

Lifespan System-Wide Policy
Standard Practice
Instruction Manual

Subject: HIPAA
Policy for Accounting of Research
Disclosures

File Under:

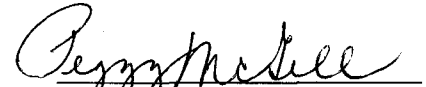
Issuing Department:
Office of Research
Administration

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Approved By:


(Director)


(Executive)

- 1. Purpose:** The purpose of this policy is to provide information, clarity and instruction to the Research Community regarding Accounting of Research Disclosures as defined by the Health Insurance Portability and Accountability Act, HIPAA.
- 2. Definitions**

Accounting of Disclosures – HIPAA and the Privacy Rule gives patients the right to receive an accounting of certain disclosures made of their protected health information (PHI). The accounting must include certain disclosures (but not uses) of the requesting patient's PHI made by Lifespan and/or business associates during the period requested by the patient up to six years prior but no earlier than April 14, 2003. (See HIPAA Corporate Policy CCPM-61)

Business Associate – A person or entity who, on behalf of a covered entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information regulated by the HIPAA Privacy Rule. (See HIPAA Corporate Policy CCPM – 56).

Disclosure – The release, transfer, access to, or divulging of PHI information in any manner outside the covered entity, CE, holding the information. This includes releasing information to or by a business associate.

HIPAA – The Health Insurance Portability and Accountability Act of 1996 Privacy Rule protects certain health information that identifies individuals who are living or deceased.

Limited Data Set – Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed for purposes of research, public health or health care operations without obtaining either an individual's Authorization or a waiver or an alteration of authorization for use and disclosure, with a data use agreement, (an agreement into which the covered entity enters with the intended recipient of the limited data set). (See HIPAA Corporate Policy CCPM – 67).

De-Identified Information – The Privacy Rule allows a covered entity to de-identify data by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members. (See appendix A of HIPAA IRB policy for list of the 18 elements).

Protected Health Information (PHI) – Individually identifiable health information that is transmitted or maintained in any form or medium by a covered entity or its business associate. This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse.

Use – The sharing of patient information that happens within the covered entity, CE, and is under direct control of that CE, i.e. given to someone who is part of the organization's workforce.

Lifespan Workforce – According to HIPAA workforce is defined as: Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of the covered entity, whether or not they are paid by the covered entity. It is important to note here: Foundation employed physicians, and OHCA (Organized Health Care Arrangement) members ARE NOT members of Lifespan's workforce

3. Eligibility:

Disclosures that apply to Research are: Prep to Research, Waiver of Authorization and Decedent Data review. Therefore, this policy applies to all researchers and their staff that apply to the IRB for any of the above. This policy is applicable when PHI is disclosed - released, accessed by, transferred to, divulged or shown to someone other than a member of the Lifespan workforce.

- For Prep to Research and Decedent Data Review this applies if a sponsor or some other non-workforce person(s) helps with or performs the Prep to research.
- For Waiver of Authorization and Decedent Data Review this applies if PHI in any other format other than a limited data set or de-identified

information is released, accessed by, transferred to, divulged or shown to someone other than a member of the Lifespan workforce. If de-identified information is released, accessed by, transferred to, divulged or shown to someone other than a member of the Lifespan workforce then no accounting is necessary.

4. Policy:

It is the policy of Lifespan to comply with those sections of the HIPAA Privacy Regulation (45 CFR 164.528 and 164.512(i)) that grants rights to patients/research subjects an accounting of disclosures for research purposes. From and after April 14, 2003 a patient shall be given, upon request, an accounting of all non-routine disclosures of Protected Health Information, PHI, maintained in his/her medical or billing record made during the six years preceding the patient's request. This shall include disclosures made by Lifespan or on behalf of Lifespan by a business associate. Accounting for Research disclosures applies to Waiver of Authorization, Prep to Research and Decedent Data Review when PHI leaves Lifespan without a patient's HIPAA authorization. The accounting of disclosures (not uses) of the requesting patient/subject's PHI must include up to 6 years prior to the request but in no event earlier than 4/14/2003.

5. Procedure:

Since an accounting of disclosures is required by law all researchers must comply and track all accounting of disclosures of any PHI released, divulged, transferred or given access to anyone outside the Lifespan Covered Entity, CE.

In order to comply with this accounting for Disclosures outside the CE a staff person from the researchers staff must go to Medical records at the affiliate the medical record is housed and the review is done to learn the tracking system for accounting procedure. Medical records will provide a form to keep track of the disclosures and instruct in the use of the tracking system.

Contact people at each location is:

RIH – Operations Mgr. HIS – ext. 45037

TMH – Dir. Patient Registration ext. 32249, or Operations Mgr. HIS – ext. 32227

Bradley – Mgr. HIS – ext. 21129

Newport – Mgr. HIS-845-1151, or Supervisor, Med. Rec. - 845-1152.

Since this accounting may result in a significant increase in the workload of a study and require a staff member to be trained by Medical Records to perform this accounting, the ORA strongly recommends utilizing other options that do not require accounting of disclosures. The options would be obtaining a HIPAA authorization; providing de-identified PHI to any

outside entity; utilizing a limited data set and signing a data use agreement.