Applicability: UW Medicine[1] and UW Medicine Affiliated Covered Entity[2]

Policy Title: Release of UW Medicine Clinical Data for Research Purposes

Policy Number: COMP.306

Superseded Policy: N/A

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PURPOSE

The purpose of this policy is to describe the circumstances when UW Medicine may disclose Protected Health Information (PHI) for Research purposes, introduces the concept of "Clinical Data" that is broader than the definition of PHI, and describes the centralized and values-based approach for reviewing and responding to requests to use or share UW Medicine Clinical Data for Research purposes.

This policy also describes Research Data stewardship obligations that traditionally fall outside the scope of UW Medicine patient privacy and security requirements, including a summary description of UW institutional standards, the requirement to execute data use agreements, and how to report unforeseen events involving data, based on the data classification.

This policy does not apply to Fred Hutchinson Cancer Center.

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[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.*

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

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. "Commercialization" or "Commercialize" means the direct access to or use of UW Medicine Clinical Data to develop a product or service used in commerce but shall not include access to or use of Clinical Data in the context of Software as a Service agreement.

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 authorization, 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 Heath 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. "**Preparatory to Research**" means a use of PHI for the purpose of preparing a Research protocol or planning the Research activity (e.g., designing a Research study, assessing whether a sufficient number or type of records exist to conduct the Research).

I. "**Protected Health Information**" (PHI) means information (verbal, paper, or electronic) maintained or transmitted by UW Medicine that relates to:
   a. The past, present, or future physical or mental health or condition of an individual;
   b. The provision of healthcare to an individual; or
   c. 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).

J. "**Research**" means a systematic investigation designed to develop or contribute to generalizable knowledge.

K. "**Research Data**" means information, records, and tangible products arising from or associated with Research conducted at, under the auspices of, or using the resources of the UW. Research Data includes both intangibles (e.g., information and copyrighted works such as software and expressions of information) and tangibles (e.g., cell lines, biological samples collected for Research purposes, synthetic compounds, organisms, and originals or copies of laboratory notebooks).

   See GIM 37, UW Research Data Policy.

L. "**Secure UW Medicine Environment**" means hosted within a UW Medicine data center or managed by UW Medicine IT Services with all required controls which align with UW Medicine Information Security Standards and APS 2.6.

M. "**Software as a Service**" or "**SaaS**" means a software licensing and delivery model in which software is licensed on a subscription basis and is hosted by a third-party vendor.

POLICY

UW Medicine may use or disclose Clinical Data, which may include PHI, for Research purposes in accordance with HIPAA, the Common Rule and Washington law. Reasonable precautions must be taken to ensure that uses and disclosures of Clinical Data for Research purposes are limited to the minimum amount of information necessary to accomplish the intended purposes.

Section A of this policy describes in greater detail the conditions in which UW Medicine Clinical Data that meets the definition of PHI may be used or shared for Research purposes. The release of Clinical Data to Researchers must meet certain standards based on the sensitivity and extent of the data request, as well as the Researcher's affiliation with UW Medicine or the UW.

Section B of this policy summarizes institutional expectations governing the storage, security, and transfer of Research Data. Clinical Data that has been disclosed for Research purposes may no longer meet the definition of PHI as defined by HIPAA and UW Medicine Compliance Patient Information Privacy Policies may no longer apply. When this occurs, UW and UW Office of Research policies and UW Medicine Information Security Standards govern the stewardship of this Research Data.

Section C of this policy summarizes the obligation to report unforeseen events that impact the privacy or result in a breach of personal data, which includes Research Data that may or may not meet the definition of UW Medicine PHI.

A. Standards for Uses and Disclosures of PHI for Research Purposes

1. Researchers requesting access to UW Medicine Clinical Data for research purposes must be either:
    a. A UW Medicine employee; or
    b. Have an affiliation with UW Medicine; or
    c. Able to demonstrate an IRB approved study or collaboration is in place with a UW Medicine employee or affiliate; or
    d. Able to demonstrate valid authorization from the patient or the patient's personal representative. See Section 2(a) for more information on UW Medicine's Informed Consent Manual.
2. PHI may be used or disclosed for Research purposes when one of the following conditions is met:
    a. With valid authorization from the patient or the patient's personal representative. In the absence of a personal representative for decedents, authorization may be provided by the individual who had authority to make healthcare decisions on behalf of the deceased patient. See the UW Medicine Informed Consent Manual UW Medicine Informed Consent Manual.
        i. An authorization is not applicable to additional future Research unless the authorization or research consent form specifically and clearly states that the data will be used in the future for additional Research.
        ii. Researchers are advised to use the UW Medicine approved HIPAA Authorization template (but may use an equivalent form).

    b. When an IRB waives the requirement for patient authorization, in accordance with federal and state patient privacy laws, and the Researcher obtaining PHI under a waiver of authorization accounts for the disclosure in accordance with COMP.104 Patient Rights Related to Protected Health Information .

    c. When the health information is de-identified prior to its release and the following conditions are met:
        i. The PHI is de-identified in accordance with COMP.103 Use and Disclosure of Protected Health Information Section VI.
        ii. The PHI is de-identified by an Honest Broker, as defined in the Honest Broker Policy for UW Medicine Clinical Data.

    d. When the information is part of a Limited Data Set and UW has executed a data use agreement with the recipient before use or disclosure of the Limited Data Set in accordance with COMP.103 Use and Disclosure of Protected Health Information Section VI.

e. When the Research involves decedent PHI, and the Researcher attests to the following:
    i. Use or disclosure is sought solely for Research on the PHI of decedents.
    ii. Documentation of the death of such individuals is available if requested by UW Medicine.
    iii. PHI of the deceased individuals is necessary for Research purposes.

f. When the information is collected as Preparatory to Research and the Researcher has attested to the following conditions:
    i. Use of PHI is sought solely to review it for the purpose of preparing a Research protocol or planning the Research activity (e.g., designing a Research study, assessing whether a sufficient number or type of records exist to conduct the Research).
    ii. No PHI will be removed from UW Medicine covered entity by the Researcher in the course of the review.
    iii. PHI for which use, or disclosure is sought is necessary for the Research purposes.
    iv. Most activities are not considered to be Research by the Human Subjects Division, which makes such determinations on behalf of the University. For example, a researcher may review PHI to design a research study or to assess whether a sufficient number or type of records exist to conduct the research.
    v. Activities that don't qualify as preparatory to research include but are not limited to: review of PHI to identify eligible subjects for recruitment, feasibility studies and/or pilot studies.

Receipt of or access to patient names and contact information to identify possible Research participants requires IRB approval, including patient authorization or a waiver of HIPAA authorization.

3. Case Reports/Studies

The policy requirements articulated in COMP.103 Use and Disclosure of Protected Health Information Section VI regarding Research apply to case reports and case studies that meet the federal definition of Research. The Human Subjects Division provides information on how to fulfill IRB requirements if any are applicable in their guidance on case reports.

4. Research Activities Involving Commercialization of Clinical Data

The following standards apply when UW Medicine uses or discloses Clinical Data for Research that may include Commercialization of UW Medicine Clinical Data:

a. Research proposals involving sharing UW Medicine Clinical Data with commercial entities that could Commercialize access to or develop models or analytics from UW Medicine Clinical Data must be reviewed and approved by the Research Access to Patient Data (RAPiD) Committee (Tier III) before Clinical Data may be

shared with or released to the commercial entity. Some of the factors the committee will consider when reviewing proposals include:

i. Whether the Clinical Data involved is de-identified or otherwise compliant with relevant privacy laws and regulations.

ii. Whether the proposal involves access to Clinical Data on a UW or UW Medicine hosted data platform or a release of Clinical Data to the commercial entity.

iii. The reputation of the commercial entity.

iv. Whether the release of Clinical Data brings value to UW Medicine patients or puts patients at risk.

v. Whether the release of Clinical Data puts the UW or UW Medicine at an unreasonable risk.

vi. Whether UW Medicine patient care is the prevailing motivation.

vii. Whether secondary use of Clinical Data interferes with its primary use.

b. If the Clinical Data includes data that meets the Cancer-Related Care definition per the Clinical Data Exchange MOU between UW and Fred Hutchinson Cancer Center, the RAPiD Committee will coordinate review by the Joint Clinical Data Oversight Committee.

c. If approved by the applicable committee(s), data use terms must be captured in an agreement incorporating the elements described in Section B.3.

d. Access to or release of UW Medicine Clinical Data to the commercial entity must be facilitated through a committee approved Honest Broker.

e. UW Medicine may charge reasonable cost-based fees to recoup the direct and indirect costs of preparing or transmitting UW Medicine Clinical Data for Research purposes or to prepare limited data sets.

B. Data Stewardship of Research Data

UW Medicine Clinical Data that has been disclosed for Research purposes may no longer meet the definition of PHI as defined by HIPAA and UW Medicine Compliance Patient Information Privacy Protection policies may no longer apply. When this occurs, UW and UW Office of Research policies and standards govern the stewardship of Research Data.

1. Data Storage

a. Research Data must be maintained in compliance with all applicable UW policies, state and federal laws, and contractual requirements, including without limitation those pertaining to human subjects and confidentiality.

b. Research Data must be stored in a Secure UW Medicine Environment along with executed contracts with external service providers when appropriate.

c. Research Data may be physically stored in the University Records Center should adequate departmental space not be available.

2. Data Security Plans
    a. UW and UW Medicine Information Security sets data security standards that must be followed, in addition to the reviewing IRB data sets security standards.
    b. If UW is the reviewing IRB, Researchers are expected to implement data security measures commensurate with the type of harm associated with a breach of the data:
        i. Suitable for public disclosure.
        ii. Little risk of harm to individuals if disclosed.
        iii. Risk of material harm to individuals if disclosed.
        iv. Risk of serious and/or long-lasting harm to individuals if disclosed.

    c. Consult with APS 2.6 Information Security Controls and Operational Practices for more information on UW standards.
    d. Consult https://depts.washington.edu/uwmedsec/restricted/security-governance/information-security-standards/UW Medicine standards for more information.
    e. Consult with GUIDANCE: Data Security Protections for more information on UW IRB standards.

3. Data Use Agreements
    a. Research Data entering or leaving UW Medicine or UW must be accompanied by a Data Use Agreement outlining how the data will be used, protected, and maintained, unless the data use terms are captured in a main agreement (e.g., research collaboration agreement, service agreement, procurement agreement).

    b. Data Use Agreements executed to permit the release of UW Medicine Clinical Data for Research purposes (i.e., that goes beyond the definition of a Limited Data Set) or to permit a UW Researcher to release UW Research Data derived from UW Medicine Clinical Data with a third party must contain substantially the same terms as the UW Medicine External DUA template. UW Medicine encourages the use of the UW Medicine DUA template, but if it cannot be used then either Regulatory and Business Affairs, Office of Sponsored Programs or CoMotion must ensure that all UW Medicine External DUA template terms are included in the DUA, see Procedure Addendum(s)/References section for templates).

    c. A separate Data Use Agreement is not required for clinical trials that include the informed consent of Research participants; the clinical trial sponsor agreement will govern the use of this Clinical Data.

4. Other Considerations
    a. When applicable, UW Researchers must abide by GIM 37 – Research Data.

b. UW Researchers should consult the NIH Data Management and Sharing Policy which applies to all NIH funded projects that generate scientific data. See UW Office of Sponsor Programs FAQs on the policy.

c. UW Researchers should consult with Guidance: Genomic Data Sharing when the Researcher plans to submit genomic data to NIH-designated repositories.

d. Additional measures to protect "identifiable sensitive information" may be required if the U.S. Department of Health and Human Services has issued a Certificate of Confidentiality for the Research study.

e. Transfers of biological specimens may need to adhere to the UW Medicine Policy on the Transfer of Human Biological Specimens.

C. Incident Reporting Obligations

All UW employees and UW Medicine workforce members have an obligation to report unforeseen events that impact the privacy or result in a breach of personal data, which includes Research Data that may or may not meet the definition of UW Medicine PHI. See COMP.105 Breach Notification.

1. Non-UW Medicine and non-UW Medicine Healthcare Components Research Data
    a. Incidents or potential or confirmed data breaches involving Research Data that does not meet the definition of PHI must be reported to the reviewing IRB (e.g. UW, Fred Hutch, Seattle Children's, commercial IRB, or others). Contractual obligations may also require reporting to the entity providing the data set.
        i. If UW is the reviewing IRB, submit a Report of New Information to the Human Subjects Division.
2. UW Medicine PHI Research Data
    a. Incidents or potential or confirmed data breaches involving Research Data that meets the definition of UW Medicine PHI must be reported to UW Medicine Compliance (comply@uw.edu) and the reviewing IRB (e.g. UW, Fred Hutch, Seattle Children's, commercial IRB, or others).
        i. If UW is the reviewing IRB, submit a Report of New Information to the Human Subjects Division.
3. University of Washington Non-UW Medicine Healthcare Components PHI Research Data
    a. Incidents or potential or confirmed data breaches involving Research Data that constitutes University of Washington non-UW Medicine Healthcare Components PHI must be reported to the Privacy Compliance Program Manager at UW Compliance, Risk Services (crs-privacy@uw.edu) and the reviewing IRB (e.g. UW, Fred Hutch, Seattle Children's, commercial IRB, or others).
        i. If UW is the reviewing IRB, submit a Report of New Information to the Human Subjects Division

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

- APS 2.6 Information Security Controls and Operational Practices
- 102.G4 PHI Guidance
- GIM 37 – Research Data
- UW Medicine Compliance Patient Information Privacy Policies
    - COMP.102 Safeguarding the Privacy and Security of PHI
    - COMP.103 Use and Disclosure of PHI
    - COMP.104 Patient Rights Related to PHI
    - Comp. 107 Information Security Policy
    - UW Medicine Informed Consent Manual
- COMP.307 Honest Broker Policy
- Comp.305 Offshore Storage and Access to UW Medicine Data by Third Parties
- UW Medicine Policy on the Transfer of Human Biological Specimens
- UW Research
    - GUIDANCE Certificate of Confidentiality
    - GUIDANCE: Data Security Protections
    - GUIDANCE Genomic Data Sharing
    - Human Subjects Division
- UW Medicine data Use Agreement templates:
    - 103.T6 Data Use Agreement for Limited Data Set (should be used for individuals or entities NOT part of UW Medicine workforce)
    - 103.T7 Data Use Agreement for Limited Data Set (should be used for UW Medicine workforce)
- Federal Demonstration Partnership Data Transfer and Use Agreements
- HIPAA Authorization template
- NIH Data Management and Sharing Policy

APPROVAL(S)

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6/27/2025
Date