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The expert will determine whether there are any missing values (not present, or represented by more than one value) in the data set being de-identified. If missing values are present, the expert will identify which ones are likely to be problematic for identifying the information. Typically, the data set being de-identified is a subset of the data set from which it is compared. For example, an address data set may be used to identify people living in the same household. In that case, the address data set is a subset of the population for whom that addresses were recorded. For certain computational situations, the expert may infer the identifiers, or data elements, in the data record that are unique, or linkable to only one person. Identification risks can be mitigated if these data elements are determined to be completely unique, or if there is no expected probability that certain data elements will appear together. The expert may also perform so-called two-sample concentration tests to determine whether the probabilities of joint occurrences of data elements are statistically different in the data set being de-identified, compared to the population for whom information is known. If the concentration tests show a statistically significant difference in such probabilities, the expert may infer that certain data elements are not expected to be unique. For example, this reasoning may be used to conclude that the probabilities that a record of an individual patient is also linked to a record of a third party who has undergone a medical procedure are statistically too similar to occur by chance. 13

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when determining the overall level of risk associated with a specific data release, there are two key approaches: the static level and the dynamic level. at the static level, the expert looks at the amount of data being released, the information released, how it is released and the analysis of the controls that exist to control the risk of disclosure. at the dynamic level, the expert looks at the rules and procedures that are in place to control the risk of disclosure. both of these approaches are absolutely necessary for the determination of the overall level of risk associated with a release. this is exactly why we need to document the specific statistical and scientific methods that we use and describe the processes that we applied in the privacy rule. ocr should have adequate information to assess the methods that are used. requiring the use of a specific protocol from the expert should make this easy for ocr to review. the disclosures of the best-practice documents and best-practice guidelines are intended to assist covered entities and business associates in identifying, evaluating, and mitigating the risk of the disclosure of identifiable health information to third-party recipients who are not disclosed to in the privacy rule consent.

the disclosures do not directly establish the applicable disclosure risk determination process, nor do they provide guidance on which method is most appropriate for each type of identifiable health information disclosure risk. rather, the disclosures provide information that can be used to assist covered entities and business associates in making an informed risk determination regarding identifiable health information and in choosing a method to protect the information from identification. the disclosures are intended to aid covered entities and business associates in determining whether particular methods could be applied to identified health information to mitigate the anticipated risks. the disclosures are not meant to supersede the statutory provisions of the privacy rule, including, but not limited to, the procedures for obtaining an expert determination or the procedures for determining which methods are appropriate for the types of identifiable health information at issue in the particular situation. 5ec8ef588b

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