



Instructions for Completion of Request for Waiver of Authorization to Use/Disclose
Protected Health Information (PHI)
Hebrew SeniorLife

Overview

A Waiver of Authorization to Use/Disclose Protected Health Information (PHI) must be requested by any researcher who wishes to access PHI for HRC residents for research related purposes. The HSL Institutional Review Board (IRB) is responsible for reviewing and granting HIPAA waivers. The most common reasons for requesting a HIPAA waiver include: In preparation to conduct research or in preparation for recruitment of research subjects, e.g. medical record review.

The following criteria must be satisfied for the HSL IRB to approve a HIPAA waiver (waiver of authorization).

1. The use or disclosure of PHI involves no more than minimal risk to the individuals.
2. The waiver will not adversely affect the privacy rights and the welfare of the individuals.
3. The research could not practicably be conducted without the waiver.
4. The research could not practicably be conducted without access to and use of the PHI.
5. The privacy risks to individuals whose PHI is to be disclosed are reasonable in relation to the importance of the knowledge that may reasonably be expected to result from the research.
6. There is an adequate plan to protect the identifiers from improper use and disclosure.
7. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research.
8. There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the disclosure of PHI would be permitted by this subpart.

Requests for HIPAA waivers are submitted to Aleksandra Baldwin, Human Protections Administrator. Ms. Baldwin will forward requests to the IRB for review. Please note that the HIPAA waiver request may receive an expedited IRB review or full IRB review at the discretion of the IRB based on the information you request. The PI will be notified whether the HIPAA waiver request is appropriate for expedited review, or whether full

IRB review is needed. The requests for HIPAA waivers follow the usual monthly IRB deadlines for submission of materials.

Instructions – Please be sure to answer every question. If the question is not applicable to your research protocol, please respond n/a.

Section 1 – Research Study Information

Please provide names and contact information for Principal Investigator and Co-investigators, and study coordinator or other contact person if main contact will not be the Principal Investigator.

Provide the title of the research proposal and purpose of the study (in one or two paragraphs). Please explain why you require access to PHI for this research.

Section 2 – Reasons for requesting this waiver of authorization

Please be sure to check all appropriate boxes – there may be more than one reason that is applicable for your study, please check all that apply.

Section 3 - Use of PHI

Please provide the total number of charts or subjects to be reviewed, the number to be reviewed per month and per year.

Please provide the names of persons who will have access to PHI at HSL, the purpose of the access and the anticipated dates PHI will be accessed; e.g.

<u>Name</u>	<u>Purpose of Access</u>	<u>Dates</u>
Mary Smith, Research Nurse	determine study eligibility	June '04 – Dec '04

Section 4 – Type of PHI to be Accessed

Please be sure to check all of the identifiers that are to be used or disclosed

Section 5 – Type of PHI to be Extracted

If PHI will be extracted from HSL, please check all of the identifiers to be extracted. If no PHI will be extracted, please be sure to check the appropriate box signifying that none will be extracted.

Section 6 – Disclosure of PHI (information sent out of HSL)

Part A - Please list who PHI will be disclosed to, the purpose of the disclosure and the dates, if there will be disclosure of PHI outside of HSL. Part B – Please state how long the PHI information will be disclosed.

Section 7 – Protection/Destruction of PHI

Part A – It is crucial to have an adequate plan to protect PHI from unapproved use or disclosure. Please describe your plan to protect PHI from disclosure.

Part B – You must have an adequate plan to destroy the identifiers/PHI at the earliest opportunity. Please describe your plan for destroying identifiers/PHI at the earliest opportunity or provide a justification for retaining identifiers.

Signatures

Please be sure to date and sign the HIPAA waiver request prior to submission to the HSL IRB, after reading and agreeing to the certifying statement.