Children's Hospital and Health System™

APPLICATION FOR IRB WAIVER OF AUTHORIZATION UNDER THE HIPAA PRIVACY RULE

Purpose of this form

To facilitate the submission and review of a request to use/disclose protected health information (PHI) under an IRB approved waiver of authorization, including a waiver for recruitment and screening purposes for research.

Instructions

A. If you are applying for approval of a new minimal risk initial review or exemption (such as retrospective medical record review) and you believe it is impracticable to obtain a signed HIPAA Authorization from some or all research subjects, you may apply to the IRB for a waiver of authorization to use/disclose the PHI of research subjects. This form may be used to use/disclose PHI located in either a medical record, clinic record, or database.

APPLICATION:

Title of Research Protocol_____

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A. This application is to request one of the following:

☐ Waiver of authorization (for all uses of PHI for this protocol, such as retrospective/prospective chart reviews).

☐ Partial waiver of authorization (for some uses of PHI for this protocol as described in the protocol submission; screening, recruitment, maintaining PHI once subjects reach age of majority).

B. Required Information.

1. The Privacy Rule requires an IRB to determine the study will use the minimum amount of PHI necessary to conduct the research. Please list the specific health information that you propose to use in this study.

- State specifically whether sensitive information (e.g., illegal drug use, sexual practices) will be collected.

- A copy of the data collection form also should be submitted. (**Identifiers collected on data collection forms should match the identifiers indicated below for retrospective/prospective chart reviews, screening).**
- For survey or interview research, the questions to be asked of research subjects should be attached to your IRB submission.

2. Specify which, if any, of the following identifiers will be associated with the health information you propose to collect.

☐	Names	☐	Telephone Numbers
☐	Address	☐	E-Mail Addresses
☐	Fax Numbers	☐	Medical Record Numbers
☐	Social Security Numbers	☐	Account Numbers
☐	Health Plan Beneficiary Number	☐	Vehicle Identifiers and Serial Numbers
☐	Certificate/License Numbers	☐	Web Universal Resource Locators (URL)
☐	Device Identifiers and Serial Numbers	☐	Biometric Identifiers (**examples include fingerprints)**
☐	Any Geographic Subdivision Smaller Than a State **(specify which of the following identifiers you will use: county ,city, parish, or zip code)**	☐	Any Elements of Dates (**specify which of the following identifiers you will use: birth date, admission date, discharge date, date of death, age over 89)**
☐	Full face photographic images and comparable images	☐	Any other unique identifying number, characteristic, or code -including initials **(please specify)**

3. List all institutions, separately, from which you plan to obtain PHI, and list each source of PHI. (e. g., CW Epic, Froedtert Hospital Epic, Versiti, paper clinic records, a departmental database, data warehouse).

4a. List the individuals or groups within CW who will receive and/or use PHI.

4b. List, if any, individuals **outside of CW/MCW** to whom you will **disclose the PHI** (e.g., research collaborators from other institutions or a research sponsor).

5. Describe your plan to protect PHI from unauthorized use or disclosure. Specify for both paper and electronic forms of PHI. (e. g., locking research files, protections for codes that link patients to their data, and security measures to protect storage and transmission of electronic data). If maintaining a screening log- please indicate where the log is secured.

6. Describe you plan for destroying the identifiers at or before the conclusion of the study (for screening purposes). For retrospective/prospective chart reviews and maintaining data of subjects who reach age of majority. Refer to the Research Records-Retention for Human Subjects Policy, which indicates all data must be kept for a minimum of 10 years. If maintaining a screening log- please indicate when the log will be destroyed.

7. Explain why the study cannot be conducted without the waiver of authorization. In order for an IRB to grant a waiver of authorization, the research cannot practicably be conducted without it. Criteria the IRB considers in determining whether a waiver of authorization should be granted include: number of subjects proposed, difficulties of obtaining individual authorization, and need for historical controls. Other criteria may apply.

C. Researcher Assurances.

As Principal Investigator of the research described above, I make the following assurances to the IRB regarding the use and disclosure of PHI:

"The investigators and research staff who use and disclose PHI in connection with this research will not reuse the PHI or disclose it to any person or entity other than those authorized to receive it, except: a) as required by law or b) for authorized oversight of the research.

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Print name of Principal Investigator Date

Signature of Principal Investigator_____