

	CHECKLIST: Waiver or Alteration of HIPAA Authorization			IRB # \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$Review\$\$
	HRP-427	3/16/2020	1 of 1	Status: \$\$Status\$\$

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

1 DOCUMENTATION OF WAIVER/ALTERATION APPROVAL – [45 CFR 164.512(i)(2)(ii)] For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following: (All must be “Yes”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	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:	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	There is an adequate plan to protect the identifiers from improper use and disclosure.
	<input type="checkbox"/> Yes <input type="checkbox"/> No	There is 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"/> Yes <input type="checkbox"/> No	There are 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.

Yes **No** The research could not practicably be 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.

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

Choose one:

- Complete waiver of authorization granted.
- Partial waiver of authorization for recruitment purposes granted.
- Waiver of documentation of authorization granted. If checked, select one option below:
 - Individual must be provided with a copy of the authorization.
 - Requirement to provide the individual with a copy of the authorization is waived.
- Alteration of authorization granted, specifically waiving inclusion of the following required statement: “The potential for information disclosed pursuant to the authorization is subject to redisclosure by the recipient and no longer will be protected by this authorization.” The PHI being accessed/used for research purposes will be disclosed to individuals who are involved in the subjects’ care and are employees of Spectrum Health, so are part of the Covered Entity. As such, these individuals are required to maintain compliance with the HIPAA regulations regarding keeping the confidentiality of the PHI which is released to them. Including this statement in the authorization gives the false impression that the subjects’ information will be sent outside the Covered Entity.
- Other alteration of authorization granted. Describe alteration:

Reviewer Signature:		Date:	
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