

Applicability: UW Medicine

Policy Title: Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information

Policy Number: PP-19

Superseded Policy(ies) or Entity Policy: N/A

Date Established: December 12, 2002

Date Effective: July 1, 2014

Dates Revised: January 23, 2006; December 4, 2007; October 14, 2010; April 11, 2013

Next Review Date: July 1, 2017

PURPOSE AND SCOPE

This policy is applicable to all UW Medicine entities.

POLICY PRINCIPLES/STATEMENT

See POLICY.

DEFINITIONS

Workforce: Workforce means faculty, employees, volunteers, trainees, students and other persons whose conduct, in the performance of work for UW Medicine or Business Associate (BA), is under the direct control of UW Medicine or BA, whether or not they are paid by UW Medicine or the BA.

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

POLICY

UW Medicine workforce members are responsible for maintaining the security and confidentiality of protected health information (PHI). PHI can be in any form, including verbal, written and electronic.

I. Protected Health Information

- A. PHI means individually identifiable health information maintained or transmitted in any form or medium.

Individually identifiable health information is a subset of health information, (including demographic information collected from an individual), created or received by UW Medicine that:

1. Relates to the past, present, or future physical or mental health or condition of an individual; *or*
2. Relates to the provision of healthcare to an individual; *or*
3. Relates to the past, present, or future payment for the provision of healthcare to an individual; *and*
4. Identifies the individual or there is a reasonable basis to believe the information can be used to identify the individual.

B. PHI excludes individually identifiable health information in:

1. Employment records held by a covered entity in its role as employer.
2. Education records covered by the Family Educational Rights and Privacy Act (FERPA); *and*
3. Records of students of post-secondary institutions which are exempt from FERPA because they are used exclusively for healthcare treatment.

Release of education records that contain healthcare information are subject to Washington State Uniform Health Care Act protections (RCW 70.02) and other state laws governing confidentiality of health information. See WAC 478-140-018(1)(c)(B)(iv).

II. Limited Data Set

The UW Medicine workforce member initiating a data use agreement is responsible for the completion of the agreement. See *Data Use Agreement for Limited Data Set - For use with individuals or entities who are not part of the UW's workforce (Attachment A)* or *Data Use Agreement for Limited Data Set - For use with individuals or entities who are part of the UW's workforce (Attachment B)* as appropriate.

A. A limited data set is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names;
2. Postal address information, other than town or city, state and zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;

8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web universal resource locators (URLs);
14. Internet protocol (IP) address numbers;
15. Biometric identifiers, including finger and voice prints; and
16. Full face photographic images and any comparable images.

B. Permitted purposes for uses and disclosures of limited data sets:

1. UW Medicine may use or disclose a limited data set for the purposes of research, public health or healthcare operations.
 - Using or disclosing a limited data set for research purposes requires an IRB waiver to create the limited data set.
2. UW Medicine may use PHI to create a limited data set that meets the requirements as above, or disclose PHI to a business associate for such purpose, regardless of whether the limited data set is to be used by UW Medicine.

C. Data Use Agreement

1. UW Medicine may use or disclose a limited data set only if UW Medicine obtains satisfactory assurance, in the form of a data use agreement, that the limited data set recipient will only use or disclose the PHI for limited and specified purposes.
2. The data use agreement between UW Medicine and the limited data set recipient must:
 - a. Establish the permitted uses and disclosures of such information by the limited data set recipient for purposes of research, public health, or healthcare operations. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that, if done by UW Medicine, would violate the requirements of this policy;
 - b. Establish who is permitted to use or receive the limited data set;
 - c. Provide that the limited data set recipient will:

- i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
- ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
- iii. Report to UW Medicine any use or disclosure of information that is not allowed by the data use agreement;
- iv. Ensure that any agents, to whom it provides the limited data set abides by the same restrictions and conditions that apply to the limited data set recipient; *and*
- v. Not try to identify the information nor contact the patients.

D. Non-compliance with Limited Data Set Requirements:

1. If UW Medicine knows of a pattern of activity or practice by the limited data set recipient that constitutes a material breach or violation of the data use agreement, UW Medicine takes reasonable steps to cure the breach or end the violation, as applicable. If such steps are unsuccessful,

UW Medicine shall:

- a. Discontinue disclosure of PHI to the recipient; *and*
 - b. Report the problem to the Secretary of the U.S. Department of Health and Human Services (DHHS).
2. A UW Medicine workforce member who suspects or discovers a violation of a data use agreement must report the violation to UW Medicine Compliance at:

Main line: 206.543.3098 (local) or 1.855.211.6193 (toll free)

Anonymous Compliance Hotline: 206.616.5248 (local) or

1.866.964.7744 (toll free)

Email: comply@uw.edu

If UW Medicine is the recipient of a limited data set and a violation of the data use agreement occurs, the UW Medicine workforce member must report the non-compliance to UW Medicine Compliance. UW Medicine will then take immediate steps to stop the unauthorized disclosure, cure any resulting breach of confidentiality, and report to the disclosing entity any use or disclosure not provided for in the Data Use Agreement.

III. De-Identification of PHI

This section of the policy discusses de-identification and re-identification requirements, and some specific guidelines for de-identifying requested PHI. It is the policy of UW Medicine to protect the privacy of patients whenever their identity is not needed for the purpose for which the information is being used or disclosed. Information is not individually identifiable if it does not identify the individual and there is no basis to believe it can be used to identify the individual. Information about relatives, employers or household members associated with a patient can be used to identify an individual.

The use or disclosure of de-identified data from PHI for purposes of research requires an IRB waiver or alteration of authorization to create the de-identified data.

IV. Requirements for De-Identification of PHI

There are two methods to demonstrate that PHI is de-identified:

- A. UW Medicine workforce may de-identify PHI by removing eighteen (18) specific identifiers, provided that the workforce member does not have knowledge that the information could be used alone or in combination with other information to identify the individual who is the subject of the information. The eighteen (18) specific identifiers are:
 1. Names;
 2. All geographic subdivisions smaller than state including:
 - a. Street Address
 - b. City
 - c. County
 - d. Precinct
 - e. Zip code and equivalent geo code
except if the initial three digits of a zip code:
 - i. Represents a geographic unit in which combining all zip codes with the same 3 initial digits contains more than 20,000 people; *and*
 - ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people are changed to "000."
 3. All elements of dates (except year) directly related to an individual including:
 - a. Birth date;
 - b. Admission date;
 - c. Discharge date;
 - d. Date of death; *and*
 - e. All ages over 89, including date elements indicative of such age, including year, except when all ages of 90 or older can be aggregated into a single category;

4. Telephone numbers;
5. Fax numbers;
6. E-mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers (including license plate numbers);
13. Device identifiers and serial numbers;
14. Web universal resource locators (URLs);
15. Internet protocol (IP) address numbers;
16. Biometric identifiers, including finger/voice prints;
17. Full face photographic images and any comparable images; *and*
18. Any other unique identifying number, characteristic or code;

Or

- B. UW Medicine may also demonstrate that health information is not individually identifiable if a person with appropriate knowledge and experience applying generally accepted statistical and scientific methods for rendering information not individually identifiable:
 1. Applies such principles/methods, determines the risk is very small that the information could be used alone or in combination with other available information to identify an individual; *and*
 2. Documents the methods/results that justify the determination.

V. Re-identification Requirements

A UW Medicine workforce member may assign a code or other means to record individual identification to allow de-identified information to be re-identified provided the following conditions are met:

- A. The code or other means of record identification is not derived from or related to information about the individual and cannot be translated to identify the individual; *and*
- B. The UW Medicine workforce member does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism used for re-identification;

- C. The UW Medicine workforce member determines how and where these codes for re-identification are located and kept secure.

Disclosure of the code or other means of record identification constitutes a disclosure of PHI and may trigger a breach or violation of a data use agreement.

VI. Case Studies/Journals for Publication

For publication of case studies or articles in a journal, please see UW Medicine Compliance Policy: *PP-18 Use & Disclosure of Protected Health Information for Research*.

REGULATORY/LEGISLATION/REFERENCES

- 45 CFR 160.103 “Definitions.”
- 45 CFR 164.514(e) “Limited Data Set.”
- 45 CFR Parts 160 and 164; Section 164.514(a)-(c) “Other Requirements Relating To Uses and Disclosures of Protected Health Information”.
- 45 CFR Parts 160 and 164; Section 164.502 (d) “Uses & Disclosures of Protected Health Information: General Rules – Uses & Disclosures of De-Identified Protected Health Information”.
- 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-18 Use & Disclosure of Protected Health Information for Research
- UW Medicine Compliance Policy: PP-19 Attachment A – Data Use Agreement for Limited Data Set (for individuals or entities NOT part of UW Medicine workforce)
- UW Medicine Compliance Policy: PP-19 Attachment B – Data Use Agreement for Limited Data Set for UW Medicine workforce

ROLES AND RESPONSIBILITIES

Defined within POLICY.

AUTHORITIES

Custodian	Responsible Officer	Implementation Officer	Administrative Officer
UW Medicine Compliance	UW Medicine Compliance	UW Medicine Compliance	UW Medicine Compliance
Author	Owner	Auditor	Endorser
UW Medicine Compliance	UW Medicine Compliance	UW Medicine Compliance	UW Medicine Executive Compliance Committee

APPROVALS

UW Privacy Official
Johnese M. Spisso, Chief Health System Officer,
UW Medicine & Vice President for Medical Affairs, UW

Date