Ascension Wisconsin IRB Guidance

Research Informed Consent and HIPAA Authorizations/Waivers in the Medical Record

Joint Commission standards require that all consent forms related to care or treatment are part of the patient's medical record. In addition, the HIPAA Privacy Rule requires accounting for use and disclosure of PHI for research. To meet these requirements, WFH has updated its policy *Medical Records: Designated Record Set and Legal Health Record* to include research informed consent documents and research HIPAA authorizations/ waivers of authorization. In addition to meeting the regulatory requirements, it is important that the research consent form be made available to other health care providers when the research procedures could reasonably impact other care or treatment patients receive.

To better outline the process and Investigator Responsibilities, the Ascension Wisconsin IRB has updated the IRB Policy Manual, forms and provided this guidance document.

What Forms Need to be Scanned into the Medical Record?

Informed consent forms that are REQUIRED to be included in the medical record:

The research consent form for any study that includes clinical procedures or interventions must be added to the medical record.

Examples of clinical intervention include the use of a drug or device, surgery, psychotherapy or any physical interaction that is more than minimal risk and is done specifically as part of the research study.

This requirement applies to all studies conducted at a Wheaton Franciscan facility, including those that are under the oversight of an IRB other than the WFH IRB (i.e. NCI CIRB). In situation where a short form consenting process is used, both the English language study consent form and the short form signed by the subject should be scanned into the medical record.

In rare cases, the IRB may waive the requirement that the signed consent form is scanned into the subject's medical record if they feel that the disclosure would negatively affect the subject's rights, welfare or safety. When applicable, the IRB will specify the waiver of the scanning requirement in the IRB approval notification to the Principal Investigator.

Informed consent forms that are NOT REQUIRED to be included in the medical record:

Research studies that do not involve clinical procedures or interventions as described above and use separate Research Consent and HIPAA Authorization forms, do not need to be scanned into the medical record.

Examples include minimal risk studies involving only medical record review or observation, or minimal risk interventions, such as surveys, interviews, focus groups, blood draws or MRI (without contrast).

In rare cases, the IRB can require that the signed consent form for a minimal risk study be scanned into the subject's medical record if they feel that including the consent in the medical record would be important to ensure the subject's welfare or safety. If required, the IRB will specify the requirement in the IRB approval notification to the Principal Investigator.

Documentation of the Use of PHI for Research that is REQUIRED to be included in the medical record:

Research HIPAA Authorization Provided by the Individual Prior to Accessing PHI for Research

- For most studies involving clinical interventions, the HIPAA authorization is incorporated into the study consent form. For these cases, scanning the signed consent form is sufficient and no additional action is required.
- For studies that use a separate HIPAA authorization, the signed Authorization must be scanned into the medical record, regardless of the kinds of research activities or level of risk of the research.

Waiver of HIPAA Authorization Granted by the IRB/HIPAA Privacy Board (for the entire research study or for recruitment activities)

- Access to PHI under a waiver must be recorded in the medical record.
- The Research HIPAA authorizations will almost always be signed by the research subject, whether incorporated into the consent form or a separate document. If IRB/Privacy Board waives the requirement to sign the HIPAA authorization form but authorization is still obtained, such as a verbal consent process, the unsigned form that was given to the subject must be scanned into the record.

Documentation of the Use of PHI for Research that is NOT REQUIRED to be included in the medical record:

Research use/disclosure of PHI does NOT need to be included in the medical record in the following cases:

- Preparatory to research activities, as defined in the HIPAA Privacy Rule
- Use of Decedent records for research
- PHI is part of a Limited Data Set (Data Use Agreement)
- Only de-identified data from the medical record is released to the researcher (researcher doesn't access, view or use PHI)

How are Research Consent and HIPAA Authorization Forms Scanned into the Medical Record?

- **The investigator or their designee must submit a photocopy of the signed consent document or HIPAA Authorization form to Health Information Management (HIM) at the study location**.
  - The original signed consent form should be retained in the research file.
  - HIM is responsible for scanning the document into the medical record.
  - The copy sent to HIM is destroyed.
- **Be sure to always use the most recent WFH ICF templates and forms found in Mentor.** The WFH ICF templates and HIPAA waiver request forms include instructions and formatting to ensure the form is scanned into the appropriate area of the medical record.
- **Other tips:**
  - Complete the subject information in the bottom right of the form (per IRB template).
  - The forms must be scanned into the medical record for every subject and/or record.
  - Forms should be forwarded to HIM in a timely manner to ensure accurate and timely documentation.

How is Access to Records under a Waiver Documented in the Medical Record?

- **If you are working with HIM to obtain the research data, the process will not change from the current practice.**
  - Provide HIM at the study location with the IRB approval letter that indicates the waiver has been granted.
  - HIM will provide you access and document the access for each record.

- **If you are accessing the medical record without assistance from HIM you can document the access in one of two ways:**
    1) Create an encounter in Epic to document the access for research.
        a. Documentation should include the reason that you accessed the record. For example " One time access for collection of data for research protocol ###. IRB granted waiver of consent."

    OR

    2) Make a copy of the IRB approval letter for each record accessed.
        a. In the lower right hand corner, add a patient sticker OR the name, date of birth and medical record number.
        b. Forward via interoffice mail to HIM at the study location.

Table of Documents and Storage/Scanning Requirements

	Type of Research/Activity	Type of Document	Storage
Research consent form	**Research procedures or interventions that Involve care, treatment or diagnosis.** *This includes any clinical interaction such as the use of a drug or device, surgery, psychotherapy or any physical interaction that is more than minimal risk, that is done for research at WFH.*	Research Consent w/ HIPAA authorization	Forward a copy to HIM for scanning
		Research Consent	Forward a copy to HIM for scanning
	Research procedures or interventions that DO NOT involve care, treatment or diagnosis. *This includes studies that involve no physical interventions or only interventions that are not more than minimal risk. Examples include studies involving only surveys, interviews, focus groups, medical record review, blood draw, etc.*	Research Consent w/ HIPAA authorization	Forward a copy to HIM for scanning
		Research Consent	Maintain in research record
HIPAA	**HIPAA Authorization form signed by an individual allowing access, use and/or disclosure of PHI for research.**	Research HIPAA Authorization form	Forward a copy to HIM for scanning
	HIPAA Waiver Granted by the IRB for research use of medical records.	IRB approval letter	Provide a copy to HIM for scanning OR create an encounter note in Epic
	Research use of medical records under the preparatory research provision of the HIPAA Privacy Rule.	IRB approval letter and/or Research records	Maintain in research record
	Research involving the use of decedent's medical records.	IRB form	Maintain in research record
	PHI used/disclosed for research is part of a Limited Data Set	Data Use Agreement	Maintain in research record
	Only de-identified data from the medical record is released to the researcher. *The researcher doesn't access the record, view use any PHI.*	n/a	n/a

For additional information, see:

- IRB SOP: Documentation of Consent
- IRB SOP: Use of PHI for Research
- HIPAA Privacy Rule: 45 CFR Part 160 and Subparts A and E of Part 164.

You may also contact IRB staff with questions.