TITLE: Waiver or Alteration of a HIPAA Authorization for Research		POLICY/PROCEDURE NUMBER: IRB 20.4	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	3/2022	DATE EFFECTIVE:	5/10/2022
Page 1 of 3			

x	CFNI Munster, Indiana	x	Community Hospital Munster, Indiana	x	St. Catherine Hospital East Chicago, Indiana	x	St. Mary Medical Center Hobart, Indiana

POLICY STATEMENT/PURPOSE:

Many health research projects and protocols cannot be undertaken using health information that has been de-identified. In addition, it may not be feasible for a researcher to obtain a signed Authorization for all PHI the researcher needs to obtain for the research. In other cases, a researcher may determine that consents obtained prior to April 14, 2003, that permit the use and disclosure of information obtained from research subjects are inadequate, insufficient, or restrict the research protocol or procedure such that an Authorization may be necessary to permit the PHI use or disclosure for the research.

The Privacy Rule does not change current requirements that specify when researchers must submit protocols to the IRB for review and approval, and obtain informed consent documents. The Privacy Rule adds to such requirements only when a researcher requests a waiver or an alteration of Authorization.

Research activities that involve PHI should be conducted, whenever practicable, with subject authorization. It may be feasible to obtain signed Authorizations from each individual in a small data set.

Waivers or Alteration of Authorization are typically not approved by the IRB when the subject's PHI is to be used in the research **AND** the researcher has face-to-face contact with the subject.

If a covered entity has used or disclosed PHI for research with an IRB or Privacy Board approval of waiver or alteration of Authorization, documentation of that approval must be retained by the covered entity for six (6) years from the date of its creation or the date it was last in effect, whichever is later.

The IRB or privacy board shall limit its approval of a waiver or alteration of the Authorization to a specific research study, which permits the investigator to collect, use and disclose PHI without the subject's written authorization. Documentation of this approval must identify the IRB or privacy board that approved the waiver or alteration, the date of the approval, and that the IRB has determined that the request for the waiver or alteration satisfies the following criteria:

1. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on the presence of the following elements:
    a. An adequate plan to protect health information identifiers from improper use and disclosure.
    b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).
    c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study,

or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

The IRB will not approved a Waiver of Authorization for use of data or specimens that are potentially highly sensitive and are linked to patient identifiers, e.g., data on major psychiatric diagnoses and specimens for studies that could produce genetic information with potentially damaging consequences.

Data obtained under a Waiver or Alteration of HIPAA Authorization is subject to the minimum necessary requirement of the Privacy Rule.

Data obtained under a Waiver or Alteration of HIPAA Authorization is subject to an Accounting of Disclosure.

DEFINITIONS: See IRB 20: HIPAA Privacy Rule In research: Use and Disclosure

PROCEDURE

1. The investigator must complete the HIPAA Waiver of Authorization/Alteration Request form and submit it to the CHS CIRB office along with the Protocol Submission Form for initial review.
    a. Adequate information must be provided by the investigator in response to the questions on this form for the IRB to determine that the waiver of authorization criteria at 45 CFR 164.512(i)(2) are met.
    b. Responses should be related to the research study under review.

2. The CHS CIRB will assure that the request involves no more that minimal risk to the privacy of the subjects.

3. The CHS CIRB office will assign an IRB number and log the Request into the Disclosure Data Base.

4. The Request form will be saved into the Disclosure Tracking Folder using the IRB number as an identifier.

5. The investigator may begin the data collection upon receipt of the approval letter from the CHS CIRB.

CROSS REFERENCE(S):

IRB 20: HIPAA Privacy Rule in Research; Use and Disclosure
Addendum I: Required Elements of a Valid HIPAA Authorization
Addendum II: HIPAA Authorization Form
IRB 20.1: Use and Disclosure of PHI Preparatory to Research
Form: Notice of Review Preparatory to Research
IRB 20.2: Research Involving Decedents PHI
Form: Request to Use or Disclose Decedent PHI
IRB 20.3: Research Involving a De-Identified Data Set or a Limited Data Set
Addendum I: Elements of a De-Identified /Limited Data Set
Addendum II: Data Use Agreement (DUA)
Form: Request for a De-Identified /Limited Data Set
IRB 20.4: Waiver or Alteration of HIPAA Authorization
Addendum I: Requirements for Waiver of Consent and HIPAA Authorization
Form: HIPAA Waiver of Authorization/Alteration Request
IRB 20.5: Accounting of Disclosures of PHI for Research
Form: PHI Disclosure for Research: Standard Accounting (Single Individual)
Form: PHI Disclosure for Research Alternative Accounting (50+ Individuals)

HIP 1.02: Accounting of Disclosures Policy/Procedure
HIP 1.03: Business Associates
Business Associate Analysis Tool
HIP 1.08: De-Identification of Data and Limited Data Set

REFERENCE(S):
Privacy (also known as Standards for Privacy of Individually Identifiable Health Information) is in Title 45 of the Code of Federal Regulations, Part 160 and Subparts A and E of Part 164
Indiana Code 16-39-1, Chapter 1. Release of Health Records to Patient and Authorized Persons

ACCEPTED BY:

Elizabeth Yee
Vice President, Ancillary Services

Andrej Zajac, M.D.
Chair, CHS CIRB

Jana L. Lacera, RN, MSA, CDM
Human Protections Administrator, CHS CIRB
Director, IRB/Bio-Ethics

Nancy Moser, BSN, JD
Vice President, Corporate Compliance &
Quality and Risk Management

DATE(S) REVISED:

REVIEWED BY: CHS CIRB 5/2022

Date	Initials