RUTGERS UNIVERSITY
Office for Research

WORKSHEET: HIPAA Waiver of Authorization

NUMBER	DATE	PAGE
6.201 (HRP-441)	04/04/2024	1 of 1

The purpose of this worksheet is to provide guidance for the Privacy Board Member designated to conduct Privacy Board Reviews to determine if a waiver or alteration of HIPAA authorization is approvable. This worksheet is to be used as a guide and does not need to be retained.

- For expedited and exempt initial review and continuing review/progress report, as well as modifications where the determinations relevant to this worksheet made on the previous review have changed, the Designated Reviewer uses this worksheet to guide them in making the determinations required by the regulations.
- For initial review using the convened IRB and continuing reviews, as well as for modifications where the determinations relevant to this checklist made on the previous review have changed.
  uses this worksheet The convened IRB uses this worksheet to guide them in making the determinations required by the regulations. The findings of the convened IRB in relation to the determinations required by the regulations are then documented in the corresponding section of the meeting with protocol specific findings justifying those determinations.

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 6.205 (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 protected health information.

Notes: