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)?
    - Yes: The disclosure of PHI related to your research is not subject to accounting of disclosures under the HIPAA Privacy Rule (45 CFR 164.528).
    - No: Proceed to Chart 2 to learn what information must be accounted for and how.

- Is the PHI being disclosed limited to that in a Limited Data Set (LDS) under a Data Use Agreement (DUA)?
  - 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.
  - No: Review the HIPAA in Research page of the OSF website to confirm your research involves disclosing PHI.

- Is any of the PHI being disclosed from decedents where no HIPAA Authorization has been obtained?
  - 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.
  - No: Is any of the PHI being disclosed accessed under a waiver of HIPAA Authorization?
    - Yes: Review the HIPAA in Research page of the OSF website to confirm your research involves disclosing PHI.
    - No: Contact OSF Research Administration with additional questions regarding PHI for research purposes.
Guidance for Investigators: HIPAA Accounting of Disclosures

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 to the HIM/HIMS Directors of all facilities that may make PHI disclosures for the research 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 to the HIM/HIMS Director of the facility that made the PHI disclosure 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.