|  |  |  |
| --- | --- | --- |
| 1. **eIRB Tracking #**
 | STU  | **⇐ Study team to enter STU #** |

**Form H.SF.**

**Short Form HIPAA Authorization Waiver/Alteration for Research Use of PHI**

UT Southwestern Medical Center Institutional Review Board

*Use this form to request access to identifiable health information without prior written permission from the subject.*

***Identifiable Health Information =* Protected Health Information (PHI)**

This completed, signed form is used to document waiver or alteration of HIPAA Authorization approval and may be presented as documentation of the approval under **45 CFR 164.512(i)** to institutional privacy offices when PHI is being requested for the research study identified at the top of this form. The confidentiality plan specified in the protocol applies.

*Using this form – To check/uncheck the checkboxes, click once on the box. To enter text in text boxes, click once on the gray box and then type your response.*

|  |
| --- |
| **Application for:** *(choose one)* |
| [ ]  | **Waiver of Authorization** | Authorization will not be sought for some or all subjects. The researchers plan to use/access identifiable health information (PHI) in order to obtain and record data without ever receiving subjects’ written permission (e.g., chart reviews or verbal consent) |
|[ ]  **Partial Waiver of Authorization** | Used to identify eligible subjects for **recruitment** in this research. Continued access to PHI will be limited to those who later volunteer for the study and provide written authorization. |
|[x]  **Alteration of Authorization** | Some or all of the elements of authorization are changed or omitted.  |
| 1. Explain why it is **not practicable** to carry out the research without this waiver.

*Select all that apply.* |
|[ ]  **Identify/recruit –** access to records is needed to identify eligible subjects (e.g., chart reviews, partial waiver for recruitment, etc.) |
|[ ]  **Limited Means/Resources–** resources needed to identify and contact eligible subjects for recruitment are limited |
|[ ]  **Large number of subjects projected –** potential subject population includes a large number of records to review and it is not feasible to attempt contact with all subjects |
|[ ]  **Outdated records –** This is a retrospective study involving subjects who may have moved or expired and researchers cannot feasibly attempt to contact required sample |
|[ ]  **Risk of breach of confidentiality –** The only record linking the subject and the research would be the signed authorization and a breach of confidentiality is the principal risk in this study (e.g., verbal consent) |
|[x]  **Other:**  | There is not time to obtain a written HIPAA authorization in the subject’s own language. The PHI to be used is described in the English HIPAA authorization form, which will be read to the subject in his/her language by an interpreter and verbal authorization will be obtained. |

|  |
| --- |
| **2.** The HIPAA regulation requires reasonable efforts to limit protected health information to the [minimum necessary](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/minimumnecessary.html) to accomplish the intended purpose of the use, disclosure or request. **Are you obtaining *only* the minimum information necessary to complete the waived activities?**  |
| [x]  | Yes |
| [ ]  | No (explain/justify why not): [Click once to explain] |

**BY SUBMITTING THIS FORM TO THE IRB, PI IS MAKING THE FOLLOWING ASSURANCES:**

* The information listed in the waiver/alteration application is accurate.
* All research staff (ALL study personnel including PI that are involved in the research) will comply with the HIPAA regulations and the waiver/alteration criteria.
* All research staff will complete HIPAA Research Training.
* The PI assures that the information obtained as part of this waiver/alteration (including protected health information) will not be reused or disclosed to any other person or entity except as permitted by this waiver/alteration, by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information has been permitted by the IRB. If at any time, the PI wants to reuse this information obtained under waiver/alteration of authorization for other purposes or disclose the information to other individuals or entity the PI will seek prior approval by the IRB.

|  |
| --- |
| ***For IRB Office Use Only:*** |
| **Type of Review** *(this may/may not be the same as level of review and may include exempt research under 45 CFR 46)* |
| [ ]  | Expedited, on behalf of the UTSW Privacy Boards (IRBs).  |
| [ ]  | Full Board; indicate by which UTSW Privacy Board (IRB):  IRB-1  IRB-2  IRB-3  IRB-4 |
| The following criteria as required by **45CFR164.512(i)** were satisfied: |
| [ ]  | The intended use and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals. |
|  | [ ]  | There is an adequate plan to protect the identifiers from improper use and disclosure |
|  | [ ]  | There is 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 |
|  | [ ]  | There are 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 by this subpart |
| [ ]  | The research could not practicably be conducted without the waiver |
| [ ]  | The research could not practicably be conducted without access to and use of the protected health information |
| ***Approved by (Signature):*** |