

Retrospective Secondary Analysis Standard Operating Procedures

Revision, Review and Approval History

Action	Name	Date	Notes
Initial Draft	Tamas Gal	2/6/2025	

Purpose

This document describes the process of how Wright Center honest brokers are providing VCUHS clinical data for retrospective secondary data analysis.

Out of scope

The following use cases are out of scope for this document:

- Studies requiring manual chart review
- Case studies
- Recruitment lists
- Studies exclusively performing analysis on de-identified TriNetX datasets

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 is not required	Department of Health and Human Services	45 CFR 164.512(i)
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

Prior to receiving data for retrospective secondary analysis, investigators must obtain approval for their project from the IRB.

Any datasets extracted from VCUHS clinical data for retrospective secondary analysis must be provisioned by an honest broker.

Adhering to the HIPAA Minimum Necessary Requirement, study teams must use de-identified or Limited datasets for their research when possible.

Sharing de-identified or Limited datasets extracted from VCUHS clinical data outside of VCU requires a Data Use Agreement (DUA) signed by the VCU Contracts Office.

The use of patient identifiers in research studies must be justified in the study protocol.

Definitions

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

Procedures

Investigators intending to share de-identified or Limited data with external entities (i.e. multi-site registries) should contact the [VCU Contracts Office](#) to establish a DUA.

De-identified Datasets

Investigators are encouraged to explore whether their research question can be answered using TriNetX as described in the [Research Using TriNetX SOP](#).

Investigators leading studies requiring de-identified or Limited data for retrospective secondary analysis should follow the process described in the [Informatics Request Process SOP](#) to secure honest broker support for their project as early as possible.

Limited/Identifiable Datasets

Some studies may require identifiable data other than MRNs to complete their analysis.

Examples of this may include, but are not limited to:

- Addresses for geocoding and geospatial analysis
- Non-shifted dates to link to other datasets temporally
- Names and birth dates to link to external identifiable datasets
- Ages >89 where specific ages are relevant to the analysis