HIPAA in the Research Context and Use of the Revised Research HIPAA Authorization Form

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Clinical Research Regulatory Affairs

Human Subjects Protection Program

Overview

What we are seeking to answer today:

- What is HIPAA?
- What is PHI?
- Who needs to comply with HIPAA?
- When does HIPAA apply?
- How does HIPAA affect research?
- What is HIPAA Authorization?
- When do you need HIPAA Authorization?
- How do we fill out the *new* CHLA HIPAA Research Authorization for study-specific use?

What is HIPAA?

- The **Health Insurance Portability and Accountability Act of 1996** (HIPAA) is a United States federal law that required the creation of national standards designed to protect sensitive (i.e., protected) patient health information provided to health plans, doctors, hospitals and other health care providers from being disclosed without the patient's consent or knowledge.

What is Protected Health Information (PHI)?

- Any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.

There are **18 identifiers** that can be **considered PHI**:

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code*

Who needs to comply with HIPAA?

- **Every healthcare provider who electronically transmits health information**
  - This is not just related to research; this applies to all health information transmitted electronically
- Health plans, Insurance companies, etc.
  - Ex: L.A. Care Health Plan
- Healthcare Institutions
  - Ex: CHLA
- Business associates that act on behalf of a covered entity (i.e., health care providers, health plans, etc.) , including claims processing, data analysis, utilization review, and billing

When does HIPAA apply?

When you…

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records

How does HIPAA affect research?

Researchers who are part of covered entities or business associates of such entities under HIPAA are subject to the HIPAA Privacy Rule.

In general, **covered entities must obtain the authorization of the individual who is the subject of the protected health information (PHI) to use it for purposes *other than* treatment, payment, health care operations, and other specific uses permitted by the Privacy Rule** (e.g., law enforcement, threat to health or safety)

…like research.

How does HIPAA affect research?

For studies where **any of the18 PHI identifiers are recorded with medical information about a subject, HIPAA applies** – when HIPAA applies, this will be indicated (and how the research team has been approved to manage it) in a study's IRB approval memo.

HIPAA affects two portions of research:

- **Preparation** (before IRB submission): Under HIPAA regulations, CHLA researchers may *review* records (*without recording research data*) to determine whether sufficient patients meeting inclusion criteria exist at CHLA to determine if the proposed research is feasible. This is known as "*activities preparatory to research*".
  - Activities preparatory to research should be selected in section 36 of your iSTAR application if the people reviewing the records to identify subjects are **not** part of the covered entity (i.e., if they are not affiliated CHLA staff and/or faculty).
- **Conduct** (following IRB approval): Identifying subjects for screening and recruitment
  - If your study is planning to review the medical records to identify potential subjects (including reviewing eligibility criteria and obtaining contact information), you can do this in one the following three ways:

How does HIPAA affect research?

There are three ways to manage recording PHI for HIPAA-relevant research protocols:

1) Obtaining HIPAA authorization from the subject (if adult) or parent/legal guardian (if minor) – most common
2) Requesting a waiver of HIPAA authorization from the CHLA IRB/Privacy Board for Research
   - This request must be sufficiently justified in the context of your research.
   - Please note that HIPAA authorization may be obtained via mail, fax, scan/email, so "not currently receiving care at CHLA" is not a sufficient justification for a waiver.
   - If you can obtain consent, a HIPAA waiver will not be granted, as HIPAA authorization may be obtained at the time consent is obtained.
3) Executing a *data use agreement (DUA)* to send a *limited data set* outside CHLA.
   - A limited data set is one that contains only specified PHI identifiers (dates, city, county, precinct, zip code, equivalent geocodes, any other unique identifying number, characteristic, or code)

What is a HIPAA Authorization?

What is a HIPAA Authorization?

- A specific, detailed document that outlines how an institution will use or disclose an individual's protected health information (PHI)
  - **IMPORTANT:** Per CA law, HIPAA authorization differs from research consent, so participants are required sign a separate form from the consent to authorize such disclosure. This also means HIPAA language may not be present in the consent forms.

Does every participant sign or receive a HIPAA Research Authorization form?

- Your IRB approval letters will state if you need a HIPAA Research Authorization form – please ensure you are checking these as they are issued
  - **NOTE:** CHLA IRB also acts as our Privacy Board for Research, so they may issue partial or full waivers of HIPAA authorization – can be requested in section 36 of your study's iSTAR application

Do you always need HIPAA Authorization?

- In general, written authorization from the patient or parent/legal guardian is needed before information may be released.
  - In some cases, we may use and share information for certain purposes without the written authorization of a patient/parent/legal guardian. For example, we may:
    - Use and share information with doctors, nurses and other healthcare providers to treat the patient.
    - Share information with health insurance companies to get paid for the services we provide.
    - Use information to review the quality of our services.
    - Share information with local health departments to report certain contagious diseases, such as meningitis.
    - Share information with local authorities about suspected child abuse or neglect.
    - Share limited information with police in certain situations, such as if the patient was the victim of a crime.

Does HIPAA Authorization expire?

- Authorization can contain either an expiration date or an expiration event.
  - Ex:
    - Authorization may expire "one year from the date the Authorization is signed," "upon the minor's age of majority," or "upon termination of enrollment in the health plan."
- HIPAA Authorization expires when research subjects reach age of majority (AOM – 18 in CA) during study participation and they are **always** reconsented.
  - If written HIPAA authorization was used, subjects are asked to sign a new HIPAA authorization form when they reach AOM
  - NOTE: The CA Experimental Subjects Bill of Rights (ESBOR) is not required to be resigned
- Authorization remains valid until its expiration date or event, unless effectively revoked in writing by the individual before that date or event.
  - Participants can revoke their HIPAA Authorization at any time point.

CHLA HIPAA Research Authorization Forms

- CHLA has fully translated HIPAA Research Authorization forms in English and Spanish and HIPAA short forms in several languages
- Templates can be found on the CHLA HSPP website – the new versions only need to be used for new studies going forward
  - These forms have been approved by CHLA Legal Counsel and the Privacy Officer, and the template content of these forms must not be altered.
  - Any changes to the approved template language, such as those requested by study sponsors, must be approved by the CHLA Legal Counsel and the Privacy Officer, and by the CHLA IRB prior to use.

CHLA HIPAA Research Authorization Forms

Can only modify instructions in red and maintain 14-point font

****Note: All instructions are in red. Please modify the form for use with a specific protocol and remove all instructions/red text (including those in the footer) before use with subjects. Please ensure that the text remains in 14 pt. font to comply with regulatory requirements.****

Children's Hospital LOS ANGELES

AUTHORIZATION FORM

PERMISSION[1] FOR USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

PRINCIPAL INVESTIGATOR (Individual in charge of the research team at CHLA): *[PI of protocol]*

Study Title (or IRB Approval Number if study title may breach Participant's privacy): *[add study title or IRB number as applicable]*

If the study title is risky and could endanger the subject, use the IRB # instead

CHLA HIPAA Research Authorization Forms

What is the purpose of this form?
State and federal privacy laws protect the use and release of your health information. Under these laws, CHLA or your health care provider cannot use or disclose your protected health information for research purposes without your permission unless a regulatory exception applies. This form describes the different ways that we can share your information with the research team, sponsors/collaborators, and people with oversight responsibility.

Patient/Subject Name: _____

Medical Record Number: _____Date of Birth:_____

_____

[1] *This form also serves as the authorization form for a parent/legal guardian/legally authorized representative to read and sign when their child is the subject in a research study. In that case, "you" refers to your child.*

Note: Study purpose is no longer necessary

Footer should include the form version and CHLA IRB #

CHLA HIPAA Research Authorization Forms

RESEARCH STUDY INFORMATION

The protected health information that is needed for this research study includes: *(Please describe, examples are provided below. Please modify, add, and/or remove types of data to only include what is relevant to your study protocol.)*

- Personal demographic information;
- History and diagnosis of your medical condition;
- Specific information about the treatments you will receive or have received, including treatment(s) you may have had in the past;
- Information about other medical conditions that may affect your treatment;

Date of Preparation: *[Version/date form was modified for this specific protocol]* Page 2 of 7
IRB#: *(CHLA#)*

[redacted]

- Medical data including laboratory test results, results of tests measuring organ function (e.g., kidney, heart, lung), results from radiology scans, pathology or other test results;
- Information on treatment and the side-effects you may experience during this research study and how they were treated; and
- Long-term information about your general health status and the status of your medical condition.

Can keep this section vague but add more information rather than less

CHLA HIPAA Research Authorization Forms

(Insert the following initials section only if applicable and remove any examples that are irrelevant to your study protocol.):

The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____ I agree to the release of HIV/AIDS testing information.

_____ I agree to the release of genetic testing information.

_____ I agree to the release of information pertaining to mental health diagnosis or treatment.

_____ I agree to the release of psychotherapy notes.

Note: This section is new and requires initials if any of these apply

CHLA HIPAA Research Authorization Forms

The research team at Children's Hospital Los Angeles *[select either]* receives *[or]* does not receive payment for your participation in this research study and subsequent use of your protected health information.

DISCLOSURE OF PROTECTED HEALTH INFORMATION

You give permission for the following persons, groups or organizations use or disclose (release) your protected health information for the resear study described in this authorization form. *(Please list only those t apply.)*

1. *[Name of Researcher]* and his/her research staff *[always keep in]*
2. All health care providers with health information about you *[always keep in]*
3. The CHLA Institutional Review Board for oversight and compliance purposes *[always keep in]*
4. Other: *[Specify]*

Select "receives" if the CHLA research team receives payment for participation

Only add in other institutions that might be disclosing further

CHLA HIPAA Research Authorization Forms

RECEIPT OF PROTECTED HEALTH INFORMATION

You give permission for the following persons, groups or organizations to receive your protected health information for the research study described in this authorization form. *(Please list only those that apply.)*

1. The sponsor of the study [*Name of the sponsor*] or its representatives *[(e.g. drug company, foundation, etc…) will have access to coded and/or directly identified data (please specify)]*
2. The following institutions/investigators that are participating in this research: [*Name of collaborating institutions/investigators (i.e., study coordinating center or protocol chair at another institution), and other collaborating researchers/Institutions*]
3. Federal, State, and foreign *[keep "foreign" if this is a multi-site protocol also being conducted outside of the U.S., whether or not CHLA is the coordinating center]* agencies that have authority over the research when required by law.
4. Our Hospital, its representatives, or other accrediting agencies. *[always keep in]*
5. A data safety board that may be formed to monitor the safety of the research. *(leave in if applicable)*

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IRB#: *(CHLA#)*

List all the collaborating investigators and institutions

6. Your health insurer or payer, if necessary, to secure their payment for any covered treatment not paid for by the research. *[always keep in]*

CHLA HIPAA Research Authorization Forms

List the investigator and MS #

[Name of Principal Investigator], Children's Hospital Los Angeles, 4650 Sunset Boulevard *[enter Mail stop #]*, Los Angeles, California 90027

Your cancellation will be effective upon receipt but will not be effective to the extent that the Children's Hospital Los Angeles research team or others have acted in reliance upon this Authorization.

You will receive a copy of this Authorization Form.

You have the right to review and/or copy your *medical records* containing your protected health information kept by Children's Hospital Los Angeles.

[Include if subjects will not be able to look at their medical records until the study is completed:] You will not be allowed to review your protected health information created or obtained in the course of research until after the study is completed. When the study is over, you will have the right to access the information again.

*Please pick **one** of the following three paragraphs below (and delete the others):*
You will be allowed to review your medical records collected for research at any time, including while the study is ongoing.

OR

You will be allowed to review your medical records collected for research only after the research is completed.

OR

You will not be allowed to review your medical records collected for research at any time.

[Include if applicable:] You have a right to receive a copy of the blank data forms used for this study.

- Select option 1 if the participant can view their research records at any point in the study
- Select option 2 if they can only view their records at the end of the study
- Select option 3 if they will never be able to look at their research records

Note: This does not apply to their non-research medical records

CHLA HIPAA Research Authorization Forms

SIGNATURES

Your signature below indicates that you give permission for the use and/or disclosure of your protected health information as described in this document. This authorization form may not be valid if it has not been filled out completely.

Printed Name_____

Signature_____Date____/____/____

Please indicate the relationship:
- ❑ patient/research subject
- ❑ legally authorized representative (for adult)
- ❑ parent/legal guardian (for child)

Printed Name of Person Obtaining Permission:

_____

Signature of Person Obtaining Permission:

_____Date____/____/____

Printed Name of Witness (if applicable):

_____

Signature of Witness:

_____Date____/____/____

Routing: Investigator's file (original), Subject (copy) & Health Information Management (copy to Medical Records)

New simplified signature process

Indicate who is signing the form (1) subject, (2) LAR, or (3) legal guardian

Document witness signature if applicable

Email a copy to HIMScanningInpatient@chla.usc.edu

THANK YOU

If you have any questions, please reach out to the Regulatory Affairs Team:

RegulatoryAffairs@chla.usc.edu

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