

TITLE: Use and Disclosure of Decedent's Protected Health Information		POLICY/PROCEDURE NUMBER: IRB 20.2	
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
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- 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:**

The Community Healthcare System must protect the privacy of a decedent's PHI in the same manner and to the same extent that is required for the PHI of living individuals for a period of 50 years following the death of the individual.

The Common Rule defines a human research subject as a living individual. Under the Common Rule, research on decedent's PHI is not considered to be human subject's research. The Privacy Rule recognizes both living and deceased humans as individuals whose privacy must be protected.

If an investigator wishes to conduct research using PHI of one or more deceased individuals, prior CHS CIRB review is required.

To disclose PHI of a deceased individual for research, The Community Healthcare System is not required to obtain an Authorization from the person's legally authorized representative (LAR) or next of kin, a Waiver or Alteration of the Authorization or a Data Use Agreement (DUA).

The Community Healthcare System is required to obtain from the researcher who is seeking access to decedent's PHI the following written representations that:

1. The use and disclosure is sought solely for research on the PHI of decedents';
2. The PHI for which use or disclosure is sought is necessary for the research purposes; and
3. The CHS CIRB may elect to require the researcher to provide evidence that the proposed subjects are deceased.

Use and disclosure of decedent's PHI is subject to the minimum necessary requirement of the Privacy Rule.

The use and disclosure of decedent's PHI is subject to an Accounting of Disclosure.

**PROCEDURE**

1. Complete and submit the Use and Disclosure of a Decedent's PHI for Research form with the Submission of a Protocol for initial review by the CHS CIRB.
2. The CHS CIRB office will assign an IRB number and log the Request into the Accounting of Disclosure Data Base.
3. The Request form will be saved into the Accounting of Disclosure Folder using the IRB number as an identifier.

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4. 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

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ACCEPTED BY:

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Vice President, Ancillary Services

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Andrej Zajac, M.D.  
Chair, CHS CIRB

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Quality and Risk Management

DATE(S) REVISED:

REVIEWED BY: CHS CIRB 5/2022

Date	Initials
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