

I. PURPOSE

This policy describes the requirements for a waiver of some or all elements of informed consent. It also describes the requirements for a waiver or partial waiver of subject authorization for use and/or disclosure of protected health information (PHI) pursuant to section 45 CFR 164.512 of the Privacy Rule (HIPAA).

II. POLICY STATEMENT

The IRB may waive some or all of the required elements for informed consent under 45 CFR 46.116(f)(3). Under 45 CFR 164.512, the IRB may waive, alter or partially waive the requirements for prospective authorization for use of PHI in research. Before the IRB can waive these requirements, it must assure that all of the conditions in the regulations are met and that its decisions are documented.

III. SCOPE

These policies and procedures apply to all IRB submissions.

IV. DEFINITIONS

Alteration of Requirement of Authorization: A waiver of one or more of the requirements of the Privacy Rule.

Partial Waiver of HIPAA Authorization: A partial waiver allows an investigator to obtain, use, and/or disclose PHI for one specified portion of a study or activity (e.g., recruitment) without first obtaining authorization.

The Privacy Rule (HIPAA): The federal regulations at 45 CFR 160 and 164.

Waiver of Authorization: A waiver issued by the IRB from the requirements of the Privacy Rule to obtain permission for the use or disclosure of PHI.

Waiver of Consent: A waiver issued by the IRB from the requirements for obtaining informed consent or to leave out or alter some or all of the elements of informed consent otherwise required under the regulations.

V. PROCEDURES

A. Waiver or Alteration of Consent Procedure (45 CFR 46.116(f)(3))

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent or that waives the requirement to obtain informed consent provided the IRB finds and documents the following:

1. The research involves no more than minimal risk to the subjects; and

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
3. The research could not be practicably be carried out without the waiver or alteration; and
4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

B. Waiver of Written Authorization for Use and/or Disclosure of Protected Health Information under the Privacy Rule

1. Researchers at the Children's Hospital of Philadelphia may use and/or disclose protected health information of one or more of the covered entities for research purposes without prospective written authorization provided that they provide a request for such waiver or partial waiver and the IRB agrees that the request satisfies the criteria at §164.512(i)(2)(ii) as listed below.

(a) The use or disclosure of the protected health information involves no more than minimal risk to the privacy of individuals based on:

(1) The provision of an adequate plan to protect the identifiers from improper use and disclosure; and

(2) The provision of an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law or institutional policies; and

(3) The provision of 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 by law; and

(b) The research could not be practicably conducted without the waiver or alteration; and

(c) The research could not be practicably conducted without access to and use of the protected health information.

2. Provided the requirements of B.1 are met, the IRB may grant an alteration or partial waiver of the Privacy Rule requirements. Examples include but are not limited to:

(a) Waiver or alteration of one or more of the required elements of authorization;

(b) Waiver of the requirement to obtain authorization in writing such as when PHI is collected over the phone, fax, internet or email from study participants;

(c) Waiver to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into a study.

C. Documentation of Waiver of HIPAA Authorization

When the IRB grants a waiver or partial waiver of Written Authorization under section B above, it will provide documentation of its determinations as required by 45 CFR 164.512(ii):

1. Identification that the waiver was granted by the IRB, and the date on which the alteration or waiver was approved; and
2. A statement that the IRB determined that the alteration or waiver of Written Authorization, in whole or in part, satisfied the criteria of section B of this policy; and
3. A brief description of the protected health information for which use or access was determined to be necessary by the IRB; and
4. A statement that the alteration or waiver of HIPAA Authorization was reviewed and approved under expedited or full IRB review procedures.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116

21 CFR 56.116

45 CFR 164.512(i)(2)(ii)

VII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB SOPs regarding waiver or alteration of informed consent and HIPAA authorization.
Chair, CPHS	Chair, CPHS, or designee is responsible for ensuring that the IRB appropriately applies the criteria for waiver or alteration of elements of consent and for waiver or partial waiver of required components of HIPAA authorization. Responsible for ensuring reviewers appropriately document their findings.

VIII. ATTACHMENTS

The IRB's website contains guidance information on the HIPAA Privacy Rule.
<https://www.research.chop.edu/services/does-hipaa-apply-to-my-study-and-what-needs-to-be-in-a-hipaa-authorization>

IX. REVISION HISTORY

03-12-2009 Revised to include partial waiver of HIPAA Authorization

06-10-2010 Revised to correct minor grammatical issues for consistency across SOPs and links the IRB's website.

09-25-2018 Revised to update definitions and minor editorial changes.

01-22-2019 Revised to update the regulatory citations to reflect the changes to the Common Rule.

12-22-2022 Minor administrative edits.

X. APPROVAL

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/22/22
 Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS