PROTOCOL TEXT EXAMPLE: Using TNX for Retro Chart Review

(De-identified Dataset plus MRNs for EMR Access)

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IMPORTANT: Researchers may choose to use this example text in preparing their protocols for retrospective studies using TNX. Please be aware that researchers are ultimately responsible for the accuracy of their protocol language, so review carefully in the context of your planned research.

4.0 Study Design

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 de-identified Cerner Electronic Medical Record data with de-identified data from up to 60 other Health Institutions, and claims data from insurance groups for study. (www.stonybrookmedicine.edu/trinetx)(Topaloglu et al). The TriNetX software collects de-identified 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 study participant identification 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 research networks: the Stony Brook Research network database and the larger, national TriNetX research network database.

Once our study cohort is selected, we will identify the cohort of patients admitted within the timeframe we are studying. Acting as Honest Broker, SBM IT will download the TriNetX synthetic patient IDs for our selected cohort of patients, then re-map them to the patients' SBM MRNs. Using these MRNs, we will access the electronic medical charts for evaluation of demographics, comorbidities, and _____{insert other information you will collect here (eg. Lab, radiology, pathology, medications etc)} for {insert time frame (e.g. inpatient admissions, outpatient visits etc)}. All patient data will be kept confidential and all patient identifiers will be removed prior to data analysis.

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects who will be enrolled or records that will be reviewed through Stony Brook

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.

5.2 If this study is only being conducted through Stony Brook, provide statistical justification (i.e. power analysis) for the number of subjects provided in 5.1 above. If qualitative research, so state, and provide general justification for the total number of subjects proposed.

Response:

N/A. This study will include all data for all patients identified by TriNetX. Thus there is no statistical justification for the number of subjects to include.

6.0 Inclusion and Exclusion Criteria

6.1 Describe, in bullet points, the criteria that define who will be included in this study:

Response:

-patients seen at Stony Brook University Hospital 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}

10.0 Research Procedures

Provide a detailed description of all research procedures or activities being performed on the research subjects

Response:

De-identified patient data provided from the Stony Brook TriNetX database will be used in preliminary analysis. Acting as Honest Broker, SBM IT will download the TriNetX synthetic patient IDs for our selected cohort of patients, then re-map them to the patients' SBM MRNs. The Honest Broker will provide the list of identified patients to the PI via a HIPAA-compliant Research Share drive. Then we will perform a chart review and collect information. The collection survey will not include any patient identifiers. All patient information will be kept in a password-protected computer only accessible by the Principal Investigator.

10.1 Describe what data, including long-term follow-up, will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: The following information will be collected during chart review:

{insert relevant items }

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

Response:

Data from Cerner Power Chart electronic medical records and TriNetX online public databases will be used to collect the above listed data.

12.0 Research Setting

12.1 Describe all facilities/sites/locations where you will be screening and conducting research procedures.

Response:

All work will be completed within {say location on campus}. Data will be stored on a secure Research IT server and accessed via a SBM PC.