UPMC
POLICY AND PROCEDURE MANUAL

POLICY: HS-RS0005 *
INDEX TITLE: Research

SUBJECT: Access, Acquisition and Disposition of Electronic Protected Health Information for Research Purposes

DATE: October 26, 2012

I. INTRODUCTION & POLICY

UPMC’s commitment to a system-wide electronic health record provides meaningful use to clinicians and patients as well as 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 access, acquisition and disposition of e-PHI for the conduct of research.

Consistent with HS-MR1000, Release of Protected Health Information, UPMC is obligated to the confidentiality and security of Protected Health Information (PHI) created, received, obtained, maintained, used or transmitted by UPMC. This policy defines appropriate guidelines to ensure the confidentiality of e-PHI when acquired from UPMC for purposes of research under a protocol approved by a nationally accredited Institutional Review Board (IRB).

e-PHI acquired under an IRB-approved protocol becomes research data and property of the respective entity hosting the IRB of record. It is the responsibility of these entities and the researchers obtaining UPMC e-PHI to ensure continued confidentiality and security of the PHI, and demonstrate that safeguards and policies exist to equal or greater rigor as required by relevant UPMC policies. Hence, it is the policy of UPMC to assure that access to, acquisition and transfer of e-PHI and subsequent disposition of the research data meet the requirements to follow.

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

e-PHI, for the purpose of this policy, is PHI transmitted by or maintained in electronic form. Storage devices for e-PHI may include, yet are not limited to, network drives, local hard drives, and portable drives (e.g. CD, DVD, external hard drive, flash drive, and etc.). Additionally, PHI transmitted via email, over the internet, or other means (e.g. ftp) meets the definition of e-PHI.

PHI faxed over dedicated phone lines does not meet the definition of e-PHI, and is summarily excluded from this policy.

III. PURPOSE

The purpose of this Policy is to set forth specific responsibilities of Research Team Members with respect to accessing, acquiring, and managing e-PHI for research purposes. It is intended to supplement (not replace) any existing policy and applicable state and federal law governing PHI, and 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 Privacy Rule
- 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)

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’s
premises, or are under the oversight of UPMC (“Research”), whether or not such individuals are employed by UPMC.

C. **Research Covered by the Policy**

All domestic research activities involving the access, acquisition, transfer, and/or storage of UPMC e-PHI are within the purview of this policy. To access UPMC e-PHI for research purposes, Researchers must utilize the services provided by CARe unless the request for access to e-PHI meets CARe Service Exemption, regardless of existing access privileges (e.g. Cerner, Epic, Stentor, etc.). Exemption criteria are only present when the request for access restricts the intended purpose to:

1. 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

2. auditing and/or monitoring information consistent with regulatory and/or sponsor requirements.

To aid in determining whether a request for access to UPMC e-PHI for purpose of research is exempt from CARe Services, visit [https://spis.upmc.com/corporate/Finance/ospars/default.aspx](https://spis.upmc.com/corporate/Finance/ospars/default.aspx) (OSPARS’ SharePoint).

Access to this share point can be requested by emailing OSPARS@upmc.edu.

Additional information may also be found by visiting the CARe website at: [http://www.eresearch.pitt.edu/](http://www.eresearch.pitt.edu/).

V. **ACCESSING, ACQUIRING AND STORING e-PHI**

The University IRB serves to function as UPMC’s privacy board respective HIPAA authorization requests for human subjects’ research. Upon issuance of an authorization and IRB-approved protocol, the investigator is granted the general right to access certain data. However, OSPARS or its delegates must authorize the specific access and acquisition of e-PHI requested by the appropriate Research Team Members.

To facilitate the management of such and offer a venue for continuity to the research community, OSPARS has delegated a portion of this responsibility to the CARe team, as it is integral to a service offering beyond administrative benefit.

CARe provides an infrastructure and environment that facilitates an investigator’s efforts to define, access, acquire, and/or receive data referenced in his/her IRB approved protocol. This effort is best commenced prior to IRB protocol submission to assure appropriate and accurate data receipt thereafter on behalf of the respective study. The
CARe team is able to effectively and seamlessly provide the Research Team recommendation for data type and origin, as well as assist in writing clinical system queries to search all applicable data repositories and subsequently export the research data via the most appropriate and secure means. In recognition of this valued central resource, OSPARS established an interface with CARe to accommodate the requisite control and oversight for accessing, acquiring e-PHI and subsequently storing the respective research data for the purpose of research. This integrated approach offers a coordinated point of entry thereby enhancing service to the Research Team.

To initiate application to access, acquire, and/or store research data originating as UPMC e-PHI for research purposes, visit the CARe website [http://www.eresearch.pitt.edu/](http://www.eresearch.pitt.edu/) and complete the request form as instructed by CARe. Following initial consult, CARe will inform you of the best means to meet your research goals and advise whether additional requirements must be met.

However, in the event that the intended purpose(s) for access is as noted within C(1) and/or C(2) above, Research Team Member shall complete a notification application, *Notification to Access e-PHI Exempt from CARe Services*, rather than work directly through CARe. Specifically, Research Team Member must coordinate the following:

1) Complete application, *Notification to Access e-PHI Exempt from CARe Services* (See Appendix A).

2) Email completed form to: [OSPARS@upmc.edu](mailto:OSPARS@upmc.edu) with subject heading: “Notification to Access e-PHI Exempt from CARe Services.”

3) For applicant(s) not having permissions to the desired UPMC clinical application(s), Research Team Member must also simultaneously request access to the desired clinical application(s) (e.g., Cerner, Epic, Stentor, and etc.). Such a request shall be based on the “minimum necessary” rule. The request for accessing UPMC clinical applications can be made through the UPMC Identity Management System (IMS) via MyHub, or via the hyperlink: [https://ims.upmc.com/](https://ims.upmc.com/).

IMS requests for accessing UPMC clinical applications for research purpose are routed to OSPARS for review. To expedite the review/approval process, submit notification form timely. Clearly indicate within UPMC IMS “Requestor Comments” that the request is for research purposes and reference applicable IRB protocol number(s).

Following receipt of the IMS request and/or notification, UPMC’s Research Compliance Officer and/or his/her designee will work with CARe and IMS teams to process the IMS requests and notification application(s). Each application is reviewed for the most appropriate access based on the approved IRB protocol, UPMC clinical applications, and UPMC’s interest to assure confidentiality of its e-PHI. Subsequently, UPMC Research Compliance Officer and/or his/her designee approves or denies the IMS and/or notification application.
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 such further investigation as may be reasonable and warranted in 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

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<thead>
<tr>
<th>Policy Code</th>
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<tbody>
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SIGNED: Barbara E. Barnes, MD, MS
Vice President, Office of Sponsored Programs and Research Support

ORIGINAL: October 10, 2011

APPROVALS:
Policy Review Subcommittee: September 13, 2012
Executive Staff: October 26, 2012

PRECEDE: October 10, 2011

SPONSOR: Executive Director and Research Compliance Officer

Attachment

* 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.
Appendix A: Notification to Access e-PHI Exempt from CARe Services

In consideration of Policy HS-RS0005, *Access, Acquisition and Disposition of Electronic Protected Health Information for Purposes of Research*, notification is being provided to OSPARS for the following study:

**PI Name:**
____________________________________

**Protocol Name:**
____________________________________

**IRB Approved Protocol #:**

**Intended Purpose:**
____________________________________

**Description:**

____________________________________

____________________________________

**Eligibility for Exception:** (Please check all that apply.)

☐ Applicant’s access to UPMC e-PHI does not extend beyond research activities such as recruitment of subjects, clinical examination of subjects, or fulfillment of research/medical orders as specified by an IRB approved research protocol.

☐ Applicant’s access to UPMC’s e-PHI is solely for the purpose of auditing/monitoring information consistent with regulatory or sponsor requirements.