

Data Use Agreement Tool

45 CFR 164.514

Implementation Data Use Agreement

- (i) Agreement required. A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes. The limited purposes are for research, public health, or health care operations.
- (ii) Contents:
 - a. Establish the permitted uses and disclosures of such information by the limited data set recipient. The agreement may not authorize the limited data set to be further disclosed in a manner that would violate this section's requirements.
 - b. Establish who is permitted to use or receive the limited data set; and
 - c. Provide that the limited data set recipient will:
 - i. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
 - iii. Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
 - iv. Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
 - v. Not identify the information or contact the individuals.
- (iii) Definition of a limited data set:
 - a. A limited data set is protected health information that **excludes** the following direct identifiers of the individual or of relatives, employers, or household members of the individual: 164.514 (e) (2)
 - Names;
 - Postal address information, except town or city, State, and zip code;
 - Telephone numbers;
 - Fax numbers;
 - Email addresses;
 - Social Security Numbers;
 - Medical record numbers;
 - Health plan beneficiary numbers;
 - Account numbers;
 - Certificate/license numbers;
 - Vehicle identifiers and serial number, including license plate numbers;
 - Web URL's;
 - IP addresses;
 - Biometric identifiers, including finger and voice prints, and
 - Full face photographic images and any comparable images