**HIPAA Waiver of Authorization Form**

Use this application form to request a waiver of the requirement for HIPAA Authorization. This means that you are requesting permission to access, obtain, use or disclose an individual’s Protected Health Information (PHI)\* for research or similar purposes without obtaining the individual’s specific authorization for that access, use, or disclosure.

**Principal Investigator Name**:

**IRB Number**:

**Study Title**:

I. List, in detail, the PHI that is to be collected for the research activity, and, explain why this PHI is the minimum necessary to meet the research objectives.

*Describe*:

II. Identify the source of the PHI (e.g., medical record). ***Note that the source (‘covered entity’) must be able to account for disclosures made under this waiver.***

*Describe*:

III. The use or disclosure of PHI for this research activity must involve no more than minimal risk to the privacy of individuals, based on the presence of the following 3 elements:

1. An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan and indicate where PHI will be stored, and who will have access (this list must be inclusive, e.g., IRB and its representatives, sponsor, OHRP, FDA, data safety monitoring boards, research team as listed in the associated IRB application, and others given authority by law).

*Describe*:

1. An adequate plan to destroy the 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 such retention is required by law.

*Describe*:

1. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for other research which would be specifically approved by the IRB and would qualify for a waiver of authorization. ***Principal investigator signature at the end of this document attests to compliance with this requirement.***

IV. Explain why the research could **NOT** practicably be conducted without the waiver or alteration of authorization.

*Describe*:

V. Explain why the research could **NOT** practicably be conducted without access to and use of the PHI.

*Describe*:

**My signature below assures that the information listed in this waiver application is accurate, and all research staff\*\* will comply with the HIPAA regulations and the waiver criteria. I assure that the PHI obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or for other research specifically approved by the IRB. 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.**

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Principal Investigator’s Signature Date