



SOP: Limited Data Sets			
NUMBER	DATE	APPROVED BY	PAGE
HRP-056c	5/6/2020	Julie Moore	1 of 3

## **PURPOSE**

To define the procedures necessary to use and disclose limited data sets for research.

## **REVISIONS FROM PREVIOUS VERSION**

1. Effective date: 10/31/2003
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

## **SCOPE**

This procedure applies to all investigators who use limited data sets for research and to health care providers who are included in a covered component of the University of South Florida (USF) covered entity who disclose limited data sets for research.

## **RESPONSIBILITIES**

Investigators and USF health care providers must adhere to the procedures stated herein prior to releasing limited data sets for research.

## **PROCEDURES**

USF health care providers who have access to individually identifiable health information for TPO purposes may create and disclose a limited data set **only if**:

1. The limited data set meets the requirements set forth in this SOP; and
2. A data use agreement (DUA) has been executed with the recipient of the limited data set, in accordance with this SOP. A "Master Data Use Agreement" template is available on the HIPAA Research Compliance Program website.

A USF health care provider may disclose limited data sets in accordance with the other provisions of this SOP and only for the purpose of research, public health, or health care operations.

No accounting is required for the disclosure of a limited data set.

Limited data sets created in accordance with this SOP may be disclosed to members of the workforce of the covered component of the USF covered entity or to entities or individuals external to the covered component of the USF covered entity without the need for approval by the USF HIPAA Research Privacy Officer.

If the USF health care provider who created and disclosed a limited data set becomes aware of any pattern, activity, or practice of the limited data set recipient that constitutes a material



SOP: Limited Data Sets			
NUMBER	DATE	APPROVED BY	PAGE
HRP-056c	5/6/2020	Julie Moore	2 of 3

breach or violation of a DUA, the USF health care provider must report the violation to the USF HIPAA Research Privacy Officer so that USF may take reasonable steps to cure the breach or end the violation.

If the violation cannot be cured within a reasonable time, USF will discontinue disclosure of information to the recipient and report the problem to the United States Department of Health and Human Services (HHS).

A limited data set must exclude the following direct identifiers of the individual, and of the individual's relatives, employers, or household members:

1. Names;
2. Postal address information, other than town or city, state, and ZIP code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic mail addresses;
6. Social security numbers;
7. Medical record numbers;
8. Health plan beneficiary numbers;
9. Account numbers;
10. Certificate/license numbers;
11. Vehicle identifiers and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web universal resource locators (URLs);
14. Internet protocol (IP) address numbers;
15. Biometric identifiers, including voice and fingerprints; and
16. Full face photographic images and any comparable images.

A DUA between USF and the recipient of the limited data set must:



SOP: Limited Data Sets			
NUMBER	DATE	APPROVED BY	PAGE
HRP-056c	5/6/2020	Julie Moore	3 of 3

1. Specify the permitted use and disclosure of such information by the limited data set recipient. USF may not use the agreement to authorize the limited data set recipient to use or further disclose the information in a manner that would violate this SOP if used/disclosed in such manner by USF;
2. Specify who is permitted to use or receive the limited data set; and
3. Specify that the limited data set recipient will:
  - a. Not use or further disclose the information other than as specified in the DUA or as otherwise required by law;
  - b. Use appropriate safeguards to prevent use or disclosure of the information other than as specified in the DUA;
  - c. Report to USF, if USF is the source of the limited data set, if the recipient becomes aware of any use or disclosure of the information not specified in its DUA with USF;
  - d. Ensure that any agents, including subcontractors, 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
  - e. Not identify the information or contact the individual(s) whose data is being disclosed.

## **REFERENCES**

45 CFR 164.514

Template: Master Data Use Agreement