

WAIVER OF AUTHORIZATION APPROVAL LETTER

In Compliance with section 164.512(i)(2)(iv)(C) of the HIPAA privacy rules, a representative from Medical IRB# _____ has reviewed the use of Protected Health Information (PHI) by expedited review.

The expedited review was conducted in accordance with 45CFR 46.110 (b)(2), the minor changes provision.

The IRB protocol# _____ meets the criteria for the waiver of authorization according to 164.512(i)(2)(ii), which are as follows:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of the individual based on:

-An adequate plan to protect the identifiers from improper use/disclosure

-An adequate plan to destroy the identifiers at the earliest opportunity consistent with the research justification unless health, research or legal justifications to retain the identifiers.

-An adequate written assurance that the PHI will not be reused or disclosed to any other person unless required by law, authorized oversight or as permitted by the following subpart:

-the research could not practicably be conducted without the waiver or alteration;

and

-the research could not practicably be conducted without access to and use of the PHI.

IRB CHAIRMAN OR DESIGNEE

DATE

see blue.