Research Privacy Frequently Asked Questions

1. What is a de-identified data set?

A: A covered entity may de-identify a data set containing PHI in one of two ways.

1) The "safe-harbor" method, is to remove all 18 identifiers enumerated in HIPAA Privacy regulations (section 164.514 (b)(2)).

2) A qualified statistician determine, using generally accepted statistical and scientific principles and methods, that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by the anticipated recipient to identify the subject of the information

2. What is a Limited Data Set, and how can I use this in my research?

A: Limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. Limited data sets may be used or disclosed only for public health, research, or health care operations purposes. They are not de-identified information under the Privacy Rule.

Before disclosing a limited data set to a researcher, a covered entity must enter into a Data Use Agreement (DUA) with the researcher, identifying the researcher as the recipient of the limited data set, establishing how the data may be used and disclosed by the recipient, and providing assurances that the data will be protected, among other requirements.

3. Can I use the review preparatory to research provision to recruit individuals into a research study?

A: The preparatory research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision does not permit the researcher to remove protected health information from the covered entity's site. The provision allows such a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose protected health information for a research study.

A researcher who is not a part of the covered entity may not use the preparatory research provision to contact prospective research subjects.

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