**Request for Waiver or Alteration of**

**Health Insurance Portability and Accountability Act (HIPAA) Authorization**

In accordance with HIPAA regulations, authorization to use and disclose Private Health Information (PHI) must always be obtained unless a waiver of authorization is approved. In order for the IRB to waive the requirement to obtain authorization, the following information must be obtained **(See last page for list of HIPAA identifiers)**:

**PI Name**:

**Study Title:**

**Type of Request:** (Check all applicable boxes)

[ ]  Full HIPAA Waiver

[ ]  Partial HIPAA Waiver (AKA “Preparatory to Research” of for recruitment purposes – A HIPAA Authorization will be obtained at the time of participant enrollment).

[ ]  HIPAA Alteration – Requesting to waive one of the required elements of the HIPAA Authorization form.

Describe the element:

Provide a description of the PHI for which use or access is necessary for the research:

[ ]  The use/disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals.

Justification:

[ ]  Identifying information will be protected from improper use and disclosure.

Where will identifiers be stored and who will have access:

[ ]  There is an adequate plan to destroy 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, if retention is required by law.

Describe the plan for destruction of identifiers:

[ ]  The PHI that is obtained 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 PHI would be permitted under HIPAA.

Describe how you will assure that PHI will not be reused or disclosed:

[ ]  The research cannot be practicably conducted without the alteration or waiver.

Justification:

[ ]  The research cannot be conducted without access to and use of the PHI.

Justification:

[ ]  Only the minimum necessary PHI will be used or disclosed.

Justification:

**List of 18 HIPAA Identifiers:**

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, 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. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, 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. Phone 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; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

There are also additional standards and criteria to protect individual's privacy from re- identification. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual and the master codes, nor can the method to derive the codes be disclosed. For example, a subject's initials cannot be used to code their data because the initials are derived from their name. Additionally, the researcher must not have actual knowledge that the research subject could be re-identified from the remaining identifiers in the PHI used in the research study. In other words, the information would still be considered identifiable is there was a way to identify the individual even though all of the 18 identifiers were removed.