TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.19, **Accounting of Research Use and 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 using and/or 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. TTUHSC El Paso. This policy applies to all TTUHSC El Paso research protocols approved with a HIPAA waiver of authorization that fall under the definition of 'use' within the entity.

D. 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.

Protected Health Information: individually identifiable health information that is created, maintained, transmitted, or received by a covered entity or its business associates.

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.

Use: With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity or health care component that maintains such information.

IV. Responsibilities of Investigators/Research Personnel

A. TTUHSC El Paso investigators/research personnel must account for use and/or 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 use and/or disclosures of PHI ("an accounting") in accordance with this policy. Use of PHI means the sharing, employment, application, utilization, examination, or analysis of protected health information within TTUHSC El Paso. 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 use and/or 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 and/or institutional policy, 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 Use and/or Disclosure of Research PHI" (Attachment A) template, available on the Research Compliance Program website.

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

The accounting of disclosures log(s) must be submitted through iRIS to Research Compliance so that they may respond to individuals requesting an accounting of disclosures.

B. *Guidance for Tracking and Accounting for Research Use and/or 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 and/or institutional accounting requirements by tracking certain uses and/or disclosures of subjects' PHI made by the team.

C. *Examples of when a request for a use and/or disclosure of PHI for a research project if the PHI was or will be obtained, used 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 uses and/or disclosures is requested by the individual.* In the event an accounting of uses and/or disclosures is requested in writing by the individual or the individual's legally authorized representative (LAR), the recipient of the request 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 and/or institutional policy. If the investigator is still part of TTUHSC El Paso, this information 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 and institutional policy regarding accounting of uses and/or 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 Uses and/or Disclosures*. The PI should track and maintain a record of any use and/or 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 use and/or disclosure;
  - name and address, if known, of person/entity that received the PHI i.e. the Principal Investigator (PI);
  - description of what PHI was used and/or disclosed and brief statement regarding the purpose of the use and/or disclosure.
    - The Accounting Log for Individual Use and/or 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. This is done through the Accounting of Research Uses and/or Disclosures Submission Form.
      - For protocols that do not require a continuing review, the form must be submitted on the annual anniversary date, through iRIS.
      - For non-exempt protocols, the form must be submitted at the time of continuing review at designated intervals, through iRIS.
      - A final report of an accounting of uses and/or disclosures will be required upon study closure.
    - When the Investigator has made multiple uses and/or 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 uses and/or disclosures made during the accounting period; and,
      - The date of the last such use and/or disclosure during the accounting period.
    - When the Investigator has made uses and/or disclosures of PHI regarding fifty (50) or more individuals in a particular research project, the Accounting Log for 50+ Uses and/or 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 used and/or disclosed;
      - The date or period of time during which the uses and/or disclosures took place, including the date of the last use and/or 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 used and/or 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. This is done through the Accounting of Research Uses and/or Disclosures Submission Form.

- For protocols that do not require a continuing review, the form must be submitted on at least an annual basis, through iRIS.
- For non-exempt protocols, the form must be submitted at the time of continuing review at designated intervals, through iRIS.
- A final report of an accounting of uses and/or disclosures will be required upon study closure.
- The master list for the approved protocol, in Excel format, including the patient's name and MRN, must also be attached to the submission.

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 uses and/or disclosures is received.
- will include a review of tracking of use and/or disclosure forms during audits and upon review of self-monitoring forms.
- will coordinate with Institutional Compliance on medical record uses and/or disclosures
- If an accounting of research is provided and if it is reasonably likely that the PHI of the individual was used and/or 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.
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B. *Escalations of Non-Compliance*

In cases where there has been no attempt to provide the tracking of uses and/or 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.