Background

For purposes of HIPAA, the University of Washington (UW) is a hybrid entity, an organization whose primary business is not the delivery of healthcare. Hybrid entities have both healthcare and non-healthcare components. A UW office or unit is designated as a healthcare component if it engages in activities ("covered functions") that make the office or unit a health plan, a healthcare professional or a healthcare clearinghouse. In accordance with federal law, the UW has designated its healthcare components (see UW Medicine Privacy Policy PP-01 Designation of Healthcare Components at the University of Washington).

Definitions

- **Case reports or case studies:** Analyses of persons, events, decisions, periods, projects, policies, institutions, or other systems that are studied holistically by one or more methods. The case that is the subject of the inquiry will be an instance of a class of phenomena that provides an analytical frame — an object — within which the study is conducted and which the case illuminates and explicates.

- **Conditioned and Unconditioned authorizations:**
  - Conditioned authorizations: UW Medicine may provide research-related treatment based on the signing or provision of a valid authorization for the use or disclosure of information for the research.
  - Unconditioned authorizations: UW Medicine will not base treatment or payment decisions on receipt of a signed authorization.

- **Limited Data Set:** Protected health information (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 or 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.

- **Protected Health Information (PHI):** A subset of individually identifiable health information maintained in health records and/or other clinical documentation in either paper-based or electronic format.

  PHI regarding decedents: Per Washington state law, the use for research purposes of PHI about individuals who are no longer alive is subject to all the requirements described in this policy document.

- **Preparatory to research.** Activities that are sometimes categorized as “preparatory to research” are considered to be research by UW Medicine and the University as a whole. 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).

  Such procedures for directly or indirectly approaching potential research subjects (or the potential subject’s legally authorized representative) must be approved in advance by an Institutional Review Board (IRB).

- **Research:** For UW Medicine, human subjects “research” means any activity that is described by any of the following definitions:
  1. A systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For
example, some demonstration and service programs may include research activities.

2. Any experiment or clinical investigation that involves a test article and one or more human subjects and that: (1) either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the Food, Drug, and Cosmetic Act, (2) is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit, or (3) involves any use of a drug “approved or not” other than in accepted medical practice.

Policy

A workforce member who conducts research using UW facilities or patient information, and/or whose research includes providing healthcare to UW patients (hereafter called “researcher”), must comply with UW Medicine policies governing patient privacy and information security. All UW research activities involving human subjects and the access, use and/or disclosure of PHI must be reviewed and approved in advance by the UW IRB or an IRB with which the UW IRB has a written cooperative agreement, except in limited circumstances involving specific types of case reports or case studies. Research activities may not begin until the IRB has granted full approval of all procedures and forms.

I. Authorization Requirements

The access, use, or disclosure of PHI for research purposes requires either authorization by the patient or a waiver of authorization approved by an appropriate IRB, in advance of the research activity. Failure to obtain advance authorization before accessing, using, or disclosing PHI for research is considered to be an unauthorized use\(^1\) and a breach of patient confidentiality, and is subject to patient notification and the corrective actions described in UW Medicine Compliance Policy PP-06 Corrective Actions for Noncompliance with Privacy and Information Security Policies.

Examples of unauthorized access include: accessing PHI for more patients than approved by the IRB; accessing PHI after the expiration date approved by the IRB; and accessing PHI for medical care delivered to patients outside of the time range approved by the IRB.

Accounting for Disclosure: When PHI is obtained under patient authorization, the researcher is not required to account for the disclosures. When PHI is obtained under a waiver of authorization, the researcher must account for the

\(^1\) Except for limited specific instances related to case reports (Section VI).
use or disclosure of PHI. See UW Medicine Compliance Policy: PP25 - Accounting of Disclosures of Protected Health Information).

A. Patient authorization for research access, use, or disclosure of PHI

1. UW IRB policy requires that patient authorization for research use of PHI be obtained by the use of a specific stand-alone form. The authorization language may not be inserted into the Informed Consent document. UW researchers must use the UW HIPAA Authorization for Research template (available on the Forms page of the Human Subjects Division (HSD) website). Per UW IRB policy, no content may be deleted, re-worded or re-organized except as indicated on the template, although minor additions are allowed.

2. The research HIPAA Authorization form must be reviewed by the IRB before it can be used with subjects, to ensure that the information in the form is consistent with the research procedures reviewed and approved by the IRB.

3. Signed patient authorizations must be maintained in the designated record set or the Research Study records in accordance to UW Medicine entity retention schedules.

B. Compound authorizations

For research purposes, UW Medicine is allowed to combine, in one form, conditioned and unconditioned authorizations, provided that the authorization clearly differentiates between the two and clearly allows the potential research participant the option to participate in the unconditioned research activities. Compound authorizations allow combining authorizations for use and disclosure of PHI for clinical trials and related tissue and data banking activities, as well as in other common research scenarios, such as a clinical trial involving an optional pharmacokinetics sub-study or a tissue banking protocol that permits future secondary research use of the data. If the authorization includes future use of the data for secondary research, it must adequately describe the future purposes such that it would be reasonable for the individual to expect that their PHI could be used or disclosed for such future research.

C. Waiver of the requirement for patient authorization

1. Authority to grant a waiver

UW Medicine entities accept waivers or alterations of authorization that are granted by the UW IRB or another appropriate IRB that has institutional cooperative agreements with the UW IRB. Researchers
request a waiver from the UW IRB by completing the appropriate form available on the HSD website.

2. Required elements of a waiver
The waiver or alteration of authorization document must contain the following elements:

a. The identity of the IRB (IRB federal registration number and local identifying name)

b. The date on which the alteration or waiver of authorization was approved.

c. Statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following criteria:

i. Use or disclosure of PHI involves no more than minimal risk\(^2\) to the privacy of individuals, based on, at least, the presence of the following elements:
   - An adequate plan to safeguard the identifiers from improper use and disclosure;
   - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   - Adequate written assurances that the protected health information 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.

   ii. The research could not practicably be conducted without the alteration or waiver; and

   iii. The research could not practicably be conducted without access to and use of PHI.

d. A brief description of the PHI for which use or access has been determined to be necessary by the IRB

e. Statement that the alteration or waiver of authorization has been reviewed and approved under either full IRB or expedited review procedures as follows:

\(^2\) Minimal risk is defined as: the probability and magnitude of harm or discomfort anticipated with the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
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.

3. Related mandatory requirement

Per Washington State law RCW 42.48, a researcher may access and use University-owned records (including individually identifiable information) without patient authorization only if: (1) an IRB has waived the requirement for authorization, and (2) the researcher has entered into a Confidentiality Agreement with the entity that owns or maintains the personal health information. A Confidentiality Agreement form is available on the Forms page of the HSD website. These actions must be taken in advance of the access and use.

The UW IRB is responsible for waiving this state authorization requirement for personal health information maintained by the UW (including UW Medicine), which it accomplishes by serving as the other party (signee) on the Confidentiality Agreement. These actions cannot be performed by another IRB, including those with which the University has a formal cooperative agreement.

4. Accounting for disclosures. Individuals accessing PHI under a waiver of authorization must abide by the requirements to account for disclosures for all PHI accessed. See UW Medicine Privacy Policy: PP-25 Account of Disclosures of Protected Health Information (PHI).

II. Specially Protected Treatment Records

Sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV), behavioral or mental health services, and drug and alcohol abuse treatment records require specific authorization from the patient to be disclosed. When research includes these types of records, the researcher must obtain the patient’s specific authorization to disclose this information from their treatment records. The IRB serves as the broker of access for research activities involving these records, to comply with the requirements of state and federal regulations.

III. Limited Data Set
A limited data set may be used for research purposes, provided that certain criteria are met, including IRB review and approval for creation of the limited data set. IRB approval of a waiver of authorization is required for the creation of the limited data set. Washington State law also applies (RCW 70.02.050; see section I.B3, above). See UW Medicine Privacy Policy: PP-19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information.

IV. De-Identified PHI

De-identified PHI may be used for research purposes, provided that the IRB reviews and approves the creation of the de-identified data set. IRB approval of a waiver of authorization is required for the creation of de-identified patient information. Washington State law also applies (RCW 70.02.050; see section I.B3, above). See UW Medicine Privacy Policy: PP-19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information.

V. Case Reports/Journals for Publication

Prospective IRB review and approval is required for all human subjects research. However, many case reports\(^3\) are not considered to be research as defined by federal human subjects regulations, even if the case reports will be published. The circumstances under which case reports require IRB review are described in the flow chart called “Case Reports: IRB and HIPAA Requirements”, located on the Human Subjects Division (HSD) website.

When researchers are not sure whether their case report activity meets the federal definition of research, they may use a simple self-determination form entitled “Case Report Research Determination”, also located on the HSD website. They may also choose to send the form to HSD for a formal determination, although this is not required.

PHI may be used for the education of UW Medicine workforce members without IRB approval or patient authorization. UW Medicine workforce members must de-identify the patient information or only use the information that is minimally necessary to accomplish the educational purpose.

If UW Medicine workforce members present patient information for educational (not research) purposes outside of UW Medicine, then the workforce member must obtain patient authorization or de-identify the information. Please see

\(^3\) Case Reports are documented retrospective reviews of a patient’s treatment and/or outcome that a healthcare professional realizes after the fact might be of value to other healthcare professionals in the treatment of a disease. Cases studies involve prospective planning involving patient treatment. For case studies discussion must occur with Human Subjects to determine whether it falls within the criteria that require IRB approval prior to implementing the treatment plan.
UW Medicine Privacy Policy PP-19 Protected Health Information, Limited Data Set, and De-Identification of Protected Health Information to appropriately de-identify the information.

VI. Safeguarding Information


All suspected privacy or security events and policy violations must be reported to UW Medicine Compliance (206-543-3098 or comply@uw.edu).

Limited Data Sets are subject to these same breach notification requirements as protected health information.

VII. Failure to Comply

Failure to comply with the specified requirements or misuse or misappropriation of patient information for research purposes may result in disciplinary action up to and including dismissal, see UW Medicine Privacy Policy: PP-06 Sanctions for the Failure to Follow Privacy and/or Information Security Policies, revocation of IRB approval, and civil or criminal penalties.

References

- 45 CFR 46.102; 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) – “Uses & Disclosures for Which Consent, Authorization or Opportunity to Agree or Object is Not Required – Research Purposes;
- RCW 42.48 – Release of Records for Research
- RCW 70.02.030 – Patient Authorization of Disclosure
- RCW 70.02.050 – Disclosure Without Patient’s Authorization
Approved Version

- RCW 71.05.390 and .690 -- Mental Illness and Treatment.
- RCW 70.24.105 -- Sexually Transmitted Disease – Exchange of Medical Information.
- RCW 70.96A.150 – Drug and Alcohol Abuse Treatment Records; 42 C.F.R. Part 2.

**Approvals**

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

**Additional Contacts**

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