IRB Review May 2023

3rd edition

Quick Take: HIPAA Authorization & Waivers of HIPAA Authorization

HIPAA Authorization: Signed permission to allow a covered entity to use or disclose protected health information (PHI).

Waiver of Authorization: A request to forgo the authorization requirement because disclosure of PHI involves minimal risk, and the research cannot practicably be done without access to PHI.

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- A **partial waiver** is most commonly requested for the screening portion of a study to access medical records to verify eligibility.

- A **full waiver** is typically used for retrospective chart reviews. The investigator must provide a **thorough explanation** for the ***impracticability*** of obtaining authorization.

Conditions for a waiver or alteration

- IRB Approval.
- The study is no more than minimal risk.
- There is an adequate plan to protect health information.
- There is an adequate plan to destroy identifiers.
- There is written assurance that PHI will not be reused or disclosed except as required by law or for authorized oversight of research.
- Written assurance that the research could not practicably be conducted without the waiver.

45 CFR 164.512 (i)(1)(i);

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Info you will be asked to provide

- Will you obtain **HIPAA authorization** or are you requesting a **waiver**?
  - **HIPAA authorization** will be obtained from all subjects and is embedded in consent.
  - **Partial waiver: HIPAA authorization** will not be obtained from subjects for the screening process only, or a retrospective cohort).
  - **Full waiver of authorization** for all subjects. HIPAA authorization will not be obtained.
  - **HIPAA Authorization** will be sought but one or more required elements will be eliminated or altered.
  - The PHI is a **limited data set** and requires a data use agreement.
  - **HIPAA authorization** is in a separate document.
- How the study team will ensure compliance with external partners that generate PHI.

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- Provide detailed information explaining why it will be impracticable to conduct this study **without the waiver**; **AND**
- Why is it impracticable to conduct this study **without access to the use of PHI**?
- Describe how the use of PHI in the study poses **no more than minimal risk to participant privacy**.
- For example: It is not feasible to obtain HIPAA authorization to verify eligibility due to the proposed sample size.

Upcoming education

- **May 11th: Quality improvement/Quality Assurance vs. Research: Noon -1 pm Teams**
- **June 8th: Advancing Justice, Equity and Inclusion of Community Perspectives in Clinical Research: JD, MBE, CIP: Johns Hopkins. Noon -1pm Teams**