

Waiver of HIPPA Authorization Request Form

Please review the following regulations prior to submitting the waiver request form: 45 CFR part 164.512. The request must meet the applicable requirements in the regulations in order to qualify for waiver.

I. STUDY INFORMATION	
Protocol Number:	
Protocol Title:	
Sponsor name and/or Funding Agency:	
Principal Investigator (if applicable):	
<p>1. This request is submitted for:</p> <p><input type="checkbox"/> All subjects in the trial</p> <p><input type="checkbox"/> A subset of subjects in the trial. If a subset, what subset of subjects and rationale:</p>	
<p>2. Has this request been submitted to another IRB? <input type="checkbox"/> Yes* <input type="checkbox"/> No</p> <p><i>*If Yes, list the name of the IRB(s), and the outcome of the review. Attach copies of correspondence from the IRB(s).</i></p>	
II. HIPPA AUTHORIZATION 45 CFR PART 164.512	
<i>Respond to the following statements. If any statements are marked NO, then research does not qualify for waiver.</i>	
<p>1. There is an adequate plan to protect the identifiers from improper use and disclosure. <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>Specify plan (or attach separate document with specifics):</i></p>	

2. There is a plan to destroy the identifiers at the earliest opportunity appropriate to the research. Note identifiers may be retained if there are health, research or legal obligations to do so. Yes No

Specify plan (or attach separate document with specifics):

3. The Principal Investigator has provided written assurance that the PHI will not be reused or disclosed except as required by law or for authorized research oversight. Yes* No

*If Yes, attach PI's written assurance.

4. The research could not practicably be conducted without the waiver. Yes No

5. The research could not practicably be conducted without access to and use of the PHI. Yes No

6. Describe the protected health information for which use or access has been determined to be necessary:

7. Describe in detail why this waiver of documentation of HIPPA Authorization is required:

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.

Form Completed By

Date

Title, Company

Phone:

Email: