



Policy and Procedure:

SDM PHI Data extraction, Export, Print and Report Policy

Purpose: This document describes the policy for extracting, exporting, printing and reporting on Protected Health Information (PHI) from any Electronic Health Record (EHR) system in the School of Dental Medicine for research and teaching purposes.

Audience: SDM faculty, staff, residents and students

Department: Office of Faculty Development and Information Management

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Related docs: <http://www.irb.pitt.edu/>
<http://www.irb.pitt.edu/hipaa/>
<http://www.irb.pitt.edu/guidance#h>
<http://www.clinicalresearch.pitt.edu/irs/corid>
<http://www.hhs.gov/ocr/privacy/>
<http://www.pitt.edu/hipaa/pdf-2013/Security%20of%20Electronic%20Medical%20Records.pdf>
<http://www.upmc.com/patients-visitors/privacy-info/Pages/notice-of-privacy-practice.aspx>

Comments: Please send comments and corrections to: cdi_offcmgr@dental.pitt.edu

Commonly Used Abbreviations and Definitions

- HIPAA – Health Insurance Portability and Accountability Act
- IRB – Institutional Review Board
- CORID – Committee for Oversight of Research and Clinical Training Involving Decedents
- PHI – Protected Health Information
- Honest Broker - A neutral party who has legitimate access to the PHI requested (such as a member of the records staff or a treating clinician) and who is separate from the research team.
- SDM-Qualified Honest Broker – Any SDM certified honest broker with signed “SDM Business Associate Agreement for Honest brokers” or any other proposed honest broker who is prospectively approved by the SDM (see “SDM Honest Broker Certification Policy” and “SDM Business Associate Agreement for Honest Brokers” available at <http://www.dental.pitt.edu/hipaa>)
- Teaching inside the SDM – Teaching activities include all educational activities performed inside the SDM to SDM students, faculty and staff, including lectures, training, online courses accessible only with Pitt password and case studies.
- Teaching outside the SDM – Teaching activities include all educational activities performed outside the SDM to a public audience, including, but not limited to, lectures, training, online courses, educational software, National Board exams, continuing education courses and case studies.

1. Introduction

Protected Health Information (PHI) is defined as personal and identifiable health information about patients under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Frequently, PHI is required for research and/or teaching purposes within the School of Dental Medicine. This policy specifies under which circumstances PHI can be made available for research and teaching purposes within the school.

2. Sanctions

It shall be the responsibility of each covered section to implement procedures to meet the requirements of HIPAA Privacy and Security Rules and the University’s HIPAA policy (see www.pitt.edu/hipaa). According to the University policy, violation of PHI privacy and security



policies may result in disciplinary action up to and including termination of employment and/or dismissal from the University. Under federal law, violation of HIPAA Privacy Rules may result in civil monetary penalties of up to \$250,000 per year and criminal sanctions including fines and imprisonment.

3. Using Protected Health Information (PHI) For Research

There are four separate methods under which researchers may access PHI for research purposes:

Written HIPAA Authorization under an IRB Approved Protocol

- 3.1 Where the IRB has approved a research protocol where research subjects provided prospective, written informed consent combined with the necessary elements of a HIPAA authorization, PHI within the scope of that consent/authorization may be extracted from the EHR. In each case, the investigator must provide a copy of the IRB approval letter, and the signed consent/authorization for each subject to SDM IT with the service request. The copies are attached to the request ticket in IT ticket system FootPrints.

Provision of a De-Identified Data Set:

- 3.2 PHI data extraction, export, print or report generation for any research purpose for existing PHI, including clinical studies, sample size estimation and pilot testing (if the investigator is not also the attending clinician), require an IRB approval with valid dates. A copy of the IRB approval letter must be presented to SDM IT with the service request.
- 3.3 In order to make the data available for research under this provision, they must be de-identified. The following 18 identifiers listed in the HIPAA Privacy Rules must be removed by a SDM-qualified honest broker:
- 1) Names
 - 2) All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census:
 - a) the geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and
 - b) the initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
 - 3) All dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
 - 4) Telephone numbers
 - 5) FAX numbers
 - 6) Electronic mail addresses
 - 7) Social Security numbers
 - 8) Medical record numbers
 - 9) Health plan beneficiary numbers
 - 10) Account numbers
 - 11) Certificate/license numbers
 - 12) Vehicle identifiers and serial numbers including license plate numbers
 - 13) Device identifiers and serial numbers
 - 14) Web Universal Resource Locators (URLs)
 - 15) Internet protocol (IP) addresses
 - 16) Biometric identifiers (including finger and voice prints)
 - 17) Full face photos and comparable images



18) Any unique identifying number, characteristic or code

Provision of a Limited Data Set:

- 3.4 PHI data extraction, export, print or report generation for any research purpose for existing PHI, including clinical studies, sample size estimation and pilot testing (if the investigator is not also the attending clinician), require an IRB approval with valid dates. A copy of the IRB approval letter must be presented to SDM IT with the service request.
- 3.5 In order to make the data available for research under this provision, only a "limited data set" may be provided. The following 16 identifiers listed in the HIPAA Privacy Rules must be removed by a SDM-qualified honest broker:
- 1) Names
 - 2) Postal address information (other than town or city, state and zip code)
 - 3) Telephone numbers
 - 4) Fax numbers
 - 5) E-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 & serial numbers, including license plate numbers
 - 12) Device identifiers & serial numbers
 - 13) Web Universal Resource Locators (URL's)
 - 14) Internet Protocol (IP) address numbers
 - 15) Biometric identifiers, including finger and voice prints
 - 16) Full face photographic images and any comparable images
- 3.6 In addition, any researcher requesting a limited data set for research purposes must first execute the SDM Data Use Agreement for Limited Data Set, in the form provided by the information technology service provider in the SDM (see "SDM Data Use Agreement for Limited Data Set" available at <http://www.dental.pitt.edu/hipaa>).

Grant of an IRB Waiver:

- 3.7 Under certain circumstances, the IRB may approve a waiver of the requirement for prospective informed consent/authorization, in which case the investigator must provide a copy of the IRB approval letter including the specific scope of the waiver granted to SDM IT with the service request. Any researcher in this case must sign a SDM PHI Research Agreement (which is available at <http://www.dental.pitt.edu/hipaa>) before data access is permitted. Even if such a waiver is granted, the SDM requires that the following four identifiers are removed. The removal can be done by either qualified de-identification software or qualified database expert paid by the principal investigator.
- 1) Patient name
 - 2) Patient SSN
 - 3) Patient home street address
 - 4) Patient phone number
- 3.8 Protecting the confidentiality of extracted data, exported data or reports, including working files, is the responsibility of the principal investigator.

Decedent Patient Records:

- 3.9 Decedent PHI data is protected by HIPAA Privacy Rule to the same extent as living PHI data for 50 years following the date of death of the individual but does include special disclosure provision for research. To review SDM decedent PHI data during the period of 50 years, the requestor must first



get CORID approval, then fill in the SDM Decedent PHI Request Form for Research and submit the completed request form in Word version via email to the Office of Clinical Affairs in the SDM (see Appendix A).

4. Using Protected Health Information (PHI) For Teaching

- 4.1 PHI data extraction, export, print and report generation for teaching outside the SDM requires procedures a to c listed below. Any eligible SDM faculty, staff, resident or student must complete each of the procedures and present the results to SDM IT before having PHI system user login or PHI data use permission.
 - a) Completion of HIPAA training required by the Office of Health Sciences
 - b) Completion of the University of Pittsburgh HIPAA Privacy and Security Awareness for Physicians, Mid-Level Providers, Dentists, Staff, and Students working in University of Pittsburgh clinical facilities and other HIPAA-covered departments or the HIPAA Researchers Privacy Requirements (Formerly RPF Module 6).
 - c) Acceptance of this SDM PHI Data Extraction, Export, Print and Report Policy (available at <http://www.dental.pitt.edu/hipaa>)
- 4.2 For teaching outside the SDM (outside the SDM's clinical environment), PHI must be de-identified, removing the 18 identifiers listed in Section 3.3 (except as outlined in Section 4.3). De-identifying PHI is the responsibility of the SDM Honest Broker per SDM Honest Broker Certification Policy and Procedures (available at <http://www.dental.pitt.edu/hipaa>).
- 4.3 For teaching inside the SDM, the de-identification process for extracted pictures or photos can be waived for patients who signed the SDM Packaged Consent Form. The individual MUST verify that each patient has a Packaged Consent document with his/her signature in the EHR system. If the individual cannot verify that the patient has signed for his/her Packaged Consent in the EHR system, all extracted pictures or photos MUST be de-identified.
- 4.4 Any teaching outside the SDM must meet 4.1 to 4.3 requirements plus complete the SDM PHI Request Form for Education (see appendix B).
- 4.5 All working files containing PHI data must remain on a restricted UNIV network drive (e.g. P drive for employees and terminal server drive for residents and students) until de-identification has been verified by the SDM Honest Broker. Any local drive (e.g. C drive), portable device (e.g. laptop, PDA, USB key, CD, DVD or portable hard disk) or cloud-based storage systems (e.g. Box) should not be used for storage of PHI data without encryption, authentication and HIPAA compliance.
- 4.6 Protecting the confidentiality of extracted data, exported data, printed data or reports, including working files and student presentations, is the responsibility of the requestor.



5. Using Protected Health Information (PHI) For Clinical Purposes

- 5.1 PHI data extraction, export, print and report generation for clinical care purposes, including clinical service, clinical treatment and clinical management, must be HIPAA compliant.
- 5.2 PHI data extraction, export, print and report generation for clinical purpose from an SDM system to another system or to an external location require an approval by the SDM HIPAA Security Officer (i.e. Associate Dean for Clinical Affairs).
- 5.3 PHI data extraction can only be requested by department chairs and unit managers (e.g. Associate Dean for Clinical Affairs is the unit manager for the Office of Patient Services and IMS/Central Stores).
- 5.4 PHI data extraction and reports for purposes of clinical management can only be requested by the Clinical Affairs Office or Business Office.
- 5.5 Protecting the confidentiality of the extracted data, exported data, printed data or reports, including working files, is the responsibility of the requestor.

Acceptance

Print Name _____ Signature _____ Date _____



Appendix A

School of Dental Medicine, University of Pittsburgh
SDM Decedent PHI Request Form for Research

TO: Office of Clinical Affairs, School of Dental Medicine (SDM)
FROM: Name of Principal Investigator:
RE: Request to review Decedent Protected Health Information for Research
Name of Research Study:
Pitt IRB # /CORID # /OSPARS #:

I, _____ and my research study staff would like to review Protected Health Information (PHI) of SDM patients to gather information for the research study listed above. It is my assertion that:

1. This PHI sought is solely for this research study;
2. Access to this PHI is necessary for this research because _____.
3. I and/or my staff have verified the death of the individuals whose PHI is sought.

De-identified data or a limited data set will not provide me with the information necessary for this research because:

I am unable to obtain the authorization for access to the necessary PHI by contacting the subject's next of kin because:

I understand that I am bound by University of Pittsburgh and SDM policy, as well as state and federal law, to handle this PHI in a manner that protects the confidentiality of the decedents.

Signature of Principal Investigator

Date

Reviewed and approved by Research Compliance Officer or designee

Signature of Research Compliance Officer / Designee

Date

Instruction:

Please submit the completed request form in Word version via email to Jessica Heath at: jeh167@pitt.edu (412-648-8880).

The request will be reviewed based on the protocol and HIPAA requirements. If revisions are necessary, the reviewer will redline the request and email back to the Principal Investigator for review. Once in agreement, the Principal Investigator will sign, date, scan the form, and email back as an attachment for signature.



Appendix B

School of Dental Medicine, University of Pittsburgh
SDM PHI Request Form for Education

Requestor Name: _____

Education Purpose : _____

Request Description (brief info): _____

Non-SDM Participants (individuals): _____

De-identification by (responsible person name): _____

Requestor's Signature

Date

Department Chair's Approval Signature

Date



| Date | Description of revision | Author |
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