

REQUEST FOR WAIVER OR ALTERATION OF CONSENT AND HIPAA AUTHORIZATION
(Form Version 06/2010)

Use this form if the procedure for this research will alter or will not include all of the required elements of consent [45CFR46.116(d)] and HIPAA authorization [45CFR164.512(i)(2)].

Please respond to each item in the allotted space below using protocol-specific language to provide justification.

Principal Investigator (PI) Name:	
--	--

Protocol Title:	
------------------------	--

1. Provide a brief explanation of why the research activity to be permitted by this waiver involves no more than minimal risk to the subjects.

2. Describe the protected health information (PHI) to be collected and the source(s) of PHI.

3. Demonstrate that the research involves no more than minimal risk to the privacy of subjects by describing the plans requested below:

- A. Describe the plan to protect the identifiers from improper use and disclosure and indicate where the PHI will be stored and who will have access.

- B. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (how and when identifiers will be destroyed). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers.

- C. Provide an explanation of written assurance that you will not re-use the PHI.

4. Explain why the research could not be practicably carried out without this waiver or alteration.

Request for Waiver or Alteration of Consent and HIPAA Authorization

5. Explain why the research could not practicably be conducted without access to and use of the protected health information.

6. Explain why this waiver or alteration will not adversely affect the rights and welfare of the subjects.

7. Explain why the risks of the research are reasonable in relation to the anticipated benefits of the research.

8. Whenever appropriate, explain how the subjects will be provided with additional pertinent information after study participation and what information will be provided.

Principal Investigator's Assurance

I assure the PH IRB that the information that I provided in this application is accurate and complete; that the PHI that I request is the minimum amount of identifiable private information necessary for my research project; and that the PHI will not be re-used or disclosed to any other person or entity, except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.

Principal Investigator

Date