Retrospective Chart Reviews Standard Operating Procedures

Revision, Review and Approval History

Action	Name	Date	Notes
Initial Draft	Evan French	2/5/2025	

Purpose

This document describes the role of Honest Brokers in projects in which members of a study team manually review and extract data elements from patient charts for retrospective analysis.

Out of scope

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

- Extracting data for subjects who have signed consent
- Case studies

Reference Policies

The most recent version of Health System policies are available in the <u>VCUHS Policy Library</u> (only accessible from the VCUHS network).

Title	Organization	Policy Number
Research Honest Broker Policy	VCU Health System Authority and Affiliates	<u>No number, search</u> <u>name</u>
Protected Health Information, Uses & Disclosures for Research Policy	VCU Health System Authority and Affiliates	<u>COMP-014</u>
De-Identification of Protected Health Information Policy	VCU Health System Authority and Affiliates	<u>MR.PH.004</u>

Protected Health Information, Minimum Necessary Uses and Disclosures Policy	VCU Health System Authority and Affiliates	<u>No number, search</u> <u>name</u>
Uses and disclosures of PHI for which an authorization or opportunity to agree or object is not required	Department of Health and Human Services	<u>45 CFR 164.512(i)</u>
Other Requirements Relating to Uses and Disclosures of Protected Health Information	Department of Health and Human Services	<u>45 CFR 164.514(b)</u>
VCU/VCUHS Enterprise Data Warehouse for Research	VCU	<u>HM20023298</u>

Policy

Prior to collecting clinical data for retrospective research from patient charts, investigators must obtain approval for their project from the IRB.

Study teams must utilize honest brokers to identify patient cohorts for their retrospective study. Investigators may only collect data related to patients identified by an honest broker.

Definitions

Please see definitions relevant to this policy in the glossary.

Procedures

Investigators leading studies requiring retrospective chart reviews should follow the process described in the <u>Informatics Request Process SOP</u> to secure honest broker support for their project as early as possible.