

**CHECKLIST: HIPAA Waiver of Authorization**

NUMBER

DATE

PAGE

HRP-441

5/1/2022

1 of 1

The purpose of this checklist is to provide support for the Privacy Board Member (IRB) designated to conduct Privacy Board Reviews using the expedited procedure or at committee review to document a waiver or alteration of HIPAA authorization. This checklist or the equivalent form or electronic equivalent needs to be completed, signed, dated, and retained.

IRB Number:**Study Title:****Short Title:****Investigator:****1 SCOPE (Check all that apply)**

- Waiver of HIPAA authorization for recruitment
- Waiver of HIPAA authorization for conduct of study
- Alteration of HIPAA authorization to not require signature of the individual and date (e.g. verbal)
- Alteration of HIPAA authorization (include specifics of alteration below in "Notes" section; refer to HRP-330 - WORKSHEET - HIPAA Authorization)

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

- The description of the PHI for which use or access is included in the protocol summary and is necessary for the research.
- 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)
 - An adequate plan to protect the identifiers from improper use and disclosure.
 - 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.
 - 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.
- 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.

Notes:

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:**