UPMC
POLICY AND PROCEDURE MANUAL

POLICY: HS-RS0005 *
INDEX TITLE: Research

SUBJECT: Research Using UPMC Electronic Protected Health Information (e-PHI)
DATE: November 10, 2016

I. INTRODUCTION & POLICY

UPMC’s commitment to a system-wide electronic health record provides meaningful use in addition to creating an enriched environment and exceptional resource to investigators conducting clinical research. This policy addresses issues related to the proper use of electronic protected health information (e-PHI) for research purposes. It also delineates a mechanism with which the Office of Sponsored Programs and Research Support (OSPARS), in collaboration with the Center for Assistance in Research using eRecord (CARe) (a joint resource established between UPMC and the University of Pittsburgh), ensures appropriate use of e-PHI for the conduct of research under a protocol approved by a nationally accredited Institutional Review Board (IRB).

In line with HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule and Security Rule, as amended by HITECH (Health Information Technology for Economic and Clinical Health) and the HIPAA Omnibus Rule, UPMC is dedicated to the confidentiality and security of protected health information (PHI) created, received, maintained, or transmitted by UPMC.

e-PHI acquired from UPMC under an IRB-approved protocol becomes research data and property of the entity hosting the IRB of record. It is the responsibility of these entities and their researchers obtaining UPMC e-PHI to ensure continued confidentiality and security of the acquired e-PHI, and to demonstrate that safeguards and policies of equal or greater rigor exist as that adopted by UPMC.

OSPARS has the ultimate responsibility for implementation, compliance monitoring and enforcement of this Policy. OSPARS may delegate responsibilities to various UPMC operational areas as it deems appropriate, and works collaboratively with CARe as described herein.

Links to policies referenced within this policy can be found in Section VII.

II. DEFINITION: ELECTRONIC PROTECTED HEALTH INFORMATION

The HIPAA Privacy Rule establishes national standards for the protection of the privacy of individually identifiable health information, i.e., protected health information (PHI). The Security Rule establishes national standards for protecting a subset of information covered by the Privacy Rule, i.e., all individually identifiable health information a covered entity creates, receives, maintains or transmits in electronic form, or “electronic
protected health information” (e-PHI). The Security Rule does not apply to PHI transmitted orally or in writing.

III. PURPOSE

The purpose of this Policy is to set forth specific responsibilities of Researchers with respect to the use of e-PHI for research purposes. It is intended to supplement (not replace) any existing applicable state and federal laws governing PHI. This policy is to be read in conjunction with other related UPMC policies, including but not limited to, the following:

- HS-EC1600 Accounting of Disclosures of Protected Health Information (PHI)
- HS-EC1601 Complaint Management Process Pursuant to the HIPAA Privacy Rule
- HS-EC1807 Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker
- HS-EC1603 Notice of Privacy Practices for Protected Health Information (PHI) Pursuant to the HIPAA
- HS-EC1609 Patient Amendments to Protected Health Information
- HS-EC1606 Privacy and Security Training Related to Protected Health Information (PHI)
- HS-EC1614 Prohibition on Sale of Protected Health Information
- HS-MR1000 Release of Protected Health Information
- HS-EC1602 Use & Disclosure of Protected Health Information (PHI) Including: Fundraising, Marketing and Research

IV. SCOPE

A. Entities Covered by the Policy

For the purpose of this Policy, “UPMC” includes UPMC and all of its United States based, managed or controlled affiliates. Affiliates not managed or controlled by UPMC are covered under this policy only to the extent this policy is specifically adopted by such affiliates.

B. Individuals Covered by the Policy

This Policy applies to all United States based Research Team Members (defined as individuals who conduct or participate in clinical research on UPMC premises, or are under the oversight of UPMC Research, whether or not such individuals are employed by UPMC. By extension, this includes any Researchers accessing and/or acquiring UPMC e-PHI for research purposes.
C. **Research Covered by the Policy**

All United States based research activities involving the access, acquisition, transfer and/or storage of UPMC e-PHI are within the purview of this policy. This includes all IRB-approved or CORID-approved (Committee for Oversight of Research and Clinical Training Involving Decedents) research projects that involve access to, and acquisition of, UPMC e-PHI.

All research projects that access UPMC e-PHI must be submitted to CARe for review, with the exception of industry-sponsored clinical trials contracted through OSPARS. Once a project is submitted, CARe staff determines whether or not further CARe review is required based on the following criteria:

(1) Research requiring CARe review:

- Prospective and/or retrospective electronic medical record review studies with a waiver of HIPAA authorization and with or without a waiver of informed consent conducted by an Investigator with patient care responsibilities, regardless of the Investigator’s existing access privileges to UPMC electronic medical record (EMR) systems (e.g., Epic, Stentor, Cerner, etc.);

- Medical record reviews utilizing a certified Honest Broker, resulting in:
  - receipt of a Safe Harbor Data set (all 18 HIPAA identifiers removed), or
  - receipt of a Limited Data Set (dates related to individuals and certain geographical information permitted; remaining 16 HIPAA identifiers removed);

- All research registries, whether or not informed consents and HIPAA authorizations are obtained from research participants;

- Any research project that requests CARe assistance in accessing and/or extracting data from UPMC EMR and/or in programming an alert or flag in the UPMC EMR.

- Any research projects that require Information Services Division services.

(2) Research meeting the exception from CARe review:

- Prospective clinical trials in which the Investigator obtains informed consent and HIPAA authorization from research participants to access their PHI for the conduct of IRB-approved clinical research procedures (i.e., recruitment, clinical examination, fulfilling research/medical orders).
This is consistent with the exception given to individuals who access e-PHI for the following research activities:

(a) performing specific research activities, such as recruiting subject(s) into an IRB-approved research study, clinically examining study subject(s) accrued into the research study(s), fulfilling research/medical orders as specified by the IRB-approved clinical protocol; and/or

(b) auditing and/or monitoring information consistent with regulatory and/or sponsor requirements.

[Additional information, including instructions for submitting a research project to CARe is available at: Center for Assistance in Research using eRecord].

V. **CARE SERVICE, ACCESS REQUESTS AND RESEARCHER RESPONSIBILITIES**

Pitt IRB serves as UPMC’s privacy board for HIPAA authorization requests for human subjects research. IRB approval of a research protocol grants the investigator the general right to access and/or acquire certain data as specified in the approved research protocol.

However, in order to access data necessary to conduct research via UPMC electronic medical records, the research project must be reviewed by CARe. In addition, the request to access e-PHI for research purposes must be approved by OSPARS.

A. **CARe Services**

CARe provides an infrastructure and environment that facilitates an investigator’s efforts to define, access, acquire, and/or receive data existing as, or derived from, e-PHI as referenced in the IRB-approved protocol. CARe services include:

**Regulatory Compliance Review.** All research projects involving the use of UPMC e-PHI must be submitted to CARe for review with the exception of industry-sponsored clinical trials contracted through OSPARS. CARe regulatory compliance facilitators determine if a research project meets the exception from CARe review per the criteria defined above in section IV.C.

Research projects not meeting the criteria for CARe review exception are subject to regulatory review by CARe regulatory compliance facilitators. Regulatory review entails a comparison of the Researcher’s IRB- or CORID-approved research project with their proposed data access plan and/or extraction plan. Recommendations for revisions will be made, if necessary, to ensure compliance in research involving UPMC e-PHI.
Data analyst services. When assistance is requested for UPMC EMR data extraction or programming, CARE data analysts liaise with UPMC EMR data teams to gather and deliver research requirements. To assure appropriate and accurate data receipt, researchers are advised to consult CARE team prior to submitting the protocol for IRB review/approval. CARE provides the researcher recommendations for data type and origin, and assist in writing clinical system queries to search applicable data repositories, and subsequently export the research data via the most appropriate and secure means.

[Visit CARE website at Center for Assistance in Research using eRecord to submit a request form.]

B. Request Access to UPMC Electronic Records for the Conduct of Research

To access UPMC electronic records for the conduct of an IRB or CORID approved research project, the Researcher must request access to the desired clinical system(s) (e.g., Cerner, Epic, Stentor and etc.) through the UPMC Identity Management System (IMS) or via MyHub. Research-related IMS requests are routed to OSPARS for review and approval.

All individuals accessing UPMC e-Record for research purposes must complete HIPAA module: HIPAA Researchers Privacy Requirements (Formerly RPF Module 6) [Available at https://cme.hs.pitt.edu/ISER/].

C. Researcher Responsibilities

Consistent with UPMC policies related to e-PHI and HIPAA regulations, researchers are responsible for storing research data in a secured environment at all times. This includes ensuring that the computer and any media (e.g., CD-ROMs, flash drives and removable drives) are encrypted and password protected. Research data can be sent through e-mail only when they are encrypted, with the key being sent separately. Research data are not permitted to be stored in or transferred via personal, unprotected, unencrypted files or devices.

VI. VIOLATIONS OF THIS POLICY

Each Research Team Member has an obligation to report to the Research Compliance Officer any situation s/he believes to be a violation of this Policy.

If the Research Compliance Officer or his/her delegates have reasonable cause to believe that a Research Team Member has failed to comply with this Policy, he/she will inform the Research Team Member of the basis for such belief and afford such person an opportunity to resolve the matter. If, after hearing the response of the Research Team Member, and making further investigation as warranted under the circumstances, the Research Compliance Officer or his/her delegates determine that the Research Team Member has in fact failed to resolve, he/she will work in collaboration with the IRB of
record and may take appropriate disciplinary action (e.g. remove access, address disposition, and etc.).

Research Team Members are encouraged to contact the Research Compliance Officer with questions concerning their obligations under this Policy.

VII. **POLICIES REFERENCED WITHIN THIS POLICY**

- **HS-EC1600** Accounting of Disclosures of Protected Health Information (PHI)
- **HS-EC1601** Complaint Management Process Pursuant to the HIPAA Privacy Rule
- **HS-EC1807** Honest Broker Certification Process Related to the De-identification of Health Information for Research and Other Duties/Requirements of an Honest Broker
- **HS-EC1603** Notice of Privacy Practices for Protected Health Information (PHI) Pursuant to the HIPAA
- **HS-EC1609** Patient Amendments to Protected Health Information
- **HS-EC1606** Privacy and Security Training Related to Protected Health Information (PHI)
- **HS-EC1614** Prohibition on Sale of Protected Health Information
- **HS-MR1000** Release of Protected Health Information
- **HS-EC1602** Use & Disclosure of Protected Health Information (PHI) Including: Fundraising, Marketing and Research

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**SIGNED:** Barbara E. Barnes, MD, MS  
Vice President, Office of Sponsored Programs and Research Support

**ORIGINAL:** October 10, 2011

**APPROVALS:**
- Executive Staff: November 10, 2016

**PRECEDE:** October 30, 2015

**SPONSOR:** Executive Director and Research Compliance Officer

* With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.