

HIPAA IRB WAIVER OF AUTHORIZATION***

IRB Protocol # _____
Title _____

1. The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals. Explain why? Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI.

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access (researchers must list all of the entities that might have access to the study's PHI such as; sponsors, FDA, data safety monitoring boards and any others given authority by law);

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (explain below).

Please describe the procedure used to destroy all the data collected during the study (electronically, paper, audio/video, photography, other). OR

Alternatively, the identifiers collected during the study will not be destroyed because: (explain below).

4. The research could not practicably be conducted without the waiver because (explain below).

5. The research could not practicably be conducted without access to and use of the PHI because (explain below).

6. 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. Please note that researchers are also accountable for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

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 that 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.

Principal Investigator Signature _____ Date _____
Name Typed _____

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on 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 is involved in the research.

***HIPAA Regulations allow IRBs to waive use of authorization form if all of the criteria listed above are met.