

TITLE: Accounting of Disclosures of PHI for Research		POLICY/PROCEDURE NUMBER: IRB 20.5	
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:

In general, the Privacy Rule gives individuals the right to receive an account of certain disclosure of PHI made by a covered entity. This accounting must include disclosures of PHI that occurred during the six years prior to the individual's request for an accounting. Exempt from the accounting requirement are:

1. Research disclosures made pursuant to an individual's authorization;
2. Disclosures of a limited data set to researchers with a data use agreement;
3. Disclosures of a de-identified data set;
4. Review of data preparatory to research. Disclosures for research purposes that are subject to the accounting requirement include PHI disclosed under an approved Waiver of Authorization.

The following information must be made available upon request to the CHS CIRB, Corporate Compliance/Privacy and the department of Release of Information (ROI):

1. Date(s) of disclosure;
2. Name, title, and contact number of the CHS workforce member making the disclosure;
3. Name and address of the entity or person who received the PHI;
4. A brief description of the PHI disclosed; and
5. A brief statement of the purpose of the disclosure that reasonably describes the basis for disclosure.

Anytime there is an unauthorized review or disclosure of PHI involving research or a breach in the protection of the privacy of the PHI, the CHS CIRB must be notified immediately. This constitutes an unexpected event according to federal regulations Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), and the Office of Research Oversight (ORO) and must be reported to the appropriate federal entities as well and the Institutional Officials. Failure to adhere to the HIPAA Privacy Rule can result in institutional and individual fines.

KEY POINT: Research that is ongoing before the applicable compliance date (April 14, 2003) is covered by the Privacy Rule's transition provisions if the research participant's informed consent, other legal permission for the research use and disclosure, or an IRB's waiver of informed consent was obtained by the covered entity before the applicable compliance date for the Privacy Rule.

TITLE:	Accounting of Disclosures of PHI for Research	POLICY/PROCEDURE NUMBER:	IRB 20.5
DEPARTMENT(S):	CHS CIRB	Page 2 of 3	

PROCEDURE

1. The PI must complete either the Accounting of PHI Disclosures Form (Single Individual) or the Accounting of PHI Disclosures Alternative Form (50+ Individuals) for the following options for obtaining PHI:
 - a. Review Preparatory to Research if PHI will be disclosed to a non-CHS workforce member
 - b. Request to Use and Disclose Decedent PHI
 - c. Request for a Waiver or Alteration of HIPAA Authorization.
2. This form must also accompany the CHS CIRB Request Form with the Protocol Submission Form for the initial IRB review of the protocol.
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.

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

TITLE:	Accounting of Disclosures of PHI for Research	POLICY/PROCEDURE NUMBER:	IRB 20.5
DEPARTMENT(S):	CHS CIRB	Page 3 of 3	

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: CHS CIRB: 3/2022

REVIEWED BY:

Date	Initials
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____