**Request for Waiver of HIPAA Authorization for Research Use/Disclosure of Protected Health Information**

This form must be completed if you wish to obtain and use identifiable "protected health information" for a study without obtaining written approval ("authorization") from the research participant for the use of the data.

**Important!** If a waiver of authorization is approved, the covered entity (such as a hospital or treating physician) that provides the protected health information for this study will need to account for all disclosures made to persons other than members of its own workforce, if the subject asks for an "accounting" under the federal HIPAA regulations. The accounting must include subject name, purpose, date, recipients, and a description of information provided. Some covered entities may have systems in place that will capture this information at the time of disclosure; other covered entities may expect the study personnel to maintain a log of all such disclosures and provide a copy to the respective data managers. It is your responsibility to determine whether a data disclosure log needs to be maintained so that it can be provided to the respective data managers.

|  |  |
| --- | --- |
| **Principal Investigator:** |  |
| **Protocol Title:** |  |
| **IRES IRB#** |  |
| **Type of Waiver:**  |
| [ ]  **Full Waiver**The investigator will access, use, or disclose research participants’ PHI for the research study ***without obtaining authorization*** for that use or disclosure. | [ ]  **Alteration**The investigator will access, use, or disclose research participants’ PHI for the research study ***with verbal authorization*** for that use or disclosure or with a written authorization that does not include all of the required HIPAA statements.[[1]](#footnote-1) | [ ]  **Partial Waiver**The investigator will access, use, or disclose research participants’ PHI for ***a portion of the research*** e.g. for recruitment or identification of potential participants without obtaining authorization for that use or disclosure. |

**All questions below must be answered.**

|  |
| --- |
| 1. **What is the purpose for which you are requesting the HIPAA waiver/alteration?**
 |
|  |
| 1. **Describe Protected Health Information[[2]](#footnote-2) that is needed for this study** *[Include the anticipated data locations as well as the type of information that will be required]:*
 |
|  |
| 1. **Who Will Have Access to the Protected Health Information** *[Describe each person and organization by name or category. Examples include the research sponsor, the investigator, the research staff, and all research monitors.]***:**
 |
|  |
| 1. **Does the use or disclosure of protected health information involve no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**
2. **An adequate plan to protect the identifiers from improper use and disclosure;**
3. **An adequate plan to destroy the identifiers at the earliest opportunity consistent with 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**
4. **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 protected health information would be permitted.**
 |
| [ ] **YES** [ ] **NO** |
| 1. **Plan for Protecting Identifiers:** *[Describe how access to study data is controlled; who will monitor access to study data; where will identified information be stored]*

**Note:** All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu. |
|  |
| 1. **Plan for Destroying Identifiers:** [Describe how, by whom and when identifiers will be destroyed; or provide justification for retaining the identifiers]
 |
|  |
| 1. **Explain why the research could NOT be practicably conducted without the waiver or alteration:**
 |
|  |
| 1. **Explain why the research could NOT be practicably conducted without access to and use of the protected health information:**
 |
|  |

**Investigator’s Assurances:**

I assure the Privacy Board that the protected health information for which I have requested this Waiver of Authorization will not be reused or disclosed to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Investigator**

**\_\_\_\_\_\_\_\_\_\_\_\_**

**Date**

# HIPAA IDENTIFIERS

|  |  |
| --- | --- |
| 1. Names
2. All geographic subdivisions smaller than a State, including:
	* street address
	* city
	* county
	* precinct
	* zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Telephone numbers
4. Fax numbers
5. E-mail addresses
6. Social Security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
 | 1. Certificate/license numbers
2. Vehicle identifiers and serial numbers, including license plate numbers
3. Device identifiers and serial numbers
4. Web Universal Resource Locators (URLs)
5. Internet Protocol (IP) address numbers
6. Biometric identifiers, including finger and voice prints
7. Full face photographic images and any comparable images
8. Any other unique identifying numbers, characteristics, or codes
9. All elements of dates (except year) for dates related to an individual, including:
	* birth date
	* admission date
	* discharge date
	* date of death
	* all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
 |

1. For HIPAA Required Statements, refer to HRPP Worksheet, HRP-330, HIPAA Authorization available in the IRES IRB Library. [↑](#footnote-ref-1)
2. For a discussion of which information is "protected health information", see Yale Procedure, “Determining Whether Human Subject Research Involves Use/Disclosure of Protected Health Information.” [↑](#footnote-ref-2)