

OIA-441 CHECKLIST: HIPAA Waiver of Authorization

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The purpose of this checklist is to provide support for the designated reviewer or IRB to conduct review and to document a waiver or alteration of HIPAA authorization. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

IRB Number:	
Protocol Name:	
Investigator:	

1 DOCUMENTATION OF WAIVER APPROVAL (Check if "Yes." All must be checked)

<input type="checkbox"/>	A description of the <u>protected health information (PHI)</u> to be accessed or used has been reviewed and the <u>PHI</u> to be accessed or used is the minimum necessary to meet the aims of the <u>research</u> .
<input type="checkbox"/>	The procedures required to meet any conditions placed on the waiver are described in the protocol.
<input type="checkbox"/>	The use or disclosure of <u>PHI</u> involves no more than <u>minimal risk</u> to the privacy of individuals, based on, at least, the presence of the following elements: (Check if "Yes." All must be checked)
<input type="checkbox"/>	An adequate plan to protect the identifiers from improper use and disclosure.
<input type="checkbox"/>	An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the <u>research</u> , unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
<input type="checkbox"/>	Adequate written assurances that the <u>PHI</u> 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 <u>research</u> for which the use or disclosure of <u>PHI</u> for which an authorization or opportunity to agree or object is not required by <u>45 CFR 164.512</u> .
<input type="checkbox"/>	The <u>research</u> could NOT practicably be conducted without the waiver or alteration.
<input type="checkbox"/>	The <u>research</u> could NOT practicably be conducted without access to and use of the <u>PHI</u> .

2 REVIEW PROCESS (Select one)

<input type="checkbox"/>	Review was conducted using the expedited procedure.
<input type="checkbox"/>	Review was conducted at a fully convened IRB meeting.

3 DETERMINATION (Select one)

<input type="checkbox"/>	Approval of a waiver of <u>HIPAA</u> authorization
<input type="checkbox"/>	Approval of an alteration/partial waiver of <u>HIPAA</u> authorization (Select one)
<input type="checkbox"/>	For screening and/or recruitment purposes only
<input type="checkbox"/>	Other: