



**De-identification and Re-identification of Protected Health Information and Limited Data Sets # 1660.140**

<b>INITIAL EFFECTIVE DATE:</b>  September 1, 2009	<b>LAST REVISION DATE:</b>  August 31, 2021	<b>RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT</b>  Office of Compliance and Integrity
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**POLICY STATEMENT**

Each Florida International University (FIU) Health Insurance Portability and Accountability Act (HIPAA) Hybrid Designated Health Care Component (Component) must determine whether health information is protected health information (PHI) and whether de-identification must occur when there is no "need to know" the identity of the patient. This determination will be made on a case-by-case basis and depend on the nature of the request for the use or disclosure of PHI.

Health information that does not identify a patient, a patient’s family or household member and with respect to which there is no reasonable basis to believe that the information can be used to identify a patient is de-identified. Health information is considered de-identified when:

1. the PHI is stripped of all of the 18 direct identifiers defined under HIPAA, or
2. an expert in statistical and scientific method determines that there is a very small risk that the information could be used alone or in combination with other information to identify a patient.

**NOTE:** HIPAA does not apply to de-identified data.

FIU health care practitioners/providers licensed under Florida Statute (F.S.) chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491 **WILL NOT** use or disclose PHI for statistical and scientific research, unless the medial records and the medial condition (information) of the patient is abstracted in such a way as to protect the identity of the patient or provided written permission is first obtained from the patient or the patient’s legal representative. (F.S. §456.057)

A Health Care Component **MAY NOT** use or disclose a Limited Data Set for research purposes when more information than is included in de-identified information is needed **unless** written permission is first obtained from the patient or the patient’s legal representative. (F.S. §456.057).

**NOTE:** It is important to note that a Limited Data Set is PHI under HIPAA. It is not de-identified information and is subject to the requirements of the HIPAA Privacy Rules and F.S. §456.057.

A Health Care Component may employ a designated entity or individual to create de-identified data or a Limited Data Set, but the designated entity or individual must sign a Business Associate Agreement prior to the Component disclosing any PHI to the entity or individual. (FIU Policy and Procedure #1660.015) (Business Associate Agreements)

Component Administrative Officers, Privacy Coordinators, and/or Designees must verify the identity of a person or entity requesting de-identified PHI and the authority of any such person or entity to have access to the information, if the identity or authority of the person or entity is not known to the Component. The Component Administrative Officers, Privacy Coordinators, and/or Designees must obtain any documentation, statements, or representations, whether oral or written, from the person or entity requesting the information when such documentation, statement, or representation is a condition of the disclosure. (FIU Policy and Procedure #1660.040) (Verification)

PHI used or disclosed for statistical and scientific research purposes must be approved by FIU Office of Research and Economic Development (ORED).

**NOTE:** Use of Protected Health Information for Research Purposes (ORED Policy and Procedure #2370.520), Use of Decedent Protected Health Information (ORED Policy and Procedure #2370.521), and Limited Data Sets and Data Use Agreements (ORED Policy and Procedure #2370.522), and **ARE NOT** permitted **UNLESS** written permission is first obtained from the patient or the patient's legal representative. (F.S. §456.057)

**NOTE:** Waiver or modification of Authorization (ORED Policy and Procedure #2370.515), **IS NOT** permitted. (F.S. §456.057).

**NOTE:** Certification of Review Preparatory to Research (ORED Policy and Procedure #2370.510), **IS NOT** permitted when review of the PHI will take place by a non-Health Care Component Workforce member, **UNLESS** written permission is first obtained from the patient or the patient's legal representative. (F.S. §456.057)

FIU Health Care Component Workforce members may use and disclose a Limited Data Set for non-research purposes when more information than is included in de-identified information is needed and without patient written authorization only for:

1. Public Health Activities when required or permitted by Federal and/or Florida law and regulation,
2. Healthcare Operations performed by FIU Health Care Component Workforce members or FIU HIPAA Hybrid Designated Unit Workforce members on behalf of a Health Care



Component. Health Care Operations performed by FIU Workforce members who are not employed within an FIU HIPAA Hybrid Designated Unit, or by an external individual(s) or entity(ies) requires a Memorandum of Understanding (MOU) or Business Associate Agreement (BAA), as determined by the Office of Compliance and Integrity or the Office of General Counsel.

Components are expected to develop procedures or protocols supplementing this policy and procedure when Component-specific procedures are needed. As a University-wide policy and procedure approved by the HIPAA Steering Committee, Component Privacy Coordinators, the Office of Compliance and Integrity, and the Office of General Counsel, this policy and procedure takes precedence over any Component-specific policies, procedures, or protocols that conflicts with this policy and procedure, unless prior approval is obtained from the Office of Compliance and Integrity.

Components may maintain HIPAA documentation in either paper or electronic form, provided that any format is sufficiently protected to ensure it will be retrievable throughout the required retention period. Unless otherwise indicated in FIU Privacy or Security Rule Policy and Procedure, each Component Privacy Coordinator will be responsible for maintaining all HIPAA documentation relevant to his/her Component. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

All Component Workforce members shall receive mandatory HIPAA Privacy and Security Rule training. (FIU Policy and Procedure #1660.075) (HIPAA Privacy and Security Rule Training)

Component Workforce members who fail to adhere to this policy and procedure may be subject to civil and criminal penalties as provided by law, and/or administrative and disciplinary action. (FIU Policy and Procedure #1660.085) (Sanctions)

Each Component must designate a HIPAA Privacy Coordinator and a HIPAA Security Coordinator. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

FIU reserves the right to amend, change or terminate this policy and procedure at any time, either prospectively or retroactively, without notice. Any ambiguities between this policy and procedure and the other policies and procedures should be harmonized consistent with the requirements of HIPAA and state law and regulation. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

#### SCOPE

The policy applies to FIU's HIPAA Health Care Components that are contained within FIU's HIPAA Hybrid Designation (FIU Policy and Procedure #1610.005), its Workforce members,

the Office of Research and Economic Development, and Business Associates as defined in this policy and FIU Policy and Procedure #1660.015 regarding Business Associates.

**REASON FOR POLICY**

To establish a policy and procedure necessary for the creation, use and disclosure of de-identified information, reidentification, Limited Data Sets and Data Use Agreements, Business Associate Agreements and the requirement for written patient permission as described in the HIPAA Privacy and Security Rules, Florida Statute, and FIU Associated Policies and Procedures.

- 45 C.F.R §164.502 Uses and Disclosures of Protected Health Information: General Rules)
- 45 C.F.R §164.512 (Uses and Disclosures for Which an Opportunity to Agree or Object is NOT Required)
- 45 C.F.R §164.514 (Other Requirements Relating to Uses and Disclosures of PHI: Deidentification)
- Florida Statute §456.057 (Ownership and Control of Patient Records; Report or Copies of Records to be Furnished; Disclosure of Information)

**DEFINITIONS**

<b>TERM</b>	<b>DEFINITIONS</b>
<b>Abstracted</b>	Withdrawn in mind. <b>Synonyms:</b> Separated; Absent; Removed or separated from something else.
<b>Access</b>	Means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any <u>system</u> resource.
<b>Authorization (HIPAA Authorization)</b>	Means a specific type of permission given by the patient to use and/or disclose PHI about the patient. FIU Component Workforce members may use their department, division, unit specific Accounting of Disclosures forms or the FIU created and approved Sample Request for an Accounting of Disclosures, Disclosure Tracking Log, and Reports of Disclosures to Third Parties forms, as the department, division, or unit deems appropriate.
<b>Availability</b>	Means the property that data or information is accessible and useable upon demand by an authorized person.
<b>Business Associate</b>	Generally an entity or person who performs a function involving the use or disclosure of PHI on behalf of a covered entity (such as claims processing, case management, utilization review, quality assurance, billing) or provides services for a covered entity that

	<p>require the disclosure of PHI (such as legal, actuarial, accounting, accreditation).</p> <p><b>NOTE:</b> A business associate relationship exists when an individual or entity, acting on behalf of an FIU HIPAA Component(s), assists in the performance of a function or activity involving the creation, use, disclosure, or access of PHI. This includes, but not limited to, claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management or repricing.</p> <p><b>NOTE:</b> A Business Associate may include any individual or entity that receives PHI from a HIPAA Component in the course of providing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, software support, or financial services. A Business Associates does not, however, include HIPAA Component workforce members.</p>
<p><b>Business Associate Agreement</b></p>	<p>Means a contract or other written arrangement with a business associate which must describe the permitted and required uses of PHI by the business associate; Provide that the business associate will not use or further disclose the PHI other than as permitted or required by the contract or as required by law; and Require the business associate to use appropriate safeguards to prevent a use or disclosure of the PHI other than as provided for by the contract.</p>
<p><b>Certification of Review Preparatory to Research</b></p>	<p>The preparatory research provision of the HIPAA Privacy Rule (RULE) permits <u>covered entities</u> (i.e. FIU Health Care Components) to use or disclose PHI for purposes preparatory to research, such as to aid study recruitment. As such, a researcher who is an employee or Workforce member of the FIU Health Care Component could use PHI to contact prospective research subjects for purposes of seeking their authorization to use or disclose PHI for a research study.</p> <p><b>NOTE:</b> The provision at <u>45 CFR 164.512(i)(1)(ii)</u> does not permit the researcher to remove PHI from the FIU Health Care Component's site.</p> <p><b>NOTE:</b> <i>Researchers or other persons who <b>ARE NOT</b> employees or Workforce member of the FIU Health Care Component <b>ARE NOT</b> permitted to access, obtain, use, or disclose PHI for preparatory to research or for research purposes <b>unless</b> written permission is first</i></p>

	<p><i>obtained from the patient or the patient’s legal representative. (F.S. §456.057).</i></p> <p>FIU Health Care Component Workforce members and patients may continue to discuss the option of enrolling in a clinical trial, but written permission (Authorization) must first be obtained from the patient or the patient’s legal representative prior to using or disclosing their PHI for research purposes. (F.S. §456.057)</p> <p>Additionally, under the RULE an Institutional Review Board (IRB) or Privacy Board is permitted to waive the authorization (written permission) requirement. However, waiver of the authorization <b><u>Is NOT</u></b> permitted under F.S. §456.057.</p> <p>Additionally, the RULE permits a non-FIU Health Care Component researcher to obtain patient contact information and PHI as necessary to recruit potential research subjects through a partial waiver of individual authorization by an IRB or Privacy Board <u>45 CFR164.512(i)(1)(i)</u>. However, a partial waiver <b><u>IS NOT</u></b> permitted under F.S. §456.057.</p>
<p><b>Code of Federal Regulations</b></p>	<p>Also known as CFR is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation.</p>
<p><b>Component</b></p>	<p>Means a component or combination of components of a hybrid entity designated by the hybrid entity (Florida International University). Those programs designated by FIU that must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996, hereinafter referred to as "Components". Components of FIU are required to comply with the Administrative Simplification provisions of HIPAA because the Components perform a covered function.</p>
<p><b>Confidentiality</b></p>	<p>Means data or information is not made available or disclosed to unauthorized persons or processes.</p>
<p><b>Covered Entity</b></p>	<p>An entity that is subject to HIPAA.</p> <ol style="list-style-type: none"> <li>1. a health plan;</li> <li>2. a health care clearinghouse; and/or</li> <li>3. a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.</li> </ol>

<p><b>Data Use Agreement or DUA</b></p>	<p>Means an agreement entered into between FIU and a third-party entity for the transfer of a Limited Data 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.</p>
<p><b>De-identified data</b></p>	<p>Means health information that does not identify a patient and with respect to which there is no reasonable basis to believe that the information can be used to identify a patient is de-identified. Health information is considered de-identified</p> <ol style="list-style-type: none"> <li>1. if an expert in statistical and scientific method determines that there is a very small risk that the information could be used alone or in combination with other information to identify a patient, or</li> <li>2. if stripped of all of the 18 direct identifiers defined under HIPAA:             <ol style="list-style-type: none"> <li>a. Name of patient(s);</li> <li>b. Geographic units smaller than a state (initial three digits of a zip code can be used if the geographic area contains more than 20,000 people);</li> <li>c. Dates (Date of Birth, Date of Death, Admission/ Discharge Dates);</li> <li>d. Ages (Over the age of 89 and any combination of date of birth that reveals an age 89 and over);</li> <li>e. Telephone numbers;</li> <li>f. Fax numbers;</li> <li>g. E-mail addresses;</li> <li>h. Social Security Numbers;</li> <li>i. Medical record numbers;</li> <li>j. Health plan beneficiary numbers;</li> <li>k. Account numbers;</li> <li>l. Certificate/License numbers;</li> <li>m. Vehicle identifiers and serial numbers (including license plate numbers);</li> <li>n. Device identifiers and serial numbers;</li> <li>o. Web universal resource locators (URLs);</li> <li>p. Internet protocol (IP) address numbers;</li> <li>q. Biometric identifiers including finger and voice prints;</li> <li>r. Full face photographic images and any comparable images; and</li> <li>s. Any other unique identifying number, characteristic or code, except a re-identification code.</li> </ol> </li> </ol>

	<b>NOTE:</b> HIPAA does not apply to de-identified data.
<b>Disclosure</b>	Means the release, transfer, provision of access to, or divulging in any other manner of PHI outside of the entity (Component) holding the information.
<b>Electronic Protected Health Information (ePHI)</b>	PHI in electronic form. See also: <u>PHI</u> .
<b>Florida Statutes</b>	Also known as F.S.
<b>Health Care</b>	Means the care, services, or supplies related to the health of a patient, including: <ol style="list-style-type: none"> <li>1. preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of a patient or that affects the structure or function of the body; and</li> <li>2. sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.</li> </ol>
<b>Health Care Component</b>	See "Component"
<b>Health Care Operations</b>	Means any of the following activities: <ol style="list-style-type: none"> <li>1. quality assessment and improvement activities, including case management and care coordination;</li> <li>2. competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation;</li> <li>3. conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs;</li> <li>4. specified insurance functions, such as underwriting, risk rating, and reinsuring risk;</li> <li>5. business planning, development, management, and administration; and</li> <li>6. business management and general administrative activities of the entity, including but not limited to: <ol style="list-style-type: none"> <li>a. de-identifying PHI,</li> <li>b. creating a limited data set, and</li> <li>c. certain fundraising for the benefit of the covered entity.</li> </ol> </li> </ol>
<b>Health Care Provider</b>	Means a provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.



<p><b>Health Care Practitioner/Provider</b></p>	<p>Means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.</p> <ul style="list-style-type: none"> <li>• 457 Acupuncture</li> <li>• 458 Medical Practice</li> <li>• 459 Osteopathic Medicine</li> <li>• 460 Chiropractic Medicine</li> <li>• 461 Podiatric Medicine</li> <li>• 462 Naturopathy</li> <li>• 463 Optometry</li> <li>• 464 Nursing</li> <li>• 465 Pharmacy</li> <li>• 466 Dentistry, Dental Hygiene and Dental Laboratories</li> <li>• 467 Midwives</li> <li>• 468 Miscellaneous Professions and Occupations             <ul style="list-style-type: none"> <li>○ Speech-Language and Audiology</li> <li>○ Nursing Home Administration</li> <li>○ Occupational Therapy</li> <li>○ Respiratory Therapy</li> <li>○ Dietetics and Nutrition Practice</li> <li>○ Athletic Trainers</li> <li>○ Orthotics, Prosthetics and Pedorthics</li> </ul> </li> <li>• 478 Electrolysis</li> <li>• 480 Massage Practice</li> <li>• 483 Clinical Laboratory Personnel and Medial Physicist</li> <li>• 484 Dispensing of Optical Devices and Hearing Aids</li> <li>• 486 Physical Therapy Practice</li> <li>• 490 Psychological Services</li> <li>• 491 Clinical, Counseling, and Psychological Services</li> </ul> <p>Florida Statute §456.057</p>
<p><b>U.S. Department of Health and Human Services</b></p>	<p>Also known as HHS.</p>
<p><b>Health Information</b></p>	<p>Means any information, whether oral or recorded in any form or medium, that 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 relates to the past, present, or future physical or mental health or condition of an</p>

	<p>patient; the provision of health care to an patient; or the past, present, or future payment for the provision of health care to an patient.</p>
<p><b>Health Oversight Agency</b></p>	<p>Means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.</p> <p><b>NOTE:</b> For the purpose of the disclosures permitted by 45 CFR §164.512, a health oversight activity does not include an investigation or other activity in which the patient is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:</p> <ul style="list-style-type: none"> <li>• The receipt of health care;</li> <li>• A claim for public benefits related to health; or</li> <li>• Qualification for, or receipt of, public benefits or services when a patient’s health is integral to the claim for public benefits or services.</li> </ul> <p><b>NOTE:</b> Organizations with oversight responsibility include those at federal, state or county level which have, as part of their charter, the legal responsibility and authority to oversee health operations or regulate or license health facilities.</p> <p>Some examples of oversight activities include:</p> <ul style="list-style-type: none"> <li>• Audits</li> <li>• Inspections</li> <li>• Licensure or disciplinary actions</li> <li>• Civil investigations, proceedings, or actions</li> <li>• Administrative investigations, proceedings, or actions</li> <li>• Criminal investigations, proceedings, or actions</li> </ul>

	<p><b>NOTE:</b> Because their focus is oversight, these rules are not designed to permit other kinds of law enforcement investigations of an individual.</p>
<b>HIPAA</b>	Means the Health Insurance Portability and Accountability Act of 1996.
<b>Hybrid Covered Entity</b>	Means a single legal entity that performs both covered and non-covered functions. The entity has a defined health care component that engages in HIPAA electronic transactions.
<b>Integrity</b>	Means the property that data or information have not been altered or destroyed in an unauthorized manner.
<b>Institutional Review Board (IRB)</b>	Means an approved board that can be used to review and approve a researcher’s request to waive or alter the HIPAA Privacy Rule’s requirements for an Authorization. The HIPAA Privacy Rule does not alter the membership, functions or operations, and review and approval procedures of an IRB regarding the protections of human subjects established by other Federal requirements.
<b>Limited Data Set</b>	<p>Means PHI that is made available for research, public health or health care operations subject to a data use agreement and excludes the following direct identifiers of the patient or of relatives, employers, or household members of the patient:</p> <ol style="list-style-type: none"> <li>1. Names;</li> <li>2. Street address (other than town or city, state, and zip code);</li> <li>3. Telephone numbers;</li> <li>4. Fax numbers;</li> <li>5. Electronic mail addresses;</li> <li>6. Social Security Numbers;</li> <li>7. Medical record numbers;</li> <li>8. Health plan beneficiary numbers;</li> <li>9. Account numbers;</li> <li>10. Certificate/License numbers;</li> <li>11. Vehicle identifiers and serial numbers (including license plate numbers);</li> <li>12. Device identifiers and serial numbers;</li> <li>13. Web universal resource locators (URLs);</li> <li>14. Internet protocol (IP) address numbers;</li> <li>15. Biometric identifiers including finger and voice prints, and</li> <li>16. Full face photographic images and any comparable images.</li> </ol>

	<p><b>NOTE:</b> The health information that may remain in the information disclosed includes:</p> <ul style="list-style-type: none"> <li>• Geographic data (town, city, state, and zip code, but no street address).</li> <li>• All dates relating to the individual (e.g. birth date, admission, discharge or service date).</li> <li>• Ages in years, months or days or hours.</li> <li>• Other unique identifiers (any unique number, characteristic or code other than those specified in the list of 16 identifiers that are expressly disallowed).</li> </ul> <p><b>NOTE:</b> It is important to note that this information is still PHI as defined by HIPAA. It is not de-identified information and is still subject to the requirements of the HIPAA Privacy Rule.</p>
<b>Patient</b>	The person who is the subject of the PHI
<b>Privacy Coordinator</b>	Means an FIU Workforce member, appointed by the director, manager, or supervisor of a HIPAA Designated Component to conduct and/or coordinate with necessary and appropriate Workforce members all HIPAA Privacy Rule activities and actions within the Component, including but not limited to tracking HIPAA training activities; coordinating HIPAA Privacy Rule implementation; participating in HIPAA Privacy and Security Rule violation investigations, as necessary and appropriate, communicating with the Director of Compliance and Privacy for Health Affairs, the HIPAA Security Officer, and the Office of General Counsel, as necessary and appropriate, regarding HIPAA Privacy and Security Rule activities and concerns; conducting and reporting monitoring activities; participate in assessments; and responding to, tracking and documenting HIPAA Privacy Rule activities. Maintain ongoing communication with the Director of Compliance and Privacy for Health Affairs and the HIPAA Security Officer.
<b>Privacy Rule</b>	Means 45 CFR Part 160 and Subparts A and E of Part 164. The U.S. Department of Health and Human Services (at <a href="https://www.hhs.gov/hipaa/for-professionals/privacy/index.html?language=es">https://www.hhs.gov/hipaa/for-professionals/privacy/index.html?language=es</a> ) identifies that the “Privacy Rule establishes national standards to protect individuals’ medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct

	<p>certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients’ rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.”</p>
<p><b>Protected Health Information</b></p>	<p>Means any individually identifiable health information collected or created in the course of the provision of health care services by a covered entity, in any form (written, verbal or electronic). PHI relates to the past, present, or future physical or mental health or condition of an individual or the past, present, or future payment for the provision of health care to an individual. PHI, however, specifically excludes:</p> <ol style="list-style-type: none"> <li>1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g (“FERPA”);</li> <li>2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and</li> <li>3. Employment records held by a covered entity in its role as an employer.</li> </ol>
<p><b>Record Owner</b></p>	<p>Means any health care practitioner who generates a medical record after a making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous record owner; or any health care practitioner’s employer, including, but not limited to, group practices and staff-model health maintenance organizations, provide the employment contract or agreement between the employer and health care practitioner designates the employer as the record owner. (F.S. §456.057)</p>
<p><b>Required by law</b></p>	<p>Means a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.</p>

<b>Research</b>	Means any systematic investigation designed to develop or contribute to generalizable knowledge.
<b>Secretary</b>	Means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.
<b>State refers to one of the following:</b>	<ol style="list-style-type: none"> <li>1. For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.</li> <li>2. For all other purposes, State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.</li> </ol>
<b>Treatment, Payment, and Healthcare Operations</b>	Also known as TPO
<b>Treatment</b>	Means the provision, coordination, or management of health care and related services among health care providers or by a healthcare provider with a third party, or consultative services among providers regarding a patient.
<b>Use</b>	With respect to patient identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within a healthcare Component that maintains such information.
<b>Workforce</b>	Means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity (FIU HIPAA Component) or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

**ROLES AND RESPONSIBILITIES**

1. **Compliance Oversight:** The Office of University Compliance and Integrity (University Compliance)
  - Evaluates all federal and state healthcare privacy laws, regulations, rules and ordinances (Rules) to ensure compliance with the Rules.
  - Develops and maintains all required University-wide Privacy Rule policies, procedures and associated forms.
  - Performs audits and assessments of the Components to ensure their compliance with the Privacy Rules and associated FIU Policies and Procedures.
  - Performs audits and assessments of the Components to ensure their compliance with the Privacy Rules and associated FIU Policies and Procedures.

- Partners with the Division of Information Technology HIPAA Security Officer to ensure compliance with all federal and state healthcare privacy and security laws, regulations rules, and ordinances.

## **2. HIPAA Components:**

- Each FIU HIPAA Hybrid Designated Component must designate a Privacy Coordinator responsible for overseeing and ensuring the Component's implementation and compliance with the HIPAA Privacy Rule, FIU's associated HIPAA Privacy Policies and Procedures, and any applicable state laws and/or regulations governing the confidentiality, integrity and availability of PHI and ePHI, including, but not limited to the creation of deidentified PHI, Limited Data Sets, and the use, and disclosure of PHI for research and non-research purposes.

## **3. Office of Research and Economic Development**

- Review and approve all research activities involving the use or disclosure of patient PHI, de-identified data, and limited data sets.

### **RELATED RESOURCES**

#### **References**

- 45 CFR §164.501
- 45 CFR §164.502
- 45 CFR §164.504
- 45 CFR §164.508
- 45 CFR §164.512
- 45 CFR §164.514
- 45 CFR §164.528
- 45 CFR §164.530
- F.S. §456.057
- F.S. §95.11

#### **Related Policies**

- FIU Policy #1610.005 (Designated Health Care Components of FIU Community)
- FIU Policy and Procedure #1640.015 (Notice of Privacy Practices)
- FIU Policy and Procedure #1640.025 (Minimum Necessary)
- FIU Policy and Procedure #1660.015 (Business Associates)
- FIU Policy and Procedure #1660.020 (Authorization for Use and Disclosure of Patient Protected Health Information)
- FIU Policy and Procedure #1660.025 (Uses and Disclosures of Protected Health Information for which an Authorization or Opportunity for the Patient to Agree or to Object is NOT Required)
- FIU Policy and Procedure #1660.040 (Verification)

- FIU Policy and Procedure #1660.070 (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)
- FIU Policy and Procedure #1660.075 (HIPAA Privacy and Security Rule Training)
- FIU Policy and Procedure #1660.080 (Policies and Procedures, Changes to Policies and Procedures, and Documentation)
- FIU Policy and Procedure #1660.085 (Sanctions)

### CONTACTS

For further information concerning this policy, please contact the FIU Office of Compliance & Integrity at (305) 348-2216, [compliance@fiu.edu](mailto:compliance@fiu.edu), the appropriate Component Privacy Coordinator, or the Office of Economic Research and Development.

### HISTORY

**Initial Effective Date:** September 1, 2009

**Review Dates** (review performed, no updates): n/a

**Revision Dates:** December 31, 2017; April 2021 (renumbered from 1640.040); August 31, 2021





**De-identification and Re-identification of Protected Health Information and Limited Data Sets # 1660.040a**

<b>INITIAL EFFECTIVE DATE:</b>	<b>LAST REVISION DATE:</b>	<b>RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT</b>
September 1, 2009	August 31, 2021	Office of Compliance and Integrity

**PROCEDURE STATEMENT**

**I. De-identification and Reidentification of Patient Protected Health Information (PHI)**

Each Component must designate a Privacy Coordinator responsible for overseeing and ensuring the Component’s implementation and compliance with the HIPAA Privacy Rule, FIU’s associated HIPAA Privacy Policies and Procedures, and any applicable state laws and regulations governing the confidentiality, integrity and availability of PHI and electronic PHI (ePHI), including, but not limited to receiving and processing requests for De-identified information and Limited Data Sets for research and non-research purposes. Privacy Coordinators may delegate and share duties and responsibilities as necessary and appropriate but retain oversight responsibility. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

A. Privacy Coordinators may determine that PHI is not individually identifiable PHI (de-identified) in the following two ways:

1. Removal of Identifiers. The Component Privacy Coordinator **MUST** remove the following identifiers of the patient and the patient’s relatives, employers or household members:
  - a. Names;
  - b. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geographic 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 unit containing 20,000 or fewer people is changed to 000;
  - c. All elements of dates (except year) for dates directly relating to a patient, including birth date, dates of admission and discharge from a health care facility, and date of death. For patients age 90 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;”

- d. Telephone numbers;
- e. Fax numbers;
- f. Electronic mail addresses;
- g. Social security numbers;
- h. Medical record numbers;
- i. Health plan beneficiary numbers;
- j. Account numbers;
- k. Certificate or license numbers;
- l. Vehicle identifiers and serial numbers, including license plate numbers;
- m. Device identifiers and serial numbers;
- n. Web Universal Resource Locators (URLs);
- o. Internet Protocol (IP) address numbers;
- p. Biometric identifiers, including fingerprints and voiceprints;
- q. Full face photographic images and any comparable images; and
- r. Any other unique identifying number, characteristic, or codes.

**NOTE:** This method requires that the Component Privacy Coordinator **DOES NOT** have actual knowledge that the remaining information could be used alone or in combination with other information to identify the patient.

- 2. **Statistical Method.** The Component Privacy Coordinator may employ a designated entity or individual with knowledge and experience of generally accepted statistical and scientific principles and methods for rendering information not individually identifiable PHI, if the entity or individual applies such methods and determines that the risk is very small that the information could be used alone, or in combination with other available information, by an anticipated recipient of such information to identify the patient(s).
  - a. The Privacy Coordinator **MUST** document the selected designated entities or individual’s knowledge and experience necessary to perform the de-identification prior to disclosing any PHI to the designated entity or individual.
  - b. The Privacy Coordinator **MUST** ensure the designated entity or individual selected documents the method and results of the analysis that justify the determination.
  - c. The Privacy Coordinator **MUST** ensure the de-identification will be performed at the data source, or, in the case of the de-identification is made by the designated entity or individual named in (I)(A)(2) immediately above, where such designated entity of individual is located, as appropriate.

B. Reidentification. The Component Privacy Coordinator, designated entity or individual performing the de-identification may assign a code or other means of record identification to allow information de-identified under this policy and procedure to be reidentified by the Component Privacy Coordinator, except that:

1. The code or other means of record identification is not derived from or related to information about the patient(s), and
2. Cannot otherwise be translated to identify the patient(s); and
3. The designated entity or individual does not use or disclose the code or other means of record identification for any other purpose, and
4. The designated entity or individual does not disclose the mechanism for reidentification to anyone other than the Component Administrative Officer, Privacy Coordinator, or Designee.

1. The Component Privacy Coordinator, designated entity or individual **MUST** document and secure the code or other means of record identification to allow information de-identified under this policy to be reidentified by the Component Privacy Coordinator.

**NOTE:** The Component Privacy Coordinator, designated entity, or individual may de-identify hardcopy PHI by obliterating (making unreadable and unrecognizable) the 18 identifiers.

**NOTE:** Regardless of the method by which de-identification is achieved, the Privacy Rule does not restrict the use or disclosure of de-identified PHI, as it is no longer considered PHI.

**NOTE:** Disclosure of a code or other means of re-identification constitutes disclosure of PHI.

**NOTE:** De-identified information that is reidentified is subject to the HIPAA Privacy Rule.

C. Business Associates

1. If the designated entity or individual employed to create de-identified data is not a Workforce member of the FIU Health Care Component, the Privacy Coordinator **MUST** ensure that a signed Business Associate Agreement is received from the designated entity or individual prior to disclosing any PHI to the designated entity or individual to create the de-identified data from a broader set of PHI. (FIU Policy and Procedure #1660.015) ((Business Associates Agreements))

## II. Limited Data Sets and Business Associate Agreements

A. Component Privacy Coordinators, designated entities, and/or individuals who create Limited Data Sets **MUST** remove the following identifiers of the patient and the patient's relatives, employers or household members from the PHI in order to create a Limited Data Set:

- a) Names;
- b) Street address (other than town or city, state, and zip code);
- c) Telephone numbers;
- d) Fax numbers;
- e) Electronic mail addresses;
- f) Social Security Numbers;
- g) Medical record numbers;
- h) Health plan beneficiary numbers;
- i) Account numbers;
- j) Certificate/License numbers;
- k) Vehicle identifiers and serial numbers (including license plate numbers);
- l) Device identifiers and serial numbers;
- m) Web universal resource locators (URLs);
- n) Internet protocol (IP) address numbers;
- o) Biometric identifiers including finger and voice prints; and
- p) Full face photographic images and any comparable images.

**NOTE:** The health information that may remain in the information disclosed in a Limited Data Set includes:

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

**NOTE:** It is important to note that Limited Data Set information is still PHI as defined by HIPAA. It is not de-identified information and is subject to the requirements of the HIPAA Privacy Rules and Florida Statute. (See **NOTE** immediately below in II(C))

B. The Privacy Coordinator must ensure the creation of the Limited Data Set will be performed at the data source, or, in the case of the Limited Data Set is made by an external designated entity or individual, where such designated entity or individual is located, as appropriate.

- C. If the designated entity or individual employed to create a Limited Data Set is not a Workforce member of the FIU Health Care Component, the Privacy Coordinator **MUST** ensure that a signed Business Associate Agreement is received from the designated entity or individual prior to disclosing any PHI to the designated entity or individual to create a Limited Data Set from a broader set of PHI. (FIU Policy and Procedure #1660.015) ((Business Associates Agreements))

**NOTE:** Once the Limited Data Set is created under the Business Associate Agreement for the FIU Health Care Component, all of the PHI, other than the PHI qualifying as the Limited Data Set must be returned to the FIU Health Care Component.

**NOTE:** Health Care Providers/Practitioners as identified in Florida Statute Chapter §456.057 **MAY** disclose PHI for statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative. (F.S. §456.057) Because a Limited Data Set does not protect the identity of the patient, written permission (Authorization) **MUST** be obtained from the patient.

- D. The recipient of the Limited Data Set for research purposes **IS NOT** required to enter into a Data Use Agreement as required by ORED Policy and Procedure #2370.522 and Policy and Procedure #2370.520 regarding the Use of Protected Health Information for Research Purposes, because the patient or the patient's legal representative must provide written permission (Authorization) prior to the disclosure of the patient's information contained within the Limited Data Set.

### III. **Record/Documentation Retention**

- A. If a communication, action, activity, or designation is required to be documented in writing, the document or record owner (e.g., the Office of Compliance and Integrity or the Component) will maintain such writings, or an electronic copy, for seven (7) years from the date of its creation or the last effective date, whichever is later. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

### IV. **Forms**

- FIU Business Associate Agreement