

HIPAA WAIVER OF AUTHORIZATION\*\*\*

Date:

IRB Protocol #:

**Title:**

The use or disclosure of Protected Health Information (PHI)\* involves no more than a minimal risk to the privacy of individuals because: [provide explanation]

The alteration or waiver will not adversely affect the privacy rights and the welfare of individuals because: [provide explanation]

The research could not practicably be conducted without a waiver because: [provide explanation]

The research could not practicably be conducted without access to and use of the PHI because: [provide explanation]

The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research because: [provide explanation]

Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access. [describe plan]

All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research. [describe procedure used to destroy all (PHI) data collected during study 9electronically, paper, audio, video, photography, other) which may be use to identify individuals] [alternative language, REMOVE if not applicable: The identifiers collected during the study will not be destroyed because [provide explanation]]

Provide a detailed list of the PHI to be collected and a list of the source(s) of the PHI. [provide list of PHI and source of PHI]

The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives. [provide explanation]

The information listed in the waiver application is accurate and all research staff\*\* will comply with the HIPAA regulations and the waiver criteria.

I assure the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time

I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB/Privacy Board.

Signature of Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_

Name (typed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*PHI: individually identifiable health information transmitted and maintained in any form (electronic means, or paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.

\*\*Note: Research staff is defined as ALL study personnel (including PI) that are involved in the research.

\*\*\*HIPAA Regulations allow Privacy Boards to issue a Waiver of Authorization if all of the criteria listed above are met.