



**WAIVER OF AUTHORIZATION**

***Full OR Partial Waiver for Recruitment***

**Institutional Review Board**

**Study Number:**

**PI:**

**Protocol #:**

**Protocol Version / Version Date:**

**Protocol Title:**

**Sponsor:**

, (**“RESEARCHER”**) hereby submits this Application to TriHealth’s Institutional Review Board (**the “IRB”**) and requests a Waiver of Authorization, as contemplated by 45 C.F.R. § 164.512(i) of the HIPAA regulations.

**Describe Research Study:**

**Requesting:**  Partial Waiver of Authorization for Recruitment\*  Full Waiver of Authorization\*\*

\*A Recruitment Waiver of Authorization is for the purpose of allowing a researcher to obtain protected health information (“PHI”) as necessary to recruit potential research subjects only. Unless a Research Waiver of Authorization is also granted, an Authorization signed by each study subject is necessary for use and disclosures of PHI for all other aspects of the study.

\*\*A Research Waiver of Authorization allows the researcher to conduct the study protocol without having to obtain a signed Authorization for each study subject.

If requesting Partial Waiver of Authorization for Recruitment specify the elements of PHI necessary to recruit potential research subjects:  Check if N/A

If requesting Full Waiver of Authorization, please specify elements of PHI necessary for the research study:  Check if N/A

**RESEARCHER** plans to use or disclose the Protected Health Information to conduct the above referenced research activity.

**RESEARCHER** has an adequate plan for safeguarding subject PHI which documents how **RESEARCHER** plans to protect any identifiers from improper use and disclosure and how **RESEARCHER** plans to destroy the identifiers at the earliest opportunity, unless retention is required by law or justified by health or research reasons.  Yes  No

**Describe your plan for safeguarding subject PHI including how you plan to protect any identifiers from improper use and disclosure:**

**Describe your plan for when and how the identifiers will be destroyed?**

**RESEARCHER** assures this IRB that the research subjects' PHI will not be reused or disclosed to any other person, except as required or permitted by law  **Yes**  **No**

**RESEARCHER** represents that the described research cannot practicably be conducted without the requested Waiver of Authorization  **Yes**  **No**

**If yes, provide a detailed explanation as to why the research cannot practicably be conducted without the requested Waiver of Authorization:**

**RESEARCHER** represents that the described research cannot practicably be conducted without access to and use of the indicated Protected Health Information of research subjects  **Yes**  **No**

**If yes, provide detailed explanation as to why the research cannot practicably be conducted without access to and use of the indicated PHI:**

**RESEARCHER** represents that the described research study involves no more than a minimal risk to the privacy of research subjects  **Yes**  **No**

**RESEARCHER** represents and warrants that the above statements are true and correct and requests that the IRB approve this Application.

**PI Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## HIPAA Definitions and 18 Identifiers

**Protected Health Information (PHI):** Information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual.

**De-identified:** Information that has certain identifiers (see “identifiers” below) removed in accordance with 45 CFR 164.514; no longer considered to be Protected Health Information.

**Identifiers:** Under the HIPAA Privacy Rule “identifiers” include the following:

1. Names
2. Geographic subdivisions smaller than a state (except the first three digits of a zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000).
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death and 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) .
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code (excluding a random identifier code for the subject that is not related to or derived from any existing identifier.