

Tip Sheet for Classifying HIPAA Data

Protected Health Information (Identifiable Data)	Limited Data Set (requires Data Use Agreement)	De-identified Data Set (no specific agreement required)
<p>Protected health information (PHI) includes all individually identifiable health information relating to the past, present or future health status, provision of health care, or payment for health care of/for an individual that is created or received by a Covered Entity or Business Associate.</p> <p>Health information is individually identifiable if it contains any of the following identifiers:</p> <ul style="list-style-type: none"> Names Geographic subdivisions smaller than a state Dates (except year only) directly related to an individual, including birth date, date of death, admission date, discharge date; and all ages over 89 (except ages may be aggregated into a single category of age 90 or older) Telephone and fax numbers Email addresses Social security numbers (SSN) medical record numbers (MRN) Health plan beneficiary numbers Account numbers Certificate/driver's license numbers Vehicle identifiers and serial numbers, including license plate numbers Device identifiers and serial numbers Web Universal Resource Locators (URL) Internet Protocol (IP) addresses Biometric identifiers (including finger and voice prints) Full face photographic images and any comparable images Any other unique identifying number, characteristic, or code. <p>*A Business Associate Agreement (BAA) is required to be entered into between a Covered Entity and/or Business Associate and any downstream Subcontractor(s) that create, maintain, receive, access or store PHI on behalf of a Covered Entity/Business Associate <i>prior</i> to use or disclosure of any PHI.</p>	<p>A limited data set is a data set that is stripped of certain direct identifiers specified in the Privacy Rule. A limited data set may be disclosed to an outside party without a patient's authorization only if certain conditions are met. <i>First</i>, the purpose of the disclosure must be for research, public health, or health care operations purposes. <i>Second</i>, the person or entity receiving the information must sign a <u>data use agreement (DUA)</u> with the covered entity or its business associate.</p> <p>Limited Data Sets may include <i>only</i> the following identifiers:</p> <ul style="list-style-type: none"> Dates, such as admission, discharge, service, and date of birth (DOB) City, state, and zip code (not street address) Any other unique code or identifier that is not listed as a direct identifier. <p>This means that in order for a data set to be considered a limited data set, all of the following direct identifiers as they relate to the individual or his/her relatives, employers, or household members <i>must</i> be removed:</p> <ul style="list-style-type: none"> Names Street addresses (other than town, city, state, and zip code) Telephone and fax numbers Email addresses Social security numbers Medical record numbers Health plan beneficiary numbers Account numbers Certificate/driver's license numbers Vehicle identifiers and serial numbers, including license plate numbers Device identifiers and serial numbers URLs and IP addresses Biometric identifiers Full face photographic images and any comparable images. <p>*A Data Use Agreement (DUA) is required to be entered into between a Covered Entity and/or Business Associate and any downstream Subcontractor(s) or third-party that will receive a Limited Data Set <i>prior</i> to use or disclosure of the Limited Data Set.</p>	<p>The Privacy Rule permits a covered entity or its business associate to release data that have been de-identified without obtaining an Authorization and without further restrictions upon use or disclosure because de-identified data is not PHI and, therefore, not subject to the Privacy Rule.</p> <p>A covered entity or business associate may de-identify a data set in one of two methods. The first method, (the "Safe Harbor" method) involves the removal all 18 HIPAA identifiers. In the second method the covered entity formally determines that there is no reasonable basis to believe the data can be used to identify an individual.</p> <p>Under the second method, the "Expert Determination" method, a qualified statistician—using generally accepted statistical and scientific principles and methods—determines that the risk of re-identification of the individual that is the subject of the information is low. The qualified statistician must document the methods and analysis that justify his/her determination.</p> <p>The two de-identification methods provided in the Privacy Rule are illustrated below.</p> <div data-bbox="1068 1102 1572 1512"> <pre> graph TD Root[HIPAA Privacy Rule De-identification Methods] --> Expert[Expert Determination § 164.514(b)(1)] Root --> SafeHarbor[Safe Harbor § 164.514(b)(2)] Expert --> ExpertStep1[Apply statistical or scientific principles] ExpertStep1 --> ExpertStep2[Very small risk that anticipated recipient could identify individual] SafeHarbor --> SafeHarborStep1[Removal of 18 types of identifiers] SafeHarborStep1 --> SafeHarborStep2[No actual knowledge residual information can identify individual] </pre> </div> <p>*Figure from OCR guidance available here: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/de-identification/guidance.html</p>