
* *All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.*
* *All engaged participating sites will safeguard data as required by local information security policies.*
* *All local site investigators conduct the study appropriately.*

Response: N/A