



SOP: Use and Disclosure of De-Identified Data for Research Purposes			
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PURPOSE

To define the procedures necessary to use and disclose de-identified data for research.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 8/22/2003
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

This procedure applies to all investigators who use de-identified data in research and to health care providers who are within a covered component of the University of South Florida (USF) covered entity who disclose data categorized as de-identified data.

RESPONSIBILITIES

Prior to giving investigators or other entities access to health information categorized as de-identified data, USF health care providers must ensure that the procedures set forth herein have been followed for the de-identification of individually identifiable health information.

PROCEDURES

USF health care providers who have access to individually identifiable health information for the purpose of treatment, payment, or health care operations may de-identify individually identifiable health information in order to use and share information for research or other appropriate functions at USF in accordance with this SOP.

A USF health care provider may determine that patient health information is de-identified, and cannot be used to identify an individual, only if either (1) **or** (2) below has occurred:

1. A statistician or other person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
 - a. Has applied such principles and methods, and determined that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by a recipient of the information to identify the person whose information is being used; and
 - b. Has documented the methods and results of the analysis that justify such determination.



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The USF health care provider is required to keep such documentation, in hardcopy or electronic format, for at least six (6) years from the date of the creation of the de-identified data.

Or

2. The USF health care provider has ensured that:

a. The following identifiers of the individual, and of the individual's relatives, employers and household members, are removed:

- I. Names;
- II. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geo codes. However, the initial three digits of a zip code may remain on the information if, according to current publicly-available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and the initial three digits for all such geographic units containing 20,000 or fewer people is changed to 000;
- III. All elements of dates (except year) for dates directly related to an individual, including birth date, dates of admission and discharge from a medical facility, and date of death; for persons age 89 and older, all elements of dates (including year) that would indicate such age must be removed, except that such ages and elements may be aggregated into a single category of "age 90 or older";
- IV. Telephone numbers;
- V. Fax numbers;
- VI. Electronic mail addresses;
- VII. Social security numbers;
- VIII. Medical record numbers;
- IX. Health plan beneficiary numbers;
- X. Account numbers;
- XI. Certificate or license numbers;



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- XII. Vehicle identifiers and serial numbers, including license plate numbers;
 - XIII. Device identifiers and serial numbers;
 - XIV. Web Universal Resource Locators (URLs);
 - XV. Internet Protocol (IP) address numbers;
 - XVI. Biometric identifiers, including fingerprints and voiceprints;
 - XVII. Full face photographic images and any comparable images; and
 - XVIII. Any other unique identifying number, characteristic, or code, except as permitted in this SOP; **and**
- b. The USF health care provider has no actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

Re-identification of de-identified information:

The USF health care provider may assign a code or other means of record identification to allow information de-identified under this policy to be re-identified by the USF health care provider, provided that:

- 1) The code or other means of record identification is not derived from or related to information about the individual and cannot otherwise be translated to identify the individual;
- 2) The code or other means of record identification is not disclosed for any other purpose; and
- 3) The mechanism for re-identification is not disclosed to anyone except the USF health care provider.

REFERENCES

45 CFR 164.514