






UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE 	<b>POLICY AND PROCEDURE</b>		
	<b>EFFECTIVE DATE:</b> 3/10/2016	<b>REVIEW DATE:</b>	<b>REVISION DATE:</b>
	<b>SUBJECT:</b> Acquisition, Decommissioning, Disposal and Sanitization of Medical Equipment Containing PHI and/or PII		<b>RESIDING MANUAL:</b> Biomedical <b>SECTION:</b> HIPAA Compliance <b>ADMINISTRATIVE</b> <input checked="" type="checkbox"/> <b>DEPARTMENTAL</b> <input type="checkbox"/> <b>POLICY NUMBER:</b> BIOMED.PHI.03.16 <b>PAGE NUMBER:</b> 1 of 9

**REVISION HISTORY**

Revision Date	Authors	Description of Changes
02/10/2016	Jose Ramirez, Matthew Evans, Ron Bogue	New Document

**APPROVAL SIGNATURES**

Name	Title	Signature	Date
Gemma Romillo	Asst. VP, Clinical Billing Compliance, Medical Compliance and HIPAA Privacy Officer		3/10/16
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### 1. PURPOSE


The purpose of this document is to define the process to ensure effective and accurate identification, securing, transferring, and removal of protected health information (PHI) and personally identifiable information (PII) stored in biomedical and diagnostic imaging equipment (here to referred to as medical equipment). This document includes the procedures for acquisition (e.g. purchase, evaluation, loaner, lease, and rental), inventorying, tracking, media sanitation, destruction, decommissioning, and disposal (reuse, recycle, destroy, return, donate) of medical equipment.

### 2. SCOPE


This policy and procedure is applicable to all University of Miami staff, independent practitioners, vendors, business associates, charitable organizations, service providers, original equipment manufacturers (OEM) and medical equipment rental companies.

### 3. DEFINITIONS

- Certification of Media Disposal – physical or electronic document that confirms the sanitation actions have taken place. Document must contain equipment manufacturer, model, serial number, sanitation method, technician’s name/title, and confirmation that process was completed.
- Electronic Protected Health Information (ePHI) - Protected health information (PHI) that is created, stored, transmitted, or received electronically. Electronic protected health information includes any medium used to store, transmit, or receive PHI electronically.
- Individually Identifiable health Information - Information that is a subset of health information, including demographic information collected from an individual, and:
  1. Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
  2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and
    - (i) That identifies the individual; or
    - (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- Medical Equipment - Fixed or portable equipment used in any stage of patient care; used for the purpose of monitoring, treatment, diagnostic, patient support, or life support.

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- Medical Equipment PHI/PII Risk Assessment Form - A form that discloses if medical equipment creates, stores, or transmits PHI/PII and indicates the method of media sanitization to be employed for a given medical equipment (See attachment "A").
- OEM - Original Equipment Manufacturer
- Personally Identifiable Information (PII) - Any information about an individual maintained by an agency, including:
  1. any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and
  2. Any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.
  3. Examples of PII include, but are not limited to:
    - a) Name, such as full name, maiden name, mother's maiden name, or alias
    - b) Personal identification number, such as social security number (SSN), passport number, driver's license number, taxpayer identification number, or financial account or credit card number
    - c) Address information, such as street address or email address
    - d) Personal characteristics, including photographic image (especially of face or other identifying characteristic), fingerprints, handwriting, or other biometric data (e.g., retina scan, voice signature, facial geometry)
    - e) Information about an individual that is linked or linkable to one of the above (e.g., date of birth, place of birth, race, religion, weight, activities, geographical indicators, employment information, medical information, education information, financial information).
- Protected Health Information (PHI) - according to the US Department of Health and Human Services Protected Health Information is Individually Identifiable health Information that is:
  1. Except as provided in paragraph (2) of this definition, that is:
    - a) Transmitted by electronic media;
    - b) Maintained in electronic media; or
    - c) Transmitted or maintained in any other form or medium.
  2. Protected health information excludes individually identifiable health information in:

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- a) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;
- b) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and
- c) Employment records held by a covered entity in its role as employer.

- Qualified Service Technician - A fully trained, certified, and qualified technician duly authorized to service, sanitize or destroy medical equipment media.

#### 4. RESPONSIBILITY

##### 4.1. Biomedical Department


- 4.1.1. Plays an active role in the acquisition and asset management of medical equipment in cooperation with the Department of Supply Chain Services.
- 4.1.2. Performs an incoming medical equipment inspection and collects the completed Medical Equipment PHI/PII Risk Assessment form from the OEM/Vendor. If the Medical Equipment PHI/PII Risk Assessment Form indicates that the medical equipment contains PHI/PII, the biomedical technician will place an identification sticker on the medical device which indicates if the medical equipment contains PHI and/or PII data
- 4.1.3. Uploads the appropriate medical equipment forms (e.g. PHI and PII Risk Assessment Form and Incoming Medical Equipment Inspection Form) as well as the original purchase contract to the Biomedical Department's computerized maintenance management system.

##### 4.2. Department (Acquiring/Disposing)

- 4.2.1. Completes and processes the Capital Equipment Justification Form through the established approval flow. All rental medical equipment must be processed through the same established approval flow.
- 4.2.2. Completes the Property Disposal Form when disposing of medical equipment and process flow for sanitation of medical equipment.

##### 4.3. Department of Supply Chain Services

- 4.3.1. Coordinates the acquisition (purchase, evaluation, loaner, lease, and rental) of medical equipment with university approved vendors.

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#### 4.4. Surplus Property Warehouse

- 4.4.1. Confirms that medical equipment media has been sanitized (where applicable) prior to obtaining the designated medical equipment.

#### 4.5. Original Equipment Manufacturer (OEM)

- 4.5.1. Determines the appropriate medical equipment media sanitization or destruction method and indicates it on the Medical Equipment PHI/PII Risk Assessment form during the contracting phase.


#### 4.6. Qualified Service Technician

- 4.6.1. Sanitizes or destroys medical equipment media containing PHI/PII data utilizing the sanitation or destruction method outlined in the Medical Equipment PHI/PII Risk Assessment form.
- 4.6.2. Provides the Certificate of Media Sanitization to the Biomedical Department

### 5. PROCEDURE

#### 5.1. Acquisition of Medical Equipment

- 5.1.1. The Acquiring Department will contact the Department of Supply Chain Services and coordinate the contractual details of purchase, lease, loan, evaluation or rental of medical equipment.
- 5.1.2. The Department of Supply Chain Services will have the OEM/Vendor complete a Medical Equipment PHI/PII Risk Assessment Form.
- 5.1.3. Once the Medical Equipment PHI/PII Risk Assessment Form is complete, the Department of Supply Chain Services will write the terms and conditions - outlining responsibility and procedure for sanitation of PHI/PII, acceptable return practices, and all other details necessary to ensure PHI/PII is secure.

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5.1.4. The Acquiring Department will contact the Biomedical Department to create a work order to perform an incoming medical equipment inspection. The Biomedical Department will review the completed Medical Equipment PHI/PII Risk Assessment Form, and if the medical device will hold PHI/PII, they will attached a yellow sticker (Contains Class I Class II) to the device to indicate PHI/PII is stored.



5.1.5. The Biomedical Department uploads the results of the completed Incoming Equipment Inspection Form and Medical Equipment PHI/PII Risk Assessment Form to the Biomedical Department's computerized maintenance management system.

5.1.6. The Biomedical Department updates the master medical equipment inventory to reflect the newly acquired medical equipment.

## 5.2. Disposal of Medical Equipment

5.2.1. When the disposing department is ready to return rental, evaluation, and/or loaner medical equipment, the department will contact the Department of Supply Chains Services to finalize the closing of the contract.


5.2.2. If the medical equipment is on a lease or purchase contract, the Disposing Department will complete and submit a Surplus Property/Transfer Form to the Department of Surplus Property and contact the Biomedical Department to determine if equipment holds PHI-PII (Call Center 1-305-243-6375) (\*See section on Rental for non-purchased/leased equipment).

5.2.3. If the Biomedical Department concludes that the medical equipment media holds PHI or PII, they will refer to the Medical Equipment PHI/PII Risk Assessment Form to note the pre-determined method and procedure to be utilized to sanitize the medical equipment media.

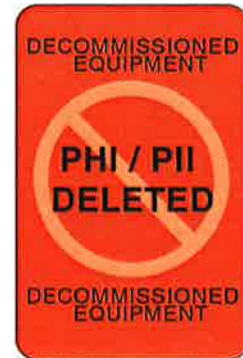
5.2.4. The contract and/or Medical Equipment PHI/PII Risk Assessment Form will outline the following process:

- The OEM or vendor will contract with a qualified service technician to sanitize or destroy the PHI/PII and/or;
- The OEM will coordinate the sanitation of the medical equipment media through internal biomedical or third party biomedical services to sanitize or destroy the PHI/PII.



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- 5.2.5. Once the sanitization process has been completed, the qualified service technician will sign the Surplus Property / Transfer Form to confirm sanitation, will place a decommissioned PHI/PII sticker on the medical equipment, and provide the Biomedical Department with a Certificate of Media Disposal.
- 5.2.6. Medical equipment must not be removed from service until destruction or sanitization of the media containing PHI/PII data is performed, documented and confirmed in the Biomedical Department's computerized maintenance management system (see 5.4)
- 5.2.7. Prior to scheduling a medical equipment pick-up, the disposing department will provide a completed Surplus Property / Transfer Form to the Department of Surplus Property. Upon arrival for pickup, the Department of Surplus Property will confirm that the medical equipment contains a decommissioned sticker.
- 5.2.8. The Biomedical Department will update the medical equipment master inventory to reflect the disposal of the medical equipment.



### 5.3. Media Sanitization And Destruction

- 5.3.1. The Department of Supply Chain Service will finalize the contract's terms and conditions for PHI/PII media sanitization through the use of the Medical Equipment PHI/PII Risk Assessment Form. This form will be utilized to indicate the appropriate medical equipment media sanitization or destruction method as determined by the Original Equipment Manufacturer (OEM). The sanitization or destruction methods are:
- Clearing - uses software or hardware to override the media with non-sensitive data before the media is re-used meeting minimum U.S. Department of Health & Human Services (HHS) data destruction standards
  - Purging - degaussing or exposing the media to a strong magnetic field meeting minimum HHS data destruction standards
  - Removal - removing a physical hard drive or flash memory from the medical equipment
  - Destroying - disintegration, pulverization, melting, or any similar method to destroy the physical storage device.
- 5.3.2. The selected method of sanitization is recorded in the appropriate section of the Medical Equipment PHI/PII Risk Assessment form as determined by the Original Equipment



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Manufacturer (OEM) or vendor. This form will also indicate who will perform the sanitization of the medical equipment. (see section 5.2)

5.3.3. If third party qualified technicians are used to complete the medical equipment sanitization, they will be required to provide a Certificate of Media disposal for each piece of medical equipment media sanitized. They will also be required to maintain, and produce upon request, audit trails showing the sanitization method employed.

5.3.4. A certificate of media disposal will be provided to the Biomedical Department once sanitization or destruction of medical equipment media is complete.

5.3.5. The certificate of media disposal will be uploaded to the Biomedical Department's computerized maintenance management system.

## 6. DOCUMENTATION

6.1. Health Insurance Portability and Accountability Act (HIPPA):

- Section 1171 of Part C of Subtitle F of Public Law 104-191 (August 21, 1996)
- Health Insurance Portability and Accountability Act of 1996: Administrative Simplification

6.2. Center for Medicare and Medicaid Serviced (CMS)

6.3. Medical Equipment PHI/PII Risk Assessment Form

6.4. Property Disposal Form

6.5. Incoming Equipment Inspection Form

6.6. University Of Miami HIPAA Security Policy - Disposal Policy #: HSP 13.1

6.7. University Of Miami HIPAA Security Policy - Media Re-Use Policy #: HSP 13.2

6.8. NIST Special Publication 800-88 - Revision 1 Guidelines For Media Sanitization

6.9. NIST Special Publication 800-122 - Guide to Protecting the Confidentiality of Personally Identifiable Information (PII)

6.10. NIST Special Publication 800-88 - Guidelines for Media Sanitization