|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **GUIDANCE HIPAA**  |

**1 PURPOSE and APPLICABILITY**

To provide guidance about the research use of protected health information (PHI), as governed by the federal HIPAA regulations, WA state laws, and UW institutional policies.

**2 RELEVANCE**

Researchers that will obtain and use PHI must obtain: **(a)** authorization from the subject; **or (b)** a waiver of authorization granted by an IRB, unless the PHI is: **(1)** de-identified; **(2)** a limited data set, **or (3)** from decedents.

**3 DEFINITIONS**

*These definitions come from the HIPAA regulations and UW Medicine Compliance Policy “Glossary of Terms”. The glossary contains additional definitions.*

**HIPAA:** The federal Health Insurance Portability and Accountability Act (HIPAA) has three components, all of which are enforced by the federal Office for Civil Rights:

* **HIPAA Privacy Rule** protects the privacy of individually identifiable health information
* **HIPAA Security Rule** sets standards for the security of electronic protected health information
* **HIPAA Breach Notification Rule** requires covered entities and business associates to provide notification following a breach of unsecured protected health information

**Protected Health Information (PHI):** Individually identifiable health information held or transmitted by a covered entity or its business associates, in any form or media, whether electronic, paper, or oral.

* **International research.** UW researchers collect individually identifiable health information in other countries. Is this considered to be PHI, and governed by HIPAA regulations? **No, because:**
	+ These researchers are neither collecting health information for a HIPAA-covered entity nor transmitting health information to or from a covered entity.
	+ UW healthcare providers who conduct research are doing their research as UW academic employees or agents rather than on behalf of the UW health care entity. Research data and records are in the academic units (not part of the covered entity).
* **PHI held in the form of clinical knowledge.** Healthcare providers may assist in study recruiting by informing (in writing, by email, or verbally) a researcher about potential subjects, or informing potential subjects about a study, based on their knowledge of their patients rather than by examining medical records. This is not considered to be an access and use of PHI.
* **Other forms of PHI.** There are other formats/media by which PHI may be stored or exchanged that may not be recognized as such by researchers. Examples include but are not limited to: verbal exchanges; clinic scheduling records; a whiteboard in an outpatient surgery suite.
* **Washington State law.** Washington State has laws governing the disclosure of health information. Those laws use the term “health care information” instead of PHI. **Health care information** is defined as “any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient’s health care, including a patient’s deoxyribonucleic acid and identified sequence of chemical base pairs.” The term PHI is used by HSD throughout its written materials to include “health care information”.

**Individually identifiable information.** Information, including demographic data, that:

* Identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual, **AND**
* Relates to:
	+ The individual’s past, present, or future physical or mental health or condition
	+ The provision of health care to the individual **OR**
	+ The past, present, or future payment for health care to the individual

**De-identified PHI.** PHI is no longer considered individually identifiable if there is no basis to believe it can be used to identify the individual. There are two ways to de-identify PHI:

* Removal of 18 HIPAA-specified identifiers ([Use and Disclosure of Protected Health Information (PHI) – COMP.103](https://depts.washington.edu/comply/docs/comp_103.pdf)), provided that there is no knowledge that the resulting information could be used alone or in combination with other information to identify individuals **OR**
* 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; **(2)** 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** **(3)** documents the methods/results that justify the determination.

**Honest Broker.** An individual or group acting on behalf of a covered entity to search the entity’s health care records, collect PHI, and make the PHI available to researchers. The PHI may be de-identified, coded (with the researcher having no access to the code link) or identifiable. The Honest Broker acts as a gatekeeper and must be independent of the research team.

**Limited data set.** PHI from which 16 specific individual identifiers have been removed ([COMP.103](https://depts.washington.edu/comply/docs/comp_103.pdf)).

**Covered entity.** The term used for the holder/transmitter of PHI. Specifically, it means: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with transactions for which the Secretary of Health & Human Services (HHS) has adopted standards under HIPAA.

**4 THE UW COVERED ENTITY**

**The UW covered entity is a hybrid covered entity.** This means that some, but not all, components of the UW provide health care and are therefore subject to HIPAA and related WA state law.

* The UW covered entity is a complex set of institutions, described in UW Medicine’s [Patient information Privacy and Security Compliance Program and Administrative Requirements - COMP.101](https://depts.washington.edu/comply/docs/comp_101.pdf) and its related resource [101.G1 UW HIPAA Designation](http://depts.washington.edu/comply/docs/101_G1.pdf). The Harborview Madison Clinic is part of the UW covered entity.
* The following regional hospitals and health care systems are affiliated with UW Medicine but are not part of the UW covered entity:
	+ Peace Health
	+ Cascade Valley Hospital and Clinics
	+ Skagit Regional Health

**The UW Medicine Privacy Office oversees HIPAA and related WA state law compliance for UW Medicine.** Researchers who will obtain and use UW Medicine PHI must comply with UW Medicine Privacy Policies. Most of the non-UW Medicine components of the UW covered entity have adopted UW Medicine Privacy Policies.

**Obtaining PHI from the UW covered entity for research purposes almost always involves removing PHI from the covered entity.** This is because researchers usually take PHI out of the health care components of the UW covered entity (e.g., UW Medicine) and place it into their research records in their academic units (e.g., Department of Medicine) which are not part of the UW covered entity.

**5 COVERED ENTITIES AND THE UW IRB**

The UW IRB is the IRB of record for all health care components of the UW, UW Medicine, and affiliated covered entity outlined in [COMP.101.G1](http://depts.washington.edu/comply/docs/101_G1.pdf), **except** Valley Medical Center and its associated clinics.

**6 CLINICAL VS RESEARCH ACCESS TO PHI**

Many UW researchers are also health care providers for the UW covered entity. This means that they have access to UW PHI in order to fulfill their clinical responsibilities. These individuals may wish to use PHI for research purposes, for the same patients they see for clinical practice. These researchers must follow all policies, procedures, and requirements about the research use of PHI. For example, accessing patient records for subject identification or recruitment requires prior IRB approval and a waiver of authorization, even for one’s own patients.

**7 REGULATORY INTERACTIONS**

**Identifiability is defined differently by HIPAA than by human subjects regulations.**

* **Human subjects regulations** describe identifiability as, “the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
* **HIPAA regulations**describe identifiability in terms of: **(1)** the presence of one or more of the 18 specific identifiers, such as name; **or (2)** the probability of identifiability as determined by a person with appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rending information not individually identifiable.
* **Implication.**This means that a data set may be considered identifiable per one set of regulations but not identifiable per the other set of regulations. This may result in a determination of “Not Human Subjects Research” per the human subjects regulations that still requires IRB review in order to issue a waiver of HIPAA authorization for the activity. The **SOP HIPAA** provides additional information.

**Decedents.** Decedents are not considered “human subjects” by federal human subjects regulations. However, obtaining and using decedent PHI for research is still subject to all HIPAA and WA state regulations.

* HIPAA regulations do not require obtaining an authorization nor an IRB-granted waiver if the requirements listed below are met. WA state law (RCW 70.02) defers to the HIPAA requirements.
	+ PHI is needed only for research on the PHI of decedents;
	+ The PHI is necessary for the research; and
	+ (Upon request) The research will provide documentation of the death of the individuals.
* **Implication.**This means that when HSD determines that a research activity involving decedent PHI is “not human subjects research” there is no need to grant a waiver of HIPAA authorization or, if the PHI is in WA state, a waiver of RCW 70.02.

**8 HIPAA AUTHORIZATION**

**Required authorization elements and process.** UW Medicine [COMP.103](https://depts.washington.edu/comply/docs/comp_103.pdf) summarizes the authorization elements and process that are required to comply with HIPAA and WA state law.

**Authorization templates.** Per agreement with UW Medicine, HSD maintains two HIPAA authorization templates on the HSD website, **HIPAA Authorization template** and **HIPAA Authorization, Pregnant Partner template**. These have been vetted and approved by UW Medicine.

* The templates include specific elements required by WA State law, as well as HIPAA, and therefore should not be revised by researchers. WA State law requires that subjects provide explicit approval for release of health care records related to:
	+ Sexually transmitted diseases
	+ Behavioral or mental health services
	+ Alcohol and drug abuse
* These HIPAA Authorization Templates are intended to be used as standalone forms. HIPAA language included in the research consent form may not be used to obtain authorization for UW Medicine**.**
* Though these templates should be acceptable to any covered entity, researchers should be aware that other covered entities may have their own required policies and templates.

**Compound and “blanket” authorizations.** A single authorization form may be used to obtain authorization for more than one study. Review [COMP.103](https://depts.washington.edu/comply/docs/comp_103.pdf) for more information.

**A****uthorization forms and consent forms.** UW IRB policy does not allow HIPAA authorization to be combined with a consent form for UW PHI or for PHI from a non-UW institution when the other institution is not relying on the UW IRB’s review. For non-UW institutions relying on the UW IRB, authorization language may be combined with a consent form if that language is provided by the non-UW institution along with written attestation that the language has been reviewed and complies with all applicable HIPAA Privacy Rule requirements. Neither HSD nor the UW IRB will review the language for compliance with the HIPAA Privacy Rule. The non-UW institution is solely responsible for ensuring that the language meets all requirements. If the non-UW institution does not have its own authorization language, researchers will be instructed to use the UW templates.

**Electronic authorization.** UW Medicine has evaluated the validity of the UW’s REDCap electronic signature function and UW IT’s DocuSign system. UW Medicine and Seattle Children’s have agreed to honor HIPAA authorizations containing electronic signatures obtained with the UW ITHS REDCap system (or equivalent, IRB-approved non-UW REDCap installations), or the UW DocuSign system. For authorization to obtain/access PHI at any other HIPAA-covered institution, consult that institution’s privacy and/or health records information office. Electronic authorization signatures captured in any other system are not acceptable.

* **UW studies reviewed by an external IRB.** The use of an electronic signature system must be approved by the external IRB. In addition, HSD must sign-off in advance.
* Review HSD’s guidance on [Documentation of Consent](https://www.washington.edu/research/hsd/guidance/consent/#10) and **WORKSHEET** **Consent Requirements and Waivers** for a description of requirements and conditions that must be met for any use of e-signatures (including HIPAA authorizations).

**HSD and IRB responsibilities concerning authorization forms.** HSD and the IRB have no responsibilities concerning authorization forms or language except to:

* **Obtain assurance** in the IRB Protocol that researchers who obtain UW PHI will use the current UW Medicine template as maintained on the HSD website.
* **Ensure that HIPAA language in the consent form is not used for authorization** unless it is for a non-UW institution as described above under the section of this guidance titled, [Authorization forms and consent forms.](#hipaaconsent)

**Written authorization is required.** When legally competent subjects are physically unable to sign an authorization form, they may allow a personal representative to sign instead.

* *If researchers expect that this is likely,* researchers should ask the IRB for a waiver/alteration, so as to obtain some other form of witnessed authorization.
* *If this is a one-time unanticipated occurrence*, the UW Privacy Office recommends that the researcher should document on the form that the subject is unable to physically sign the authorization but that the subject has read and agreed to the authorization.

**9 WAIVER OR ALTERATION OF HIPAA AUTHORIZATION**

**Waiver for any covered entity.** HIPAA allows any IRB to approve a waiver/alteration of the HIPAA authorization process for any covered entity. However, covered entities may have institutional policies that additionally require their own IRB, Privacy Board, or other group to approve a waiver.

* Failure to know about, and comply with, institution-specific requirements can quickly make entities reluctant to allow *any* UW researcher to have access to their records or patients for research purposes. For example, clinic staff and reception staff at non-UW health care organizations are not authorized to provide UW researchers with patient information from their clinic records and schedules, without prior permission from the organization’s medical records and/or research compliance office.

**Identification of the need for a waiver.** HSD staff assess the proposed activities to make this assessment. If yes, a waiver may be granted as described in the **SOP HIPAA**.

**Criteria for waiver.** The IRB uses the **CHECKLIST Waiver or Alteration of HIPAA Authorization** to determine whether the HIPAA and WA State law for granting a waiver are met.

**Documentation of waiver.** The waiver is documented by uploading the **CHECKLIST Waiver or Alteration of HIPAA Authorization** to the Zipline application. The IRB approval letter documents the granting of a HIPAA waiver for the researcher.

**Full or partial waiver.** A full waiver is for all aspects of the research involving PHI. A partial waiver is for only some aspects of the research involving PHI. The requirements and criteria are the same.

* Example of a partial waiver: Researchers request a waiver to screen medical records to identify possible subjects. When subjects enroll, they sign an authorization form for the researchers to obtain medical records information to use as research data.

**Activities that are not human subjects research.** Case studies may not meet the Common Rule definition of “human subjects research” yet they may require an IRB-approved HIPAA authorization. The UW IRB is authorized by the UW covered entity to grant a waiver in these circumstances, applying the same criteria and process. Refer to the **SOP HIPAA** for more details.

**10 ACTIVITIES PREPARATORY TO RESEARCH**

Federal HIPAA law allows researchers to access PHI without obtaining authorization or a HIPAA waiver if the PHI will be used solely to prepare a research protocol or plan 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.

Screening records to identify possible subjects is **not** considered an activity preparatory to research.

Review [COMP.103](https://depts.washington.edu/comply/docs/comp_103.pdf) for additional requirements.

**11 EXEMPT STATUS**

**Exempt status and the use of PHI.** Human subjects regulations do not require IRB review of some human subjects activities, which are therefore said to be exempt from the regulations. **UW policy** does not currently allow research involving the use of PHI to qualify for exempt status.

**12 LIMITED DATA SETS**

**Is IRB review required?** The research use of a Limited Data Set may or may not be considered human subjects research, depending on whether the data are individually identifiable as defined by the human subjects regulations. If the data are not individually identifiable, then the use of the Limited Data Set does not require IRB review.

* **Researcher self-determination.** Researchers may use the **WORKSHEET Human Subjects Research Determination** self-determine whether the data are individually identifiable.
* **HSD determination.** Researchers may prefer to have HSD make the determination, or the covered entity providing the Limited Data Set may require a formal determination. To request the determination, researchers send HSD a completed **APPLICATION IRB Protocol, No Contact with Subjects** which is reviewed following standard procedures.

**Data Use Agreement (DUA).** To obtain a Limited Data Set, HIPAA regulations require the researcher to enter into a DUA with the covered entity providing the data. The DUA promises specified safeguards for the data. **HSD is not authorized to sign DUAs.**

* **UW Limited Data Sets.** The researcher should contact the UW unit that will provide the Limited Data Set, for information about the DUA.
* **Limited Data Sets from non-UW covered entities.** If the non-UW entity requires a UW institutional signature in addition to the researcher’s signature, the researcher’s Department Chair, Department Administrator, or Vice Dean of Research is usually the appropriate individual to sign on behalf of the UW.
* **Required by the IRB?** The UW IRB does not require the researcher to provide a copy of the DUA as part of the IRB review and approval process.
* **Review** [**COMP.103**](https://depts.washington.edu/comply/docs/comp_103.pdf)**,** “Special Circumstances: Limited Data Sets and De-Identification of PHI” for more information.

**13 RELATED MATERIALS**

[APPLICATION IRB Protocol, No Contact with Subjects](https://www.washington.edu/research/forms-and-templates/zipline-application-irb-protocol-no-contact-with-subjects/)

[GUIDANCE Case Reports, IRB Review and HIPAA](https://www.washington.edu/research/policies/guidance-case-reports-irb-review-hipaa/)

[GUIDANCE Consent](https://www.washington.edu/research/hsd/guidance/consent/)

[SOP HIPAA](https://www.washington.edu/research/policies/sop-hipaa-2/)

[TEMPLATE HIPAA Authorization](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization/)

[TEMPLATE HIPAA Authorization, Pregnancy](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization-pregnancy/)

[WORKSHEET Consent Requirements and Waivers](https://www.washington.edu/research/forms-and-templates/worksheet-consent/)

[WORKSHEET Human Subjects Research Determination](https://www.washington.edu/research/forms-and-templates/worksheet-human-subjects-research/)

**14 REFERENCES**

Health Insurance Portability and Accountability Act (HIPAA) 45 CFR 164, [“Security and Privacy”](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164?toc=1)

Office of Civil Rights, [“Summary of the HIPAA Privacy Rule”](https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html)

WA RCW 70.02, [“Medical Records – Health Care Information Access and Disclosure”](https://app.leg.wa.gov/rcw/default.aspx?cite=70.02)

WA RCW 70.96A.150, [“Treatment for Alcoholism, Intoxication, and Drug Addiction”](https://app.leg.wa.gov/RCW/dispo.aspx?cite=70.96A.150)

UW Medicine Compliance Policy COMP.101, [“Patient Information Privacy and Security Compliance Program and Administrative Requirements”](https://depts.washington.edu/comply/docs/comp_101.pdf)

UW Medicine Compliance Policy COMP.103, [“Use and Disclosure of Protected Health Information (PHI)”](https://depts.washington.edu/comply/docs/comp_103.pdf)

|  |  |  |  |
| --- | --- | --- | --- |
|  **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 2.3 | 05.01.2025 | 05.01.2025 | Add note that HIPAA Authorization for UW Medicine PHI may not be obtained using language in the research consent form |
| 2.2 | 04.27.2023 | 04.27.2023 | Add information about when embedded HIPAA authorization language in the consent form is permitted; remove reference to UW as IRB of record for Bloodworks, Northwest Kidney Centers and PHSKC |
| 2.1 | 09.20.2022 | 09.20.2022 | Remove reference to SCCA |
| 2.0 | 11.23.2021 | 11.23.2021 | Additional clarification about decedents |
| 1.9 | 06.24.2021 | 06.24.2021 | Updated information about decedents and WA State law RCW 70.02; updated links |
| Previous versions |  |  | For older versions: HSD staff refer to the SharePoint Document Library; Others – contact hsdinfo@uw.edu.  |

**Keywords:** HIPAA