STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH
Title: Obtaining De-identified Data Using TriNetX

SOP Number: SS 308

1. PURPOSE:
   This Standard Operating Procedure (SOP) describes the process for obtaining de-identified data to aid in research studies through the Clinical Research Center’s use of the global health research network, TriNetX.

2. SCOPE:
   This SOP provides instruction and sets minimum standards regarding the process for submitting, reviewing, and releasing de-identified data for protocol creation. This SOP also addresses limitations on the use of that data. Any requests for data not being used for research purposes must comply with all UH policies including but not limited to IS-22.

3. RESPONSIBLE INDIVIDUALS:
   This SOP applies to all University Hospitals (UH) personnel who are interested in obtaining de-identified data for purposes of applying for grants, creating protocols, conducting research with de-identified data, or for other needs preparatory to research.

4. DEFINITIONS:
   TriNetX - A global health research network that brings together healthcare organizations, biopharmaceutical companies, and contract research organizations to optimize clinical research and enable discoveries through the generation of real-world evidence. UH CRC has contracted with TriNetX to provide the ability to query the UH electronic medical record.

   UH Honest Broker - The person from the Clinical Research Center who will receive the UH PI’s request for information and ensures that datasets are completely de-identified prior to release.

   Health Information Portability and Accountability Act (HIPAA) - The HIPAA Privacy Rule defines how covered entities use individually-identifiable health information or the PHI (Personal Health Information). PHI must be utilized, maintained and protected in accordance with these Federal Regulations. UH facilities are considered “covered entities” and as such, must abide by the HIPAA Privacy Rules for the use and disclosure of PHI maintained under its jurisdiction.

   Human Subject - As defined by DHHS: “a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains either data through intervention or interaction with the individual, or identifiable private information.” As defined by FDA: “An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A subject is also an individual on whose specimen a medical device is used.”

Approved by the UH CRC Research Policy Oversight Committee
5. POLICY STATEMENT:
The UH Clinical Research Center must approve each request to obtain de-identified patient data.

Federal regulations prohibit the conduct of human subject research (45 CFR 46.102(f)) without appropriate IRB review. As such, any researcher who wishes to use identifiable patient data must obtain IRB approval prior to the collection and use of this information.

When seeking de-identified patient data (meaning no elements of PHI are included) IRB approval is not necessary because obtaining de-identified data without a link to identifiers does not meet criteria for human subject’s research.

The UHCMC IRB considers the use of de-identified data obtained from the TriNetX system through the UH CRC Honest Broker to meet criteria for a determination of not human subjects research (NHR). In addition, UHCMC IRB has determined that use of this de-identified patient data does not require a HIPAA waiver as no elements of PHI will be included.

UH personnel using TriNetX for the sole purpose of obtaining de-identified patient data under this SOP are not required to submit a “Research Determination” form in the electronic IRB system. If you are obtaining de-identified patient data from any other source, in any other manner, you must submit a “Research Determination” form in the electronic IRB system.

UH personnel must follow all other UH policies related to research, record retention and IT&S policies related to use of UH electronic systems, data storage and data security.

6. PROCEDURES:
Please note that this process should only be used by individuals who seek to obtain strictly de-identified data, with no link, and no need to ever re-identify patient data. If you require a link to identifiers, or you may need to re-identify patient data in the future, please contact the IRB and submit a Human Subjects Research protocol in advance of your project.

6.1 To initiate the process of requesting data, a data request should be submitted in the form of an email from the UH requester, describing the proposed activity. The email should answer at least the following questions:

6.1.1 What specific UH data is being requested (please list all elements / data points)?
6.1.2 Please provide the names of all UH personnel who will have access to the data.
### 6.1.3 Will any non-UH party(ies) receive the UH data (ex: CWRU employees or students, registries, biostatisticians)?

### 6.1.4 How will you or any non-UH party(ies) use the UH data?

### 6.1.5 Where will you store the UH data (storage must meet IT security standards, typically in UH REDCap, in a password protected folder on the S:Drive, or on a UH encrypted device)?

### 6.1.6 How long will you retain the UH data?

### 6.1.7 What is your plan for data destruction?

#### 6.2 The email request must also include a statement that you agree you will never attempt to re-identify patients

#### 6.3 Each email requesting approval for the UH de-identified patient dataset must be sent to [CRCExportID@UHhospitals.org](mailto: CRCExportID@UHhospitals.org), after which it will be reviewed by the UH CRC Honest Broker. All requests must be received from a UH email address and all data will only be sent to a UH email address.

#### 6.4 Please note, data will not be coded and no link will exist to allow re-identification. Under no circumstances are you permitted to attempt to re-identify these patients. Datasets that contain less than 25 patients will not be released, as data sets that small could lead to identifiability.

### 7. REFERENCES

- UH System Policy [IS-22 - Sharing of UH Clinical or Business Data with Third Parties](http://example.com)

### APPROVALS

Signed by Dr. Grace McComsey, Vice President of Research, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center – March 2, 2020

Approved by the UH CRC Research Policy Oversight Committee