Departmental Honest Brokers Standard Operating Procedures

Revision, Review and Approval History

| Action | Name | Date | Notes |
|---------------|-------------|-----------|---|
| Initial Draft | Evan French | 2/25/2025 | |
| 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 approved process of designating departmental honest brokers and outlines the training requirements and duties of this role.

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 | 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

Departmental honest brokers are responsible for providing VCU Health clinical data from data sources that the Wright Center honest broker team is not able to access. This includes, but not limited to the following:

- Identifying cohorts of patients for research studies
- Providing data from departmental clinical systems
- Providing data from departmental or multisite registries

Departmental honest brokers may not be part of the study personnel or receive authorship credit for any publications resulting from a research project in which they are acting as an honest broker.

Any data request directed to departmental honest brokers has to be submitted at https://informatics.vcu.edu and follow the Informatics Request Process.

Any data curated by the departmental honest broker will be transferred to the Wright Center honest brokers before it is transferred to the study team.

Each individual acting as an honest broker must be designated separately. Supervisors designated as honest brokers may not delegate honest broker responsibilities to their employees unless those employees have themselves been designated as honest brokers.

VCU and VCUHS will monitor departmental honest broker performance and adherence to this SOP.

Definitions

Please see definitions relevant to this policy in the glossary.

Procedures

Eligibility

Departmental honest brokers must be VCUHS employees with access to some clinical system or data which is not programmatically accessible to the Wright Center honest broker team. VCU employees may also be considered on a case-by-case basis.

Request

Requests to designate a new departmental honest broker can be emailed to complianceservices@vcuhealth.org.

Training

Honest broker training requirements are detailed in the **Honest Broker Training SOP**.

Duties

Departmental honest brokers are responsible for identifying cohorts of patients and provide clinical data for research studies in circumstances where the Wright Center honest brokers are unable to do so from the data available in the Enterprise Data Warehouse. The departmental honest brokers should be involved in requirements discussions with the study team, but any data curated by the departmental honest broker must be transferred solely to the Wright Center honest brokers. Failure to do so may result in corrective action. The Wright Center honest brokers are responsible for performing Accounting of Disclosures and reviewing regulatory/compliance documentation to ensure that the study team is approved to receive the data being transferred. Once approved, the Wright Center honest brokers will transfer the data to the study team.

Departmental honest brokers will transfer data to the Wright Center honest brokers, along with a completed <u>Departmental Honest Broker Manifest</u> describing the data being provided and a list of unique MRNs for Accounting of Disclosures.