



<b>GUIDANCE: Use of an Honest Broker</b>		
NUMBER	DATE	PAGE
HRP-936	01/15/2025	1 of 2

## **GUIDANCE: Use of an Honest Broker**

### **SCOPE:**

This document defines an honest broker, details the role of honest brokers in human subjects research, provides guidance for study teams seeking to work with an honest broker, and outlines the PPHS suggestions and requirements for the use of honest brokers in human subjects research within the Icahn School of Medicine at Mount Sinai.

### **HONEST BROKER DEFINITION:**

An honest broker is an individual, or system, acting on behalf of the institution, repository or research team to assemble and provide information/samples to researchers that are stripped of direct identifiers such as name, address, SSN, MRN, etc. The researchers can then receive data and/or specimens that are not readily identifiable which can significantly reduce or even eliminate IRB review requirements.

- The honest broker cannot be one of the investigators, study coordinators, or statisticians on the study and cannot serve as a co-author on any publication. The honest broker must act as an independent party completely separated from researchers, and if the data released are coded, they are the only entity able to track the codes linked to clinical identifiers. If the honest broker is employed by the registry or repository supplying the information, there must be a Memorandum of Understanding or a Standard Operating Procedure in place delineating the independence of the honest broker.
- An honest broker cannot release, to anyone, the linking code without PPHS approval.
- The honest broker must be able to sufficiently de-identify PHI or other clinical identifiers and so ensure regulatory compliance before the release of information to investigators. The standard is that upon delivery the data is not readily identifiable to the recipient. De-identified data will meet this standard, as will most limited data sets. The approved IRB protocol should make clear the extent any identifiers might be released.
- The honest broker should not release the data or samples for purposes not approved by IRB and report to the IRB in cases when it appears the honest broker cannot properly provide the requested information.

### **HOW TO USE AN HONEST BROKER:**

- An honest broker is often best used to code data and/or specimens that are provided by an investigator or a registry/repository to another researcher. By removing the identifiers (even if a coded link is left) the honest broker can facilitate secondary uses of data/specimens without the need for prior IRB review and approval.



<b>GUIDANCE: Use of an Honest Broker</b>		
NUMBER	DATE	PAGE
HRP-936	01/15/2025	2 of 2

- If the data provided by the honest broker contains dates or zip codes, then the data set is considered a limited data set/biospecimens. The data provider and the data recipient must enter into a data use agreement before the data/specimens are shared. A Not Human Subjects Research determination may still be possible.
- When submitting an application in RUTH that involves a repository with an honest broker system, the individual who will serve as the honest broker will need to be designated the “honest broker” role, under the Local Study Team Members section of the RUTH SmartForm. Additionally, a description of the responsibilities, functions, and limitations of the honest broker will need to be included in either the protocol, the HRP-503 document, or preferably as a standalone document (e.g., Honest Broker Standard Operating Procedure). If the honest broker is not at Mount Sinai, contact the PPHS office at [IRB@mssm.edu](mailto:IRB@mssm.edu) for guidance.
- The honest broker will need to complete the following education requirements:
  - Investigators/Research Staff course – Basic or Refresher (note: the refresher course can only be used for renewing certification)
  - Data Security and HIPAA training course
  - HIPAA Research Update course

Please reference the PPHS website, Training and Education [page](#), for further information.