

## Institutional Review Board

## Request for Waiver or Alteration of HIPAA Authorization Requirement for Access to Protected Health Information for Research

Please complete this form if, in conjunction with your request for approval of a research activity, you are also requesting that the IRB waive or alter the normal requirement to obtain the authorization of each patient for the use or disclosure of their protected health information. Your answers to the questions below will permit the IRB to determine if this request meets the regulatory requirements for the waiver or alteration (use additional sheets if necessary).

Protocol # \_\_\_\_\_ (if already assigned)

Protocol Title:

Name of Investigator:

□ Complete Waiver □ Alteration Requesting:

If "Alteration" is checked, please describe the nature of the requested alteration.

Please describe how the research project addresses each of the following requirements for approval of the waiver or alteration.

An adequate plan to protect health information identifiers from improper use and disclosure. (If no identifiers will be recorded, answer "No identifiers, Not Applicable").

An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). (If no identifiers will be recorded, answer "No identifiers, Not Applicable").

The research could not practicably be conducted without the waiver or alteration. [why you can't get patients' authorization]

The research could not practicably be conducted without access to and use of the PHI. [how each of the specific items of information you will collect are related to the scientific purpose of your project]

I certify that the PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule.

Signature

Date

Printed Name