

**Children's Hospital Institutional Review Board  
Information Sheet  
Federal Privacy Rule – HIPAA and Research**

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**1)           *What is HIPAA?***

HIPAA stands for the Health Insurance Portability and Accountability Act. **This information sheet focuses on the HIPAA privacy rule as it pertains to use of health care information in research. The HIPAA privacy rule went into effect on April 14, 2003.**

**2)           *What is the HIPAA privacy rule?***

The HIPAA privacy rule provides a number of privacy standards for use, access and disclosure of health information. The privacy rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. A covered entity includes health care providers (organizations and individuals), health plans (insurers and payors), and health care clearinghouses (billing services). **Children's Hospital and Regional Medical Center is a covered entity.**

**3)           *How does the federal privacy rule impact researchers?***

**Washington state law and federal regulations for human subjects research have always required IRB review of research involving participants' confidential, private health care information. Washington State law (the Uniform Health Care Information Act) has strict privacy provisions to protect individuals whose health care information is being used in research.**

Under the federal privacy rule, researchers need to:

- Provide specific information to IRBs on how protected health information may be used, created or shared in individual research studies. For example, *“existing medical records will be **used** to determine if the individual is eligible to take part in the research and if it is safe for the individual to do so. PHI will be **shared** with the data and safety monitoring board, data coordinating center, regulatory agencies, e.g., U.S. Food and Drug Administration, the study sponsor, and designees of the study sponsor, e.g., Clinical Research Organization monitoring the study.”*
- Provide research participants and their representatives, i.e., parents or legal guardians, specific information on how their or their child's health care information will be used, created or shared during the research study;

- Obtain permission (authorization) from research participants or their parents to use, create or share the participants' protected health information for the research. In some cases the IRB may waive the requirement for authorization if the IRB finds the HIPAA criteria for waiver of authorization are met (see section 9. below).

#### 4) ***How does the federal privacy rule apply to research participants?***

Under the federal privacy rule research participants or in the case of children, their parents have the:

- Right to privacy of their/their child's protected health information;
- Right to authorize use of identifiable PHI for research purposes;
- Right to an accounting from the covered entity of how their/their child's identifiable PHI was disclosed without their authorization. Patients or their parents may request an accounting for the past six years;
- Right to revoke authorization in writing. No further PHI may be collected for the research after the authorization is revoked. (Researchers may continue to use and disclose PHI that was collected under the authorization to maintain the integrity of the research. Such uses might include adverse event reporting, submissions of marketing applications to FDA, accounting for participants withdrawal from the research, investigation of scientific misconduct.)

#### 5) ***How does the HIPAA privacy rule affect research approved before April 14, 2003?***

- **Beginning April 14, 2003, all research participants enrolled in a research study with consent must also sign an authorization form allowing their PHI to be used in the specific research study.** Children's requires a separate authorization form to be used for research that involves protected health information (PHI). The authorization form is explained in section 6.
- Research participants, who were enrolled in a research study **before** April 14 2003, do not have to sign a separate authorization form. The consent form they signed is valid. However, if the research involves changes and participants **are re-consented (asked to sign a new consent form) after April 14, 2003**, then the researcher must also obtain authorization to use PHI for the research.
- If the IRB approved a waiver of consent (permission) for the research before April 14, 2003 under existing federal regulations, the waiver of consent remains valid. However, effective April 14, 2003, **disclosures** of protected health information under a waiver of authorization must be tracked. See sections 10 and 11 for information on tracking (accounting) of disclosures of PHI.

6) ***How do I create and use the authorization form for my research study?***

**Creating a HIPAA Authorization Form For Your Project**

- **Children’s has prepared an authorization form to be used for research studies that use, create or share protected health information.** The authorization form is titled “Permission to Use, Create and Share Health Information for Research” and is found on the IRB web site under Forms and under HIPAA and Research <http://irb.seattlechildrens.org>.
- In some unique cases, the majority of research participants may be based at sites other than Children’s. If there is another authorization form that is more appropriate for use with patients at other sites, you may request the IRB to consider use of another covered entity’s authorization form.
- The text of Children’s authorization form is protected and **may not** be altered. However, there are specific fields within the form that are completed by the researcher. The following fields need to be completed for each research study authorization form:
  - The title of the research study;
  - The IRB study number;
  - The name of the sponsor;
  - The specific types of information that will be collected;
  - The names of other centers taking part in the study that will receive research data with protected health information (PHI);
  - The names of others that may receive PHI collected or created during the research;
  - The length of time the permission will last;
  - The name and address of the principal researcher;
  - The signature section for the research participant and the researcher obtaining authorization;
  - **If the participant is a Children’s patient (i.e., has a Children’s medical record), researchers must complete an additional section in the box at the end of the form.** Provide the medical record number and date of birth of the research participant.

For new IRB applications, submit a copy of the authorization form with your IRB application. For existing, approved IRB applications, submit a copy of the authorization form to the Human Subjects Protection Program, Office of Institutional Assurances, Mailstop MPW5-1. The copy will be placed in your IRB file.

## **Obtaining a Signed Authorization**

- At the time of consent, the research team member obtaining consent will also obtain authorization to create, use and share PHI as part of the research project. The person obtaining authorization will explain the authorization form and answer questions. **Authorization is obtained from the participant if they are an adult (18 and older) or the parent (if the research participant is under 18 years of age.) The person authorizing use of their/their child's PHI needs to sign and date the authorization form.**
- Attach the signed authorization form to the signed copy of the research consent form. It is important that the principal investigator retain the signed and dated research consent form and authorization form in their research records.
- Provide the participant or their parent a **copy** of the signed authorization form.
- If the research participant is a Children's patient, send a **copy** of the signed authorization form to Medical Records-Filing Mailstop A-4902. **Be sure you have provided the information requested in the box at the end of the form for Children's patients. This information is necessary to file the authorization form in the patient's medical record.**

### **7) *What is protected health information (PHI)?***

Protected health information (PHI) includes all individually identifiable health information transmitted or maintained by a covered entity. It includes information on:

- past, present or future physical or mental conditions;
- past, present or future provision of care to individuals;
- or past, present or future payment for provision of health care to individuals.

PHI includes information that is recorded electronically, on paper, or orally. PHI includes living individuals and individuals who have died (referred to in the law as "decedents"). **PHI does NOT include information that has been "de-identified" (see section 8). Biological tissue or specimens are not considered PHI if they have been de-identified.**

### **8) *What is considered identified and de-identified health information?***

Individually identifiable means the information identifies the individual or can identify the individual. There are 18 items under the federal privacy rule that are considered identifiers.

The 18 identifiers include:

- Names
- Medical Record Numbers

- Geographic subdivisions smaller than a state (street address, city, county, zip code)
- All elements of dates – date of birth, date of death, date of services, e.g., transplant, surgery, admission and discharge dates, and all ages over 89
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate and license numbers (including driver’s license)
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locator (URL)
- Biometric identifiers, including finger or voice prints
- Full face photographic images or comparable images
- Internet Protocol Address numbers
- Any other unique identifying number, characteristic or code (including unique study codes)

**De-identified health information** would be health care information that does not contain any of the identifiers listed above.

HIPAA also allows the use of statistical methods to establish de-identification instead of removing all 18 identifiers. Under this approach a person knowledgeable about statistical and scientific principles and methods must certify that there is a very small risk that the information provided to the recipient could be used to identify individuals who are the subject of the information. This certification must document the methods used as well as the result of the analysis that led to the determination.

When reviewing a research that uses “de-identified” health information, the IRB needs to review all the data fields that will be used in the research project to be assured that the PHI information collected could not be used to identify the individual.

## **9) *What is a waiver of authorization?***

Under the federal privacy rule researchers may ask the IRB to approve a waiver of authorization. If you are requesting the IRB to approve the use of protected health information for research purposes without authorization from the patient or the parent, the following criteria for waiver of authorization under HIPAA must be met:

- **The use or disclosure of PHI will involve no more than minimal risk to the privacy of the individual.** To qualify as minimal risk, the researcher must explain:
  - Their plan to protect PHI from improper use or disclosure;

- When identifiers will be destroyed. This must be done at the **earliest** opportunity consistent with the purposes of the research;
  - Written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research participant;
  - Identify and justify what identifiable information is needed. Researchers applying for a waiver must request only the **minimum necessary** amount of protected health information needed for the research.
- **The research could not practicably be conducted without the waiver;**
  - **The research could not practicably be conducted without access to PHI.**

Children’s IRB anticipates that most requests for waiver of authorization will be for research involving the review of existing records, data or specimens (e.g., chart review). For such research studies, researchers would complete:

- The IRB application form entitled “For Research Involving the Use of Existing Confidential Data, Records or Specimens” available on the IRB web site under Forms. <http://irb.seattlechildrens.org/forms.asp>
- The Oath of Confidentiality. Also, available on the IRB web site under Forms, HIPAA Related Forms.

**Researchers may also need to review PHI to recruit potential research participants.** For example, researchers may want to review a clinical database to obtain names and addresses of patients who meet the research entry criteria in order to send them a letter inviting them to take part in the research. **Recruitment of potential research participants is part of the research project and requires IRB review and approval before any recruitment procedures are initiated.**

The IRB may approve a waiver of authorization for purposes of recruiting potential research participants when the following conditions are met:

- Only the minimal necessary information needed to recruit participants is recorded;
- All PHI recorded for recruitment purposes remains within Children’s, the covered entity. PHI recorded for recruitment purposes may not be disclosed to persons outside of Children’s.
- If a potential research participant does not respond to recruitment efforts or declines to take part in the research, all PHI collected on that individual is to be destroyed.
- Only PHI on participants who consent to take part may be retained. These participants (or their parents) will sign and date the research consent form **and** the authorization form to allow use of their PHI in the research project.

Researchers who wish to obtain a waiver of authorization for recruitment purposes would make the request to the IRB and complete the **Oath of Confidentiality – Recruitment. (This version of the Oath is solely for a waiver of authorization for recruitment**

purposes. Do not confuse with the Oath of Confidentiality used for waiver of authorization for the entire research project.) This version of the Oath is found on the IRB website, under Forms or under HIPAA and Research <http://irb.seattlechildrens.org/>.

## 10) **When do researchers need to track disclosures of PHI?**

Under HIPAA, patients have the right to obtain an accounting of how their (their child's) PHI was disclosed without their authorization. Covered entities must track disclosures of PHI that were done without authorization, i.e., with a waiver of authorization, beginning April 14, 2003. Covered entities must keep records of unauthorized disclosures for six years. This accounting requirement includes PHI disclosed for research purposes.

To understand accounting for disclosures it is important to understand the terms "use" and "disclosure." In general, "use" refers to communicating PHI within the covered entity. "Disclosure" means communicating information outside the covered entity or from a health care component to a non-health care component of a hybrid entity.

Researchers who fall into one of the following categories would be considered part of Children's workforce:

- Employee of Children's
- Employee of Children's University Medical Group (CUMG)
- Residents and fellows working at Children's

If all research team members are part of Children's workforce, use of patients' PHI for research without authorization would be considered a **use**. This means you do not need to track (or account for) the patients whose private health information was used in the research.

If any research team member is not part of Children's workforce, access to patients' PHI for research purposes without authorization would be considered a **disclosure**. **All such disclosures require tracking (or accounting).**

The information that needs to be tracked includes:

1. Patient Name;
2. The date of the disclosure;
3. The name of the principal investigator who received the PHI and address;
4. A brief description of the PHI disclosed;
5. A brief purpose statement that reasonably informs the individual (patient or parent) of the basis for the disclosure.

Children's has prepared a form for researchers to use to track disclosures. The Research Disclosure Tracking Form is available on the IRB web site, under Forms and under HIPAA and Research.

**In summary, no accounting is required for:**

- **PHI disclosed with an authorization.**
- **“De-identified” PHI.** (See section 8 on what is identified and de-identified PHI.) If a member of Children's work force reviews a Children's medical record (electronic or paper) and records the information in a de-identified manner this is considered a use and does not require accounting. If a person outside Children's work force, e.g., a medical or nursing student, reviews the medical record and records data in a de-identified form, this is considered a disclosure and requires tracking.
- **“Limited data sets.”** (Limited data sets are defined below in section 13).
- **PHI used by persons within Children's for purposes of recruiting participants.**
- **PHI obtained under waiver of authorization if used within the covered entity (all members of the research team are considered part of Children's workforce).**

## **11) *How do I track disclosures of PHI when it is required?***

**Tracking is required when the research involves access to PHI without authorization from the patient or parent and there are members of the research team who are not part of Children's work force.** Children's has several methods of tracking the disclosure of PHI for Research, depending on the source of the information.

Researchers requesting and receiving protected health information from a Children's department (e.g., Medical Records, Decision Support, Laboratory) are responsible for notifying the department that tracking is required.

Researchers accessing PHI on their own via CIS or other databases or records, are responsible for tracking that access. Access to PHI may be recorded on a Web-based form or in hardcopy (the links to the web form and paper form are on the IRB website). Instructions for completing the form are included on the form.

Submit your Disclosure Tracking Form on line or mail a hardcopy to Medical Records, mailstop A-4902. Please send these tracking reports on a monthly basis.

## **12) *How do I request access to patient medical records?***

To access medical records (in paper form) for research purposes, complete a Research Study Chart Pull Request form. This form is available on the IRB website or from the Medical Records File Room, P-401. Complete the form and send to the Medical

Records-Filing Department (Room P-401 or mailstop A-4902). **Include documentation of IRB approval with the completed form.**

If you do not know the charts you would like pulled and are contacting Medical Records to develop a list based on a set of search criteria, complete all fields except the patient information, and send the form along with IRB approval letter to Carol Bettis in Medical Records (A-4902) and discuss selection criteria with her. Once you have determined your list of patients and medical record numbers, provide the list to Medical Records Filing.

If your research project requires tracking (project contains researchers who are not part of Children's workforce) indicate this on form.

For other areas from which you may request patient health information, e.g., Decision Support, Laboratory, Radiology, please provide the study's IRB approval letter and complete any other information about the request that may be required. **If your research project requires tracking (project contains researchers who are not part of Children's workforce) you must indicate this when requesting PHI from other departments.**

### **13) *What is a limited data set and data use agreement?***

Limited data sets contain a limited number of identifiers from the list of 18. A limited data set may include:

- 1) Date of birth; date of death
- 2) Dates of admission, discharge or service dates
- 3) Age
- 4) Geographical information such as state, county, city, precinct or 5 digit zip code.

Children's may **disclose** a limited data set for research purposes to researchers who are not part of Children's workforce after there is IRB approval for the research. Researchers who receive this limited data set are required to sign a data use agreement with the covered entity. The data use agreement specifies permitted uses and disclosures, who may use or receive the data set, restricts further use and disclosure, restricts re-identification of data or contact with the individuals as well as the disposition of the data set when use is complete.

For research that requires a data use agreement with Children's, contact Research Contracts in the Office of Sponsored Research by email at [ResContracts@seattlechildrens.org](mailto:ResContracts@seattlechildrens.org).