PI WORKSHEET: HIPAA Waiver of Authorization

This worksheet is required for the following submission types when research involves a waiver of HIPAA authorization: Exempt research that requires IRB review, Expedited research, or Full Committee research.

The purpose of this worksheet is to provide support for the Privacy Board Member designated to conduct Privacy Board Reviews to document a waiver of HIPAA authorization using the expedited procedure or at committee review. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information, visit: [Protected Health Information (HIPAA)](https://research.uci.edu/human-research-protections/assessing-risks-and-benefits/privacy-and-confidentiality/protected-health-information-hipaa/).

Attach this worksheet to the “Local Site Documents” section of the ZOT IRB application.

**1. Submission Information**

|  |  |
| --- | --- |
| **1.1 Basic Information** | **Submission Details** |
| **1.1.1 IRB Number:** | ​​ Click or tap here to enter text. |
| **1.1.2 Short Title:** | ​​ Click or tap here to enter text. |

2. Scope (Check all that apply.)

(Partial) Waiver of HIPAA authorization for recruitment

Waiver of HIPAA authorization for conduct of study

3. Documentation of Waiver Approval (Check if “Yes.” All must be checked.)

The description of the PHI for which use or access is included in the protocol narrative and is necessary for the research.

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (Check if “Yes.” All must be checked.)

An adequate plan to protect the identifiers from improper use and disclosure.

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.

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 for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

Specify if any entities outside the UCI study team (e.g., contract research organization, sponsor) will access, use, or disclose a research subject’s PHI and explain why the entity need PHI to conduct the study.

|  |
| --- |
| Click or tap here to enter text. |

The research could **NOT** practicably[[1]](#endnote-2) be conducted without the waiver or alteration. (Check if “Yes”. One must be checked.)

Only minimal contact information will be obtained for recruitment purposes and prescreening medical records is necessary to identify potential eligible subjects.

It would not be feasible to individually contact the large numbers of potential subjects in the study

It would not be possible to locate many of the individuals whose records would be used for the study

Many of the individuals, whose records would be used for the study, are now deceased

Requiring HIPAA authorization may introduce systemic bias into the information

The risk of contacting the subjects to obtain HIPAA authorization is greater than the risk of the study procedures

Other, provide scientifically and ethically justifiable rationale.

|  |
| --- |
| Click or tap here to enter text. |

The research could **NOT** practicably be conducted without access to and use of the protected health information.

1. Practicably means [capable of being done](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html); it should not be determined by considerations of convenience, cost, or speed. [↑](#endnote-ref-2)