Case Reports 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 case reports

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

Honest Brokers have no role in case report projects.

Medical case studies involving no more than two patients are <u>not considered systematic</u> <u>investigations</u>

Definitions

Please see definitions relevant to this policy in the glossary.

Procedures

Researchers writing case reports should use the Case Study Authorization form available from the VCUHS Compliance Office.