**Ascension Wisconsin IRB**

**HIPAA Authorization Template for Case Reports**

You must obtain HIPAA Authrorization from individuals involved in case reports, unless the IRB (also the Research HIPAA Privacy Board) has granted a waiver.

**Directions**

* Black text should not be modified unless otherwise stated.
* On the title page, replace the red text with the study specific information.
* Instructions are highlighted.
* Do not modify the margins, header or footer of document.
* Before submitting to the IRB:
	+ Delete this page.
	+ Make sure all red text, check boxes and spaces are completed accurately for the study.
	+ Make sure the text is black in color and all highlighting is removed.
* Resources:
	+ IRB Guidance: Research Informed Consent & HIPAA Authorizations/Waivers in the Medical Record

**Accounting of Disclosures of PHI**

* Once signed:
	+ Provide a copy provided to the subject.
	+ File a copy in the medical record of each subject. The method to do this may vary by site and the site’s medial record system. See the HIPAA and Research tab on the [Research Integrity and Protection- Researcher References](https://www.axiommentor.com/wfhc/Researchers)  in Mentor.
* The Subjects must sign and enter the time and date for themselves.
* The signature time must be included on documents that will be part of the medical record.
* The form should be signed using black ink.

**HIPAA Authorization for a Case Report**

**Project Title:**[Study Title]

**Project Lead:** [Name]

 [Phone number]

 [Hospital or Clinic name & address]

The purpose of this form is to seek your authorization (permission) for the Project Lead listed above and their team to use and share use your individual health information for the purpose of this case report.

**Why will this information be used and shared with others?**

*[briefly (1-2 sentences) describe why the case is of interest].*  We plan to prepare a report to submit to medical journals for publication. Other medical professionals may find your case interesting, and sharing the details could help them learn about the condition and enhance their clinical knowledge to better manage and treat others.

**What information will you use and share for the study?**

If you allow your doctor(s) to use some information about you and your health information that describe your condition, such as: age, gender, race, state of residence, medical diagnoses, prior medical history, presenting symptoms, laboratory results, imaging results, treatment, present complaints and follow-up.

 *[modify as needed, include a description any other records, photos, etc.]*

**Who is this information shared with?**

In general, under federal laws, individual health information is kept private. But there are some exceptions and you should know who will have access to this information and might see it.

The study team may review and use information that identifies you for this project. The only other people that may have access to this information would be individuals at Wheaton Franciscan Healthcare who review projects like this to make sure they are done correctly. Your name and other identifiers will not be included in the case report, but some unique characteristics about you and your case may be shared.

**What happens if I say no?**

The case report will not be written without your permission. The care you get from your doctor will not change.

**May I change my mind later?**

The case report would be submitted no earlier than *[date]*. You would have until *[date]* to change your mind. If you decide to change your mind, you need to tell us in writing. You can send a letter to Project lead listed above.

**Giving permission**

By signing this form, I agree to allow the use and disclosure of my health information for the purposes described above. You will get a copy of this form.

Signature of Subject or Authorized Representative Date Time

**If signed by other than patient, indicate relationship or authority and obtain witness signature:**

Patient is: ☐ a Minor ☐ Incompetent ☐ Deceased

I am: ☐ Parent ☐ Legal Guardian ☐ Next of Kin of Deceased ☐ Executor of Estate ☐ POA for health care (activated)

Signature of Witness Date Time

If unable to sign this form, document reason \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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