

Honest Broker

Background

This guidance provides information about Honest Brokers and how to properly utilize the service. Access to clinical data for the purposes of research can occur in several ways:

- An investigator can review identifiable medical records or medical data by obtaining Informed Consent and HIPAA Authorization from participants (review is limited to the express permission provided in the HIPAA authorization).
- An investigator can review identifiable medical record or medical data under the issuance of a Waiver of Informed Consent and/or Waiver of PHI Authorization by the IRB (review is limited as provided for in the waiver received).
- An investigator can utilize an honest broker as an honest broker can provide a firewall between the investigator, research team, and subjects' identifiable information. For example, an honest broker could generate or receive a dataset and then strip out subject identifiers so that the data is no longer readily identifiable. They could either create a de-identified data set or a limited data set.
- An investigator can receive a Limited Data Set (LDS) after entering into a Data Use Agreement (DUA) with the entity holding the clinical data. The LDS can then be made available through an honest broker or delivered directly to the investigator via the entity's preferred method.

For more information regarding access to department records, employment records, and educational records, please reference HSPP Guidance, *Access to Records*.

What is an honest broker?

An honest broker is:

- An individual who has access to the desired data by virtue of his or her responsibilities or agreement with the data holder.
- A neutral third party, who is not part of the research team in any way.
 - The honest broker <u>cannot</u> be one of the investigators or study coordinators and cannot serve as a co-author on any publication. Therefore, an honest broker cannot be listed on the protocol in any way.
- An individual, or system, acting on behalf of the researcher to collect and provide de-identified information or specimens to the research team.

What can an honest broker do?

The honest broker can add a layer of protection to enhance the confidentiality of subjects' data and specimens. For example, an honest broker can assign a code to data and specimens so that the researchers are no longer able to identify the individuals from whom they were obtained.

However, employing an honest broker is a decision that should be made with great care; it can prevent an investigator from being able to re-identify individual subject's data or specimens. There have been studies where the use of an honest broker has prevented the investigator from going back to the subject or their records for additional data or to recruit subjects to participate in a new study.

By removing all links to individually identifiable data, the honest broker can facilitate secondary uses of data/specimens. If the investigator and research team are provided with a de- identified data or de-identified biospecimens, the use of the data does not constitute research with human subjects because

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there is no interaction with any individual and no identifiable private information or biospecimens being used.

How to become an honest broker

The University of Arizona does not have a formal process to be designated as an Honest Broker. Any individual who will access identifiable data must have the appropriate authority or permissions to proceed. This individual should also have a formal procedure about how they are going to receive and vet requests for de-identified data. This would have to be done in accordance with any restrictions they agreed to when they first acquired the data. If a limited data set will be supplied by the Honest Broker to the data recipient, a DUA may need to be established. Please contact the HSPP for more information.

Training, Security, and Oversight

Honest Brokers should work with the HIPAA Privacy Program (HPP) to ensure correct systems and controls are in place to process and store any identifiable data.

Resources

- Banner Health Honest Broker Team: <u>BHHonestBrokerDataRequest@bannerhealth.com</u>
- UA HIPAA Privacy Program
- For institutional data (non-clinical), University Analytics & Institutional Research (UAIR) acts as an honest broker for data requests. UAIR data requests can be made here: <u>https://uair.arizona.edu/content/data-request-form</u>.
- Institutional COVID-19 data can be requested through the COVID-19 Data Governance Committee here: <u>https://privacy.arizona.edu/privacy-governance-committees</u>.