

Research Using TriNetX

Standard Operating Procedures

Revision, Review and Approval History

Action	Name	Date	Notes
Initial Draft	Evan French	2/6/2025	
Discussion	Evan French	2/25/2025	Discussed at Research Data Provisioning meeting
Approval	Evan French	3/4/2025	Approved after 7-day comment period

Purpose

This document describes the role of Honest Brokers in research using TriNetX.

Reference Policies

The most recent version of Health System policies are available in the [VCUHS Policy Library](#) (only accessible from the VCUHS network).

Title	Organization	Policy Number
Research Honest Broker Policy	VCU Health System Authority and Affiliates	No number, search name
Protected Health Information, Uses & Disclosures for Research Policy	VCU Health System Authority and Affiliates	COMP-014
De-Identification of Protected Health Information Policy	VCU Health System Authority and Affiliates	MR.PH.004
Protected Health Information, Minimum Necessary Uses and Disclosures Policy	VCU Health System Authority and Affiliates	No number, search name
Uses and disclosures of PHI for which an authorization or opportunity to agree or object	Department of Health and Human Services	45 CFR 164.512(i)

is not required		
Other Requirements Relating to Uses and Disclosures of Protected Health Information	Department of Health and Human Services	45 CFR 164.514(b)
VCU/VCUHS Enterprise Data Warehouse for Research	VCU	HM20023298

Policy

Research entirely within the TriNetX platform does not require any regulatory approval or involvement from honest brokers.

De-identified data downloaded from TriNetX must be provided by the Wright Center honest broker team and must meet all regulatory and compliance requirements from both the VCU IRB and the VCUHS Compliance Office. To ensure these requirements are met, all projects must undergo a review described in this SOP.

Investigators can request to re-identify cohorts of VCU patients identified in the TriNetX platform.

Definitions

Please see definitions relevant to this policy in the [glossary](#).

Procedures

Obtaining TriNetX Access

Investigators wishing to obtain access to TriNetX may request credentials at go.vcu.edu/fhrn. Non-faculty members are required to have a faculty sponsor. Only employees or students at VCU, VCUHS, and certain partner institutions (ODU, VSU) are eligible for TriNetX access.

TriNetX Platform Functionality

Within the TriNetX platform, investigators can identify cohorts of patients (either at VCU or in a research network of 100+ health care organizations), explore characteristics of their cohorts, and perform statistical analysis.

De-identified Data Download

Some analyses, such as those examining complex relationships between covariates, are too complex to be conducted within the TriNetX platform. In such cases, investigators have the

option to download a dataset from TriNetX containing de-identified clinical information related to their cohort(s) for further analysis. Prior to receiving a de-identified dataset from TriNetX, study teams must submit a request through the [Informatics Request Process](#) and provide regulatory/compliance documentation for the honest broker team to review as described in the [Honest Broker Quality Control Review SOP](#). These research projects usually require Not Human Subject Research determination from the IRB or PROC.

The de-identified datasets provided by TriNetX are formatted as 17 raw CSV files, which require significant transformation before they can be statistically analyzed. Due to the scale of TriNetX data, significant data expertise and/or advanced computing capabilities may be necessary to successfully utilize the data.

Cohort Re-identification

Identifiable information about cohorts of VCU patients identified by TriNetX queries for recruitment or retrospective review will require an IRB review and may be requested through the [Informatics Request Process](#).