

CCTS Enterprise Data Trust (EDT) Honest Broker Services

Biospecimens will be obtained, processed, and stored according to the Biobank Research Registry; however, the clinical data associated with the specimen will not be stored together. Honest broker services are offered by a team of neutral persons within the Enterprise Data Trust (EDT) that are necessary to provide separation of duties in clinical research activities. The separation removes possible conflicts of interests in research. The honest broker serves as a barrier or firewall between the clinical data which may obtain identifiers and the research activities which require a deidentified data set.

EDT honest broker(s) are not part of the clinical or research team. The EDT has an approved deidentification scheme in UK IRB protocol 11-0750-F6A, entitled, "Umbrella IRB for Use of Health Information in the CCTS Enterprise Data Trust- UK HealthCare dataset."

EDT honest broker services for researchers include:

- Receive research requests for access to data held in the EDT
- Determine feasibility for research access requests
- Provide advice to EDT Access Applicants on the necessary approvals prior to release of data
- Extract data required for the approved research request
- Removes all protected health information denoted in the HIPAA regulations, to provide the researcher with a deidentified data set for analysis
- Retain a crosswalk table for linkage of data, but does not release this information to the researcher
- Reverse linkage of data with proper approvals
- Provide linkage of data and assure the integrity of the linkage
- Perform data quality assessments when necessary
- Distribute data to users on an ad-hoc basis or as an automated regular basis
- Manage data transfer between clinical and research systems
- Maintain reference data for researcher to support future analysis of data provided
- Audit compliance of researcher recipients with terms and conditions associated with EDT Access Application approvals

The researcher signs a data use agreement which prohibits reidentification and prevents linkage of datasets. In the rare instance that the researcher needs to link data, the researcher must obtain IRB approval. If a researcher needs to link data sources, receives IRB approval, then the honest broker can use the crosswalk for linking needed data.