

Safe Harbor De-Identification Chart

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Introduction

Disclaimer: The following information is intended for guidance purposes only and does not replace appropriate legal or regulatory advice.

This chart is a schematic that shows how data may qualify as “de-identified”. The process of creating de-identified data is part of healthcare operations in the HIPAA privacy regulation. De-identified data are exempt from HIPAA regulation and can be used by the covered entity in ways that the HIPAA regulations might not otherwise allow. De-identified data may be subject to other state or federal regulation.

Please note that this reference to “safe harbor” is not the same as the “safe harbor” data protection framework developed by the U.S. Department of Commerce in consultation with the European Commission and approved by the EU in July of 2000. This use of 'safe harbor' is from the preamble of the privacy regulations Federal Register of 28 December 2000, and refers to §164.514(b)(2).

Also note that “de-identified” data is not the same as “anonymized” or “unlinked” data as used by the Institutional Review Board (IRB) because de-identified data allows for the inclusion of a link field. The “link field” [§164.514(c)] allows the identity of an individual to be determined by the covered entity. Federal guidelines under which the IRB acts explicitly require that this “link field” be removed for research to be eligible for exemption from IRB review. Thus it is possible for data to be de-identified and exempt from HIPAA regulation, but not exempt from IRB regulation.

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Page 3 of 3

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