



**HIPAA & Research: Use of Limited Data Sets and Data Use
Agreements # 2370.522**

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| INITIAL EFFECTIVE DATE: | LAST REVISION DATE: | RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT |
| September 20, 2019 | June 2, 2021 | Office of Research and Economic Development |

POLICY STATEMENT

A Florida International University (FIU) Covered Entity may Use, Disclose or request a Limited Data Set for research purposes only when more information than is included in de-identified information is needed to perform the research and only after a properly fully executed Data Use Agreement is in place. In such circumstances, patient Authorization for the Use, Disclosure or request of the Limited Data Set is not needed.

SCOPE

University Community (faculty, staff and students)

REASON FOR POLICY

The purpose of this policy is to ensure that the University community understands when a Limited Data Set may be used for research purposes and the parameters of use for such information.

DEFINITIONS

| TERM | DEFINITIONS |
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| Authorization | An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid authorization. |
| Covered Entity | A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a healthcare transaction. |
| Data Use Agreement | "Data Use Agreement" or "DUA" is an agreement entered into between a Covered Entity and the intended recipient of a Limited Data |

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| | Set that establishes the ways in which the information in the Limited Data Set may be used and how it will be protected under HIPAA standards. |
| Disclosure (or Disclose) | The release, transfer, provision of access to, or divulging in any other manner of protected health information outside of the entity holding the information |
| Health Information | Any information, whether oral or recorded in any form or medium, that <ol style="list-style-type: none"> 1. is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and 2. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. |
| HIPAA | The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and implementing regulations (hereinafter "HIPAA" or "HIPAA regulations"). One such implementing regulation is the HIPAA Privacy Rule which may be found at 45 CFR Part 160 and Part 164, Subparts A and E. |
| Limited Data Set | "Limited Data Set" or "LDS" is PHI that excludes all of the following direct identifiers of the individual or of relatives, employers, or household members of the individual: <ol style="list-style-type: none"> 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 finger and voice prints; and 16. Full face photographic images and any comparable images. |



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| Protected Health Information (PHI) | Individually identifiable health information that is: <ul style="list-style-type: none">• Transmitted by electronic media;• Maintained in electronic media;• Transmitted or maintained in any other form or medium.• Protected health information specifically excludes:<ol style="list-style-type: none">1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g (“FERPA”);2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and3. Employment records held by a covered entity in its role as an employer. |
| Research | A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research. |
| Use | With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within the entity or health care component (for hybrid entities) that maintains such information. |

ROLES AND RESPONSIBILITIES

All FIU researchers are responsible for following the requirements stated in this policy. Prior to giving access to PHI belonging to FIU for research purposes, the affected FIU Covered Entity, must take reasonable steps to ensure that the requirements and procedures stated herein have been followed by the researcher seeking to use the LDS.

RELATED RESOURCES

Policy 2370.510: HIPAA and Research Certification of Review Preparatory to Research

Policy 2370.515: HIPAA and Research Obtaining Authorization or Waiver of Authorization to Conduct Research

Policy 2370.520: HIPAA and Research Use of Protected Health Information for Research Purposes

Policy 2370.521: HIPAA and Research Certification for Research Using Decedent Protected Health Information

Policy 1610.010: HIPAA Privacy & Security: Responsibilities of University IT Security Officer & HIPAA Security Administrators.



CONTACTS

Office of Research Integrity
Florida International University
11200 S.W. Eighth Street - MARC 430
Miami, Florida 33199
Telephone: (305) 348-2494

HISTORY

Initial Effective Date: September 20, 2019

Review Dates (*review performed, no updates*): January 29, 2024

Revision Dates (*updates made to document*): June 2, 2021



HIPAA & Research: Processing Data Use Agreements for Limited Data Sets in Research #2370.522a

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PROCEDURE STATEMENT

All requests for Data Use Agreements (“DUA”) for the use of a Limited Data Set (“LDS”) for research purposes must be processed through the Office of Research and Economic Development (“ORED”) as follows:

1. The Principal Investigator (PI) for the research project who is requesting the DUA must provide to ORED (via oredagremnts@fiu.edu) a fully completed and signed Agreement Request Form (which may be found on the ORED Forms library webpage);
2. ORED will determine if a DUA is appropriate and if so, will negotiate the DUA with the entity with which the University will execute the DUA. Such negotiation will be done in consultation with the PI, the Office of Research Integrity and the General Counsel’s Office, as necessary. Once the DUA is finalized and executed by both ORED and the outside entity, ORED will provide a copy of the fully executed DUA to the PI and the Limited Data Set may then be shared per the DUA. Note that a DUA is needed when an FIU Covered Entity will provide a LDS even when the recipient of the LDS is an FIU unit.
3. Neither the PI nor any other FIU faculty and staff other than authorized ORED signatories may sign Data Use Agreements on behalf of the University.

The HIPAA Privacy Rule requires that the Data Use Agreement must:

1. Establish that the permitted uses and disclosures of the LDS are limited to the purposes of the research project (a DUA cannot authorize the recipient to use or further disclose the information in a way that, if done by the Covered Entity, would violate the Privacy Rule);
2. Establish who is permitted to Use or receive the LDS; and
3. Provide that the LDS recipient will:
 - a. Not use or disclose the information other than as permitted by the DUA or as otherwise required by law;
 - b. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the DUA;

- c. Report to the Covered Entity any use or disclosure of the information not provided for by the DUA of which it becomes aware;
- d. Ensure that any agents, including subcontractors, to whom it provides the LDS agrees to the same restrictions and conditions that apply to the recipient with respect to such information; and
- e. Not seek to identify or contact the individuals from which the LDS was derived.

The DUA will also provide for the return of the LDS to the Component or the destruction of the LDS by the data recipient or that if the return or destruction is not feasible that the data recipient will continue to apply the protections of the DUA to the LDS.

All 16 identifiers referenced in the “Limited Data Set” definition must be excluded from the PHI to create an LDS. The LDS is only permitted to include the following identifiers:

1. Geographic data (town, city, state and zip code, but no street address).
2. All dates relating to an individual (e.g., birth date, date of death, admission, and discharge or services date).
3. Other unique identifiers (any unique identifying number, characteristic or code other than those specified in the list of 16 identifiers that are expressly disallowed).

It is important to note that this information is still protected health information or “PHI” under HIPAA. It is not de-identified information and is still subject to the requirements of the Privacy Regulations.