Use and Disclosure of Protected Health Information for Fundraising Purposes #1640.035

INITIAL EFFECTIVE DATE: September 1, 2009
LAST REVISION DATE: TBD
RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT: Office of University Compliance and Integrity

POLICY STATEMENT

Florida International University (FIU) follows the HIPAA, HITECH, the Omnibus Rules, and all other federal and Florida state statutes and regulations regarding when patients must provide written authorization (Authorization) for the use and disclosure of their PHI for fundraising activities and when an Authorization is not required for such activities.

The FIU HIPAA Hybrid Designated Health Care Components/Units (Components/Units) and the FIU Foundation shall be permitted to use or disclose certain limited PHI consisting of demographic information and dates of service for fundraising purposes of the Components/Units only in narrow circumstances described below.

1. The fact that disclosures for fundraising purposes are permitted must be specifically set forth in the Component’s/Unit’s Notice of Privacy Practices.
2. The use or disclosure can only consist of demographic information and dates of service.
3. The disclosure can only be to the Component/Unit, a Business Associate of the Component/Unit, or an institutionally related foundation (e.g., the FIU Foundation) for the purpose of fundraising for the benefit of the Component/Unit only.
4. All fundraising materials must include information about how the recipient of the information may opt-out of future fundraising communications. If the individual opts out, reasonable steps must be taken to ensure that the individual is not sent further fundraising communications.

NOTE: Use or disclosure of PHI for any other fundraising activity requires written authorization by the patient or the patient’s legally authorized representative (Representative).

All FIU Workforce members shall receive mandatory HIPAA Privacy and Security Rule training, as well as Florida state statute training in support of FIU’s commitment to the proper use, disclosure, and safeguarding of PHI/ePHI from any intentional, unintentional, or incidental use or disclosure to unauthorized individuals.

Workforce members who fail to adhere to this policy and procedure may be subject to criminal and civil penalties as provided by law, and/or administrative and disciplinary action, including, but not limited to termination of employment or expulsion. Violations will be
handled through FIU disciplinary policies applicable to employees and students. FIU may also refer suspected violations of applicable law to appropriate licensing and law enforcement agencies.

Each Component/Unit must designate a Privacy Coordinator/Liaison responsible for overseeing and ensuring the Component’s implementation and compliance with the HIPAA Privacy Rule, HITECH, the Omnibus Rule, FIU’s associated HIPAA Privacy Policies and Procedures, and any applicable federal and Florida state statutes and regulations governing the confidentiality, integrity and availability of PHI and electronic PHI (ePHI), including, but not limited to fundraising and marketing to patients.

Each Component/Unit must notify the Director of Compliance and Privacy for Health Affairs, Office of Compliance and Integrity, the name and title of their designated HIPAA Privacy Coordinator/Liaison.

**SCOPE**

This policy applies to the Components/Units contained within FIU’s HIPAA Hybrid Designation (FIU Policy and Procedure #1610.005), its Workforce members and Business Associates as defined in the policy and FIU Policy and Procedure #1660.015 regarding Business Associate Agreements.

**REASON FOR POLICY**

The intent of this policy is to address the specific and limited uses of patient Protected Health Information (PHI) for fundraising and marketing purposes, where patient authorization for use and disclosure is required, and provisions for opting out of such activities.

**DEFINITIONS**

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<td>Administrative Officer</td>
<td>Means the Component Workforce member responsible for financial management, human resources administration, management of facilities and equipment, and other administrative functions required to support the teaching and research missions of the FIU HIPAA Hybrid Designated Health Care Component. The Administrative Officer is the senior administrative staff position in the department, Division or Office and provides continuity as academic leadership changes.</td>
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<tr>
<td>Authorization</td>
<td>Means 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 HIPAA Privacy Rule, a covered entity</td>
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may not use or disclose PHI for research purposes without a valid Authorization.

| Business Associate | 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 require the disclosure of PHI (such as legal, actuarial, accounting, accreditation).

**NOTE:** 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.

**NOTE:** 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.

| Code of Federal Regulations | 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.

| Component/Unit | 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.

| Covered Entity | An entity that is subject to HIPAA.
1. a health plan;
2. a health care clearinghouse; and/or
3. a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.
| **Demographic Information** | Means a name, address and other contact information, age, gender, and date of birth. The term does not include any information about the illness or treatment. |
| **Designated Record Set** | 1. A group of records maintained by or for a covered entity that is:  
   a. The medical records and billing records about patients maintained by or for a covered health care provider;  
   b. The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or  
   c. Used, in whole or in part, by or for the covered entity to make decisions about patients.  
2. For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity. |
| **Disclosure** | Means the release, transfer, provision of access to, or divulging in any other manner of PHI outside of the entity holding the information. |
| **Electronic Protected Heath Information (ePHI)** | PHI in electronic form. See also: PHI. |
| **Florida International University** | Means the Institutionally Related Foundation that performs fundraising activities for Florida International University. |
| **Florida Statutes** | Also known as F.S. is a permanent collection of state laws organized by subject area into a code made up of titles, chapters, parts, and sections. The Florida Statutes are updated annually by laws that create, amend, transfer, or repeal statutory material. |
| **Fundraising** | Means a communication by or on behalf of a Covered Entity or a Business Associate on behalf of the Covered Entity for the purpose of raising funds for the Covered Entity, including donations, appeals, or sponsorship of events, but not royalties or remittances for sale of products. Fundraising communication is a solicitation for funds and can be in writing or oral. An acknowledgement or thank you letter for receipt of a donation or update of current development project without request for additional donation would NOT be a fundraising communication. An event invitation that includes a request for a donation to attend an event, would be a fundraising communication. |
| **Health Care Component** | See “Component/Unit” |
| **Health Information** | 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, |
| **U.S. Department of Health and Human Services** | Also known as HHS is a federal department concerned with promoting the health and wellbeing of U.S. citizens. The Department is also responsible for promoting research in social services, medicine, and public health. It has 11 operating divisions and over 100 programs across its various agencies. In addition to providing human services, HHS also implements programs related to social service, civil rights, and healthcare privacy. Two of the most well-known divisions of the HHS are the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). |
| **HIPAA** | Means the Health Insurance Portability and Accountability Act of 1996. |
| **HITECH** | Means The Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, to promote the adoption and meaningful use of health information technology. |
| **Hybrid Covered Entity** | 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. |
| **Institutionally Related Foundation** | Means a foundation that qualifies as a nonprofit charitable foundation under section 501(c)(3) of the Internal Revenue Code and that has in its charter statement of charitable purposes an explicit linkage to the covered entity. The Florida International University Foundation is the institutionally related fundraising foundation for the Florida International University Health Care Components. |
| **Minimum Necessary** | Means the limit use, disclosure, or request of PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. |
| **Opt-In** | To chose to participate in something. |
| **Opt-Out** | To choose not to be part of an activity or to stop being involved. |
| **Patient** | The person who is the subject of the PHI |
| **Permitted** | Means health care providers may, but are not required to, use or disclose patient PHI without authorization for its own treatment, payment, or healthcare operations (except for marketing purposes), and, in most cases, for treatment, payment and healthcare operations of other covered entities. |
| **Privacy Coordinator** | 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.

**Protected Health Information**

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:

2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and  
3. Employment records held by a covered entity in its role as an employer.

**Record**

Any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a Health Care Provider/Component/Unit.

**Treatment**

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.

**Use**

With respect to patient identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

**Workforce**

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 and procedures.
   - Develops and maintains HIPAA health care Privacy Rule training modules and ensures appropriate Workforce members complete the required training.
   - Performs audits and assessments of the Components to ensure their compliance with the Privacy Rules and associated FIU Policies and Procedures.
   - Assist and provide guidance as necessary and appropriate to establish and maintain patient DRSs.
   - 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. **The Florida International University (FIU) Foundation**
   - Partners and assists Healthcare Components/Units with fundraising activities.

3. **HIPAA Components/Units:**
   - Each Component/Unit must designate a Privacy Coordinator/Liaison responsible for overseeing and ensuring the Component’s/Unit’s implementation and compliance with the HIPAA Privacy Rule, HITECH, FIU’s associated HIPAA Privacy Policies and Procedures, and any applicable Florida state statutes and regulations governing the confidentiality, integrity and availability of PHI and ePHI.
   - Responsible for adhering to this policy and procedure and engaging the FIU Foundation with all fundraising activities.

4. **Compliance Oversight: The Division of Information Technology**
   - Evaluates all federal and state healthcare privacy laws, regulations, rules and ordinances (Rules) to ensure compliance with the security rules.
   - Develops and maintains all required University-wide Security Rule policies and procedures.
   - Develops and maintains HIPAA health care Security Rule training modules and ensures appropriate Workforce members complete the required training.
   - Performs audits and assessments of the Components/Units to ensure their compliance with the Security Rules and associated FIU Policies and Procedures.
   - Partners with the Office of Compliance and Integrity Director of Compliance and Privacy for Health Affairs to ensure compliance with all federal and state healthcare privacy and security laws, regulations rules, and ordinances.
RELATED RESOURCES

References
- 45 CFR §164.501 (HIPAA Privacy Rule)
- 45 CFR §164.504 (BAAs)
- 45 CFR §164.514 (Minimum Necessary)
- 45 CFR §164.530 (Record Retention/Documentation)
- F.S. §456.057 (Record Retention/Documentation)

Related Policies
- FIU Policy and Procedure # 1610.005 (Designated Health Care Components of FIU Community)
- FIU Policy and Procedure #1660.001 (Representatives)
- FIU Policy and Procedure #1660.015 (Business Associate Agreements)
- 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)
- FIU Policy and Procedure #1660.120 (Minimum Necessary)
- FIU Policy and Procedure #1660.130 (Uses and Disclosures of Protected Health Information for Marketing)

CONTACTS

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

HISTORY

Initial Effective Date: September 1, 2009
Review Date: N/A
Revision Dates: December 31, 2017, TBD
I. **Fundraising**

Healthcare Components/Units must designate a Privacy Coordinator/Liaison responsible for overseeing and ensuring the Healthcare Component’s/Unit’s implementation and compliance with the HIPAA Privacy Rule, HITECH, the Omnibus Rules, FIU’s associated HIPAA Privacy Policies and Procedures, and any applicable federal and Florida state statutes and regulations governing the use, disclosure, confidentiality, integrity and availability of PHI and electronic PHI (ePHI), including, but not limited to fundraising to patients. (See FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

A. All fundraising activities by or for Healthcare Components/Units that involve the use and disclosure of PHI and/or ePHI and require patient authorization **must** be done in coordination with the FIU Foundation, an Institutionally Related Foundation.

B. Requirements of the Privacy Rule of HIPAA, HITECH, the Omnibus Rules, and any applicable federal and Florida state statutes and regulations for Use and/or Disclosure of PHI for Fundraising by the Components/Units.

1. **Fundraising Requiring Patient Written Authorization.**

   a. If a Healthcare Component/Unit desires to use or disclose any PHI/ePHI of a patient other than as described below in I.B.2. for fundraising purposes, this may be done only after the patient has authorized this use and disclosure by completing a Media, Public, Marketing, Sale of PHI, Fundraising, and/or Public Relations Authorization form (Marketing and Fundraising Authorization) (See Section III below).

   b. All such fundraising **must** be done in coordination with the FIU Foundation. If needed, the FIU Foundation will assist in obtaining the required patient Marketing and Fundraising Authorizations for this type of fundraising.
c. The Healthcare Component/Unit and the FIU Foundation must retain the Marketing and Fundraising Authorization as required by the HIPAA Privacy Rule and Florida state statutes and regulations.

2. **Fundraising that Does Not Require Patient Written Authorization.**

   a. Fundraising that does not involve the use or disclosure of patient PHI/ePHI by the Healthcare Component/Unit and/or the FIU Foundation or that involves the use or disclosure by the Healthcare Component/Unit of only that information described below in I.B.3 & 4 does not require a patient’s written authorization.

3. **Fundraising that Does Not Involve the Use or Disclosure of PHI/ePHI by a Healthcare Component/Unit.**

   a. If an individual (patient, family, or friend) approaches an FIU Workforce member and requests information about how to donate, this information may be provided and any donation accepted without written authorization from the individual. When individuals spontaneously donate, not in response to a Healthcare Component/Unit fundraising solicitation, this donation is not covered by the HIPAA Privacy Rule, HITECH, or the Omnibus Rules.

4. **Fundraising that Involves the Use or Disclosure of Demographic Information and Other Limited Information as Described Below to an Institutionally Related Foundation (FIU Foundation) or Business Associate.**

   a. The Healthcare Component/Units may use internally or disclose outside of the Healthcare Component/Unit to the FIU Foundation or Business Associate (See FIU Policy and Procedure #1660.015) (Business Associate Agreements), without the patient’s written authorization, for fundraising on its behalf:
      1. Demographic information (as defined above in the definitions).
      2. Dates of health care provided to the patient.
      3. Department of service (e.g., cardiology, pediatrics).
      4. Treating physician/healthcare provider.
      5. Outcome information (including death or sub-optimal treatment), and
      6. Health insurance status (not defined in the Privacy Rule but interpreted to mean whether the patient is insured and type of insurance).

5. **The Healthcare Component/Unit Notice of Privacy Practices (See FIU Policy and Procedure #1640.015 (Notice of Privacy Practices (NPP) Distribution and Acknowledgement)).**

   a. The Healthcare Component’s/Unit’s Notice of Privacy Practices must contain a statement that the Healthcare Component/Unit may contact the patient to raise funds for the
Healthcare Component/Unit and describe the patient’s right to opt out of receiving communications.

**NOTE:** The actual opportunity to opt out is not required to be provided pre-solicitation.

6. **Clear and Conspicuous Opt-Out Notice.**

   a. Each fundraising communication **must** provide the patient with a clear and conspicuous opportunity to opt-out of receiving any further fundraising communications. The method for opting-out **must not** require the individual to incur an undue burden or more than a nominal cost. The FIU Foundation and Healthcare Components/Unit should consider offering a toll-free number, an e-mail address, a web page, or similar opt-out mechanisms that are simple, quick, and low or no cost to the patient.

   **NOTE:** Requiring a patient to send a written letter opting-out of fundraising communications would constitute an undue burden, although including a mailing a pre-printed, pre-paid, business reply postcard or directing a patient to an opt-out on a web page would be permitted.

   b. The FIU Foundation and Healthcare Components/Units **may** permit general opt-out for all future communications, or to a particular fundraising campaign. Once implemented, however, the Healthcare Component/Unit and FIU Foundation **must not** send further fundraising communications.

   c. The Healthcare Components/Units **may not** condition treatment or payment on the patient’s choice concerning the receipt of further communications related to fundraising.

   d. The Healthcare Components/Units **may not** make fundraising communications to a patient who has opted-out of receiving such communications.

7. **Opting Back In**

   a. Patients who have opted-out of receiving fundraising communications **may** be given the opportunity to opt back in, but only through an affirmative step to opt back in.

   **NOTE:** An opt-out **may not** lapse after a period of time).

C. **Mailing Lists**

   1. The Healthcare Components/Units **may** use PHI/ePHI, including disease or condition information, without a patient’s authorization, to develop mailing lists for purposes of identifying patients to whom an authorization for use of PHI for fundraising should be sent.
D. Minimum Necessary

1. The Healthcare Components/Units must identify and use and/or disclose only the minimum necessary amount of PHI/ePHI when using or disclosing PHI/ePHI for fundraising. (See FIU Policy and Procedure #1660.120 (Minimum Necessary))

E. Educational Events Co-Sponsored with a Third Party

1. The FIU Foundation and Healthcare Components/Units may offer educational or awareness campaigns co-sponsored by a third party (e.g., American Heart Association) or include speakers or information from such third parties.

2. The FIU Foundation and Healthcare Components/Units, however, are prohibited from sharing PHI/ePHI with the third party or permitting the third party to use an FIU Foundation or FIU Health Care Component/Unit patient mailing list or “Permitted Fundraising PHI” to send co-sponsored fundraising solicitations.

3. The FIU Foundation and Health Care Components/Units should not include third party fundraising information within the event’s communications (e.g., invitation, brochure, or similar communication tools).

4. At the event, the third party may invite patients to provide their contact information in writing, such as a signup log, that clearly identifies the third party’s request to contact the patients attending the event, including the possibility that they will be contacted for the third party’s own fundraising efforts.

5. No fundraising related to the third party should occur at the event.

II. Record Retention

A. The Health Care Components/Units and the FIU Foundation shall maintain all documentation and patient written authorizations for seven (7) years from the date of its creation and patient signature or the date when it was last in effect, whichever is later.

III. Form

A. Marketing/Fundraising Authorization for Use/Disclosure of Medical Information.