TITLE: Research Involving a De-Identified Data Set or a Limited Data Set		POLICY/PROCEDURE NUMBER: IRB 20.3	
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SUPERSEDES:	None	ISSUED BY:	CHS CIRB
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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:

DE-IDENTIFIED HEALTH INFORMATION

De-Identified Health Information: Health information that has been stripped of all 18 identifiers as defined by the Privacy Rule (See Addendum I: De-Identified /Limited Data Set), so that the information can not be traced back to an individual. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:

a. The code is not derived from or related to information about the individual;
b. The code could not be translated to identify the individual; and
c. The covered entity does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

Research on non-identifiable information, or on coded private information where the researchers never have access to "re-identify", does not qualify as research involving human subjects.

a. Under the Common Rule, a dataset is "de-identified" only when no one could "re-identify" the data: not the recipients, nor the data provider, nor anyone else. If the data were "coded" any "key to the code" must be destroyed to "de-identify" the data set.
b. The Common Rule does not recognize as "de-identified" information that retains a code to permit re-identification; rather, this is "coded" information, which is "indirectly identifiable". Therefore, a dataset can be "identifiable" under Common Rule definitions while also meeting HIPAA "de-identified" criteria.

De-identified health information is exempt from the Privacy Rule and may be used or disclosed for research purposes without a HIPAA Authorization or IRB Waiver of Authorization.

De-identified health information does not require an accounting of disclosure.

De-identified health information is not subject to the minimum necessary standard. The data are not protected nor is the use of them restricted.

Investigators must provide a written certification to the CHS CIRB that the health information has been de-identified by one of two methods of creating a de-identified data set, which involves the removal of HIPAA identifiers. A covered entity is required to keep such certification, in written or electronic format, for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

1. **Safe Harbor Method: Removal of all 18 identifiers** enumerated in the Privacy Rule that could be used to identify the individual or the individual's relatives, household members, and employers.

2. **Expert Determination Method** is based on statistical analysis. In order to be considered de-identified under this method, an individual with knowledge of and experience with generally accepted statistical and scientific methods for rendering information not individually identifiable must provide certification that the data is de-identified. When making such a determination, the individual should find that the risk is very small that the information could be used (either alone or in combination with other reasonably available information) to identify any individual who is a subject of the data.

3. The methods and results of the analysis must be documented, and retained by the covered entity for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

Zip codes, counties, census tracts, and other equivalents must be removed; the first 3 digits of a zip code may be replaced by three zeros (000) and included in a de-identified data set for an area where more than 20 people live.

Many records contain dates of service or other events that imply age. Elements of dates that are not permitted in a HIPAA de-identified data set include the day, month, and any other information that is more specific than the year of an event. For instance, “January 1, 2009” and “January 2009” are both considered to contain PHI. Not only birth or death dates, but also dates of service (appointment, biopsy, surgery, etc.) are considered dates “directly related to the individual”.

PROCEDURE

1. In order to request a de-identified data set, the Investigator must complete the Request for a De-Identified or Limited Data Set Form and submit it to the department of Data Analytics and Informatics (DAI).
2. DAI will send the de-identified data set and the Certification of De-Identification to the Investigator.
3. The Certification of De-identification and the Request for a De-Identified or Limited Data Set form must accompany the Protocol Submission to the CHS CIRB for initial review of the protocol.
4. DAI will retain the Certificate for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

LIMITED DATA SET

Limited Data Set: Protected health information that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP Code, elements of dates, and other numbers, characteristics, or codes not listed as direct identifiers.

A Limited Data Set **is not** considered de-identified data according to the Privacy Rule.

A Limited Data Set can only contain the following of the 18 identifiers enumerated in the Privacy Rule:

- City or State
- ZIP Code
- Geocode
- Date of Birth
- Admission/Discharge date
- Date of Death
- Dates of Service

A Limited Data Set is considered to be PHI and is subject to the minimum necessary requirements of the Privacy Rule. The investigator will be required to specify the information that they will be requesting.

A Limited Data Set does not require an accounting of disclosure.

A signed Data Use Agreement (DUA) must be submitted with the Protocol Submission Form to the CHS CIRB. The CHS CIRB will only provide conditional approval of the protocol if needed in order to get a DUA signed, but final approval will not be granted until a signed copy is received by the CHS CIRB.

A data use agreement (DUA) is a contractual document used for the transfer of non-public or restricted use data. DUAs address issues such as limitations on use of the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfer of confidential or protected data.

For human subjects research purposes, only Corporate Compliance/Privacy may approve and sign a DUA. Investigators are not permitted to negotiate or sign a DUA.

The DUA stipulates that the recipient will:

- Not use or disclose the information other than permitted by the agreement or otherwise required by law.
- Use appropriate safeguards to prevent he use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation for the agreement of which the recipient becomes aware.
- Holds any agent of the recipient (including subcontractors0 to the standards, restrictions and conditions stated in the DUA with respect to the information.
- Not identify the information or contact the individuals.

For Human Subjects Data, a DUA is typically required when:

- Disclosure of data is for research purposes, and
- Individual authorization for disclosure to this recipient is not/has not been obtained(i.e. through use of a HIPAA authorization signed by the subject), and
- When no other form of contract concerning the transfer of data exists between the provider and the recipient (i.e. sub-award agreement, contracted services agreement, business associate agreement.

Examples of Data that might be exchanged under a DUA

- Records from governmental agencies or corporations
- Student record information
- Existing human research subject data
- A limited data set

For Human Subjects Data, a DUA is NOT typically required when

- When data is publically available in the public domain
- When data is exchanged that is not subject to legal or restriction on its use
- If a research subject signs a HIPAA authorization form that authorizes data sharing with the recipient
- When another agreement, such as a sub-award, contracted services agreement or a business associate agreement is in place
    - Data transfer as part of such a collaborative research project is often addressed in the study protocol or in the funding agreement terms and conditions

If a covered entity is the recipient of a limited data set and violates the DUA, it is deemed to have violated the Privacy Rule. If the covered entity providing the limited data set knows of a pattern of activity or practice by the recipient that constitutes a material breach or violation of the DUA, the covered entity must take reasonable steps to correct the inappropriate activity or practice. If the steps are snot successful, the covered entity must discontinue disclosure of PHI to the recipient and notify HHS.

PROCEDURE

1. The Investigator will contact the CHS Contract Specialist to begin the process to obtain a DUA.
2. CHS prefers that the CHS Master DUA Template (Addendum II) is used. If utilizing the recipient of the Limited Data Set's DUA, the CHS entity/researcher must send the agreement to the Office of Corporate Compliance for review and signatures.
3. In order to request a Limited Data Set, the Investigator will complete a Request for a De-Identified or Limited Data Set Form and submit it to the Department of Data Analytics and Informatics (DAI).
4. A signed DUA must accompany the Protocol Submission form to the CHS CIRB for initial review of the protocol. The CHS CIRB will only provide conditional approval of the protocol if needed in order to get a DUA signed, but final approval will not be granted until a signed copy is received by the CHS CIRB.

5. The signed DUA will be retained in Meditract. The investigator should retain the original signed DUA in the protocol regulatory binder.

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	Initials