

I. PURPOSE

The purpose of this SOP is to describe the general requirements for documentation of HIPAA authorization and to enumerate the situations where an authorization or waiver is required.

II. POLICY STATEMENT

Members of the Hospital's workforce who are conducting research must comply with CHOP Policy for **Use & Disclosure of Protected Health Information for Research**. Investigators must obtain written Authorization from all participants in the research study prior to the use or disclosure of protected health information (PHI) for any research-related purpose unless the IRB has issued a waiver or alteration (**IRB SOP 706**) or for the limited situations where the Privacy Rule does not require authorization or waiver.

III. SCOPE

This policy and these procedures apply to all research submitted to the IRB that involves protected health information.

IV. DEFINITIONS

Combined Consent/Authorization Form: The written document that combines the requirements for informed consent and the HIPAA requirements for documentation of authorization.

Individually Identifiable Health Information: A subset of health information, including demographic information collected from an individual, that (1) is created or received by a health care provider, health plan, employer, or healthcare clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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

Protected Health Information (PHI): Individually Identifiable Health Information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. There are 18 PHI identifiers of individual patients, their relatives, household members or employers. These include: name; all geographic identifiers smaller than a state, including address and zip codes; dates except for years (including birth, admission, discharge or death dates); Social Security numbers; telephone and fax numbers; e-mail addresses; and medical record and health plan numbers.

Written Authorization: Written permission for the use or disclosure of PHI.

V. PROCEDURES

A. Use or Disclosure of PHI in Research with Authorization

Investigators must comply with CHOP Policy: Use & Disclosure of Private Health Information in Research.

1. A written Authorization must be signed by an individual who is authorized under law to provide consent or permission to participation in the research.
2. The requirement for written authorization applies to all uses and disclosures of PHI for research purposes unless the investigator:
 - (a) Obtains a waiver or alteration of the requirement as described in **IRB SOP 706**;
 - (b) Receives a limited dataset from a provider under the provisions of a duly executed data use agreement in accordance with CHOP Policies; or
 - (c) Provides the IRB with an attestation for use and disclosure of PHI without authorization or waiver for work preparatory to research or research involving decedents' PHI in accordance with CHOP Policies.
3. Stand-Alone Authorization. The investigator is responsible for the content and format of the stand-alone written Authorization and for ensuring that it meets the requirements listed in Section B.
 - (a) The investigator is required to submit a copy of the stand-alone authorization customized with study-specific information to the IRB to complete the study file.
 - (b) The IRB will review the authorization for accuracy and completeness and may provide suggested edits.
 - (c) The IRB does not approve stand-alone authorizations; the ultimate responsibility for compliance with HIPAA requirements rests with the investigator.
4. Combined Consent/Authorization Form. When a combined consent/authorization form will be used, the investigator must submit the document to the IRB for review and approval prior to use.
5. Authorization will be required if the research involves the use or disclosure of Mental Health Records, as outlined in the CHOP Policies on: Storage and Release of Mental Health Records and HIPAA Psychotherapy Notes (Pennsylvania and New Jersey).

B. Authorization Document Requirements

An Authorization for use and disclosure of PHI for research must be written in plain language and contain all of the core elements and required statements unless one or more are waived (**IRB SOP 706**).

1. Core Elements

- (a) A specific and meaningful description of the information to be used or disclosed;
- (b) The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes;
- (c) The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes;
- (d) A description of the purpose of each use or disclosure;
- (e) An expiration date or event, or a statement “end of research study” or “none” when appropriate (e.g., for a research database).

2. Required Statements

- (a) A statement that the individual may revoke the Authorization and how to do so. The investigator may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such Authorization before it was revoked;
- (b) A statement that an individual’s clinical treatment may not be conditioned upon whether or not the individual signed the Authorization; however, participation in research may be conditioned on a signed Authorization;
- (c) A statement that information disclosed under the Authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA.

C. Procedures for Reviewing Combined Consent/Authorization Documents

Whenever the investigator combines a written Authorization with an informed consent document, the IRB will review the document and approve it prior to use.

1. The reviewer will assure that the combined form meets the requirements for informed consent as enumerated under **IRB SOP 701**.
2. The reviewer will also ensure that the document contains all of the required elements of written authorization enumerated in B.1 – B.2 (above), unless the IRB has provided a waiver of alteration of one or more elements. See **IRB SOP 706**.


D. Protocols Approved Prior to April 3, 2003

1. Investigators may use and/or disclose PHI for research protocols approved prior to 4/13/2003 that have not been amended. Such use and/or disclosure is limited to that outlined in the original approved protocol and informed consent.
2. Protocols initially approved prior to 4/13/2003 which have been amended since that date require the application of the HIPAA privacy requirements as outlined in this policy as it pertains to use and disclosure of PHI.

E. IRB Procedures for Receipt and Acknowledgement of Reviews Preparatory to Research and Research on Decedents' Protected Health Information

Under the Privacy Rule, investigators may use or disclose PHI for research purposes without IRB approval for reviews preparatory to research and research on decedents' protected health information provided that they meet the requirements below and adhere to CHOP Policy.

1. Reviews preparatory to research provided that the IRB obtains from the investigator representation that:
 - (a) The use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;
 - (b) No PHI will be removed from CHOP by the researcher in the course of the review; and
 - (c) The PHI for which use or access is sought is necessary for the research purposes.
2. Research on decedents' protected health information (decedents are not considered human subjects under the Common Rule but use of their protected health information is subject to the requirements of the Privacy Rule) provided that the IRB obtains representation from the researcher that:
 - (a) The use or disclosure sought is solely for research on PHI of decedents;
 - (b) The PHI for which use or disclosure is sought is necessary for the research purposes;
 - (c) The researchers can produce documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought.
3. Investigators can submit attestations for the use of PHI preparatory to research and research on decedents' protected health information to the IRB through the

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electronic IRB Management system. The IRB will check the HIPAA attestations for accuracy and acknowledge receipt.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 164.508

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

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 701: Required Elements of Consent and Documentation of Consent

SOP 706: Waiver of Elements of Consent and Waiver of Written Authorization


VIII. RESPONSIBILITIES

Title	Responsibility
Director, Human Subjects Research	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures involving the consent process.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB responsibilities pertaining to ensuring that HIPAA authorization when combined with written consent meets the requirements of HIPAA.
Investigator	Responsible for obtaining written authorization from research subjects, their parent/guardian(s) or the legally authorized representative of the subject as required by this SOP unless waived or altered by the IRB.

IX. ATTACHMENTS

The IRB maintains the following related documents on its website:

- Consent Templates with and without Written Authorization
- CHOP-approved Stand-alone HIPAA authorization
- Guidance related to HIPAA and compliance with HIPAA

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X. REVISIONS

- 06-10-2010 Revised to correct minor grammatical issues for consistency across SOPs.
- 09-25-2018 Revised to update the definitions and minor edits.
- 01-22-2019 Revised to update referenced SOPs.
- 12-22-2022 Revised to reflect updated policies.

XI: 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