## Headquarters, US Army Medical Research and Development Command

**Institutional Review Board (HQ USAMRDC IRB)**

## Application for Waiver/Alteration of HIPAA Authorization

**Research Protocol Title:**

**Principal Investigator**:

**Background:** The DoD Health Information Privacy Regulation and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allow for waiver or alteration of the requirement to obtain authorization for the use or disclosure of protected health information (PHI) for research purposes.

The HQ USAMRDC IRB (acting as a Privacy Board) must find and document that the criteria for waiver or alteration are adequately addressed.

**Instructions:** To request a waiver or alteration, provide a detailed response to each item below. **Describe/explain:**

1. The PHI (\**see definition on next page*) to be used or disclosed and the source(s) of the PHI. Provide a comprehensive list in the table [add rows as needed] or cite a specific list within the research protocol.

All health information held or maintained by a covered entity that is used or disclosed for research purposes is considered PHI if any of the identifiers listed on the next page are collected and linked to that information.

Note: The *identifiers themselves are not the PHI*; PHI is health information that becomes individually identifiable due to its link to one or more of the identifiers.

|  |  |
| --- | --- |
| **PHI** | **Source** |
|  |  |
|  |  |

2. How the use or disclosure of Protected Health Information (PHI) involves no more than a minimal risk to the *privacy* of individuals, based on the following:

a. The plan to protect PHI from improper use or disclosure, describing specifically where PHI will be stored and who will have access.

b. The plan for destroying all PHI identifiers collected during the research at the earliest opportunity, consistent with the conduct of research. Explain when identifiers will be destroyed and why this is the earliest opportunity to do so. (Note: you may keep the identifiers if there is a health or research justification for retaining them or if retention is otherwise required by law.)

3. Why the research could not practicably be conducted without the waiver or alteration.

4. Why the research could not practicably be conducted without access to and use of the PHI.

**Principal Investigator Assurance.** I affirm that:

The PHI to be obtained for this research is the minimum necessary to accomplish the intended purpose of the use, disclosure or request.

The information in this application is accurate. All research staff will comply with the DoD Health Information Privacy Regulation, the HIPAA Privacy Rule and the waiver/alteration criteria.

I will not reuse or disclose health information (including PHI) obtained as part of this research to any other person or entity except (a) as required by law; (b) for authorized oversight of the research; or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

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Principal Investigator Signature Date

**\*Protected Health Information Definition:** The federal Privacy Rule protects all *“individually identifiable health information”* held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information “protected health information (PHI).” PHI is information, including demographic data that relates to

* the individual’s past, present or future physical or mental health or condition
* the provision of health care to the individual
* the past, present, or future payment for the provision of health care to the individual

and that identifies the individual, or for which there is a reasonable basis to believe it can be used to identify the individual.Individually identifiable health information includes many common identifiers in the table below.

**Identifiers:**

|  |  |
| --- | --- |
| * *Names* * *Address* * *Dates except year* * *Ages over 89 (can be grouped as age 90 or older)* * *Phone numbers* * *Fax numbers* * *E-mail addresses* * *Social security numbers* * *Medical record numbers* * *Account numbers* * *Certificate/license numbers* | * *Health plan beneficiary numbers* * *Vehicle identifiers and serial numbers, or license plate numbers* * *Device identifiers and serial numbers* * *Web Universal Resource Locators (URLs)* * *Internet Protocol (IP) address numbers* * *Biometric Identifiers, including finger and voice prints* * *Full face photographic images and any comparable images* * *Any other unique identifying number, characteristic, or code* |

Regulatory References: DoD 6025.18-R, March 13, 2019, “DoD Health Information Privacy Regulation”

45 CFR 160 & 164, “Health Insurance Portability and Accountability Act of 1996”