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## INTRODUCTION

This policy is part of, and is incorporated by reference into, The Children's Hospital of Philadelphia's (Hospital's) Privacy of Patient Information Policy. The use and disclosure of protected health information (PHI) for research purposes by the Hospital's workforce is permitted only as outlined within this policy. Use and/or disclosure of PHI for purposes unrelated to research are governed by the Hospital's Patient Care Manual - Policy IM-1-01 Privacy of Patient Information. CHOP researchers who wish to use or disclose PHI for research purposes should be familiar with the provisions of this policy and the Hospital's [Privacy of Patient Information Policy](#), as well as the relevant standard operating procedures, forms, and guidance maintained by the Office of Research Compliance & Regulatory Affairs (ORCRA), located on the CHOP Research intranet > Organizations > Research Compliance and Regulatory Affairs > [HIPAA and Research](#).

## POLICY STATEMENT

It is the policy of The Children's Hospital of Philadelphia to maintain the privacy and security of PHI used and disclosed for research purposes in accordance with the provisions of the Health Insurance Portability and Accountability Act (HIPAA).

## PURPOSE

The purpose of this policy is to describe how to implement applicable provisions of the HIPAA Privacy Rule.



## SCOPE

This policy applies to the use and disclosure of PHI for research purposes at The Children's Hospital of Philadelphia.

## PHI DATA ELEMENTS

PHI data elements are 18 categories of information used to identify the individual or the individual's relatives, employers, or household members; these are enumerated in CHOP's [Confidentiality of Patient and Institutional Information](#) and [Privacy of Patient Information](#).

## DE-IDENTIFIED DATA

**De-identified data is not PHI and thus not subject to the HIPAA Privacy Rule requirements.** De-identified data may be used or disclosed for research purposes without the need for further authorization by the subject or review/approval by the IRB. Certain coded data is considered de-identified (refer to [Coded Data](#)). In addition, certain data sets obtained through an honest broker may be considered de-identified (refer to [Use of Honest Broker for Creation of Data Sets](#)). De-identification does not necessarily preclude IRB review. Researchers are advised to consult with the IRB regarding any specific project.

- **De-identifying PHI** – PHI may be de-identified in one of two ways:
  - **Safe Harbor Method** - Removing all 18 data elements that could be used to identify the individual or the individual's relatives, employers, or household members (see [PHI Data Elements](#) above), provided that the remaining information cannot be used alone or in combination with other information to identify the individual who is the subject of the information.
  - **Statistical Method** – Instead of removing all 18 identifiers, statistical methods may be used to establish that a data set is de-identified. The researcher may obtain certification by a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable that there is a "very small" risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information. The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination.

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## DE-IDENTIFIED DATA (cont.)

- **Use of Coded Data** – Data that has been de-identified or is part of a limited data set may be assigned a code that can be affixed to the research record that will permit the information to be re-identified or linked back to a specific research subject if necessary. The code itself is not considered PHI and the data set will still be considered de-identified or a limited data set provided that:
  - the code or mechanism used for record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual (e.g., cannot be derived from a subject's initials, the last four digits of his/her social security number, birth date, or date of admission); and
  - the researcher does not use or disclose the code for other purposes or disclose the mechanism for re-identification.
  
- **Use of Honest Broker Creation of a Data Set** - An honest broker is an individual who has access to the desired data by virtue of his or her Hospital responsibilities and who is not involved as a listed researcher on the respective research study.
  - The honest broker accesses the desired medical record information and provides the researcher with de-identified data or a limited data set.
  - If the honest broker is providing the researcher with a limited data set, the broker must present an internal data use agreement to the researcher prior to receiving the data set.
  - The honest broker can assign a code to the data, provided that the researcher does not have access to the information linking the code to the identities of the research subjects. Using the code, the researcher can request, through the honest broker, additional medical information corresponding to a given research subject.
  - If the honest broker provides coded data to the research but not the method to de-code the data, then the information provided will be considered de-identified or a limited data set depending upon the data elements included in the data set.



## USE/DISCLOSURE OF PHI WITH AUTHORIZATION

- **HIPAA Authorization** - Except as otherwise allowed in this policy, written authorization from the research subject or personnel representative must be obtained for the use and/or disclosure of PHI for research purposes. The actual uses and disclosures made by the researchers and research staff must be consistent with what is stated in the authorization.
  - **Form and Content of Authorization** - The HIPAA authorization may be combined with a research consent document, or it may be a separate, stand-alone form. For a HIPAA authorization to be valid it must include certain required elements, which are identified in [CHOP SOP 707: Requirements For and Documentation of HIPAA Authorization in Research](#).
- **Review of Authorization** - IRB review is required for a HIPAA authorization that is combined with a research consent document. For any studies in which the HIPAA authorization is not combined with the research consent **and** the researcher makes any modification to the stand-alone HIPAA Authorization Template for use in a research study, the modifications must be reviewed by the Hospital Privacy Officer.
  - **Right of Revocation** – Research subjects have the right to revoke previously signed authorization permitting PHI to be used or shared for purposes of research. This must be done in writing. Data collected prior to the revocation request may be used for the research study, but no further data may be collected or shared about that research subject. Revocation will result in subjects being withdrawn from the study.

## USE/DISCLOSURE OF PHI WITH WAIVER/ALTERATION OF AUTHORIZATION

The IRB may approve a complete or partial waiver or an alteration of the HIPAA authorization requirement. A **complete waiver** occurs when the IRB determines that no authorization will be required for a researcher to use and disclose PHI for a particular research project. A **partial waiver** of authorization occurs when the IRB determines that an authorization is not needed for some research activities associated with a research protocol purpose. An alteration of the HIPAA authorization requirement occurs when the IRB reviews and approves a request to alter one or more of the required elements. For example an alteration may be granted permitting verbal authorization instead of written authorization.

The IRB may not grant a waiver or alteration of HIPAA authorization for the use or disclosure of psychotherapy notes. The HIPAA Privacy Rule provides special protections for psychotherapy notes (see CHOP's [Storage & Release of Mental Health Records & Psychotherapy Notes - Pennsylvania](#)). **Note:** Refer also to [IRB SOP 706, Waiver of Elements of Consent](#).



## USE AND DISCLOSURE OF PHI WITHOUT AUTHORIZATION OR WAIVER

Under certain circumstances, a researcher may use or disclosure PHI without the subject's written authorization or a waiver from the IRB. In these circumstances, the researcher must attest or certify to the IRB that they will meet HIPAA's requirements for such use and disclosure. **Note:** Refer also to [IRB SOP 706, Waiver of Elements of Consent](#).

- **Use of PHI Preparatory to Research** – (Refer to guidance document – [HIPAA Attestation – Use of PHI Preparatory to Research](#).) A researcher may review PHI in medical records or elsewhere to prepare a research protocol; to identify, but not contact, potential research subjects; or for similar purposes preparatory to research. The researcher must submit a written attestation to the IRB that:
  - the use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or other similar preparatory purposes; and
  - no PHI will be removed from the Hospital during the review; and
  - the PHI for which use or access is requested is necessary for the research purposes.

The IRB will issue an acknowledgement of receipt of the attestation, but will not issue an approval.

**Note:** Refer also to [Minimum PHI Necessary Standard](#).

- **Research Involving Decedents' PHI** – Researchers may use and disclose a decedent's PHI for research provided that the researcher certifies to the IRB that:
  - the use or disclosure will be solely for research on the PHI of a decedent;
  - the PHI is necessary for the purposes of the research; and
  - at the request of the IRB, documentation of the death of the individuals whose PHI is sought.

The IRB will issue an acknowledgement of receipt of the attestation, but will not issue an approval.

**Note:** Refer also to [Minimum PHI Necessary Standard](#).

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## USE AND DISCLOSURE OF PHI WITHOUT AUTHORIZATION OR WAIVER (cont.)

- **Limited Data Set** - PHI that consists of a limited data set may be used and disclosed for the purpose of research when a data use agreement is in place between the person releasing the data (e.g., researcher or data custodian at CHOP) and the recipient of the data (e.g., external collaborator, another researcher). A limited data set, as defined in this policy, may be used or disclosed for purposes of research without obtaining either an individual's authorization or the IRB's waiver or alteration of the requirements for authorization as long as a data use agreement is in place. **Data Use Agreements** are required prior to a limited data set being used internally or being disclosed outside of the Hospital (see also [Data Use Agreements](#)). The information in a limited data set may be coded, provided the researcher does not possess the key to the code (refer to [Coded Data](#)).
- A limited data set **may include** the following **two categories** of direct identifiers when determined to be the minimum necessary for the research activity:
  - **all elements of dates**, including, for example, date of birth and date of admission; and
  - **geographic data**, such as city; state; ZIP Code (except street address).
- A limited data set **must EXCLUDE** the following 16 categories of **direct identifiers**:

#	Limited Data Set - Excluded Direct Identifiers
1	Names
2	Street address information, other than town or city, state, and ZIP code
3	Telephone numbers
4	Facsimile numbers
5	Electronic mail addresses
6	Social security numbers
7	Medical record numbers
8	Health plan beneficiary numbers
9	Account numbers
10	Certificate/License numbers
11	Vehicle identifiers and serial numbers, including license plate numbers
12	Device identifiers and serial numbers
13	Web universal resource locators (URLs)
14	Internet protocol (IP) address numbers
15	Biometric identifiers, including fingerprints and voiceprints
16	Full-face photographic images and any comparable images



## DATA USE AGREEMENTS

A Data Use Agreement (DUA) is a written agreement that establishes how the limited data set may be used and disclosed by the recipient and how it will be protected by the recipient of the data set. An **internal** data use agreement must be used by CHOP researchers when requesting limited data sets for research purposes from databases and repositories owned by the Hospital. An **external** data use agreement must be in place between the Hospital and the recipient of the limited data set before such information may be disclosed to a researcher outside of CHOP. Contact the [Office of Technology Transfer](#) (OTT) for assistance with Data Use Agreements.

## ADDITIONAL REQUIREMENTS

- **Research Subject's Access to Research Information** – During the course of a study, a research subject may be denied access to the research records created or obtained in the course of that study. In such cases, the researcher must inform the research subject or representative that the right to access personal information from the research study is being denied while the study is in progress and that the information may be accessed after the research study has ended. An explanation should be provided to the research subject in the research consent and HIPAA authorization document.
- **Minimum PHI Necessary Standard** – The HIPAA regulations require that only the minimum necessary information be used and disclosed for purposes of the research being conducted. As part of the review and approval of a research protocol, the IRB will determine that the minimum necessary requirement has been met. The documentation provided to the IRB for approval of the research protocol must describe, with sufficient specificity, the PHI necessary to conduct the research activity. **Note:** The minimum necessary standard does not apply to use or disclosure pursuant to a HIPAA authorization; however, only that information that has been authorized by the research subject may be used or shared by the researcher for the study.

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## ADDITIONAL REQUIREMENTS (cont.)

- **Accounting of Disclosures** - Individuals have a right to seek an accounting of their PHI that has been disclosed without authorization during the prior 6 years. Therefore, accounting for disclosures is required when PHI is disclosed
  - ❖ under an IRB approved waiver of authorization, or
  - ❖ for purposes preparatory to research in which researcher attests in writing to the IRB such use, or
  - ❖ of decedents' information in which the researcher certifies in writing to the IRB such use.
- **The disclosure accounting must include:**
  - 1) Date and purpose of disclosure;
  - 2) Name of the recipient;
  - 3) Address of recipient, if known; and
  - 4) Brief description of the PHI disclosed.
- Note:** Contact the [Office of Compliance and Privacy](#) or the [Health Information Management Department](#) for more information about disclosure accounting.
- **For research involving more than 50 subjects** - If a researcher has disclosed the records of 50 or more individuals for a particular research purpose in which an accounting of disclosure must be tracked, a more general accounting is permitted. The researcher shall document and provide the following information according to established guidelines available on CHOP Research intranet:
  - ✓ The name and description of the protocol or other research activity;
  - ✓ A brief description of the type of PHI disclosed;
  - ✓ The date or time period of the disclosures;
  - ✓ The contact information of the researcher and the research sponsor; and
  - ✓ A statement that the PHI of the individual may or may not have been disclosed for a particular protocol or research activity.
- **Record Retention** - The following records are required to be retained for a period of ten years (in accordance with CHOP policy) by the IRB or by the Principal Investigator:
  - The signed HIPAA authorization, or combined informed consent/HIPAA authorization, for 10 years from the date the study is closed;
  - Records related to waivers of authorization or alterations of authorization, for 10 years after the individual's records are disclosed or the identifiers are destroyed;
  - A certification of statistical de-identification, in written or electronic format, for 10 years from the date of its creation or the date when it was last in effect, whichever is later; and
  - Records of PHI disclosures subject to accounting, for 10 years from the date of the disclosure.

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## ADDITIONAL REQUIREMENTS (cont.)

- **Relationship to Other Federal and State Laws** - Any federal or state law that is more restrictive continues to apply in addition to the Privacy Rule requirements outlined in this policy. For example, some types of PHI are afforded greater privacy protections by federal or state law and cannot be used or disclosed without explicitly being stated in an authorization signed by the research subject or a court order (e.g., drug or alcohol treatment or testing, HIV and mental health information). In such cases, the IRB will consult with the Office of General Counsel to determine applicable requirements for all studies involving such information.
- **Other Administrative Requirements** - Other administrative requirements are covered by the Hospital's [Patient Care Manual IM-1-01, Privacy of Patient Information](#).

## IMPLEMENTATION - ROLES AND RESPONSIBILITIES

Role	Responsibility
Office of Compliance & Privacy	<ul style="list-style-type: none"> <li>Documents and communicates the guidelines for the use and disclosure of PHI for research purposes, in accordance with the HIPAA Privacy Rule regulations.</li> <li>Reviews modifications made to stand-alone HIPAA authorizations to ensure that the authorization contains the required elements.</li> </ul>
ORCRA	<ul style="list-style-type: none"> <li>Documents and communicates the requirements for the use and disclosure of PHI for research purposes, in accordance with the HIPAA Privacy Rule regulations.</li> <li>Monitors the application of and compliance with HIPAA requirements by the IRB and research staff.</li> </ul>
IRB	<ul style="list-style-type: none"> <li>Ensures a stand-alone HIPAA Authorization Template (that is HIPAA-compliant) is available for use by researchers; and</li> <li>Ensures HIPAA authorizations that are combined with an informed consent contain the required elements.</li> <li>When appropriate, reviews and approves waivers or alternation of the HIPAA authorization requirement; and retains documentation of such for the required period.</li> <li>Acknowledges receipt of required documentation for reviews preparatory to research and use of decedents' PHI.</li> <li>Determines that the minimum necessary requirement has been met for each study reviewed.</li> </ul>
Researchers	<ul style="list-style-type: none"> <li>Obtain, as needed, a data use agreement from the OTT.</li> <li>File, with IRB, the required certifications for use of PHI preparatory to research or of decedents' information.</li> <li>Maintain HIPAA records for the required period.</li> <li>Account for disclosures as needed.</li> <li>Abide by internal and external data use agreements.</li> <li>Present required documentation to data custodians.</li> <li>Seek only the minimum information necessary to conduct the study.</li> <li>Ensure that the documentation provided to the IRB for approval of the research protocol describes, with sufficient specificity, the PHI necessary to conduct the research activity.</li> <li>Safeguard all PHI in their possession from loss, theft and/or unauthorized access/disclosure.</li> </ul>
Data Custodians/ Holders of PHI	<ul style="list-style-type: none"> <li>De-identify information so that all PHI data elements are removed.</li> <li>Remove identifiers from information in accordance with Limited Data Set Checklist.</li> <li>Obtain, as needed, a data use agreement from the OTT.</li> <li>Report to the IRB and the Office of Compliance and Privacy any incidents involving unauthorized access, use, disclosure, loss or theft of PHI or devices that contain PHI.</li> </ul>
OTT	<ul style="list-style-type: none"> <li>Prepares data use agreements, as needed.</li> <li>Prepares business associate agreements as needed.</li> </ul>



## RELATED POLICIES AND PROCEDURES

- [HIPAA and Research web page](#)
- CHOP's [Patient Privacy](#) web page
- CHOP's [Privacy of Patient Information Policy](#)
- CHOP's [Patient/Personal Representative Access to Patient Information](#)
- CHOP's [Confidentiality of Patient and Institutional Information](#)
- CHOP's [Information Security Policy](#)
- CHOP's [Rules of Conduct](#)
- CHOP's [Securing Paper Patient Health Records & Documents Containing Patient Information](#)
- IRB - [HIPAA and Research](#)
- [HIPAA Research Forms](#)
- IRB's [Policy and Procedures](#) web page, specifically the following IRB SOPs:
  - IRB SOP 402 – Criteria for IRB Approval
  - IRB SOP 706 – Waiver of Elements of Consent and Waiver of Written Authorization
  - IRB SOP 707 – Requirements for and Documentation of HIPAA Authorization in Research
- IRB's [Consent Form Template](#) web page

## REFERENCES

- [NIH and HIPAA Privacy Rule – Information for Researchers](#)
- [Office of Civil Rights – HIPAA and Research Web site](#)

## WHO SHOULD BE KNOWLEDGEABLE ABOUT THIS POLICY

Those who are responsible for following the guidelines/performing the procedures that implement this policy, those who have the oversight and/or supervisory responsibility for these guidelines/procedures, and those who have the responsibility to authorize this policy and its related processes/procedures should be knowledgeable about this policy. Refer also to [Implementation – Roles and Responsibilities](#).



## POLICY ADMINISTRATIVE INFORMATION:

### POLICY MAINTENANCE RESPONSIBILITY

**Policy Owner:** Office of Research Compliance & Regulatory Affairs; Office of Compliance & Privacy

**Policy Contact:** Deb Barnard, Director of Research Compliance & Regulatory Affairs; Beth Thornton, Director of Compliance & Privacy

### POLICY AUTHORIZATION

**Approved by:** Approved by Leadership on 08/20/13  
CHOP Research Executive Leadership

### VERSION/REVISION HISTORY

Reassessment of this policy will occur once every 24 months; interim revisions will be incorporated as needed. The table below documents the version/revision history for this policy. A cumulative history for this document is maintained for ten years.

Approval Date	Version	Version/Revision Summary
various	V1.0	Initial documentation/publications.
8/12/09	V2.0	Assessment and combination of various HIPAA/Privacy documents to create a new version document.
08/16/11	V3.0	Re-assessment and republication.
08/20/13	V4.0	Re-assessment and republication. Updates made throughout for clarification and brevity purposes.