Guidance for Investigators: HIPAA Accounting of Disclosures

Chart 1: Is an Accounting of PHI Disclosures Required?

My research involves disclosing PHI outside of the covered entity.

Is the PHI being disclosed limited to that included in a HIPAA Authorization that was signed by the research subjects (or their representative)?

No

Is the PHI being disclosed limited to that in a Limited Data Set (LDS) under a Data Use Agreement (DUA)?

No

Is any of the PHI being disclosed from decedents where no HIPAA Authorization has been obtained?

No

Is any of the PHI being disclosed accessed under a waiver of HIPAA Authorization?

No

The disclosure of PHI related to your research is not subject to accounting of disclosures under the HIPAA Privacy Rule (45 CFR 164.528).

Yes

The disclosure of PHI related to your research is subject to accounting of disclosures under the HIPAA Privacy Rule (45 CFR 164.528). Proceed to Chart 2 to learn what information must be accounted for and how.

Yes

Review the HIPAA in Research page of the OSF website to confirm your research involves disclosing PHI. Contact OSF Research Administration with additional questions regarding PHI for research purposes.
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Chart 2: What Information is Required for Accounting of PHI Disclosures and How Do I Report It?

My research is subject to accounting of PHI disclosures (45 CFR 164.528).

Are you disclosing PHI about 50 or more individuals for your research?

Yes

OSF must be able to provide individuals with an accounting of possible PHI disclosures that includes the following information:
- The name of the protocol or research activity
- A plain-language description of the research protocol or activity, purpose of the research, and criteria for selecting particular records
- A description of the type of PHI disclosed
- The date or period of time during which the disclosure(s) occurred or may have occurred, 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

Submit a completed PHI Disclosure for Research Alternative Accounting Form after IRB approval to conduct the research is received. This reporting will ensure research-related PHI disclosure information is included in responses to requests for accounting of PHI disclosures.

No

OSF must be able to provide individuals with an accounting of actual PHI disclosures that includes the following information:
- Date of disclosure
- The name of the person or entity that received the PHI and address, if known
- A brief description of the PHI disclosed
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or, in lieu of the statement, a copy of the written request for a disclosure, if any
- The frequency or number of disclosures made during the accounting period
- The date of the last disclosure for the accounting period

Submit a completed PHI Disclosure for Research Standard Accounting Form after the first disclosure event. This reporting will ensure research-related PHI disclosure information is included in responses to requests for accounting of PHI disclosures.