



SOP Accounting of Disclosures of PHI			
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PURPOSE

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).

REVISIONS FROM PREVIOUS VERSION

PROCEDURES

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 USF covered component to a non-covered component. Investigators who disclose PHI for research conducted (1) without an authorization or under a waiver of authorization, (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,



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- x Name of person/entity receiving PHI, and, if known, the address of such entity or person;
- x Brief description of PHI disclosed; and
- x Brief statement of the purpose of disclosure that reasonably informs the individual of the basis for the disclosure, or in lieu of such statement, a copy of a written request for a disclosure, if any.

Alternative Accounting:

When the Investigator has made disclosures of PHI regarding fifty (50) or more individuals in a particular research project, the accounting can be limited to the following information:

- x The name of the protocol or other research activity;
- x A plain-language description of the research protocol or other research activity, including the purpose of the research and criteria for selecting particular records;
- x A brief description of the type of PHI disclosed;
- x The date or period of time during which the disclosures took place, including the date of the last disclosure during the accounting period;
- x The name, address, and telephone number of the entity that sponsored the research and of the researcher who received the PHI; and
- x A statement that the individual's PHI may or may not have been disclosed for a particular protocol or other research activity.

If the particular research project warrants an alternative accounting, the Investigator must, if requested by the particular individual, assist the individual in contacting the research sponsor if there is a reasonable likelihood that the individual's PHI was ~~actually~~ disclosed to conduct the particular research. If the :hee of the researaing wHclart w y did of 3



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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 HIPAA Research Privacy Officer.

The HIPAA Research Privacy 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 HIPAA Research Privacy Officer, and the Investigator shall not send any correspondence to the requesting party without having such correspondence reviewed by the HIPAA Research Privacy 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 in accordance