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Department: Administration

Subject: PP-19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information

Policy Number: 19

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**Policy:**

Members of the UW Medicine<sup>1</sup> workforce<sup>2</sup> are responsible for maintaining the security and confidentiality of protected health information (PHI). PHI can be in any form, including oral, 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:

- Relates to the past, present, or future physical or mental health or condition of an individual; or
- Relates to the provision of health care to an individual; or
- Relates to the past, present, or future payment for the provision of health care to an individual; and
- Identifies the individual; or with respect to which 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 Right and Privacy Act (FERPA); **and**

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<sup>1</sup> UW Medicine includes the following entities: University of Washington Medical Center and Clinics; Harborview Medical Center and Clinics; UW Medicine Neighborhood Clinics (University of Washington Physicians Network); UW Sports Medicine Clinic; UW Physician's Eastside Specialty Center; Hall Health Primary Care Center; and University of Washington Physicians.

<sup>2</sup> See "Definitions" section for description of "workforce."

- 3) Records of students of post-secondary institutions that are exempt from FERPA because they are used exclusively for health care treatment.

Release of education records that contain health care 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:**

- 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 health care operations.

- a) Using or disclosing a limited data set for research purposes requires an IRB waiver or alteration of authorization 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<sup>3</sup> 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 protected health information for limited 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, consistent with policy section (II) (B). 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; **and**
  - 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 the information not provided for by its data use agreement of which it becomes aware;
    - iv. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; **and**

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<sup>3</sup> See "Definitions" section for further description of "business associate."

v. Not identify the information or contact the individuals.

D) 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 shall take 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.
- 2) A UW Medicine workforce member who suspects or discovers a violation of a Data Use Agreement shall follow the steps set forth in Procedure II below regarding Suspected or Known Violations of a Data Use Agreement.
- 3) If UW Medicine, as a recipient of a limited data set, violates a data use agreement, UW Medicine will be considered non-compliant with the limited data set regulations; must report to the disclosing entity any use or disclosure not provided for in the Data Use Agreement; must take immediate steps to stop the unauthorized disclosure and cure any resulting breach of confidentiality; and must follow the steps set forth in Procedure II regarding Suspected or Known Violations of a Data Use Agreement.

**III. De-Identification of Protected Health Information (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 requested. 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. It is important to recognize that information about relatives, employers or household members may be used to identify an individual.

This section of the policy discusses de-identification and re-identification requirements, and some specific guidelines for de-identifying requested protected health information (PHI).

A) Requirements for De-Identification of PHI

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

- 1) A UW Medicine entity may de-identify PHI by removing eighteen (18) specific identifiers, provided the entity 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 3 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 3 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**

- 2) A UW Medicine entity 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:
  - a) 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**
  - b) Documents the methods/results that justify the determination.
  - c) Note: 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.

#### B) Re-identification Requirements

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

- 1) 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**
- 2) The UW Medicine entity 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.
- 3) Each UW Medicine entity determines how and where these codes for re-identification are located and kept secure.

NOTE: 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.

#### IV. **Case Studies/Journals for Publication:**

Patient identifiable information can not be used for case studies and journal stories for publication without patient authorization. Additionally, UW Medicine

encourages workforce members to obtain patient authorization prior to submitting deidentified case studies or journal stories for publication.

**Procedure:**

**I. Initiating a Data Use Agreement for the Limited Data Set**

<b>Step</b>	<b>Action</b>
1	UW Medicine workforce member creating a limited data set initiates a Data Use Agreement with the recipient of the limited data set.
2	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.

**II. Suspected or Known Violations of a Data Use Agreement**

<b>Step</b>	<b>Action</b>
1	If a violation(s) of the Data Use Agreement is suspected or discovered, the UW Medicine workforce member is required to alert the entity’s Privacy Official of the violation(s) and request investigation.
2	If the suspected violation is substantiated, the UW Medicine workforce member works with the entity’s Privacy Official to cure the breach or end the violation.
3	If the breach cannot be cured or the violation ended, the UW Medicine workforce member works with the entity’s Privacy Official to terminate the existing agreement.
4	If the breach cannot be cured or the violation ended, in addition to the termination of the Data Use Agreement, the entity’s Privacy Official will work with the UW Medicine Privacy Officer to report the violation to the Secretary of the U.S. Department of Health & Human Services.

**III. De-Identifying PHI When Requested**

<b>Step</b>	<b>Action</b>
1	When protected health information contained in the paper medical record is to be de-identified the documents should be photocopied and all 18 identifiers detailed in the policy should be obliterated from

	the photocopy with black broad tipped pin [such as a permanent marker]. The photocopied documents are then recopied and reviewed to carefully determine that all the redacted identifying information is completely obliterated.
2	If information is printed from the electronic medical record the same procedure is followed as noted above.
3	If electronically stored information is to be shared electronically, care must be taken to utilize only a copy of the original document, remove all 18 identifiers, and carefully review the remaining data to be sure all identifiers have been removed and cannot be restored.
4	Documentation must be maintained regarding the redaction activities, what information was requested, what information was sent, who released it, to whom and when it is sent. This information must be maintained for six years.
5	If the de-identification is part of an IRB-approved research protocol, then all IRB requirements must be followed; an approved method or program for de-identification must be used; all information must be used, maintained and destroyed in accordance with the IRB's instructions; and all appropriate security requirements for the workstation(s), application(s), server(s), and data transfer(s) must be implemented. For more specific information please refer to the UW Medicine Security Program Document.

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**References:**

- I. 45 CFR 164.501 "Definitions."
- II. 45 CFR 164.514(e) "Limited Data Set."
- III. 45 CFR Parts 160 and 164; Section 164.514(a)-(c) "Other Requirements Relating To Uses and Disclosures of Protected Health Information".
- IV. 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".

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UW Privacy Officer: \_\_\_\_\_ Date: \_\_\_\_\_  
 Kathryn Waddell, Executive Director, Health Sciences Administration

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