TITLE: HIPAA Privacy Rule in Research: Use and Disclosure		POLICY/PROCEDURE NUMBER: IRB 20	
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SUPERSEDES:	None	ISSUED BY:	CHS CIRB
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POLICY STATEMENT/PURPOSE:

In 1996, Congress passed the Health Insurance Portability and Accountability ACT (HIPAA). Privacy standards (Privacy Rule) pursuant to this law were issued by the U.S. Department of Health and Human Services in 2000 and provided for the protection of the privacy of certain individually identifiable health data, referred to as Protected Health Information (PHI). These regulations [45 CFR 160 & 164Subparts A and E] were implemented for research on April 14, 2003.

A HIPAA Authorization differs from an informed consent in that a HIPAA Authorization focuses on privacy risks and states, how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent, on the other hand, provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected among other things.

The HIPAA Privacy Rule permits a covered entity to use or disclose PHI for research under the following circumstances and conditions:

- If the subject of the PHI has granted specific written permission through an Authorization that satisfies HIPAA Privacy Rule Requirements [45 CFR 164.508]
- For reviews preparatory to research with representations obtained from the research that satisfies HIPAA Privacy Rule requirements [45 CFR 164.512 (i)(1)(ii)] [See policy IRB 20.1]
- For research solely on decedents' information with certain representations and, if requested, documentation obtained from the researcher that satisfies HIPAA Privacy Rule requirements [45 CFR 164.512(i)(1)(iii)] [See policy IRB 20.2]
- If the covered entity receives appropriate documentation that an IRB or a Privacy Board has granted a waiver of the Authorization requirement that satisfies HIPAA Privacy Rule requirements. [45 CFR 164.512(i)] [See policy IRB 20.4]
- If the covered entity obtains documentation of an IRB or Privacy Board's alteration of the Authorization requirement as well as the altered Authorization from the Individual [See policy IRB 20.4]
- If the PHI has been de-identified in accordance with the standards set by the HIPAA Privacy Rule, in which case, the health information is no longer PHI [45 CFR 164.514(a)-(c)] [See policy IRB 20.3]

- If the information is released in the form of a limited data set, with certain identifiers removed and with a data use agreement between the research and the covered entity, as specified in the HIPAA Privacy Rule [45 CFR 164.514(e)] [See policy IRB 20.3]

SCOPE

It is the policy of the CHS CIRB, in its role as the Privacy Board, that research data be used, stored and/or disclosed according to current HIPAA regulations. These policies and procedures covers all PHI, which is or may be created, used or disclosed by, through or during research activities, and applies to all staff who conduct research, assist in the performance of research, or otherwise use or disclose PHI in connection with research activities

These policies and procedures apply to all research being conducted within the Community Healthcare System and its affiliate institutions that use and/or disclose Protected Health Information (PHI) obtained from a participant's medical records in the course of a research protocol.

These policies and procedures apply to all medical records (electronic or paper), clinical databases and specimen or tissue banks or repositories that are being accessed for research purposes.

These policies and procedures define the circumstances under which Protected Health Information (PHI) may and may not be used internally or disclosed externally in connection with research activities.

Anytime there is an unauthorized use 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 as Institutional Official. Failure to adhere to the HIPAA Privacy Rule can result in institutional and individual fines. The CHS CIRB will immediately notify the Office of Corporate Compliance of the breach. Corporate Compliance will be responsible to report the breach to the Office for Civil Rights (OCR).

When medical records from an institution outside of the Community Healthcare System and its affiliated institutions provide the data for a research study, HIPAA documentation is not required with the research submission to the CHS CIRB. In this case, the CHS CIRB is not considered the Privacy Board for the PHI. The outside institutions' Privacy Board is responsible for the HIPAA oversight in that case.

If a data set received by a researcher has no elements of PHI within it and no link is available to the researcher that would connect the participant to the information, it is considered de-identified or anonymized data and HIPAA does not apply to that research protocol.

When health information is collected directly from the participant in a research study through interviews, questionnaires or surveys, and if the research team will never access medical records to verify that information, HIPAA oversight by the CHS CIRB is not required.

HIPAA permits the investigator and the CHS CIRB to condition research participation and any consequent need to obtain previously created PHI, on the patient/subject's signing both the HIPAA authorization and the IRB-approved investigational consent or the combined document. Continued medical treatment cannot be changed or withheld if the patient does not decide to participate in the research.

If a decisionally impaired individual is incapable of providing informed consent and HIPAA authorization for research participation, the consent/authorization must be obtained from the individual's legally authorized representative. If the individual has been declared mentally incapacitated by the court, the court documents should be reviewed to determine if legal authority for consent for participation in research is addressed and, if so, to whom such authority is granted. If the court documents do not address proxy consent for participation in research, the individual should be excluded from participation unless the IRB specifically grants a waiver of the informed consent requirement for this individual.

Document Retention Requirements:
HIPAA regulations require documentation to be retained for six (6) years from when it was last in effect. This would include:

- Signed HIPAA Authorizations;
- IRB determinations for Waiver/Alteration of HIPAA Authorization; and
- The accounting of all disclosures of PHI when required under HIPAA.

Issues of HIPAA and Recruitment:
The CHS CIRB requires that the person in a clinical relationship with the patient be the one to introduce the potential participant to the study. If the participant is interested, the research personnel can then be introduced to the participant and start the consent and enrollment process. This can be accomplished in several different ways.

a. Face-to-face introductions in the clinical setting.
b. Letters, information sheets or other documents generated from the clinician's office that are mailed or given to patients in the clinical setting. The document can be used to introduce the potential participant to the research study and inform him/her that he/she may be called regarding her research. These contact documents should allow the participant to refuse a contact by the research team member if he/she chooses.

DEFINITIONS:

Anonymous Data: Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA, and no code is assigned which would allow data to be traced to an individual. (un-identified data)

Anonymized data: Human data that were initially collected with identifiers but, prior to research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This process does not preclude linkage with existing clinical, pathological, and demographic information before participant identifiers are removed (Unlinked data)

Authorization: A customized document, usually as a part of the informed consent document, that gives an Investigator permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the Investigator other than for treatment, payment or healthcare operations. This authorization is distinct from the subject's consent to participate in research, which is required under the Common Rule and FDA regulations. The Privacy Rule allows a HIPAA authorization for research to be combined with another authorization and/or with a consent for research. Just as a valid consent must meet certain requirements, a valid authorization must contain certain core elements (45 CFR 164.508(c)). (See Addendum I: Required Elements of a Valid HIPAA Authorization)

The subject's right to revoke authorization is limited. The investigator and the institution may continue to use and disclose PHI that was obtained before the subject revoked authorization to the extent that the investigator or institution has acted in reliance on the authorization, such as to use or disclose PHI in order to maintain the integrity of the research (45 CFR 164.508(b)(5)(i)).

While consent may be given verbally under the Common Rule and FDA regulations for minimal risk research activities, authorization under the Privacy Rule must be in writing (signed and dated). Therefore, if a verbal (or other non-written) consent process will be used in research and it that research involves PHI, a waiver request of all elements of HIPAA authorization should be submitted for CHS CIRB review and approval.

Business Associate Agreement (BAA): An Agreement between a covered entity and an external party is typically required before a covered entity discloses PHI to the external party for activities related to payment, healthcare operations, or certain activities defined in the Privacy Rule as giving rise to a business associate relationship. In the context of a research study, a BAA is typically only required if a person or entity outside the covered entity receives PHI to perform a "healthcare operation" activity in connection with the research study.

Coded Information/Data: Collected data are de-identified for research purposes by use of a random or arbitrary alphanumeric code but the data may still be linked to their sources through use of a key to the code available to an investigator or collaborator.

Covered Entity: A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form and is therefore subject to the HIPAA regulations. Covered entities can be institutions, organizations, or people. For the purpose of this policy, any individual creating or accessing Protected Health Information (PHI) for the delivery of healthcare at Community Healthcare System is within the covered entity. Research Health Information (RHI as defined below) is not considered part of the covered entity.

Data Use Agreement: An agreement required by the Privacy Rule [45 CFR 164.514 (2)(4)(ii)(c)] between Community Healthcare System and the recipient of a limited data set. This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will use or disclose the information in the limited data set only for specific limited purposes.

a. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
b. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
c. Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
d. Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
e. Not identify the information or contact the individuals.

De-Identified Health Information: Health information that has been stripped of all 18 identifiers as defined by HIPAA (See Addendum I: De-Identified /Limited Data Set), so that the information could 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 the information about the individual;
b. The code could not be translated to identify the individual; and
c. The covered entity (as described above) does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

Disclosure of PHI: The release, transfer, or provision of access to, or divulging in any manner of information outside of the covered entity. The sharing of PHI outside of the Community Healthcare System is a disclosure. In general, a disclosure of PHI requires an accounting at the request of the individual who is the subject of the PHI, unless that individual gave permission for the disclosure by signing an authorization.

Existing data: Data that exists at the time the research is proposed. The data may include data sets, interview notes, audio or video tapes. The data may have been originally collected or created for research or non-research purposes.

Individually identifiable data: A subset of health information, including demographic information collected from an individual, and;

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse, and
b. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment of the provision of health care to an individual, and
c. Identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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. [45 CFR 164.514(e)]

Minimum Necessary Standard: The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request for PHI.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)] [21 CFR 50.3]

Practicably: It is feasible to obtain a subject's consent to participate in research without affecting the scientific integrity of the study.

Preparatory to Research: 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 PHI is accessed to prepare a research protocol.

Privacy Board: A board established to review and approve requests for waivers or alterations of authorization regarding use or disclosure of PHI. The CHS CIRB will serve as the Privacy Board for the Community Healthcare System. [45 CFR 164.512(i)(1)(i)(B)]

Protected Health Information (PHI): Individually identifiable health information that is or has been collected or maintained by a health care provider, health plan, employer, and/or health care clearinghouse in the course of providing healthcare that can be linked back to the individual participant. The Privacy Rule [45 CFR 160.103] defines PHI to include information that :

a. Is created or received by a "covered" entity," including a health care provider, and
b. Relates to the past, present, or future physical or mental health, or condition of an individual, or
c. Relates to payment for an individual's health care, or
d. Relates to the provision of health care in the past, present, or future, and
e. Identifies an individual or could be used for identifying an individual.

Psychotherapy Notes: Notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or group, joint, or family counseling session and that are separated from the rest of the individual's medical record.

Psychotherapy notes exclude medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. [45 CFR 164.501, psychotherapy notes]

Prospective: Research using human subjects' specimens/data that will be collected after the research is approved by the IRB.

Publicly available: The general public can obtain the data. Data are not considered "publically available" if access to the data is limited to researchers.

Readily identifiable: The identity of the subject could be ascertained by the investigator or associated with the data without requiring time or special effort.

Research Health Information (RHI): Individually identifiable health information that is or has been collected solely for the purposes of research.

Retrospective: Research using human subject's specimens/data that were previously collected before the research was approved by the IRB.

Use of PHI: Querying, viewing, and/or extracting any protected health information for research purposes within the Community Healthcare System. The sharing of PHI within the Community Healthcare System is a use. Uses, unlike disclosures, of PHI do not require an accounting at the request of the individual who is the subject of the PHI.

Waiver of Authorization: When obtaining subject/participant authorization is "impracticable", the CHS CIRB may approve a waiver of authorization for the research to use and disclose PHI. The purposes of the research must be described in the Review Preparatory to Research and Waiver of HIPAA Authorization Request and the CHS CIRB must determine that the research has satisfied all Privacy Rule requirements. An **altered authorization** is a form of waiver of authorization.

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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