



HIPAA AND CHART REVIEWS



HIPAA AND CHART REVIEWS USING A PREPARATORY (PREP) TO RESEARCH

- To conduct a chart review a researcher is required to submit and obtain approval from the IRB. Along with the usual IRB documents a Prep to Research and a Waiver of Authorization are required.

Prep to Research

Investigators who are members of the covered workforce Lifespan employees, official volunteers, etc, may gain access to protected health information (PHI) in order to prepare a research application or protocol and/or identify subjects who are eligible for a study, (chart review).

Preparatory to Research There are limitations and restrictions on Prep to Research

Use or disclosure is sought solely to review PHI as necessary to prepare the research protocol OR other similar purposes (i.e., chart review)

PHI will be reviewed only on Lifespan premises.

The PHI will NOT be removed from the health care facility (see below what constitutes PHI)

The PHI is necessary for purposes of conducting the research

No PHI will be reviewed using remote access; from external medical record files/location.

No research PHI data may be removed by the researcher from Lifespan in the course of review. All researchers are required to certify as part of the IRB approval process that they **will NOT remove any PHI from the premises** in conducting reviews using Prep to Research. **Electronic review may also only be conducted on the Lifespan premises.**

Waiver of Authorization

Authorization would be getting permission from the person whose chart you want to view. So for a chart review you ask the IRB for a Waiver of Authorization just as you would ask for a Waiver of Consent to do the chart review.

There are limitation and restrictions on a Waiver of Authorization as well

- The use or disclosure involves no more than minimal risk to the individuals because:
 - There is an adequate plan to protect the “identifiers”
 - there is an adequate plan **to destroy** the “identifiers” at the earliest opportunity, unless there is a health (*i.e.*, individual care) or research justification for retaining the identifiers or their retention is required by law; *and*
 - There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under this policy.
- The research could not practicably be conducted without the waiver; *and*
- The research could not practicably be conducted without access to and use of the protected health information.
- You certify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

What is PHI? PHI is Protected Health Information

Identifiable PHI according to HIPAA has at a minimum 18 identifiers. Any of the identifiers even one, is considered identifiable PHI. To de-identify PHI you must remove all 18 identifiers



HIPAA AND CHART REVIEWS



What are the 18 Identifiers? 18 Identifiers according to HIPAA

1. Name	2. Fax Number
3. Health care beneficiary #	4. address (except State)
5. email address	6. member or account #
7. ANY Dates , such as DOB (except year), or date of treatment/surgery , etc	8. SSN #
9. certificate/license #	10. Phone number
11. Medical record Number (MRN)	12. biometric id-voice prints/finger prints
13. device identifier	14. web URLS
15. IP address	16. vehicle ID #
17. full face photo	18. any other unique ID

Identifiable data cannot leave the institution under Prep to Research

When reviewing charts for a chart review you may want to collect an MRN and perhaps a DOB and maybe some other form of identifier. If you collect any of the above identifiers the data collection sheet **cannot leave the premises**. Therefore, you should not store your data on your laptop and take your laptop home.

So, how do you do a chart review and not take identifiable data out of the institution?

There are several ways:

- Use a Lifespan issued Laptop and Lifespan issued USB flash drive (this self destructs after 3 password tries). Using the Lifespan issued laptop or USB flash drive does not mean that laptop or the USB flash drive can leave the premises with identifiable data it simply adds another layer of protection.
- Store the identifiable data on the USB flash drive. The flash drive **CAN NOT** leave the institution no matter what flash drive you use. Use a Lifespan issued USB flash drive.
- You can load the data from the flash drive to a Lifespan Network drive. **You cannot view identifiable data from outside the institution so that means you cannot do your chart review from home using your electronic access. Electronic review must also be done only on the premises.**
- You collect identifiable data, DOB, MRN, **dates of treatment**, surgery, lab test, etc., and save that to a Network drive or USB flash drive and then create another data set that does not include the identifiers (this does not mean you hide the columns on an excel spreadsheet).
- You store the identifiable data at Lifespan and you can take the totally de-identified data out of the institution.
- You can use your laptop and save the data **de-identified** to a USB flash drive. The laptop and/or flash drive may now leave the institution (**data is de-identified**)
- **You can take DE-IDENTIFIED data out of the institution**

Contact for further Information

HIPAA and Research Janice Muratori, RNP, MSN, CIP Director, Research Protection Office Research Privacy Officer (401) 444-6897	HIPAA and Research S. Candace Frater, MD, MHA Manager, Research Protection Office Research Privacy Officer (401) 444-5808
HIPAA questions in General Thomas Igoe VP Corporate Compliance Lifespan Corporate Privacy Officer (401) 444-8565	