

Guidance

Honest Broker System and Honest Broker Assurance Process

Background

This guidance provides information about **Honest Brokers** and how to properly utilize the service at Children's Wisconsin (CW).

An **Honest Broker** can facilitate secondary uses of data/specimens. If the investigator and research team are provided with deidentified data and/or deidentified biospecimens, the use of the data does not constitute research with human subjects because there is no interaction with any individual and no identifiable private information or biospecimens is being used.

Access to clinical data and specimens for the purposes of research can occur in several ways:

- An investigator can utilize an **Honest Broker**, who is an individual that 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 to the researchers.
- 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. This method would require prospective IRB review and may qualify for an exempt determination.

Alternative methods to access data/specimens:

- Under IRB oversight, 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).
- Under IRB oversight, an investigator can review identifiable medical records or medical data under the issuance of a Waiver of Informed Consent and/or Waiver of PHI Authorization granted by the IRB of record (review is limited as provided for in the waiver received).

Clarification regarding **FDA-regulated studies**: An Honest Broker process cannot be used because the U.S. Food and Drug Administration (FDA) requires IRB review for all clinical investigations of devices that involve human subjects, including those that use leftover, deidentified human specimens in FDA-regulated studies. This requirement pertains to data used to support an investigational device exemption, device marketing application, or submission to the FDA, including in vitro diagnostic (IVD) technical or analytical studies that use human specimens. For further explanation, see the *Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices 2018 final rule*.

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What can an Honest Broker do?

The Honest Broker is an individual, or system, acting on behalf of the researcher to collect and provide deidentified information or specimens to the research team. 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 linkage code to data and specimens so that the researchers are no longer able to identify the individuals from whom they were obtained. The linkage code could permit information collation and/or subsequent inquiries, however the information linking this reidentification code to the patient's identity must be retained by the Honest Broker, secured and separate from research/other documents; all subsequent inquiries must be conducted through the Honest Broker. This must be described in the request, and any changes need to be reviewed to ensure that the project has not become human subjects research.

CAUTION

Employing an Honest Broker is a decision that should be made with great care; it can prevent an investigator from being able to reidentify 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.

Honest Broker Criteria

To serve as Honest Broker, individuals must:

- be a neutral third party who is not part of the research team in any way (i.e., cannot be one of the investigators or study coordinators), and cannot serve as a co-author on any publication
 - As such, an Honest Broker cannot be listed on or involved with the protocol in any way (except for their Honest Broker role);
- have access to the desired data by virtue of his or her organizational responsibilities or agreement with the data holder;
- undergo and maintain CW HRPP and CW Corporate Compliance directed orientation.

How to become an Honest Broker

CW HRPP does not have a formal process to be designated as an Honest Broker. Any individual who meets the criteria and intends to access identifiable data must have the appropriate authority and permissions to proceed, and approval of their department leader or direct report to serve in this capacity. This individual should also have a formal procedure documenting how they are going to receive and vet requests for deidentified 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 CW Research Compliance Manager for more information.

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All Honest Brokers must sign a written *Honest Broker Assurance Agreement* [form available only in Connect], documenting that they will abide by all relevant laws, regulations, CW HRPP and CW Corporate Compliance guidelines, policies, and procedures, orientation requirements, and the terms and conditions of the CW Business Associate Agreement (if applicable).

Required Orientation

Honest Brokers must review the educational materials (see section below) and meet with CW HRPP and/or CW Research Compliance Manager for in-person (Teams or Zoom) orientation. Once orientation is complete, documentation will be filed in the CW HRPP office and verified each time a request is made to serve as the Honest Broker. To schedule the orientation, please email cwhrpp@childrenswi.org.

Request for Review of Projects Involving Honest Brokers

Investigators intending to use an Honest Broker system must submit a *Request for Human Subjects Research Determination* form (available on Connect and the CW HRPP external site), following directions outlined on the request form. The project may move forward once a written determination has been made by the CW HRPP Research Integrity Manager or designee.

Ongoing Oversight

Projects using an Honest Broker system are subject to quality monitoring review by CW HRPP and CW Corporate Compliance.

References

1. HIPAA: 45 CFR §164.302-318 (Security Standards); §164.514(d) (Minimum Necessary Requirements), §164.530 (Administrative Requirements)
2. OHRP guidance <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html>
3. FDA Guidance <https://www.fda.gov/medical-devices/investigational-device-exemption-ide/acceptance-data-clinical-investigations-medical-devices>

Educational Module

Data Privacy, Confidentiality, and the Honest Broker Framework

This comprehensive guide establishes the standards for protecting patient data in research at Children's Wisconsin (CW). It serves to educate investigators and staff on the ethical, legal, and procedural requirements for accessing clinical data and biospecimens.

Conceptual Foundations: Privacy vs. Confidentiality

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While often used interchangeably, these terms represent two distinct stages of participant protection:

- **Privacy (relates to the Person):** This is the right of an individual to control how and when their information is gathered. Privacy involves behavior and data provided for specific purposes where a person has a reasonable expectation that no observation or recording is taking place (e.g., a medical consultation in a private room; closing a curtain and providing a discreet gown when conducting a physical exam).
- **Confidentiality (relates to the Data):** This refers to the obligation of researchers and the institution to safeguard patient data/information once it is disclosed. The rigor of these protections is determined by the potential risk of harm to the subject if their data were inadvertently disclosed.

Regulatory Landscape: HIPAA and the Common Rule

Data protection at CW is governed by overlapping federal regulations that work in tandem. The Honest Broker must be familiar with these regulations prior to serving in that capacity.

- **The Common Rule (45CFR46 subpart A):** Sets the standard for informed consent, IRB review, and protective measures for subjects who participate in human subjects research.
- **HIPAA (Health Insurance Portability and Accountability Act):** Focuses on **Protected Health Information (PHI)**. This includes health data in any medium that relates to past, present, or future physical or mental conditions, healthcare provision, or payment.

Technically, research using an Honest Broker process is not human subjects research, but the Honest Broker should be familiar with these regulations to prevent noncompliance.

Technical Methods for Data De-identification

De-identification under HIPAA is the process of removing or modifying Protected Health Information (PHI) so that it no longer identifies a patient and there is no reasonable basis to believe it can be used to identify them. CW recognizes two primary paths:

1. The Safe Harbor Method

This requires the removal of **18 specific identifiers**, including:

- Names and geographic subdivisions, smaller than a state (Address, City, ZIP).
- All elements of dates (except year) related to an individual (Birth, Admission, Discharge).
- Contact info (Phone, Email), SSNs, and identifying numbers (MRNs, Account numbers).
- Biometrics (Fingerprints, Full-face photos) and Web/IP addresses.

2. The Expert Determination Method

Used when a researcher must retain certain data points (like precise dates) that violate Safe Harbor. A statistical expert must certify in writing that the risk of re-identification is "very small."

3. Practical De-identification Strategies

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- **Generalization:** Converting specific values into ranges (e.g., Age 42 becomes "Age 40-50";).
- **Aggregation:** Reporting data in groups rather than individual data points.
- **Perturbation:** Slightly altering values (e.g., shifting a date by a few days) to preserve trends while preventing exact record matching; use elapsed time (replace the date of a visit with the number of days from an initial "index" event, such as an initial diagnosis or admission date).

The Limited Data Set (LDS) and Data Use Agreements (DUA)

If research objectives require data that cannot be fully de-identified (specifically precise dates or geographic identifiers), the **Limited Data Set** serves as a regulatory middle ground.

- **Retained Data:** An LDS may retain town, city, state, zip code, and all elements of dates.
- **Data Use Agreement (DUA):** Because an LDS is not fully de-identified, a legally binding DUA is required. This contract prohibits the recipient from identifying the information or contacting subjects.

Summary Table: Data Access Tiers

Data Type	Identifying Info	Regulatory Requirement	Oversight
Identifiable PHI	Full PHI	Informed Consent & Authorization	IRB
Limited Data Set	Dates/ZIP codes	Data Use Agreement (DUA)	HRPP/Compliance
De-identified Data	None (Safe Harbor)	Determination Letter	HRPP

LASTLY, if you have agreed to serve as an Honest Broker and are being asked to do something that is outside the original scope or that you know is not consistent with how the project was initially set up, speak to the Principal Investigator or to a member of the CW HRPP office or Corporate Compliance prior to moving forward.

Questions? Contact **CW HRPP** or **CW Corporate Compliance** for more information on DUAs, Honest Broker procedures, or de-identification strategies.