

Honest Broker Quality Control Review Standard Operating Procedures

Revision, Review and Approval History

Action	Name	Date	Notes
Initial Draft	Evan French	2/5/2025	
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 quality control processes in place to ensure the validity and compliance of all datasets provisioned by the Honest Broker team.

Reference Policies

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

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

Any data provided by the Wright Center honest broker team 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.

Honest brokers are only responsible for reviewing elements of regulatory/compliance documents directly relevant to the data being provided.

Definitions

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

Procedures

Honest Brokers will collect, review, and verify the documents listed below for each project requesting clinical data ensuring they meet the outlined criteria. All documents, except the results spreadsheet will be stored in Jira. The results spreadsheet will be stored on a secure drive. The elements described for each document will be verified by at least three honest brokers prior to the release of any data.

IRB Approval Letter

- IRB number is consistent across all documents
- PI is consistent across all documents
- Title is conceptually consistent across all documents
- Date of approval is prior to the export date on the IRB application on file
- Approval is valid as of the data release date

Protocol Document

The protocol document generally should follow the [VCU IRB templates](#). For some studies, such as those initially submitted before 2023, or multi-sites studies in which VCU is a participant, a

protocol document using the IRB 503 template may not be available containing all of the items listed below. In such circumstances, analysts will attempt to find analogous information in the IRB application or non-standard protocol.

- The involvement of the honest brokers is described in the protocol (honest brokers provide editing suggestions after consultation)
- PI is consistent across all documents
- Title is conceptually consistent across all documents
- The total number of patients whose data is being released to the study team by the honest broker does not exceed the maximum number approved for screening or review
- The index date for study inclusion falls wholly within the date parameters documented
 - Note that some studies may include data up to the present, in these cases the end date of inclusion will be documented in the dataset release notes
- The study inclusion/exclusion criteria are consistent with the programmatic filters applied to the extent that they are programmatically feasible. For some studies, manual review of a broader set of patients may be necessary. In such cases, the protocol will describe the inclusion/exclusion criteria defining the patient population that the honest broker will provide.
- The dataset produced by the honest broker only includes categories of HIPAA variables explicitly outlined in the protocol.
- The categories of data elements are mentioned
- Any vulnerable populations (i.e. children, prisoners) discernable in the dataset are mentioned

IRB Application

- IRB number is consistent across all documents
- PI is consistent across all documents
- Title is conceptually consistent across all documents
- Export date from RAMS IRB is after the most recent approval letter
- The Wright Center EDW protocol (HM20023298) is referenced
- All recipients of the data are listed in the Personnel section
- Any study sharing data with external sites must have an external DUA
- Study is approved to access PHI (if relevant)
- Studies receiving PHI for retrospective review have a Full HIPAA waiver
- Studies receiving contact information for recruitment or screening have a Partial HIPAA waiver

DMS Plan

DMS plans are only required for study teams receiving datasets containing identifiable information.

- IRB number is consistent across all documents

- The project start/end dates are valid as of the release date
- The list transmission methods include the modality by which data will be sent to the study team. For projects with no other explicitly approved transmission methods, data will be sent via the Horizon system.

PI Assurances

- IRB number is consistent across all documents
- PI is consistent across all documents
- Title is conceptually consistent across all documents
- Questions in the form correspond to the project type
- PI has agreed to all questions and signed the form

External DUA

Any study sharing VCUHS clinical data with external sites must provide an external DUA approved by the VCU contracts office

- PI is consistent across all documents
- Title is conceptually consistent across all documents

Results Spreadsheet

- The Notes tab accurately summarizes the project metadata and is consistent with the project approvals specified in the other documents
- All PHI data elements follow standard naming conventions
- Prisoners and decedents are excluded from recruitment lists, unless specifically included in the study
- Data values appear to be within valid ranges
- Only approved PHI data elements are provided.
- Categories of non-identifiable data being provided are specified in the protocol
- Patient count does not exceed approved/stated patient count in the protocol/application
- Date ranges match study's time period of interest specified in the protocol/application

PHI Profiler

- All HIPAA identifiers identified are explicitly approved

Honest Broker Checklist

- All checkboxes checked for correct level of identifiability
- Correct PI name
- Correct release date(s)
- Method of distribution matches DMS plan