Applicability: UW Medicine

Policy Title: Use & Disclosure of Protected Health Information for Research

Policy Number: PP-18

Superseded Policy(ies) or Entity Policy: N/A

Date Established: April 10, 2003

Date Effective: March 15, 2017

Dates Revised: August 20, 2003; September 22, 2003; August 22, 2005; February 17, 2010; June 14, 2011; July 30, 2013; March 15, 2017

Next Review Date: March 15, 2020

PURPOSE AND SCOPE
This policy establishes the conditions under which UW Medicine protected health information (PHI) may be used or disclosed for research purposes in accordance with the Health Insurance Portability and Accountability Act (HIPAA), the Privacy Rule (45 CFR Part 160 and Part 164), the Common Rule (45 CFR 46) and Washington law.

This policy applies to the following:

- All designated healthcare components of the University of Washington (UW) covered entity as defined in UW Medicine Compliance Policy: PP-01 Designation of Healthcare Components at the University of Washington, and
- To all use or disclosure of UW Medicine PHI for research purposes, including the PHI of deceased patients (decedents).
- To case reports and case studies that meet the federal definition of research.

DEFINITIONS
See UW Medicine Compliance Policy: PP-00 Glossary of Terms.

POLICY

A. UW Medicine PHI may be used or disclosed for research purposes when one of the five following conditions is met:

1. With a valid authorization of 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 PP-08 Use & Disclosure of Protected Health Information Requiring Authorization.
a. An authorization is not applicable to additional future research unless the authorization specifically and clearly states that the data will be used in the future for additional research.

b. Researchers are advised to use the UW Medicine approved HIPAA Authorization template (but may use an equivalent form):
   http://www.washington.edu/research/hsd/docs/866

2. When an Institutional Review Board (IRB) waives the requirement for patient authorization, in accordance with federal and state patient privacy laws, and all of the following conditions are met:

   a. The waiver or alteration of authorization document contains the following elements:
      i. The identity of the IRB (IRB federal registration number and local identifying name).
      ii. The date on which the alteration or waiver of authorization was approved.
      iii. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board.
      iv. Statement that the alteration or waiver of authorization has been reviewed and approved under either full IRB or expedited review procedures as follows:
         i. The IRB followed the requirements of the federal human subjects regulations, including the criteria for full or expedited IRB review, and
         ii. The IRB chair or designee has signed the documentation of the alteration or waiver of authorization.
      v. Statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following criteria:
         • Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
            o An adequate plan to safeguard the identifiers from improper use and disclosure;
            o An adequate plan to destroy the identifiers consistent with the conduct of the research and in accordance with retention policies, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
            o Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
         • The research could not practicably be conducted without the alteration or waiver.
         • The research could not practicably be conducted without access to and use of PHI.

   b. The researcher has entered into a confidentiality agreement with the designated data custodian or the data custodian’s designee in accordance with Washington State law (Revised Code of Washington (RCW) 42.48). (See additional guidance and an agreement template at http://www.washington.edu/research/hsd/docs/393).
c. The researcher obtaining PHI under a waiver of authorization accounts for the disclosure of all PHI used, in accordance with UW Medicine Compliance Policy: PP25 Accounting of Disclosures of Protected Health Information.

3. When the health information is de-identified prior to its release for research and the following conditions are met:
   a. De-identification must be in accordance with UW Medicine Compliance Policy: PP19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information.
   b. De-identification may be made by an individual who is designated and trained to perform this function, is either part of the UW Medicine workforce or a business associate of UW Medicine and is not a member of the research team to which the de-identified information will be provided.

4. When the information is part of a limited data set and the UW has executed a data use agreement\(^1\) with the recipient before use or disclosure of the PHI in accordance with UW Medicine Compliance Policy: PP19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information.

5. When the information is collected as preparatory to research\(^2\) and the researcher has attested to the following three conditions:
   a. Use or disclosure of the PHI is sought solely to review it for the purpose of preparing a research protocol or planning the research activity. (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);
   b. No PHI will be removed from the UW Medicine covered entity by the researcher in the course of the review;
   c. The PHI for which use or disclosure is sought is necessary for the research purposes.

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.

B. Minimum Necessary Standard

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\(^1\) Data use agreement templates are provided in attachments to PP19. Attachment A - Data Use Agreement for Limited Data Set should be used for individuals or entities NOT part of UW Medicine workforce: [http://depts.washington.edu/comply/docs/PP_19_A.doc](http://depts.washington.edu/comply/docs/PP_19_A.doc), Attachment B - Data Use Agreement for Limited Data Set should be used for UW Medicine workforce: [http://depts.washington.edu/comply/docs/PP_19-B.doc](http://depts.washington.edu/comply/docs/PP_19-B.doc)

\(^2\) Preparatory to research. Most activities that are sometimes categorized as “preparatory to research” are considered to be research by the Human Subjects Division, which makes such determinations on behalf of the University. These include but are not limited to: screening activities such as review of PHI to identify possible research subjects, feasibility studies and/or pilot studies. Such activities may involve the use of human subjects directly or indirectly (through individually identifiable health records, the collection or review of other data such as samples, specimens or autopsy materials).
UW Medicine will disclose only the minimum amount of PHI necessary to accomplish the purpose of a given request for the use and disclosure of patient information for research, regardless of the conditions under which it is requested.

C. Case Reports/Studies

The policies articulated in Sections A and B above apply to case reports and case studies that meet the federal definition of research. The Human Subjects Division website provides information on how to fulfill IRB requirements if any are applicable.

D. Safeguarding Information

Patient information used or disclosed for research must be protected in accordance with UW Medicine privacy and information security requirements:

- UW Medicine Information Security Policies and Standards: 
- UW Medicine Compliance Policy: PP-30 Safeguarding Patient Information: 
  [https://depts.washington.edu/comply/docs/PP_30.pdf](https://depts.washington.edu/comply/docs/PP_30.pdf)

E. All suspected research-related privacy or security events and policy violations must be reported to:

- The IRB of record and
- UW Medicine Compliance through any of the following:
  - Main line: 206.543.3098 (local) or 855.211.6193 (toll free)
  - Compliance Anonymous Hotline: 206.616.5248 (local) or 866.964.7744 (toll free)
  - Email: comply@uw.edu

F. Failure to Comply

Failure to comply with this and other applicable policies governing PHI will result in corrective actions, up to and including dismissal, revocation of IRB approval and civil or criminal penalties.

REGULATORY/LEGISLATION/REFERENCES

- 45 CFR.102; 21 CFR 50.3.
- 45 CFR Parts 160 and 164; Section § 164.508 “Uses and disclosures for which an authorization is required.”
- 45 CFR Part 160 and 164; Section § 164.512(i) “Standard: Uses and disclosures for research purposes.”
- RCW 42.48 – Release of Records for Research.
- RCW 70.02 – Medical Records – Healthcare Information Access and Disclosure.
PROCEDURE ADDENDUM(s) REFERENCES/LINKS

- UW Medicine Compliance Policy: PP.00 Glossary of Terms
- UW Medicine Compliance Policy: PP.01 Designation of Healthcare Components at the University of Washington
- UW Medicine Compliance Policy: PP.06 Corrective Actions for Noncompliance with Privacy and Information Security Policies
- UW Medicine Compliance Policy: PP.19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information
- UW Medicine Compliance Policy: PP.25 Account of Disclosures of Protected Health Information (PHI)
- UW Medicine Compliance Policy: PP.30 Safeguarding Patient Information

ROLES AND RESPONSIBILITIES
Defined within POLICY.

AUTHORITIES

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APPROVALS

UW Privacy Official                     Date
Sue Clausen                              
Chief Compliance Officer, UW Medicine
Associate VP for Medical Affairs &
Interim Privacy Official, UW