

Applicability:	UW Medicine ¹ and UW Medicine Affiliated Covered Entity ²
Policy Title:	Honest Broker Policy for UW Medicine Clinical Data
Policy Number:	COMP.307
Superseded Policy:	N/A
Date Established:	July 01, 2025
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PURPOSE

The purpose of this policy is to define the function of an Honest Broker at UW Medicine and describe the core principles, training requirements, duties and responsibilities to assure a compliant release of UW Medicine Clinical Data to researchers.

This policy applies to all UW Medicine Honest Brokers with the exception of Fred Hutchinson Cancer Center (Fred Hutch). See Fred Hutch Honest Broker Policy.

DEFINITIONS

- A. **“Business Associate”** means an individual or entity, that is not a workforce member of the University of Washington, that performs a service or activity “for” or “on behalf of” the University of Washington or UW Medicine, with or without compensation, that involves protected health information (PHI). [COMP.106 Use and Disclosure of Protected Health Information by Business Associates](#)

¹ UW Medicine is an integrated clinical, research and learning system with a single mission to improve the health of the public. The clinically integrated parts of UW Medicine consist of the following:

- Airlift Northwest
- Fred Hutchinson Cancer Center (*Please note, the UW Medicine Compliance Program and this policy apply to UW faculty. Fred Hutchinson employees who are not also UW faculty are required to comply with Fred Hutchinson compliance policies only.)
- Harborview Medical Center
- UW Medical Center
- UW Medicine Primary Care
- UW Physicians
- UW School of Medicine
- Valley Medical Center

² The University of Washington (UW) is a hybrid covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), comprised of healthcare and non-healthcare components. For the purposes of HIPAA, the UW has designated healthcare components, and further designates a group of healthcare components to be one affiliated covered entity known as UW Medicine Affiliated Covered Entity (UW Medicine ACE). Healthcare components of the UW Medicine ACE are represented in [101.G1 University of Washington \(UW\) HIPAA Designation – UW Medicine – Affiliated Covered Entity](#).

- B. **“Clinical Data”** means data created or received by UW Medicine in clinical care decision making, provision, billing or payment. Clinical Data includes healthcare delivery records (including PHI), provider data, de-identified healthcare data, data utilized for Quality Improvement activities, metadata, reference data, healthcare supply chain data, laboratory data, referral data, patient-level financial data, other forms of confidential or sensitive data within healthcare records or databases of UW Medicine (including metadata and reference data).
- C. **“Conflict of Interest”** means when a person involved with a research study also has financial, personal, or other interests from which they can benefit based on the results of the study. A conflict of interest may compromise, or have the appearance of compromising, a person’s judgment in facilitating, conducting, or reporting research.
- D. **“Database”** means a collection of information elements (i.e., data) arranged for ease and speed of search and retrieval. Most databases are now maintained electronically, but the term can also be applied to paper record systems. Examples of databases include a set of observations resulting from a research study, an electronic file containing patient’s records, a collection of diagnosis, treatment, and follow-up information for a hospital’s oncology patients, a file of outcomes information compiled for quality assurance activities, and a list of prospective research subjects.
- E. **“De-Identified Health Information”** means data that has been de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), see [COMP.103 Use and Disclosure of PHI](#), Section VI.B. See also [102.G4 PHI Guidance](#). (Source: 45 C.F.R. § 164.514(a)).
- F. **“Honest Broker”** means an individual, software application, organization or team acting to search UW Medicine patient medical records to collect Clinical Data and/or review the collected Clinical Data to respond to a researcher’s approved request to access or use Clinical Data. Provides identified or de-identified information to the research team in accordance with applicable IRB approval, UW Medicine policies, and core principles. The Honest Broker resides within the covered entity or is a Business Associate and acts as a Neutral Intermediary between the covered entity and the research team.
- G. **“Limited Data Set”** means when Protected Health Information (PHI) excludes certain direct identifiers of the patient or of relatives, employers, or household members of the patient. See [COMP.103 Use and Disclosure of PHI](#), Section VI on Limited Data Sets.
- H. **“Protected Health Information”** (PHI) means information (verbal, paper, or electronic) maintained or transmitted by UW Medicine that relates to:
- The past, present, or future physical or mental health or condition of an individual;
 - The provision of healthcare to an individual; or
 - The past, present or future payment for the provision of healthcare to an individual and either a) identifies the individual or b) provides a reasonable basis to believe the information can be used to identify the individual.

See [COMP.103 Use and Disclosure of PHI](#). See also [102.G4 PHI Guidance](#). (Source: 45 C.F.R. § 160.103).

- I. **“Honest Broker Re-Identification Key”** means a unique code or identifier held by a designated individual, known as an "honest broker," which allows them to link de-identified patient data back to the original patient record, but is strictly controlled to prevent unauthorized re-identification of individuals in research studies, ensuring patient privacy while enabling data analysis.

POLICY

- A. **Honest Broker Core Principles:**
1. UW Medicine Clinical Data sharing practices cannot put patients at risk.
 2. UW Medicine Clinical Data sharing practices must honor patient autonomy, as demonstrated by consent (or IRB waiver of consent).
 3. UW Medicine Clinical Data sharing practices cannot put the University of Washington or UW Medicine at unreasonable risk. Institutional risks associated with inappropriate release or unapproved use of Clinical Data, sensitive utilization data, financial data, or quality improvement data include loss of patient confidence, legal exposure, and reputational harm.
 4. Secondary use of Clinical Data cannot interfere with primary data use.
 5. Data release practices should promote the appropriate use of Clinical Data in research consistent with the [mission](#) of UW Medicine.
 6. UW Medicine Clinical Data sharing practices must comply with all applicable laws, regulations and UW/UW Medicine policies. [Release of Clinical Data for Research Purposes](#).
- B. **Honest Broker Functional Criteria:** Honest Brokers must meet the functional criteria listed below, as governed by the Senior Director Enterprise Records & Health Information. [UW Medicine Honest Broker Program - Home](#)
1. Complete the required annual Honest Broker training [Honest Broker Training Information Site](#) which includes an attestation to abide by all relevant UW Medicine and IRB guidelines, policies, and procedures.
 2. Independent of and lacks Conflicts of Interest with the requestor to which the Honest Broker supplies Clinical Data.
 3. Maintain a signed [Privacy, Confidentiality, and Information Security Agreement \(PCISA\)](#).
 4. Maintain auditable records of requests and fulfillments.
- C. **Training Requirements:** Honest Brokers must complete the required training prior to performing any Honest Broker functions. Training requirements are governed by the Senior Director, Enterprise Records & Health Information and managed by Research IT.
1. Training assures competency in:
 - a. Compliance with the HIPAA Privacy Rule, the federal regulations for human subject protections (45 CFR 46; 21 CFR 50 and 56).
 - b. Compliance with UW Medicine policy on safeguarding the privacy and security of PHI. [COMP.102 Safeguarding the Privacy and Security of PHI](#).
 - c. Human subjects research ([CITI Training](#)).

- d. Processes and/or systems to be used to develop both fully De-Identified Health Information data sets and Limited Data Sets.
 - e. Audits and/or quality checks to determine the efficacy of de-identification mechanisms.
 - f. Security and management of Re-Identification Keys.
 - g. Maintenance and retention of work-product documentation for all work performed.
 - h. Identification of Conflicts of Interest.
2. Training outlines the required duties and responsibilities of an Honest Broker, including but not limited to:
- a. Adherence to all terms and conditions specified by the IRB of record (if IRB approval was required) for any release of data.
 - b. Execution of a data use agreement when required and/or evidence of an appropriately executed data use agreement (as it applies to Limited Data Sets) before being granted access to the PHI.
 - c. Thoroughly documented requestor information, including:
 - i. Researcher's name, institutional affiliation, contact information
 - ii. Date/time of request
 - iii. Study name, the internal or external Institutional Review Board (IRB) of record (e.g., University of Washington, Seattle Children's, Fred Hutchinson Cancer Center, other), and the IRB approval number.
 - iv. A detailed description of the request
 - d. Thoroughly documented Honest Broker information, including:
 - i. Name of the person(s) acting as Honest Broker
 - ii. The data source(s) to be used (where the data originated from)
 - iii. The fields required to retrieve the data
 - iv. The method of output for the data
 - v. Validation of the concordance between the data elements requested by the researcher and the data elements identified in the IRB protocol as approved for extraction
 - vi. Attesting to no Conflict of Interest for each instance of honest brokering
 - e. Final status of the request, including the following:
 - i. Data retrieval date
 - ii. Report(s) delivery date
 - iii. Name of the Honest Broker delivering the report, if different from the requestor
 - iv. Name of the person accepting the report
 - f. Compliance with the retention requirements as outlined in the [UW Medicine Retention Schedules](#).

D. Auditing

Enterprise Records & Health Information Records and Information Governance (ERHI RIG) is responsible for ensuring the Honest Broker training is completed at least annually. In the event an Honest Broker does not complete their annual training within the timeframe specified, these results can be escalated to applicable leadership. Additionally, ERHI RIG will perform routine spot checks of Honest Broker Clinical Data pulls for research purposes to ensure consistency with the information approved by the IRB and all applicable duties and responsibilities outlined above were followed. Follow-up will occur by the Senior Director of Enterprise Records & Health Information if an Honest Broker does not follow the proper process. If an Honest Broker has more than two incidents of failing to follow the proper process, after education/training is provided, their Honest Broker privileges may be revoked.

- E. **Honest Broker Software:** Honest Broker software may be leveraged but must meet certain criteria and must be approved by the Research Access to Patient Data (RAPiD) Committee (Tier III) prior to use. See the list of existing approved software [Approved Honest Broker Software List](#).

REGULATORY/LEGISLATION/REFERENCES

- [Security Standards for the Protection of Electronic PHI, 45 C.F.R. § 164, Subpart C.](#)
- [Privacy of Individually Identifiable Health Information, 45 C.F.R. § 164, Subpart E.](#)
- [Protection of Human Subjects, 21 C.F.R. § 50.](#)
- [Protection of Human Subjects, 21 C.F.R. § 56.](#)
- Public Records, [WAC 434-662-020](#), [RCW 42.56](#), and [RCW 40.14](#)

PROCEDURE ADDENDUM(S) REFERENCES/LINKS

- [COMP.306 Release of Clinical Data for Research Purposes](#)
- [COMP.102 Safeguarding the Privacy and Security of PHI](#)
- [COMP.103 Use and Disclosure of PHI](#)
- [COMP.305 Offshore Storage and Access to UW Medicine Data by Third Parties](#)
- [UW Medicine Retention Schedules](#)
- [Privacy, Confidentiality, and Information Security Agreement \(PCISA\)](#)
- Data Use Agreement templates:
 - 307.F1: Data Use Agreement for Use with University of Washington Recipients:
https://depts.washington.edu/comply/docs/307_F1.pdf
 - 307.F2: Data Use Agreement for Use with Non-University of Washington Recipients:
https://depts.washington.edu/comply/docs/307_F2.pdf

APPROVAL(S)

/s/ Beth DeLair
 Beth DeLair
 Chief Compliance Officer, UW Medicine
 Associate VP for Medical Affairs, UW

6/27/2025
 Date