Institutional Review Board

Checklist: HIPAA Waiver of Authorization

NUMBER	HRP-441

Once completed, return this checklist to the IRB manager.

IRB Number	
Protocol Name	
Investigator	

The purpose of this checklist is to provide support for the IRB Members or the Designated Reviewer when research involves a waiver or alteration of HIPAA authorization. This checklist must be used for all reviews when research involves a waiver or alteration of HIPAA authorization.

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer, completes this checklist to document determinations required by the HIPAA regulations, and send the completed checklist to the IRB Manager.
- For initial review using the convened IRB and for modifications and continuing review where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer for the convened IRB completes this checklist to document determinations required by the HIPAA regulations. The Reviewer completes this checklist and sends it to the IRB manager.

1 Documentation of Waiver Approval (Check if "Yes". All must be checked)	
☐	The description of the PHI for which use or access is documented, and is necessary for the research.
☐	The use of disclosure of protected health information involves *no more than a minimal risk* to the privacy of the subjects, based on at minimum the presence of the following elements: (Check if "Yes". All must be checked)
☐	An adequate plan to *protect the health information identifiers* from improper use and disclosure.
☐	An adequate plan to *destroy the identifiers* at the earliest opportunity
☐	Adequate written assurances that the *PHI will not be reused or disclosed* (share with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule.
☐	The research could NOT practicably be conducted without the waiver or alteration.
☐	The research could NOT practicably be conducted without access to and use of the protected health information.

Using the expedited review procedure the designated IRB 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.

The HIPAA Waiver of Authorization is: (Please check one, and sign/date)

- ☐ APPROVED
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full (Convened) IRB Meeting
- ☐ Do Not Recommend approval at this time. List Reasons. (Convened board must agree by a vote if study is not approved.)

Comments Section:

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(Reviewer) (Date)