

Children’s Hospital and Health System, Inc. Administrative Policy and Procedure

This policy applies to the following entity(s):

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| <input checked="" type="checkbox"/> Children’s Hospital of Wisconsin | <input checked="" type="checkbox"/> Children’s Hospital of WI -Kenosha | <input checked="" type="checkbox"/> Children’s Hospital of WI-Fox Valley |
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SUBJECT: *Privacy-- Uses and Disclosures of Protected Health Information (PHI) for Research Purposes*

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POLICY

PURPOSE: *The purpose of the this policy is to set forth the conditions under which individually identifiable health information protected by the regulations adopted under the federal Health Information Portability and Accountability Act of 1996 (HIPAA) (referred to as “protected health information” (PHI)) may be used or disclosed by Children’s Hospital and Health System for research purposes.*

A. Introduction

In accordance with applicable federal, state and institutional policies, CHHS has developed this policy to outline the appropriate use and disclosure of PHI for research purposes. Researchers should be advised that this policy does not supersede the requirement of all persons involved in the conduct of human subject research to comply with applicable federal regulations governing the protection of human research subjects (i.e., the HHS regulations at Title 45, Part 46 (the "Common Rule") of the Code of Federal Regulations and the FDA regulations at Title 21, Parts 50 and 56 of the Code of Federal Regulations).

B. Definitions

De-Identified: Health information is de-identified or not individually identifiable if it does not identify an individual, and if CHHS has no reasonable basis to believe that the information can be used either alone or in combination to identify an individual.

Individual: Individual means a patient or the patient's Legal Representative.

Legal Representative: A parent, guardian or other person who has authority to act on behalf of a minor patient in making decisions related to health care unless the minor patient can legally consent to health care services without the consent of an adult. For adult patients, Legal Representative means the legal guardian of an incompetent patient, the health care agent designated in an incapacitated patient's health care power of attorney, or the personal representative or spouse of a deceased patient. If no spouse survives a deceased patient, Legal Representative also means an adult member of the deceased patient's immediate family. (45 CFR 164.502(g) and Wis. Stat. §146.81(5)).

Protected Health Information (PHI): Any information, whether oral, written, electronic, magnetic or recorded in any form that:

1. Is created or received by CHHS as a health care provider,
2. Relates to an individual's past, present or future;
 - a) Physical or mental health condition
 - b) Health care treatment
 - c) Payment for health care services, and
3. Either clearly identifies an individual (such as name, social security number or medical record number) or can be used to find out the person's identity (address, telephone number, birth date, e-mail address and names of relatives or employer).

Research: Research means a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

C. Type of Research Subject to this Policy

1. Any research involving the use of CHHS PHI is subject to this policy.

D. Role of HRRB as Privacy Board

1. Privacy Board Responsibilities and Composition. The HRRB shall serve as the Privacy Board and shall have the responsibility for reviewing and approving requests to waive the requirement for researchers to obtain an individual's authorization before using his or her PHI for research purposes. Requests for authorizations for use or disclosure of PHI may be reviewed and approved by the HRRB Chair or his/her designee when the research involves no more than a minimal privacy risk to the individuals. All requests posing greater than minimal privacy risk must be reviewed by the full Board at a convened meeting conducted in accordance with the following requirements:
 - a) HRRB members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests are present;
 - b) At least one member of the HRRB who is not affiliated with CHHS, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities is present; and
 - c) No HRRB member participating in a review of the authorization waiver has an actual or perceived conflict of interest.
2. Privacy Board Documentation. In documenting its waiver decisions, the Privacy Board (or, if the request qualifies for expedited review, the IRB Chair or his or her designee) must include at least the following statements in its minutes (or, if reviewed by expedited means, a written record signed by the Chair or his or her designee):
 - a) A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board;
 - b) A statement that the waiver satisfies the criteria set forth in Section G of this policy for a waiver of authorization;
 - c) A statement that the waiver has been reviewed and approved by either the full HRRB committee or by expedited review procedures; and
 - d) A statement identifying the HRRB members present and/or the name of the expedited reviewer and the date on which the waiver request was approved.

E. Accessing PHI for Research Purposes

Under the HIPAA privacy regulation CHHS is permitted to use and disclose PHI for research purposes only under the following conditions:

1. The individual whose PHI will be used or disclosed for research-related purposes signs a written authorization, which satisfies the requirements set forth herein.
2. The HRRB approves a waiver of authorization for the research or a specified research-related use of the PHI.
3. The research or research-related use of the PHI falls within and satisfies the criteria set forth for one of the following categories:
 - a) Preparatory research; or
 - b) Research/research-related activity involving deceased individual's PHI.
4. The researcher will be using a Limited Data Set pursuant to a signed, written data use agreement with CHHS and there is a Business Associate Agreement in place with the person or entity who will create the Limited Data Set.
5. Prior to being used for research purposes, the PHI is de-identified by using one of the two following methods:
 - a) Safe Harbor/Removal of All Identifiers
 - b) Statistical De-Identification
6. De-identification can be done only by CHHS employees or Business Associates.

F. Research With Patient Authorization

1. Authorization Elements. Unless otherwise permitted under this policy, a researcher must obtain a written authorization from all research subjects before he or she may use such individual's PHI for any research related purpose. (See Section G, H and I below for research activities, which do not require an authorization.) Researchers must use the CHHS Research Authorization Form attached to this policy, and/or a CHHS-approved combined informed consent/authorization form, or an authorization form that has been approved by the HRRB and which contains all of elements listed below. (Reference Administrative Authorization Policy). Authorizations or consents missing one of the following listed elements will not be valid:
 - a) A specific and meaningful description of the PHI to be used or disclosed;

- b) The name or other specific identification of the person(s), or class of persons, authorized to disclose and/or use the PHI for research-related purposes (e.g., the hospital, the researcher);
- c) The name or other specific identification of the person(s), or class of persons who may receive and use the PHI for research-related purposes (e.g., the researcher, the hospital, the sponsor, the HRRB);
- d) A description of each purpose of the use or disclosure;
- e) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure.
- f) Signature of the individual and date. If a Legal Representative of the patient signs the authorization, a description of the Representative's authority to act for the patient must also be provided.

2. Provision of Authorization Copy to Individual. A copy of the *signed* authorization must be provided to the individual by the researcher.
3. Revocation of Authorization. Research participants have the right to cancel or revoke their authorization at any time. An individual's revocation must be in writing and presented to the researcher or the applicable CHHS Medical Record Coordinator. The revocation is effective as of the date that it is received by the researcher, however, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual pursuant to a valid authorization before it was revoked, therefore allowing activities such as the reporting of adverse events. No additional information, i.e., ongoing review of medical records, may occur after the revocation. The Researcher is responsible for ensuring that any revocation received is provided to the Patient Health Information or applicable Medical Records Department.
4. Authorization Must Inform Subject If Right to Access Research Records or Results Will Be Suspended or Delayed During Study. The HIPAA privacy regulation gives individuals the right to inspect and obtain a copy of their PHI that is maintained by a researcher or by CHHS in relation to their participation in a clinical trial, if such information impacts decisions made about the individual's care. Research records are subject to access by the individual participant only if they contain information that is used in the clinical management of the individual or for billing purposes. HIPAA allows researchers to suspend the individual's right to access such records while the clinical trial is in progress, if the authorization clearly identifies and explains that access rights may be suspended or delayed. Once the trial is concluded, the investigator must give the individual access to inspect any records that meet the definition of a designated record set. (See Administrative Policy Designated Record Set).

G. Research with HRRB Approval of a Waiver of Authorization

1. Criteria for Approval. Researchers seeking a waiver of authorization must complete a Request for Privacy/Board Waiver of HIPAA Authorization for Research form (attached to this policy) that provides an explanation of how, and certifying that in fact, all of the following criteria are satisfied:

- a) The use of disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
 - i. An adequate plan to protect the identifiers from improper use and disclosure;
 - ii. 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; and
 - iii. Adequate written assurances that PHI 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 PHI would be permitted.
- b) The research could not practicably be conducted without the waiver or alteration; and
- c) The research could not practicably be conducted without access to and use of the PHI.

2. Minimum Necessary. The researcher also must certify in his or her waiver request that the PHI requested is the minimum amount of information necessary to conduct the research or the research-related activity.
3. Accounting of Disclosures. The researcher also must document his or her plan to ensure that disclosures of the PHI are tracked as required under the HIPAA privacy regulation in order for CHHS to be able to generate an accounting of disclosures for the individual. (Refer to Administrative Policy – [Accounting for Disclosures](#)).

H. Reviews Preparatory to Research

1. Description of Preparatory Research. The preparatory research exception to authorization allows researchers to access medical records or other sources of PHI to conduct research-related activities. For example, a researcher may assess how many patients with a certain diagnosis exist at CHHS to establish whether CHHS would be an appropriate recruiting site. Alternatively, a researcher may desire access to PHI to assist in formulating his or her hypothesis or establishing appropriate inclusion and exclusion criteria for their protocol. **At the point when the researcher needs to record PHI, even if only name, address, telephone number for purposes of recruiting, another PHI access method must be used (e.g., authorization or Privacy Board waiver of authorization).**
2. Criteria for Approval. PHI may be used or disclosed for research purposes without individual authorization or a waiver of authorization where a review of such information is conducted

preparatory to research (e.g., to assist in the development of a research hypothesis). Before CHHS will grant a researcher access to PHI for preparatory research activities, the researcher must certify in writing using the Request to Access PHI for Preparatory Research Form attached to this policy:

- a) The title of and reason for the research;
- b) A list of PHI the researcher intends to use and the plan for pre-screening the PHI
- c) That the use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
- d) That no PHI will be recorded or removed by the researcher from CHHS in the course of the review; and
- e) That the requested PHI is necessary for the research purposes.

3. Minimum Necessary. The researcher also must certify in his or her waiver request that the PHI requested is the minimum amount of information necessary to conduct the research or the research-related activity.
4. Accounting of Disclosures. The researcher also must document his or her plan to ensure that disclosures of the PHI are tracked as required under the HIPAA privacy regulation in order for CHHS to be able to generate an accounting of disclosures for the individual.

I. Research on Decedent's Information

1. Criteria for Approval. For research conducted on decedents' information, the researcher must certify in writing the following by completing a Request to Access PHI of Deceased Patients for Research Purposes attached to this policy:
 - a) The use or disclosure of the information sought is solely for research on the PHI of decedents and no Legal Representative will be contacted;
 - b) Documentation, at the request of CHHS, of the death of the patient(s) about whom information is being sought; and
 - c) That the PHI for which use or disclosure is sought is necessary for research purposes.
2. Minimum Necessary. The researcher also must certify in his or her request that the PHI requested is the minimum amount of information necessary to conduct the research or the research-related activity.

3. Accounting of Disclosures. The researcher also must document his or her plan to ensure that disclosures of the PHI are tracked as required under the HIPAA privacy regulation in order for CHHS to be able to generate an accounting of disclosures for the individual.

J. Limited Data Sets

1. Description. A Limited Data Set is a compilation of data de-identified as described below that may be used or disclosed by a researcher for research purposes pursuant to a written data use agreement with CHHS. To constitute a Limited Data Set, PHI must be stripped of all of the following direct identifiers regarding the individual, and the individual's relatives, employers, and household members of the individual:
 - a. Names
 - b. Street address information, other than town or city, state and zip code
 - c. Telephone numbers
 - e. Fax numbers
 - f. E-mail addresses
 - h. Medical record numbers
 - g. Social Security number
 - i. Health plan beneficiary numbers
 - j. Account numbers
 - k. Certificate/license numbers
 - l. Vehicle identifiers and serial numbers, including license plates
 - m. Device identifiers and serial numbers
 - n. Web Universal Resource Locators (URLs)
 - o. Internet Protocol (IP) address numbers
 - p. Biometric identifiers, including finger and voice prints
 - q. Full face photographic images and any comparable images

Notably, a Limited Data Set may, however include the individual's town, city, state and zip code and all dates directly related to an individual, including birth date, admission date, discharge date, and date of death. A researcher may de-identify the data if the researcher enters into a Business Associate Agreement with CHHS and agrees to destroy all data with identifiers after the de-identification process is complete.

2. Criteria for Approval. Prior to accessing a Limited Data Set containing PHI of CHHS, a researcher must sign a data use agreement specifying the following:
 - a) The permitted uses and disclosures of the information by the recipient;
 - b) That the researcher will not further use or disclose the Limited Data Set;
 - c) Who is permitted to use or receive the Limited Data Set; and

- d) That the researcher will:
 - a. Not use or further disclose the information other than as permitted by the agreement or as otherwise required by law;
 - b. Use appropriate safeguards to prevent unauthorized use or disclosure of the Limited Data Set;
 - c. Report to CHHS any unauthorized use or disclosure of which it becomes aware;
 - d. Ensure that any agent to whom it provides the Limited Data Set agrees to the same restrictions and conditions; and
 - e. Not identify or contact the individuals.

3. Minimum Necessary. The researcher also must certify in his or her waiver request that the PHI requested is the minimum amount of information necessary to conduct the research or the research-related activity.

K. De-Identification

1. Circumstances Requiring De-Identification

- a) PHI must be de-identified if a use or disclosure of PHI normally requires an authorization and one has not been obtained. De-identification allows PHI to be used and disclosed without being subject to the Privacy Rule.
- b) De-identification must be performed when using or disclosing information for certain health care operations or the collection of data to be used preparatory to research.

2. Procedure for De-Identification.

- a) The following identifiers of the individual, and the individual's relatives, employers and household members must be removed for purposes of de-identification:
 - a. Name
 - b. Street address, city, county, precinct, zip code
 - c. All dates (excluding year) for admission date, discharge date and dates of death and birth. (The year must be de-identified for those individuals 89 years and older.)
 - d. Telephone numbers
 - e. Fax numbers
 - f. E-mail addresses
 - g. Social Security number
 - h. Medical record numbers
 - i. Health plan beneficiary numbers
 - j. Account numbers
 - k. Certificate or license numbers

- l. Vehicle identifiers and serial numbers including licenses plates
 - m. Device identifiers and serial numbers
 - n. Web Universal Resource Locators (URLs)
 - o. Internet Protocol (IP) address numbers
 - p. Biometric identifiers such as finger and voice prints
 - q. Full face photos and other comparable images
 - r. Any other unique identifying number, characteristic or code
- b) The person who will use or disclose PHI is responsible for de-identifying it. De-identification can be performed only by CHHS employees or Business Associates.
 - c) Original documentation must never be altered. The only acceptable method for de-identifying a medical record document is:
 - a. Make a photocopy of it,
 - b. Use a marker to black out all of the patient identifiers described above, and
 - c. Make a photocopy of the blacked-out photocopy because the identifiers may be readable even though they were marked over.

L. Accounting for Research Disclosures

1. Right to An Accounting of Disclosures. The HIPAA privacy regulation gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure. (Refer to Administrative Policy and Procedure [Accounting for Disclosures](#))
2. Research Disclosures, Which Must Be Tracked. Among the types of disclosures for which an accounting may be requested by an individual are:
 - a) Research disclosures made pursuant to a waiver of authorization;
 - b) Research disclosures made for preparatory research; and
 - c) Research disclosure made of decedent's PHI.
3. Research Disclosures Not Subject to Accounting Requirement. Among the types of disclosures that do not need to be tracked are:
 - a) Research disclosures made pursuant to an individual's authorization; and

- b) Disclosures of the Limited Data Set to researchers with a data use agreement.

4. Required Information/Process for Accounting of Disclosures. The accounting of disclosures must contain at least the following information:

- a) The date of the disclosure (if multiple disclosures, the start and stop dates and the frequency);
- b) The name of the entity or person who received the PHI and, if known, the address of such entity or person;
- c) A brief description of the PHI disclosed; and
- d) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure.

5. Modified Accounting Requirement For Studies Involving More Than 50 Participants. For research and/or research-related disclosures of PHI involving 50 or more participants, the HIPAA privacy regulation allows for a simplified accounting process. Under this simplified accounting process, covered entities may provide individuals with a list of all protocols for which the individual's PHI may have been disclosed, as well as the researcher's name and contact information.

M. Recruitment of Individuals into a Research Study

1. Recruitment Generally. Consistent with CHHS policy, a health care provider is free to discuss all available treatment options, including experimental treatments, with his or her patients. However, researchers who wish to obtain PHI about an individual with whom they do not have a direct treatment relationship may not access PHI for the purposes of recruitment without obtaining an authorization from the individual or receiving a waiver of such authorization from the HRRB.

2. Examples of Allowable Recruitment Strategies:

- a) A researcher contacts his/her own patients to invite their participation in research.
- b) A treating physician may share de-identified information with a researcher to determine a patient's eligibility for a study in accordance with the requirements for de-identification discussed above without seeking a waiver of authorization.
- c) A researcher sends out an HRRB-approved letter to colleagues asking for the referral of eligible patients who may be interested in participating in the researchers study. The treating physicians are invited to contact potential

research participants using an HRRB-approved “Dear Patient” letter. Patients who wish to be contacted to learn further about the study must complete and sign an authorization to be contacted.

- e) A researcher may develop and post HRRB-approved recruitment materials (e.g., flyers, WebPages, newspaper announcements, etc.) describing the nature of the study and inviting the participation of interested individuals.
- f) A researcher may seek HRRB-approval for an authorization waiver and then, upon receiving approval of the waiver, access individuals PHI for recruitment purposes.

N. Transition Provisions

1. Ongoing Research For Which Authorization or Waiver is Not Required On or After April 14, 2003. Hospital researchers may continue to use or disclose a participant’s PHI that was created or received for a specific study *either before or after April 14, 2003* (provided that there is no agreed to restriction), if one of the following was obtained prior to that date:
 - a) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;
 - b) The informed consent of the individual to participate in the research; or
 - c) A waiver of informed consent by an HRRB in accordance with the Common Rule or an exception under the FDA’s human subject protection regulations.
2. Ongoing Research Which May or Will Require an Authorization or a Waiver of Authorization On or After April 14, 2003.
 - a) Informed consent form is not signed prior to April 14, 2003;
 - b) The research was exempt from IRB review (no waiver of informed consent was obtained) but involves PHI (i.e., data collected does not satisfy either the safe harbor de-identification standard or the statistically de-identified standard); or
 - c) If a waiver of informed consent was obtained prior to the compliance date, but informed consent is subsequently sought after the compliance date (e.g., if there was a temporary waiver of informed consent for emergency research under the FDA’s human subject protection regulations, and informed consent was later sought after the compliance date).

O. Reporting of Violations or Suspected Violations of this Policy

All violations or suspected violations of this policy should be reported to the CHHS Privacy Officer.

PROCEDURE

A. General

1. All requests for protected health information, medical records, or electronic data from CHHS for research purposes must go through the Patient Health Information Department or applicable Medical Record Coordinator.
2. Protected health information should not be used or disclosed for research purposes without following one of the procedures outlined in B through F.

B. HRRB Approved Study with Patient Authorization

1. In order for a researcher to receive PHI from CHHS, the following items will have to be submitted before any information is released:
 - a) Copy of the research protocol (one copy must be submitted the first time information is requested and when there are updates and/or changes to the protocol)
 - b) Signed Consent Form stamped with the HRRB Approval stamp (need a consent form for each individual's PHI being reviewed)
 - c) Approval Letter
 - d) Application (2 page document)
 - e) A list signed by the Principal Investigator with any members of the research team who may be requesting PHI who are not listed on the application.
2. If any of the items a through e above are missing, the request to obtain PHI will be denied.
3. Any researcher not identified on the application or a separate list signed by the Principal Investigator of the study, who requests PHI, will be denied access to PHI.
4. If all of the items are submitted, the request for PHI will be processed by the Patient Health Information Department or applicable Medical Record Coordinator.
5. The disclosure(s) of the PHI will be tracked in the Patient Health Information or appropriate CHHS Medical Records Department.

C. HRRB Waiver

1. If a waiver has been obtained by the HRRB, the Principal Investigator will need to submit the following in order to receive PHI from CHHS:
 - a) Copy of the approved Waiver of Authorization Form from the HRRB
 - b) The name of each individual whose information will be reviewed

2. If this document is not obtained or not completed to CHHS's satisfaction, the request to receive or review PHI will be denied.
3. If the document is provided and completed adequately, the Patient Health Information Department or applicable Medical Record Coordinator will process the request for PHI.
4. The information disclosed will be tracked in the Patient Health Information or appropriate CHHS Medical Records Department.
5. Once the information is released or disclosed, the copy of the Request for Approval or Waiver of Authorization Form will be filed in the patient's medical records.

D. Preparatory to Research/Research on Decedent's Information

1. For information requests that are preparatory to research, the Principal Investigator or designee will need to submit the following in order to receive PHI from CHHS:
 - a) Copy of the completed Request for Access to PHI for Preparatory Research or Request to Access PHI of Deceased Patients for Research form, as appropriate.
 - b) The name of each individual whose information will be reviewed
 - c) If the purpose is to research decedent's information, investigator must provide documentation of death of such individuals proposed in the research
2. If information listed above is not obtained or does not contain all the required elements, the request to receive or review PHI will be denied.
3. If the information is provided and contains the required information, the Patient Health Information Department or applicable Medical Record Coordinator will process the request for PHI.
4. The information disclosed will be tracked in the Patient Health Information or appropriate CHHS Medical Records Department.

E. Limited Data Set

1. In order for a Principal Investigator or designee to receive a limited data set from CHHS, the Principal Investigator or designee will need to submit the following:
 - a) Copy of the approved Request for Approval or Waiver of Authorization Form from the HRRB
 - b) A CHS Data Use Agreement
2. If the Principal Investigator or designee does not have a Data Use Agreement, the Patient Health Information Department or Medical Record Coordinator will facilitate the process of obtaining one.
3. Once the Data Use Agreement has been signed by the Principal Investigator, the request will be processed.

4. The Patient Health Information Department or Medical Records Coordinator may assign a code or other means of record identification to allow information de-identified to be re-identified. This code will be kept in the Patient Health Information or applicable Medical Records Department and will not be disclosed to the recipient of the information.

F. De-identified PHI

1. In order for a Principal Investigator or designee to receive de-identified PHI from CHS, her or she will need to submit a Copy of the approved *Request for Approval or Waiver of Authorization Form* from the HRRB.
2. The information requested will be provided according to the De-identification procedure in Section K of this policy.
3. The Patient Health Information Department or Medical Records Coordinator may assign a code or other means of record identification to allow information de-identified to be re-identified. This code will be kept in the Patient Health Information or applicable Medical Records Department and will not be disclosed to the recipient of the information.

[Privacy-Authorization for Protected Health Information form](#)
[Privacy-Authorization for Protected Health Information form-Spanish Version](#)

DISTRIBUTION: Administrative Policy Manual

AUTHORIZATION: Director, Patient Health Information
Corporate Compliance Officer
Corporate Vice President –General Counsel
Directors of Clinical Operations
Vice President Finance, Chief Financial Officer

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