Informatics Request Process
Standard Operating Procedures

1. Revision, Review and Approval History

Action	Name	Date	Notes
Initial Draft	Evan French	5/21/2025	

2. Purpose

This document describes the process of requesting informatics support for clinical research projects.

3. 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

4. Policy

Requests for informatics support for clinical research projects must be submitted and tracked through the Wright Center's intake system.

Regulatory and compliance documentation must be collected and reviewed by the Wright Center for all research projects utilizing Honest Broker services. No data elements may be provided for research which do not conform to the data descriptions approved in the regulatory and compliance documents.

All clinical datasets provisioned to study teams for research purposes must be rigorously reviewed for correctness prior to release as described in the Honest Broker Quality Control Review SOP.

5. Definitions

Please see definitions relevant to this policy in the glossary.

6. Procedures

Submitting a request

Requests for informatics support for research projects can be submitted at informatics.vcu.edu. The IRB may require a letter of support from Informatics for any research project that requires Honest Broker involvement. Informatics will supply the study team with a letter of support after the requirements gathering is complete.

Initial consultation

Upon receipt of a request for informatics support, a Wright Center analyst will contact the requestee to schedule an initial consultation over Zoom to discuss the overall project and what involvement informatics needs to have. Study teams will be asked to provide a research protocol and list of requested data elements.

Requirements gathering

Following the consultation, a Wright Center analyst will prepare an informatics requirements document which defines the inclusion/exclusion criteria of the cohort and each data element that will be included in the final dataset. The Wright Center will also review the research protocol to confirm that the data extraction methodology is accurately described and all regulatory approvals relevant to data provisioning have been requested in the protocol. Once the client agrees to the scope of work outlined in the requirements document, the Wright Center will provide a letter to the IRB confirming informatics support for the project.

Compliance review

After a research project receives IRB approval, a Wright Center analyst will collect and review the relevant regulatory and compliance documentation as described in the Honest Broker Quality Control Review SOP. The analyst will confirm that the dataset described in the informatics requirements document is fully compliant with the approved documentation.

Data extraction

An Honest Broker analyst will curate the dataset described in the informatics requirements document. During this process, the requirements document may need to evolve in response to an iterative process of discovery in the data and discussion with the study team. If changes to the project requirements alter the scope of the project beyond what is described and approved in the regulatory and compliance documentation, the study team will need to request an IRB amendment to their protocol. Following any amendment, the Compliance Review step must be repeated.

Quality control

All code written by an Honest Broker analyst to curate clinical datasets for research must be peer reviewed by another Honest Broker analyst to confirm the proper implementation of the informatics requirements document. The resulting dataset must also be reviewed to confirm face validity of the data.

Following peer review, projects must be presented to a committee for review and approval as described in the Honest Broker Quality Control Review SOP.

Data release

Following successful peer review and Quality Control committee approval, an Honest Broker will release the data to the study team. Data will be sent via a transmission modality approved in the study's DMS plan. If the DMS plan does not specify a transmission modality of Horizon, Filelocker, or REDCap Send-It, the data will be sent via REDCap Send-It by default.