Title: HIPAA and Research
Type: Privacy
Number: RENOWN.CCD.780
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Scope:
Accountable Care Organization; Administrative & Business Offices; Ambulatory; Behavioral Health; Breast Health Center; Center for Advanced Medicine B; Center for Advanced Medicine C; foundation; Healthcare Center; Home Health; Hometown Health; Hospice; Hyperbaric; Laboratory; Medical Group; Monaco Ridge; Pregnancy Center; Regional Medical Center; Rehabilitation Hospital; Skilled Nursing; South Meadows Medical Center; Surgical Arts; Therapies; Urgent Care; Wound Care; X-ray & Imaging

Policy Statement:
All research studies conducted and/or sponsored by the Renown Health that involve the use and/or disclosure of protected health information (PHI) of research subjects, living or dead, must be reviewed and approved in accordance with the Policies and Procedures of the Renown Health Institutional Review Board. Renown Health is committed to protecting the privacy of PHI while ensuring that researchers continue to have access to medical information necessary to conduct vital research. Renown Health shall apply the minimum use standard (as defined in Renown Health system HIPAA – RENOWN.CCD.770 Minimum Necessary) to all research involving PHI.

Definition of Terms:
1. Business Associate Agreement – A written contract with other entities that utilize Protected Health Information ("PHI") obtained from Renown-affiliated entities (called "Business Associates" in the HHS privacy regulations). Compliant business agreements include:
   a. Contract termination for privacy violations;
   b. Specific specifications as to how the business associate is allowed and/or required to use the PHI;
   c. Specifications for the destruction of PHI when no longer needed; and
   d. Requirements for reporting improper uses and disclosures of the PHI
2. Data Use Agreement – A Data Use Agreement is an agreement between the source of the Limited Data Set (LDS) and the recipient of the LDS that:
   a. Establishes the permitted use of the LDS;
   b. Establishes who is permitted to use or receive the LDS;
   c. Provides for appropriate safeguards; and
   d. Includes the same termination and cure provisions as the Business Associate

4. Designated Record Set – A designated record set is a group of records which a covered entity uses to make decisions about individuals, and includes health care provider’s medical records, billing records, health plan’s enrolment, payment, claims adjudication, and case or medical management record systems. Research records or results maintained in a designated record set are accessible to research participants unless one of the Privacy Rule’s permitted exceptions applies.

5. Disclosure – PHI shared outside Renown Health

6. Institutional Review Board (IRB) – Are independent ethics committees that are formally designated to approve, monitor and review biomedical and behavioral research. They also protect the rights of human subjects and the use and disclosure of PHI. The IRB:
   a. Must have members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual’s privacy rights and related interests;
   b. Must include at least one member who is not affiliated with Renown Health, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
   c. Does not have any member participating in a review of any project in which the member has a conflict of interest.

7. Identifiers –
   a. Names;
   b. All geographic subdivisions smaller than a State, including street address, city, country, precinct, zip code and their equivalent geo-codes;
   c. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
   d. Telephone numbers;
   e. Fax numbers;
   f. Electronic mail addresses;
   g. Social security numbers;
   h. Medical record numbers;
   i. Health plan beneficiary numbers;
   j. Account numbers;
   k. Certificate/license numbers;
   l. Vehicle identifiers and serial numbers, including license plate numbers;
   m. Device identifiers and serial numbers;
   n. Web Universal Resource Locators (URLs);
   o. Internet Protocol (IP) address numbers;
   p. Biometric identifiers, including finger and voice prints;
   q. Full face photographic images and any comparable images;
   r. Any other unique identifying number, characteristic, or code.

8. Limited Data Set (LDS) – A limited data set excludes all of the identifiers except dates, geographic information (may not contain street address), or other unique
identifying numbers, characteristics, or codes that are not expressly excluded.

9. Minimum Use Standard – The investigator shall use or disclose only the least amount of PHI necessary for a specific research purpose.

10. Patient Authorization – A patient’s written permission to use and/or disclose PHI. A valid patient authorization is written in plain language and contains the following elements:
   a. A specific description of the PHI;
   b. The name of the person(s) authorized to use and/or disclose the PHI;
   c. The name of the person(s) authorized to receive the PHI;
   d. The purpose of the use and/or disclosure;
   e. The expiration date or event that relates to use and/or disclosure;
   f. Statement of patients’ right to refuse the authorization;
   g. Statement of patients’ right to refuse to sign the authorization;
   h. Statement that patients’ other benefits will not be affected if the authorization is not signed;
   i. Statement that once PHI is disclosed, it may not be protected by the recipient;
   j. The signature of the patient and the date of the signing

11. Protected Health Information (PHI) – For the purpose of this policy, is defined as any individually identifiable health information collected or stored by a facility. Individually identifiable health information includes demographic information and any information that relates to past, present or future physical or mental condition of an individual and billing records. PHI does not include education records covered by the Family Educational Rights and Privacy Act (FERPA); Employment records by a Covered Entity in its role as an employer; and regarding a person who has been deceased more than 50 years.

12. Research – A systematic investigation designed to develop or contribute to generalized knowledge. [45CFR46.102(d)]


14. Workforce Member - Employees, volunteers, trainees, medical staff, residents and other persons whose conduct, in the performance of work for Renown Health, is under the direct control of Renown, whether or not they are paid by Renown.

Procedure:

1. Investigators conducting research for which the approval of an Institutional Review Board (IRB) is required involving the use and/or disclosure of PHI of living or dead individuals must submit a written protocol for review and approval by the IRB prior to initiating any research procedures.

2. The IRB may allow the use of PHI if the investigator documents that one of the following conditions has been met:
   a. A patient authorization is obtained. The authorization must state what will be used-disclosed, who may use-disclose, to whom the PHI will be disclosed, and why the use-disclosure is being made. The patient must be given a copy of the signed authorization.
   b. All PHI has been de-identified in accordance with Renown Health’s policy for de-identification of patient data (HIPAA – RENOWN.CCD.781). That is, either the data set contains none of the 18 identifiers (listed in definition above) or a
statistician has determined that the risk of re-identification is very small and has documented how this determination was made. PHI coded to allow for re-identification by the code cannot be derived from identifying information nor can the code be used or disclosed for any other purpose.

c. The requirement for patient authorization is waived by an IRB (see 6. below) (Also see d-f below and 3. below).

d. Information is collected only for preparatory work for research. In this case, the researcher must confirm in writing that the use of PHI is necessary to prepare a research protocol, the PHI will not be removed by the researcher during the review, and the information is necessary for research purposes.

e. The PHI is from deceased persons. In this case, the researcher must confirm in writing that the use/disclosure of PHI is for research purposes only and the PHI is necessary for such research purposes. The researcher must provide documentation that the person is deceased. All disclosures of decedent PHI must be tracked.

f. Only a limited data set is being collected and a data use agreement is established. A limited data set can only include identifying dates and the town, state, and zip code of the patient. It may not contain the street address. The data use agreement must establish the permitted uses and disclosures and identify who is permitted to use or receive the limited data set. The recipient must also agree to reciprocate safeguards and reporting procedures and ensure that individuals will not be identified.

3. FDA-regulated research does not require an authorization for the collection and reporting of adverse events.

4. The IRB shall apply the following rules to currently active research studies:

   a. If enrollment is closed, all consents for that research study can be grandfathered.
   b. If enrollment is open, all enrollment after 4/13/03 will require new consent/authorization forms. All consent forms signed before 4/14/03 can be grandfathered.

5. The IRB shall establish procedures allowing research subjects to:

   a. Have access to their designated record set (this access can be suspended while the research is in progress);
   b. Request amendment of their designated record set;
   c. Receive a record of disclosures within the previous six years if authorization has been waived;
   d. Request restrictions on uses and disclosures of their designated record set;
   e. Revoke their authorization;
   f. Request communication of their designated record set by alternative means.

6. The IRB shall apply the following criteria for granting waivers of authorization:

   a. The IRB must verify that there is no more than minimal risk to privacy;
   b. The IRB must verify that there is a plan to protect PHI from improper
use/disclosure and a plan to destroy identifiers as soon as possible; and

c. The IRB must verify that use/disclosure of PHI will not occur except as
   required by law and for the specific research study (or studies) approved by
   the IRB.

d. The researcher must confirm in writing that the research cannot be done
   without waiver and without this specific PHI.

7. The IRB shall establish a procedure for tracking of and accounting for disclosures of
   PHI for the previous six years if the authorization has been waived. The requirement
   to track and account for disclosures does not apply to disclosures pursuant to an
   authorization or disclosure of a limited data set. For each disclosure, the investigator
   must record the name of the recipient, the date of the disclosure, a brief description of
   the PHI disclosed, and a brief statement of the purpose of the disclosure. The IRB
   shall establish a modified procedure for tracing and accounting of PHI disclosures for
   the previous six (6) years if the research involves the disclosure of PHI from fifty (50)
   or more subjects. (See Patient Right to an Accounting of Disclosures–
   RENOWN.CCD.750)

8. The IRB shall require a description in writing of how potential research subjects will
   be identified and recruited. The IRB must be notified if a sponsor receives PHI
   from screening logs. If the IRB does not grant a waiver of authorization, patient
   authorization must be obtained before PHI can be accessed. To recruit research
   subjects when the investigator is not the treating physician, the investigator must
   contact the patient’s physician and provide him/her with the IRB approved study
   information. The patient’s physician can then provide the patient with an introduction
   to the study and the contact information for the investigator or a research team
   member. The patient may then contact the investigator or research team member.
   The investigator or research team member may not contact the patient directly
   without prior written authorization from the patient or a waiver of authorization from
   the IRB.

9. Business Associate Agreements do not apply to outside researchers, sponsors, and
   coordinating and statistical centers but do apply to third parties assisting with
   recruitment and screening.

10. The IRB shall establish the criteria for expedited review and approval of requests to
    use and/or disclose PHI for research that is determined to be of no more than minimal
    risk.

11. The IRB shall require that the informed consent document (ICD)/authorization be in
    the IRB approved template and be maintained for at least six years. This can be
    satisfied by placing a copy of the consent document in the medical record and
    keeping the original in the study’s research files.

12. When both the Privacy Rule and the Common Rule apply, both sets of regulations
    must be followed. If there is a conflict, the more restrictive regulations will apply.
13. Each workforce member with treatment, payment or health care related responsibilities is responsible for compliance with these policies and principles.

14. The Compliance and Privacy Officer has the responsibility of facilitating compliance with these procedures.

15. Enforcement will be consistent with Renown Health’s Code of Conduct and Renown Health Human Resource Progressive Discipline Policy RENOWN.HRM.810.

**References/Regulations:**
- 45 CFR §164.512(i).
- RENOWN.HRM.810 Coaching and Corrective Action
- RENOWN.CCD.550 Record Retention Policy – Schedule 2, Research Record Retention

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