

Frequently Asked HIPAA Research Questions

1. **What is HIPAA?**

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) has an "Administrative Simplification" title that authorizes the federal Department of Health and Human Services to set standards to simplify administration of the health care system. This includes provisions to standardize health care claims and transactions and setting standards for the privacy and security of individually identifiable health information.

2. **Who is covered by HIPAA?**

HIPAA covers health care providers and health plans that bill health care claims electronically (“Covered Entities”). Rady Children’s Hospital-San Diego is a Covered Entity.

3. **What is Protected Health Information (“PHI”)?**

Protected Health Information is individually-identifiable health information that relates to the health care of the individual and any payment related to that health care that is held by a Covered Entity, including demographic information. The protections of the HIPAA Privacy Standards apply to PHI.

4. **Is my research subject to HIPAA?**

If the research involves access, use or disclosure of PHI, then it is subject to HIPAA Privacy Standards.

5. **When do the HIPAA Privacy Standards become effective?**

Compliance is required as of April 14, 2003.

6. **If my research is subject to HIPAA, what do I have to do to comply?**

Research projects that are subject to HIPAA will require the following:

a.	(1) A HIPAA-compliant authorization that addresses the types of PHI that will be necessary for the research, or (2) an IRB approval for waiver of the HIPAA authorization requirement. HIPAA authorization will be required for newly consented study participants effective April 14, 2003. Research participants who signed consents prior to April 14, 2003 do not need to be re-consented. A separate HIPAA authorization form will need to be used in conjunction with the IRB-approved consent form.
b.	Confidentiality of the information must be safeguarded, that may

	include protections for physical security, access controls such as password-protected computer applications, and by the general principle of "minimum necessary".
c.	When PHI is disclosed by the Hospital to the researcher who is not a member of the Hospital's workforce (i.e., employees or trainees - interns, residents, fellows, certain students) or the Hospital's Medical Staff, a log of certain disclosures needs to be maintained, and Health Information Department must provide an accounting of certain disclosures to patients upon request.

7. What is the general principle of "minimum necessary"?

The Privacy Standards require that we make reasonable efforts to limit our request, use or disclosure of PHI to the minimum amount needed to accomplish the intended purpose. For instance, if the researcher can conduct the research by using a limited data set or de-identified information, then the principle of minimum necessary requires that the more limited amount of information be used or disclosed for the research purpose.

8. How does HIPAA affect language in Informed Consent documents?

For research studies that involve PHI, HIPAA mandates that additional elements be explained in a HIPAA authorization form for use of PHI:

1.	Description of information to be used or disclosed.
2.	Description of each purpose of requested use or disclosure
3.	Name of person(s) or class of persons that will disclose PHI to name of person or class of persons will use the information
4.	Name of persons or organizations outside of covered entity to whom PHI will be disclosed. (e.g., central coordinating offices of multi-center trials, FDA, NIH, OHRP)
5.	Expiration date or event that ends authorization to use PHI (e.g., completion of the research), or statement that authorization does not expire.
6.	Statements regarding: subject's right to revoke authorization (may be part of withdrawal from study procedures); research-related treatment may be conditioned on signing authorization.
7.	If information will be disclosed to other organizations, statement that information may no longer be protected by federal law.
8.	Researcher must stipulate if individual's right to inspect or request a copy of his/her medical record is suspended during research (e.g., placebo study).

9. **Should a researcher use a Sponsor provided template for creating a separately signed HIPAA authorization?** No. As of April 14th all RCHSD researchers should use the RCHSD HIPAA authorization form for any study that is recruiting subjects and obtaining a signed informed consent. The form should be customized for each study. A dual-tracked authorization form with UCSD-RCHSD exists and is available with the dual-tracked forms at <http://irb.ucsd.edu>.
10. **Does each customized HIPAA Authorization Form need to be submitted to the IRB for approval?** Yes. In customizing the form, the researcher should insert applicable language directly from the approved study consent. The customized forms should be submitted with the initial IRB application and via amendment requests if revisions are required after initial approval.
11. **Do HIPAA Authorizations need to be translated into Spanish?** Yes. Please submit each customized authorization for Spanish translation as soon as possible. These translations will also need to be reviewed and approved by the IRB prior to use.
12. **What is de-identified information?** De-identified information is the term used for health information that has had identifiers removed. HIPAA protections do not apply to information that has been stripped of all identifiers or that has been found de-identified by a statistician. The de-identified health information fact sheet can be obtained at <http://www.chsd.org/documents/Research/IRB%20Forms/030414%20De-Identification%20Research%20Fact%20Sheet.doc>.
13. **What is a limited data set?**
A limited data set is a partially de-identified dataset that contain all or a subset of the following: diagnostic information; city, town, state or zip code information; and relevant dates, including birth, death, admission or discharge dates. Because a limited data set retains information that could be used to re-identify an individual (such as hospital admissions dates or birth dates), research involving use or disclosure of a limited data set must either be authorized by the subject, granted a waiver of HIPAA authorization from the Institutional Review Board, or accompanied by a Data Use Agreement specifying the data recipient's agreement to use the data only for approved research purposes, and that the researcher will not attempt to re-identify individuals. Researchers must submit the proposed study to the IRB for approval. The IRB approval letter and Research Administration Ready to Accrue Letter must be presented to the Health Information Department in order to access the records.

14. How does HIPAA affect subject identification and recruitment for research studies at Rady Children’s Hospital? Each investigator is required to submit the plan for the identification and recruitment of potential subjects. Greater scrutiny will be applied by the IRB on this plan as of April 14th. Subject identification must be done in accordance with the HIPAA Privacy Standards and state law. Access to PHI will require one of the following:

1.	Written authorization from each potential subject.
	OR
2.	A partial waiver of the HIPAA authorization for subject identification and recruitment purposes only.

Example: Dr. X would like to identify potential subjects for a new antibiotic study. Children ages 2-14 years, admitted to any floor of the hospital may be eligible for participation. The most effective way to recruit patients is for Dr. X’s research staff to review admission diagnoses for patients admitted to each unit. Dr. X may apply for a partial waiver of individual HIPAA authorization for subject identification only.

Without the HIPAA authorization or this waiver, Dr. X and the research staff will be unable to review patient medical records and may not access patient records for research purposes via the hospital’s electronic systems, e.g., Meditech, ChartMaxx.

15. How does an Investigator obtain a partial or total waiver of individual authorization?

The investigator must apply for a partial waiver by submitting the application for waiver of HIPAA authorization to the IRB at the time of initial review or via amendment request if the study has already been approved. The application can be obtained at http://www.chsd.org/documents/Research/IRB%20Forms/Ap_Waiver_of_HIPAA_Auth_071503.doc.

16. What criteria must be met for the IRB to grant a partial or total waiver of the HIPAA authorization requirement?

The researcher must demonstrate the following:

- There is no more than minimal risk to individual’s privacy because:
 - There is an adequate plan to protect identifiers;
 - There is an adequate plan to destroy identifiers, unless required by law or justified by health or research considerations (the researcher will need to specify the legal

justification or health or research consideration that requires retention; and

- The researcher provides 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 research, or for other permitted research;
- The research could not be practicably conducted without the waiver or an alteration of the authorization requirement; AND
- The research could not be practicably conducted without access to and use of the Protected Health Information.

17. Are there ways to identify potential research subjects without accessing PHI? Yes. An investigator may request IRB approval for identification methods that include: waiting room flyers, radio and print ads, or All User Meditech announcements, etc. The treating physician and clinical staff may also refer patients with the patient's (or parent's) authorization.

18. Can a researcher-clinician contact potential subjects from within his/her own medical practice without obtaining an IRB waiver of HIPAA Authorization?

Yes in certain limited circumstances if the research is related to the patient's ongoing treatment. Even in this instance, IRB review and/or approval would be required for the research prior to contact.

Example: Dr. X would like to identify potential candidates from within his own practice for a new surgical technique study. Dr. X and other members of his clinical team may discuss any relevant clinical trial that s/he thinks may be helpful to the patient. However, Dr. X may not disclose his patient list or any PHI to his research coordinator to contact potential subjects without first obtaining a HIPAA authorization or a waiver of the authorization requirement.

19. Will HIPAA affect the current screening and recruiting practices of studies that have received IRB approval prior to April 14, 2003? No, not necessarily. Any study that has received IRB approval may proceed to identify and recruit subjects under the approved protocol. However, every researcher should review his/her current screening and recruitment practices to ensure that these practices protect patient privacy to the greatest extent practicable. By the time the research study is submitted for continuing review, the researcher may need to provide the IRB with additional information regarding these practices and may need to revise these practices after IRB review. If the researcher has any questions, the IRB or Privacy Officer should be consulted in advance of the review.

Example: Dr. Y has an approved protocol that allows the hem-onc clinic to provide her research team with a list of all patients that have been seen in clinic with elevated white blood cell counts and that have verbally agreed to be contacted for Dr. Y's study. Dr. Y and her research team may continue to contact the hem-onc patients who have verbally agreed to be contacted pending continuing review of her protocol.

20. Can a researcher access PHI to assess the feasibility of a potential research project? Yes. The Privacy Standards permit reviews that assist in developing a hypothesis or a research protocol or assessing the feasibility of a study. The researcher must consult the IRB for guidance as to whether or not IRB review is required and provide certain written assurances by completing the Researcher Assurances-Preparatory Research Activities Form

<http://www.chsd.org/documents/Research/IRB%20Forms/030414%20Researcher%20Assur-Prep%20Rs%20Activities.doc>. If the researcher is not a member of the Rady Children’s Hospital workforce or medical staff and s/he accesses less than 50 records, then the researcher must complete and submit to the Health Information Department the Report of Health Information Disclosure Form for each record.

Example: Dr. X, a member of the RCHSD medical staff, would like to know the number of children admitted to RCHSD within the past 5 years who were treated for acetaminophen overdose to assess the feasibility of studying long-term effects of acetaminophen overdose. This information may be given to Dr. X if the information is de-identified, e.g., there were 125 patients and the Researcher Assurances-Preparatory to Research Activities Form has been completed and accepted by the IRB. If any PHI will be used by Dr. X to assess the feasibility of this project, then Dr. X must also submit the Researcher Assurances-Preparatory to Research Activities Form to the IRB for acceptance. Dr. X may not use the PHI obtained in this activity for the research project. Dr. X may consult the IRB regarding whether this activity should be submitted as a study proposal if the PHI is intended to be used for the study, should it prove feasible. As a member of the Medical Staff, this access to PHI is considered an internal use and not a disclosure. Dr. X does NOT need to complete any Report of Health Information Disclosure forms.

21. What documentation will the Health Information Department or other Hospital database controllers) require from a researcher who requests access to PHI? A copy of the Ready to Accrue (RTA) letter, IRB approval letter and, if a HIPAA authorization has been obtained, a copy of the signed authorization.

22. Is a HIPAA authorization or waiver of HIPAA authorization necessary for a retrospective chart review? It depends on the type of information the researcher requests:

No PHI accessed or recorded. Information is stripped of all identifiers (de-identified data set)	No HIPAA authorization or waiver of HIPAA authorization required.
Limited data set requested, i.e., information is stripped of all direct identifiers-but may contain diagnostic information; city, town, state or zip code information; and relevant dates, including birth, death, admission or discharge dates.	HIPAA authorization or waiver of HIPAA authorization or data use agreement required.
Patient identifiers requested.	HIPAA authorization or Waiver of

Information including names, medical record numbers, etc.	HIPAA Authorization required.
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23. What is the purpose of the Report of Health Information Disclosure form? This form will enable the Health Information Department to account for certain disclosures of PHI for certain research purposes.

24. Who should complete the Report of Health Information Disclosure? This form should be completed by any researcher who is not a member of the RCHSD Medical Staff or workforce and who accesses **less than** 50 records. Members of the RCHSD workforce include employees and trainees, e.g., residents, fellows, medical or graduate students who are training at RCHSD as part of an affiliation agreement.

25. What disclosures need to be reported on the Report of Health Information Disclosure? All disclosures of less than 50 records made for: (1) preparatory research activities; (2) research on deceased individuals; and (3) research done after the IRB waives, partially or totally, the HIPAA authorization requirement. The form does not need to be completed for disclosures made with a HIPAA authorization or as a Limited Data Set or for de-identified information.

26. What is required to conduct research on deceased individuals? The researcher should consult the IRB regarding the need for IRB approval, complete the Researcher Assurances-Decedent Research Form <http://www.chsd.org/documents/Research/IRB%20Forms/030414%20Researcher%20Assur-Decedent%20Research.doc>, and, if a non-RCHSD employee or medical staff member and less than 50 records are accessed, track the names of the subjects using the Report of Health Information Disclosure Form.

Example: Dr. X, a researcher from UCSD, requires medical records of deceased children who may have died of Sudden Infant Death Syndrome in the last 10 years. Dr. X must consult the IRB and must submit the Researcher Assurances-Decedent Research Form. This includes an agreement to provide documentation of the patient's death if requested. Dr. X, if accessing less than 50 records, must complete a Report of Health Information Disclosure form and submit it to the Health Information Department.

27. When is a Business Associate Agreement required for research?

This agreement is necessary when a researcher who is not a member of the RCHSD medical staff or workforce is provided access to PHI in order to **create** de-identified information or a limited data set.

Example: Dr. X has been contracted by a local community clinic to do a retrospective medical record review to assess the effect of the provision of mental health services on certain at risk youth. Dr. X has determined that the minimum amount of PHI necessary for the data analysis is a Limited Data Set. The community clinic does not have the resources to create the Limited Data Set for the analysis and has asked Dr. X's research analyst to do so. In order to access and use PHI to create the Limited Data Set, the research analyst will need to sign a Business Associate Agreement that includes specifying the work that she will do on the clinic's behalf and what PHI will be needed to create the Limited Data Set.

28. Have new research forms been created as a result of the new HIPAA regulations? Yes. These forms are available on the IRB Forms page at <http://www.chsd.org/body.cfm?id=548>.

- Researcher's Assurances-Preparatory to Research Activities Form
- Researcher's Assurances-Decedent Research Form
- HIPAA Research Authorization Forms (Parent and Adult versions)