TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.19, **Accounting of Research Disclosures of Protected Health Information**

PURPOSE: The purpose of this Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to establish a process for receiving and processing requests for an accounting of Protected Health Information (PHI) disclosures from study subjects in the research context. The Privacy Rule gives individuals the right to an accounting of certain disclosures of their PHI made during the previous six (6) years (but no earlier than April 14, 2003). The contents of this policy comply with requirements established by the Department of Health and Human Services (DHHS) Privacy Rule Section 164.528, as well as guidance from the Office of Human Research Protections to Institutional Review Boards[2] (IRBs), and include processes to identify and manage any such requests.

REVIEW: This HSCEP OP will be reviewed August 1 of each even-numbered year (ENY) by the Research Compliance Officer, the Senior Director of the Office of Research, and the Assistant Managing Director of the Office of Research (OR), with recommendations for revision submitted to the vice president for research (VPR) or designee.

POLICY/PROCEDURE:

I. **Introduction**

Under HIPAA, investigators may obtain, create, use, disclose, and/or otherwise access PHI from the TTUHSC El Paso covered entity for research purposes through one of the following methods:

- By obtaining an authorization from an individual;
- By obtaining an IRB waiver of the authorization requirement;
- By using de-identified information;
- By using limited data sets with a data use agreement (DUA);
- By using only decedents' information, with certain assurances; or
- By using PHI for purposes preparatory to research, with certain assurances.

This procedure applies to investigators who are disclosing PHI obtained from the TTUHSC El Paso covered entity in the course of research.

The HIPAA Privacy Rule gives individuals the right to request an accounting of certain disclosures made of their protected health information (PHI) by the covered entity without the individual's authorization. Accounting requirements include all covered disclosures, as defined in section 164.528 of the DHHS Privacy Rule, in the six (6) years prior to the individual's request.

II. **Applicability**

A. TTUHSC El Paso. This policy applies to all TTUHSC El Paso investigators/research personnel and applies to all research, regardless of funding.

B. Non-TTUHSC El Paso. The policy also applies to sub-recipients, sub-awardees or collaborators of TTUHSC El Paso involved in research activities.

C. Not applicable. This policy does not apply to:

- Disclosures to entities listed on the informed consent/HIPAA form and authorized and signed by the subject or their Legally Authorized Representative (LAR);
- Disclosures of PHI in the form of a limited data set;
- Disclosures made to the subject of the PHI;
- Disclosures made for treatment, payment, Quality Assurance/Quality Improvement (QA/QI), or internal audit/investigation purposes;
- Disclosures of de-identified information.

III. Definitions

Accounting: A log of certain disclosures of PHI that must be made available to a patient upon request that includes information about the disclosure including but not limited to the date it occurred, the name of the recipient, a description of the PHI and the purpose.

Authorization: Documented HIPAA authorization provided by a research subject

Disclosure: A disclosure is defined as the release, transfer, provision of access to or divulging in any manner any PHI outside of TTUHSC El Paso, which is considered the 'covered entity'.

Investigator: the principal investigator (PI) who is responsible for the design, conduct or reporting of research.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.

Research Personnel: any personnel participating in research regardless of funding source.

IV. Responsibilities of Investigators/Research Personnel

A. TTUHSC El Paso investigators/research personnel must account for disclosures of PHI in accordance with the procedures stated herein.

Accounting of Disclosures: For each research study in which subjects were enrolled after April 14, 2003, the Investigator must maintain a record of disclosures of PHI ("an accounting") in accordance with this policy. Disclosure of PHI means the release, transfer, or provision of access to or divulging PHI in any manner outside the covered entity holding the information. Disclosure includes the communication of PHI from a TTUHSC El Paso covered component to a non-covered component.

Investigators who disclose PHI for research conducted (1) without an authorization or under a waiver of authorization (including chart reviews), (2) on decedents, or (3) who disclose PHI as required by law must keep a list of all patient records reviewed, the dates on which the PHI was reviewed, and a description of the type of information that was reviewed (e.g., date of birth, medical record number, telephone number, diagnosis, procedure code, etc.). This information should be kept on the "Accounting Log for Individual Disclosure of Research PHI" (Attachment A) template, available on the Research Compliance Program website.

If more than 50 records are disclosed for the same research protocol, the Investigator may complete the "Accounting Log for 50+ Disclosures of Research PHI" (Attachment B) form.

B. *Guidance for Tracking and Accounting for Research Disclosures of PHI.* Under the Privacy Rule, researchers are permitted to use and disclose Protected Health Information (PHI) with authorization from the research subject. In certain circumstances, a waiver from this requirement may be obtained from the IRB where it may not be practical to conduct research without the waiver. However, a waiver of HIPAA authorization does not mean that the research is exempt from HIPAA requirements. It only means that the PI does not need to obtain signed authorization(s) from individuals to use and disclose their PHI. PIs with IRB approved protocols where HIPAA authorization is waived must still comply with HIPAA accounting requirements by tracking certain disclosures of subjects' PHI made by the team.

C. *Examples of when a request for a disclosure of PHI for a research project if the PHI was or will be obtained or disclosed without an individual authorization would apply*.

- Waiver of authorization i.e., Medical Record review
- Partial waiver of authorization i.e., for screening/recruitment purposes
- When PHI will be disclosed for research limited to decedents' information (although authorization is not required, disclosures must be tracked)

D. *When an accounting of disclosures is requested by the individual.* In the event an accounting of disclosures is requested in writing by the individual or the individual's legally authorized representative (LAR), the recipient of the request shall advise the Investigator for the study for which the accounting is requested. If the Investigator receives the request directly or is advised of the request by a third party, the Investigator shall immediately notify the Research Compliance Officer.

The Research Compliance Officer shall respond to the written request for an accounting in accordance with the process outlined in the Privacy Rule; such process shall be communicated to the Investigator by the Research Compliance Officer, and the Investigator shall not send any correspondence to the requesting party without having such correspondence reviewed by the Research Compliance Officer, who shall ensure compliance with HIPAA regulations regarding accounting of disclosures.

An individual's right to receive an accounting of disclosures of PHI to a health oversight agency or law enforcement official may be suspended if the agency/official provides a written statement that such an accounting would be reasonably likely to impede the activities of the agency/ official, specifying the time for which such suspension is required.

- *Procedures for Tracking of Disclosures*. The PI should track and maintain a record of any disclosure that includes
  - the name of the subject and ID#;
  - title of the protocol or other research activity and IRB number;
  - the date of the disclosure;
  - name and address, if known, of person/entity that received the PHI;
  - description of what PHI was disclosed and brief statement regarding the purpose of the disclosure.
    - The Accounting Log for Individual Disclosure of Protected Health Information (PHI) in Research tracking form must be utilized and maintained with the research record.
    - In addition, the individual tracking form must be provided to Research Compliance in the event that a subject makes a request for disclosure.
      - For exempt protocols, the form must be submitted on at least an annual basis, through iRIS.
      - For non-exempt protocols, the form must be submitted with the continuing review form at designated intervals, through iRIS.

        - A final report of an accounting of disclosures will be required upon study closure.
    - When the Investigator has made multiple disclosures of PHI to the same person or entity for a single purpose, the accounting may, with respect to such multiple disclosures provide:
        - The information listed above;
        - The frequency, periodicity, or number of disclosures made during the accounting period; and,
        - The date of the last such disclosure during the accounting period.
    - When the Investigator has made disclosures of PHI regarding fifty (50) or more individuals in a particular research project, the Accounting Log for 50+ Disclosures of Protected Health Information (PHI) in Research form must be utilized and will include the following information:
        - The title of the protocol or other research activity and IRB number;
        - A plain-language description of the research protocol or other research activity, including the purpose of the research and criteria for selecting particular records;
        - A brief description of the type of PHI disclosed;
        - The date or period of time during which the disclosures took place, including the date of the last disclosure during the accounting period;
        - The name, address, and telephone number of the entity that sponsored the research and of the researcher who received the PHI; and
        - A statement that the individual's PHI may or may not have been disclosed for a particular protocol or other research activity.
    - The 50+ tracking form must be utilized and maintained with the research record.
    - In addition, the 50+ tracking form must be provided to Research Compliance in the event that a subject makes a request for disclosure.
        - For exempt protocols, the form must be submitted on at least an annual basis, through iRIS.
        - For non-exempt protocols, the form must be submitted with the continuing review form at designated intervals, through iRIS.
        - A final report of an accounting of disclosures will be required upon study closure.

V. Responsibilities of Research Compliance

A. *Research Compliance*

- shall receive and maintain submitted tracking forms in the event a written request for an accounting of disclosures is received.
- will include a review of tracking of disclosure forms during audits and upon review of self-monitoring forms.
- will coordinate with Institutional Compliance on medical record disclosures
- If an accounting of research is provided and if it is reasonably likely that the PHI of the individual was disclosed for such research protocol or activity, the [covered entity] shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

B. *Escalations of Non-Compliance*

In cases where there has been no attempt to provide the tracking of disclosures at the designated intervals, the Research Compliance Officer may attempt to communicate with a PI and/or their research personnel. Inquiries may be time-sensitive and contingent on a response from research personnel. A total of three attempts by email and/or by phone will be made to reach out to a PI and/or their research personnel. If all attempts at communication are unsuccessful, then the situation will be escalated to the PI's department chair. If communication is still

unsuccessful, then the situation will be escalated to the Vice President for Research (VPR). The VPR will then implement follow-up corrective action.