

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

---

## **1) *What is HIPAA?***

HIPAA stands for the Health Insurance Portability and Accountability Act. The purpose of the Act was to make it easier for persons to transfer their health care information from one insurer or provider to the next. Congress was to pass a medical record privacy act by August 1999 and if it did not, the Department of Health and Human Services (DHHS) would develop the privacy regulations. Congress did not pass an act by the deadline and DHHS issued proposed regulations in November 1999. After public comment, a final rule was published in December 2000 which was put on hold in January 2001. Further public comment was received. The final privacy Rule was issued on August 14, 2002.

There are other parts to HIPAA that involve national standards for transferring electronic data between providers and health plans and security standards for protecting the confidentiality and integrity of health care information. **This information sheet focuses on the final privacy rule as it pertains to use of health care information in research.**

## **2) *When does the HIPAA privacy rule take effect?***

The HIPAA privacy rule compliance date is April 14, 2003.

## **3) *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). **Researchers who use, create or share health care information are a covered entity. Children's is a covered entity.**

Under the federal privacy rule researchers are permitted to use and disclose health care information for research if they have individual authorization from the individual or the individual's legally authorized representative, i.e., the parent or legal guardian when the research involves children. Under limited circumstances, the researcher may request a waiver of authorization from the IRB.

## **4) *How will the new federal privacy rules 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's Uniform Health Care Information Act**

**already has strict privacy provisions to protect individuals whose health care information is being used in research.** Implementation of the new federal privacy rules will have a much smaller impact on local researchers than on researchers in other parts of the country.

Under the new federal privacy rules, researchers will need to:

- provide more specific information to IRBs on how protected health information may be used, created or shared in individual research studies.
- provide research participants and their representatives, i.e., parents or legal guardians, more specific information on how their or their child's health care information will be used, created or shared during the research study. Research participants will need to give permission (authorization) for the use of their protected health information. In some cases authorizations may be waived by the IRB if it finds the waiver criteria are met.

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

- **All research participants who are enrolled in a research study beginning April 14, 2003 must sign an authorization form allowing their PHI to be used in the specific research study.** Note this presumes your research was approved with a requirement to obtain informed consent from participants or their parents (when participant is a minor). Children's has prepared a standard authorization to be used for research that involves protected health information (PHI).
- 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), then the researcher must also obtain authorization to use PHI for this 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, the privacy rule does go into effect on April 14, 2003 and any disclosure of identifiable PHI collected or disclosed under the waiver must be tracked. See the section on tracking (accounting) of disclosures of PHI below.

**6) *How do I use the authorization form?***

- The authorization form is titled "Permission to Use, Create and Share Health Information for Research." The form contains the required elements for authorization under HIPAA <http://www.seattlechildrens.org/programs/research/IRB/HIPPA.htm>
- **Children's authorization form must be used for all research studies that use, create or share protected health information.**
- The text in the form is protected and **may not** be altered by the researchers.

- For each research project, the researchers need to include the following five items information specific to the research project:
  - Top of page 1, the title of the research study
  - Page 1, provide the name of the sponsor
  - Page 1, provide the name of the other centers taking part in the study
  - Page 1, provide the name of others that may receive PHI collected or created during the research
  - Page 2, the name and address of the principal researcher
- Provide the participant or their parent a copy of the signed authorization.
- Attach the signed authorization form to the signed copy of the research consent form. It is important that the principal investigator retain signed copies of the research consent form and the signed authorization form in their research records.
- Send a copy of the signed authorization form to Medical Records-Filing Mailstop 4P-2.
- **For research that was approved before April 14, 2003, researchers do not need to send a modification request to the IRB to use Children's standard authorization form. Researchers must begin using the standard authorization form on April 14, 2003 and thereafter. At the time of renewal, with your renewal materials please enclose one copy of the authorization form used for the specific research study.**
- **For research approved after April 14, 2003, the IRB will request the authorization form to be completed as part of the IRB approval.**

## **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." 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. 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 are the requirements for obtaining an authorization for use of PHI?**

Under the federal privacy rule, the following elements are required in an authorization:

- What PHI will be used or disclosed – the description is to be meaningful and specific

- Who may use or disclose the PHI.
- Who may receive the PHI
- Why the use or disclosure is being made – each purpose
- How long the use or disclosure will continue – an expiration date on the authorization
- That the authorization may be revoked (cancelled)
- That the information may be disclosed to others not subject to the Privacy rule
- How the authorization will affect treatment or payment
- Individual's signature and date

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

Under the federal regulations for protection of human subjects in research there are specific criteria that must be met for the IRB to approve a waiver of consent. Waivers of consent are granted in very limited circumstances. **The most common request Children's IRB receives for waiver of consent involves research using existing data, specimens or records.** Children's anticipates that most requests for waiver of authorization to use protected health care information for research will involve retrospective review of existing data, records, or specimens. Note that when the IRB receives such a request for waiver, both the federal regulations for the protection of human subjects and the federal privacy rules for PHI will apply. **Effective April 14, 2003, all researchers requesting waiver of authorization to use PHI will need to use the new IRB application "For Research Involving the Use of Existing Confidential Data, Records or Specimens."**

Researchers may wish to use PHI to recruit potential research participants. Recruitment of research participants is part of research and requires IRB review and approval. To use PHI to recruit participants the researcher needs to request a waiver of authorization from the IRB. If researchers wish to request a waiver of authorization to recruit participants they must meet the criteria for waiver as described below.

To apply for a waiver of authorization to use PHI in research the research must meet the following criteria:

- The use or disclosure of PHI will involve no more than minimal risk to the privacy of the individual.
- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to PHI

To qualify as minimal risk, the researcher must also 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.

### **11) What additional information does the IRB need to ensure compliance with the new federal privacy rule (HIPAA)?**

**When completing the IRB application, researchers need to identify how PHI will be used or created in the research.** For example, existing medical records will be used to determine if the individual is eligible to take part and to ensure that it is safe for the individual to take part. PHI will be used to monitor ongoing participants for safety and well-being. Researchers must also explain how PHI will be disclosed or shared with others including data and safety monitoring boards, data coordinating centers, regulatory agencies, e.g., U.S. Food and Drug Administration, the study sponsor, designees of the study sponsor, e.g., Clinical Research Organization monitoring the study.

Researchers must also provide an authorization form or a request for waiver of authorization to use and disclose PHI in the research study.

### **12) 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.

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 of the basis for the disclosure

Use the Accounting for Disclosure Tracking Form on the IRB web page.  
<http://www.seattlechildrens.org/programs/research/IRB/HIPPA.htm>

**No accounting is required for:**

- **PHI disclosed with an authorization.**

- **“De-identified” PHI.** (See section on what is identified and de-identified PHI.)
- **“Limited data sets.”** (Limited data sets are defined below).
- **PHI disclosed to persons within Children’s for purposes of recruiting participants, e.g., 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. The IRB will only allow PHI on individuals to be retained if the individual or their representative agrees to take part in the research and signs a research consent form and the Children’s authorization form to use PHI in the research study.**

### **13) *How do I use the accounting for disclosure of PHI without authorization tracking form?***

At this point, Children’s is using a paper-based method to track disclosures of PHI without authorization. Children’s is however exploring developing a database that will facilitate data entry and tracking.

1. The accounting for disclosure of PHI tracking form must be used for all research projects that the IRB granted a waiver of authorization.
2. For each research project, the researcher needs to complete the tracking form including:
  - Research Study Title
  - IRB#
  - Principal Investigator’s Name
  - Check if authorizations have been waived for this study
  - Identify Information Source;
    - if information comes from a database, please identify the name of the database and location
    - if information comes from a source not listed, please specify the source
3. If you are accessing medical records and using the Medical Records-Filing Department to retrieve charts, filing will complete the date field when they actually pull the chart for you.
4. Under the Medical Record # identify the Medical Record numbers of the patients for which you would like charts pulled.
5. Either email or mail (Mail Stop 4P-2) your tracking form to Medical Record-Filing to request having the records pulled. Filing will forward the form to Medical Records once the charts have been pulled.
6. 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 Date Disclosed and Medical Record Number and send the form to Carol Bettis in Medical Records and discuss selection criteria with her. Once you have determined your list of subjects and medical record numbers, provide the list to Medical Records Filing. Filing will complete the tracking form and give it to Medical Records.

7. If you are not using Medical Records, indicate the date the patient protected health information (PHI) was given to you or when you accessed CIS or a database.
8. If your source of data is not Medical Records, once you have completed accessing data, send the completed form to Medical Records (Mail Stop 4P-2).
9. Note: Please ensure that you submit your Accounting for Disclosure Tracking Form to Medical Records monthly for any new records accessed in a given month and upon completion of your study.

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

Limited data sets allow researchers to use and disclose PHI that 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.

Researchers 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, restrict further use and disclosure, restricts re-identification of data or contact with the individuals.

#### **15) What are the rights of research participants under HIPAA?**

- Right to privacy of protected health information
- Right to authorize use of identifiable PHI for research purposes
- Right to an accounting of how identifiable PHI was disclosed for research without authorization. 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.)