TITLE: Use and Disclosure of Data Preparatory to Research		POLICY/PROCEDURE NUMBER: IRB 20.1	
AUTHOR:	Jana L. Lacera, RN, MSA, CDM	APPLICABLE TO:	CHS CIRB
SUPERSEDES:	None	ISSUED BY:	CHS CIRB
DATE ORIGINATED:	3/2022	DATE EFFECTIVE:	5/2022
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:

To provide guidance regarding any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where protected health information (PHI) is accessed to prepare a research protocol.

SCOPE

The research pathway, **Preparatory to Research,** permits Covered Entities to use or disclose PHI without an individual's Authorization, a Waiver or an Alteration of Authorization, or a Data Use agreement. However, the Covered Entity must obtain from a researcher written representations that;

1. The use or Disclosure is requested solely to review PHI as necessary to determine feasibility or to prepare for the proposed research;
2. The Principal Investigator (PI) may identify (but not contact) the names of potential research subjects;
3. The PHI will not be recorded or removed from the Covered Entity in the course of review, and
4. The PHI reviewed is necessary for the research.

Preparatory to Research is subject to the minimum necessary requirement of the Privacy Rule, therefore the researcher will be required to specify the information that is pertinent to their question on the Notice of Review Preparatory to Research form.

The PHI may not be recorded during the Preparatory to Research review. If the investigator intends to record PHI, he/she must first obtain CHS CIRB approval of the research protocol and either obtain the consent of the research subject or obtain an IRB approved Waiver or Alteration of Consent.

The investigator may identify but **cannot** contact potential study participants to ask for their participation in the research under the Preparatory to Research provisions of the Privacy regulations. He/she must first obtain CHS CIRB approval of the research protocol.

The PHI is subject to an Accounting of Disclosure if it is disclosed to a non-CHS Workforce Member. The non-CHS Workforce Member must view the PHI on-site at a CHS facility. An Accounting of Disclosure form must be completed.

PROCEDURE

An investigator may conduct a Review Preparatory to Research after notifying the CHS CIRB of his/her intent.

1. Submit the completed Notice of Review Preparatory to Research form to the CHS CIRB Office

2. The investigator may proceed with the review of PHI prior to receiving an acknowledgment from the CHS CIRB

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

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

5. The CHS CIRB office will send a letter of acknowledgment to the PI.

6. If PHI was disclosed to a non-CHS Workforce Member, complete the appropriate Accounting of Disclosure form and send it to the CHS CIRB office. The form will be scanned into the Accounting of Disclosure folder.

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:

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DATE(S) REVISED:

REVIEWED BY: CHS CIRB 5/2022

Date	Initials