

CHECKLIST: HIPAA Waiver of Authorization

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The purpose of this checklist is to provide support for the Privacy Board Member designated to conduct Privacy Board Reviews using the expedited procedure to document a waiver or alteration of HIPAA authorization. This checklist is to be used. This checklist needs to be completed, signed, dated, and retained.

IRB Number:	
Protocol Name:	
Investigator:	

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

<input type="checkbox"/>	The description of the PHI for which use or access is included in the protocol summary and is necessary for the research.
<input type="checkbox"/>	The use or disclosure of protected health information involves no more than a minimal risk 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 research, 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 protected health information 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 protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.
<input type="checkbox"/>	The research could NOT practicably be conducted without the waiver or alteration.
<input type="checkbox"/>	The research could NOT practicably be conducted without access to and use of the protected health information.

Using the expedited review procedure the designated privacy board member signing below has determined that the above requirements are met, access to the protected health information described in the protocol is necessary, and waived or altered the requirement for authorization.

Reviewer Signature:		Date:	
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