Important note: the purpose of this document is to provide sample text (highlighted in yellow) for investigators to include in an eForm protocol when requesting data from the TriNetX Research Network.
This document is not intended to serve as eForm protocol template, and it should not be copied and uploaded to eIRB.

JHM IRB - eForm S–Secondary Research Protocol

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1. Research Question (include all primary and secondary objectives)

[aims]

2. Background

[background]

3. Methods

a. Describe the study design and the database(s) that will be utilized, including the specific sources from which you will collect data or samples. Include in your description whether you will use JHM clinical data (e.g., EPIC) or a research resource (provide IRB protocol number) Provide your inclusion/exclusion criteria and describe your method of case/patient/sample identification.

Retrospective cohort study using **a limited dataset** from the TriNetX Research Network Database, a web-based tool for research population cohort and feasibility queries that provides access to clinical data of dozens of academic medical centers and health care organizations.

We will perform a search query, designed in consultation with the TriNetX analysts, across 45 participating health care organizations within the TriNetX Research Network, using [specify data elements (ICD codes, lab results, etc.] to identify the patients of interest.

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required.

[answer here]

c. Clarify whether there was an ethical review process for initial collection/derivation of data/biospecimens. If applicable, provide the determination of the ethics committee or IRB study number. Indicate whether consent was obtained and whether the consent covered the use as proposed in this research.

[answer here]

d. If biological materials are involved please describe all the experimental procedures and analyses in which they will be used.

[answer here]

e. Specify the targeted number of individuals from whom you plan to include data/samples in this secondary use. Please be sure to specify the initial/largest cohort of eligible cases from which you will identify the final sample. Where applicable, please include an estimate of the time period that will be covered (e.g., will you include data within a certain range of dates?) (You should contact the Johns Hopkins Center for Clinical Data Analysis (CCDA) if you need help to determine the number of individuals for whom your desired data is available. https://ictrweb.johnshopkins.edu/ictr/connection/)

An initial trial query of the TriNetX Research Network identified a total of [overall count].

Eligibility criteria:
[inclusions]

Exclusion criteria:
[exclusions]

f. Explain how your data are being extracted (manual chart review, bulk query). If you are planning to collect data from text documents (e.g., pathology/radiology reports) specify exactly how this will be accomplished. Are you planning to download text documents themselves? Storing copies of original documents from EPIC requires consultation with the CCDA and identification of an honest broker.

We will perform a query of the TriNetX Research Network that will generate a limited dataset with the clinical data of interest. This dataset will be downloaded in coordination with the Core for Clinical Research Data Acquisition (CCDA) as the Honest Broker.

g. Explain how your data are being recorded (paper, laptop, etc.).

Data will be obtained from a query of the TriNEtX Research Network and will be saved as an Excel file in the study team's SAFE desktop.

h. Explain how the data are being moved to the final storage location.

The dataset will be exported by the CCDA into an Excel file that will be saved in the SAFE desktop secure storage to share only with the study members.

i. Provide the name and location of the server where the data will be housed.
   a. The SAFE desktop is the required storage platform for TriNetX Research Network downloads.

j. Provide the name of the study team member responsible for data management and security.

[answer here]

k. Provide any plans for de-identification of the dataset. Identifiers (MRN, Name) should be stored in a separate file with the data file using unique IDs.

The dataset provided to the study members will consist of a limited dataset (no MRN, patient names or contact information will be included in the dataset). The CCDA, as the honest broker, will download the dataset and deliver the dataset to the study team's SAFE desktop folder.

l. Explain how access to the data will be controlled and whether the access is logged.

The dataset will be saved in a secure SAFE desktop, accessible only to the study team.

m. List the computer programs being used to store and to analyze the data.

[answer here – using tools available on the SAFE desktop (Stata, SAS, R, Python, Excel, etc.]

n. If you are using data from several sources explain what variables will be used to merge files.

The study uses data derived from a single source (TriNetX Research Network). No other data sources can be merged with this data.

o. Will the data set include any sensitive information (e.g., HIV status, psychiatric diagnosis)?

[answer here].

p. Provide an estimate of how long it will take you to complete the study, including the time for data analysis.

[answer here].