



| SOP: Accounting of Disclosures of PHI | | | |
|---------------------------------------|----------|-------------|--------|
| NUMBER | DATE | APPROVED BY | PAGE |
| HRP-056a | 5/6/2020 | Julie Moore | 1 of 4 |

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

1. Effective date: 9/18/2003
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

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

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

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

RESPONSIBILITIES

Investigators must account for disclosures of PHI in accordance with the procedures stated herein.

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,



| SOP: Accounting of Disclosures of PHI | | | |
|---------------------------------------|----------|-------------|--------|
| NUMBER | DATE | APPROVED BY | PAGE |
| HRP-056a | 5/6/2020 | Julie Moore | 2 of 4 |

telephone number, diagnosis, procedure code, etc.). This information should be kept on the “Accounting Log of Disclosures of PHI” template, available on the HIPAA Research Compliance Program website.

If multiple records are disclosed for the same research protocol, the Investigator may complete the entire form with the exception of the patient name and make photocopies of the form. The Investigator will then need to print the patient name and other identifying information for each patient record that is reviewed on the form.

What is a disclosure?

A disclosure is defined as the release, transfer, provision of access to or divulging in any manner any PHI outside of the USF covered entity. The following types of research disclosures do not require an accounting:

- Disclosures made pursuant to an individual’s authorization;
- Disclosures made to an individual about the individual;
- Disclosures of a limited data set with a DUA;
- Disclosures of de-identified data;
- Disclosures made to an individual’s insurance carrier for payment or billing purposes;
- Disclosures made to a federal agency such as the FDA or NIH (so long as provided for in the consent/authorization form);
- Disclosures made for the purpose of adverse event reporting or similar data safety monitoring purposes (so long as provided for in the consent/authorization form);
- Disclosures made for treatment purposes; or
- Disclosures made for health care operations.

What information must be accounted for?

Standard Accounting:

When an accounting is required, it must include for each disclosure:

- Date of disclosure;

| SOP: Accounting of Disclosures of PHI | | | |
|---------------------------------------|----------|-------------|--------|
| NUMBER | DATE | APPROVED BY | PAGE |
| HRP-056a | 5/6/2020 | Julie Moore | 3 of 4 |

- Name of person/entity receiving PHI, and, if known, the address of such entity or person;
- Brief description of PHI disclosed; and
- 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:

- The name of the protocol or other research activity;
- 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.

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 IRB/Privacy Board receives an appropriate request for an accounting of disclosures that were made relating to the individual over a given period of time (the "accounting period"), the IRB/Privacy Board will ask the Investigator to state, to the extent possible, the following:

- The date or period of time during which the disclosures in the study occurred, including the date of the last such disclosure during the accounting period; and
- Whether the individual's PHI may or may not have been disclosed in the study during the accounting period.



| SOP: Accounting of Disclosures of PHI | | | |
|--|----------|-------------|--------|
| NUMBER | DATE | APPROVED BY | PAGE |
| HRP-056a | 5/6/2020 | Julie Moore | 4 of 4 |

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 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.

REFERENCES

45 CFR 164.528

45 CFR 164.512(d), (f)

Template: Accounting Log of Disclosures of PHI