



VA Facility Name  Station Number

Title of Study

Principal Investigator (Last, First, Middle)

Give a brief description of the Protected Health Information (PHI), including the identifiers, for which use or access has been determined to be necessary by the IRB. Example: name, initials, medical record information, x-rays, etc.

**FOR IRB USE ONLY BELOW THIS LINE**

*NOTE: For an IRB or Privacy Board to approve a waiver of HIPAA authorization for research, it must determine that the following criteria have been met as required by 45 CFR 164.512(i).*

**The IRB has determined that (check all that apply):**

- The use or disclosure of the PHI involves no more than minimum risk to the privacy of individuals, based on, at least, the presence of all the following elements:
  - An adequate plan to protect the identifiers from improper use and disclosure.
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
  - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

**Note:** *If an IRB determines that all criteria are not meet, the IRB cannot approve the waiver.*

# IRB Documentation of Waiver of HIPAA Authorization for Research - Page2

**This waiver of authorization is for: (Check only one of the following)**

- Use of PHI only of recruitment of study subjects
- Use or disclosure for recruitment of study subjects and one or more phases or aspects of the study.  
List/describe the phase or aspects.

- Use or disclosure for one or more phases or aspects of the study but not recruitment. List/ describe the phase or aspects.

**This waiver has been approved by:**

- Convened board review
- Expedited board review

Signature IRB Chair or Voting Member of the IRB	Date

Name of the IRB

Name of the IRB's sponsoring institution

Location (City, State)