Health Insurance Portability and Accountability Act (HIPAA) Waiver of Authorization Form

Principal Investigator: **IRB Number:**

Project Title:

Under the federal privacy rule, 'HIPAA', research use or disclosure of an individual's identifiable health information (IIHI) requires the individual's authorization, unless the use or disclosure is determined by the IRB to qualify for a waiver.

Will your study involve looking at, using or disclosing IIHI? ☐ *Yes* ☐ *No*
If "No", then HIPAA does not apply. ***Check "No" and submit form to the IRB.***
If "Yes" fill out the form below as indicated.

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

II. *Identify the source of the health information (e.g., medical record etc). Note that the source ('entity') must be able to account for disclosures made under this waiver.*

III. **The use or disclosure of IIHI 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: (a and b below must be addressed)**

a. *An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan and indicate where IIHI will be stored, and who will have access (this list must be inclusive, i.e., sponsor, OHRP, FDA, data safety monitoring boards, research team as listed on the associated IRB application etc.).*

b. *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.*

IV. **The research cannot practicably be carried out without the waiver.**
Explain why:

V. **The research could not practicably be conducted without access to, and use of, the IIHI.**
Explain why:

My signature below assures that the IIHI obtained as above will not be reused or disclosed to any other person or entity, except as required by law, or for other research specifically approved by the IRB (and again, qualifying for a waiver of authorization)

Principal investigator signature at the end of this document signifies assurance of compliance with this requirement.

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Principal Investigator **Date**