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|  | Diagram  Description automatically generated | **FORM: HIPAA Supplement** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

Use this supplement to request a **waiver** of HIPAA Authorization or an **alteration** of HIPAA (waiver of the signature requirement).

A waiver may be required from the IRB when using or accessing protected health information (PHI) from individuals who are not signing a HIPAA authorization. This form will assist in ensuring compliance with HIPAA, and with other federal and state laws related to the protection of confidentiality of individually identifiable information about research participants.

1. Are you accessing, recording, analyzing or removing [protected health information](https://extranet.fredhutch.org/en/u/irb/glossary.html#phi) (“PHI”) from a HIPAA [covered entity](https://extranet.fredhutch.org/en/u/irb/glossary.html#covered_entity) or a [business associate,](https://extranet.fredhutch.org/en/u/irb/glossary.html#business_associate) beyond a [limited data set,](https://extranet.fredhutch.org/en/u/irb/glossary.html#limiteddataset) without a signed HIPAA authorization?

[ ]  Yes → You will be required to obtain an IRB-approved Waiver of HIPAA Authorization. Complete and submit this form.

[ ]  No → **You do not need to submit this form.** However, a data use agreement might be required. Contact the Fred Hutch Office of General Counsel at generalcounsel@fredhutch.org, or for sites outside Washington state, contact your own institution’s legal counsel or privacy officer for assistance.

1. Type of waiver requested:

[ ]  **Full Waiver** for all aspects of the study.

[ ]  **Partial Waiver (select one):**

[ ]  For recruitment purposes. This type of waiver is typically used to access medical records solely for purposes of ascertaining potential subject eligibility prior to initial contact for recruitment.

[ ]  For other purposes (e.g., for a specific retrospective cohort only). Describe:

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1. Type of alteration requested. An alteration is a request to omit a HIPAA requirement, generally used to omit the signature requirement. Select all that apply.

[ ]  **Alteration of HIPAA** to waive the HIPAA signature requirement for some or all participants. Describe:

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[ ]  **Alteration of HIPAA** to waive the HIPAA signature requirement to accommodate enrollment of **non-English speaking participants.** This means you plan to obtain and document verbal HIPAA authorization for any participants for whom a translated HIPAA authorization is not provided.

1. Provide a brief description of the “Minimum Necessary” PHI required for the purpose of this research or recruitment.

(Note: “Minimum Necessary” is a HIPAA Privacy Rule standard requiring that when PHI is used or disclosed for research, only the information that is needed for the immediate use or disclosure should be made available by the health care provider or other covered entity.)

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1. Describe the plan to protect information obtained under this waiver from improper use/re-disclosure.

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1. Describe the reasonable safeguards that will be taken to project against identifying, directly or indirectly, any patient in any report of the research.

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1. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, provide this information as well.

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1. Explain why the research or recruitment activity could not be practicably conducted without a waiver.

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1. Explain why the research or recruitment activity could not be conducted without access to and use of the PHI.

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1. Explain how the recruitment or research activity is of sufficient importance to outweigh the risks associated with the intrusion into the patient’s privacy to use PHI without the patient’s authorization.

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Note: If the Waiver is approved by the IRB, you must “account” for all disclosures of PHI by a covered entity. This accounting must include a specific listing of the PHI, the date of the access, and the purpose for the access. If access to the PHI is through the electronic medical record (EMR) system at UW Medicine, SCCA and/or Seattle Children’s, you may be able to work with EMR and/or HIPAA compliance staff at those institutions to establish a mutually convenient method to “account” for the disclosures. If you have any questions regarding this “accounting” requirement, contact the Office of the General Counsel at generalcounsel@fredhutch.org for more information.

1. Is this waiver for research conducted outside Washington State?

[ ]  Yes → Describe any additional state law requirements (if known) which the IRB needs to consider in granting a waiver (contact the Fred Hutch Office of the General Counsel at generalcounsel@fredhutch.org if you are unsure; or for sites outside Washington state, contact your own institution’s legal counsel or privacy officer for assistance).

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[ ]  No

**By submitting this form, the Principal Investigator acknowledges and agrees that protected health information (PHI) will only be used for this specific research project and will not be used or disclosed except as permitted or mandated by applicable law or regulation.  Access to PHI pursuant to a waiver of HIPAA Authorization will be documented to permit an accounting by Fred Hutch or other HIPAA covered entities if required.**