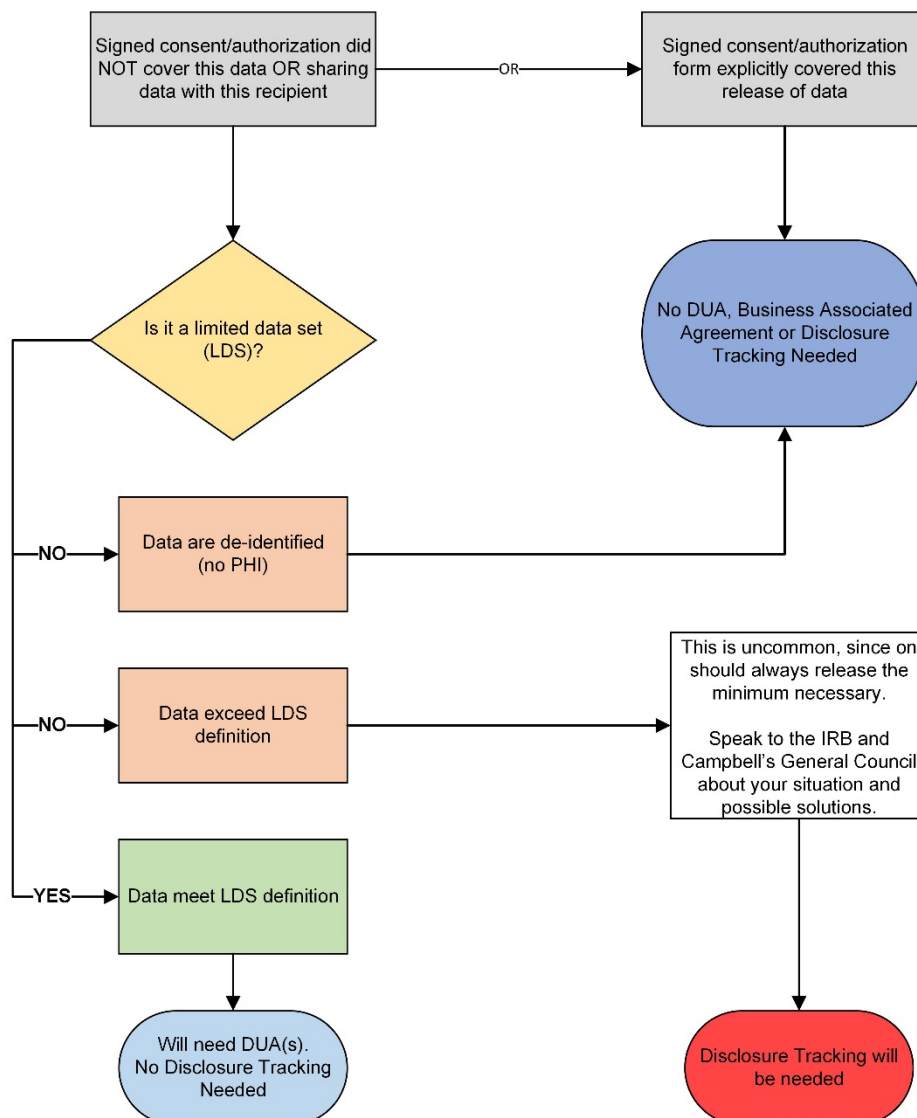




IRB Guidance: When to Use a Data Use Agreement

You need to use a Data Use Agreement (DUA) anytime you are sharing data that are NOT de-identified in a manner that was not explicitly covered in the consent form. Sharing of de-identified data does not require a DUA. A limited data sets (LDS), applied to only HIPAA covered private health information may be shared only after a DUA is in place. The first step is to determine what type of data you are working with. DUAs are most used for the sharing of HIPAA covered information such as identifiable private health information (PHI) but may be used for other types of personally identifiable data, such as student educational records. This document is specific to PHI. Contact the IRB Office if your data is not PHI for further instructions.

Flow Diagram: Do I need a DUA?





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Do I have a de-identified data set?

Data are de-identified if there is no reasonable way the data could be used to identify a person. Therefore, de-identified data sets may NOT contain any of the 18 elements that HIPAA identifies as protected information. See IRB Guidance: Identification & Protection Levels in Research for detailed information regarding PHI identifiers.

Do I have a limited data set (LDS)?

Limited data sets (LDS) are NOT de-identified and may contain some (but not all) of the 18 elements that qualify as PHI.

For example: An LDS may NOT include directly identifying information (i.e., name, SSN, or address). The LDS MAY contain indirect identifiers such as, but not limited to:

- city, state, zip code;
- ages in years up to 90 years (after 90 years must aggregate all 90 or older);
- dates directly related to an individual (birth date, admission date, visit date, intake/discharge date, diagnosis date, etc.) (*Limited to month and year is preferred*).

A unique study ID can be included in both limited and de-identified data sets, but the number can NOT be an encoded identifier, such as a scrambled birthdate, subject initials, medial record number, and so on.

Disclosure Tracking

Disclosures of PHI information must be tracked any time protected health information is disclosed and either of the following apply:

- Authorization or a waiver of authorization has not been granted.
- Data exceed the definition of an LDS.

The covered entity is responsible for maintaining a list of disclosures. Check with the covered entity regarding their disclosure policies regarding the use of data for research purposes.