CHECKLIST: HIPAA Waiver of Authorization

NUMBER	DATE	PAGE
HRP-204	11AUG2023	1 of 1

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 review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations.
- For review using the convened IRB this checklist is to be completed by the convened IRB to document determinations required by the regulations and protocol specific findings justifying those determinations and retained in the protocol file.

1 Documentation for Wavier Approval (All must be **Yes**)

☐ **Yes** ☐ **No**	The description of the PHI for which use or access is documented, and is necessary for the research.	
☐ **Yes** ☐ **No**	The use of disclosure of PHI involves no more than a minimal risk [1] to the privacy of the subject, based on the at minimum the presence of the following elements. (All the following must be **Yes**)	
	☐ **Yes** ☐ **No**	An adequate plan to protect the health information identifiers from improper use and disclosure.
	☐ **Yes** ☐ **No**	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.
	☐ **Yes** ☐ **No**	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 project, or for other research for which the use or disclosure of protected health information would be permitted
☐ **Yes** ☐ **No**	The research could not be practicable conducted without the waiver or alteration.	
☐ **Yes** ☐ **No**	The research could not practicably be conducted without access to and use of the protected health information.	

[1] **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of or during the performance of routine physical or psychological examinations or tests.