

**UPMC
POLICY AND PROCEDURE MANUAL**

POLICY: HS-EC1602 *
INDEX TITLE: Ethics & Compliance

**SUBJECT: Use & Disclosure of Protected Health Information (PHI) Including:
Fundraising, Marketing and Research**
DATE: February 29, 2016

I. POLICY

It is the policy of UPMC to comply with the Health Insurance Portability and Accountability Act rule, as revised by the 2013 HIPAA Final Rule (HIPAA), as well as the privacy requirements that are contained within the American Recovery and Reinvestment Act of 2009 (ARRA) and any applicable related state laws that are not preempted by HIPAA.

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

II. PURPOSE/SCOPE

This policy identifies the requirements for adhering to the HIPAA and ARRA privacy regulations regarding a patient's right to request restrictions to be placed on the patient's record, the "minimum necessary" rule, and uses and disclosures of PHI for the purposes of fundraising, marketing and research. This policy applies to all United States based UPMC entities and locations.

III. DEFINITIONS

CFR refers to the Code of Federal Regulations.

Fundraising generally means the organized activity of requesting charitable gifts in support of research, education, training or other aspects of the advancement of health care delivery.

Business Associate refers to an individual or organization that is not a member of the UPMC workforce and that acts on behalf of UPMC to assist in performing functions that involve the use or disclosure of PHI. These functions may include providing legal, accounting, consulting, management, administrative, accreditation or financial services.

Marketing means (1) to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service, unless the communication is made (a) to describe a health related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, UPMC, including communications about: the entities participating in a health care provider

network or health plan network; replacement of, or enhancement of, or enhancements to, a health plan; and health related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; (b) for treatment of the individual; or (c) for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers or settings of care to the individual; (2) an arrangement between UPMC and another entity whereby UPMC discloses PHI to the other entity in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Protected Health Information (PHI) means information collected from an individual that is (1) created or received by UPMC, (2) relates to the past, present or future physical or mental health or condition of an individual, (3) relates to the provision of health care to an individual or to the past, present or future payment for providing health care to the individual and (4) that identifies or could identify the individual. PHI includes clinical and demographic information.

UPMC 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 UPMC.

IV. REQUIREMENTS

A. **MINIMUM NECESSARY STANDARD FOR THE USE & DISCLOSURE OF PHI.**

1. UPMC shall limit access and use of PHI to only those persons or classes of persons, as appropriate, who need such access to carry out or perform their job responsibilities. UPMC related policies include (a) System Management and Change Control Policy, HS-IS0217, (b) Authentication and Access Controls HS-IS0204, (c) Information Systems Security Policy Administration HS-IS0201 and (d) Physical Access, HS-IS0205.
2. UPMC shall identify the category or categories of PHI which these individuals need access to along with any conditions appropriate to such access.
3. All disclosures of PHI shall be limited to the amount reasonably necessary to achieve the purpose of the disclosure.
4. *Minimum necessary does not apply.* This requirement does not apply to:
 - (i) Disclosures to or requests by a health care provider for treatment;

- (ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) or as required by paragraph (a)(2)(i) of 164.502;
 - (iii) Uses or disclosures made pursuant to an authorization under 164.508;
 - (iv) Disclosures made to the Secretary in accordance with subpart C of 45 CFR 160;
 - (v) Uses or disclosures that are required by law, as described by § 164.512(a); and
 - (vi) Uses or disclosures that are required for compliance with applicable requirements of HIPAA
5. UPMC shall be entitled to rely (if reasonable under the circumstances) on a requested disclosure as the minimum necessary for the stated purpose when:
- a) making permitted disclosures to public officials if such official represents that the information requested is the minimum necessary
 - b) the information is requested by another “Covered Entity” (as defined in the privacy regulations at 45 C.F.R. § 160.103)
 - c) the information is requested by a professional or a UPMC business associate for the purpose of providing professional services to UPMC, provided they represent the information being requested is the minimum necessary or
 - d) representations that comply with the requirements of § 45 C.F.R. § 164.512 (I) have been provided by a person requesting the information for research purposes.
6. UPMC shall only request information that is reasonably necessary to accomplish the purpose of the request.
7. UPMC shall use reasonably necessary efforts to secure and maintain the confidentiality of PHI, regardless of form or media.

B. USE & DISCLOSURE OF PHI FOR FUNDRAISING

1. UPMC may use or disclose to a Business Associate or a UPMC Foundation the following PHI for the purpose of raising funds to benefit UPMC, without an authorization and provided the UPMC Notice of Privacy Practices contains a statement that UPMC may contact the individual to raise funds for UPMC:

- (a) demographic information that can include, but not be limited to, name, address, other contact information (e.g., phone numbers, emails), age, race, gender and date of birth;
 - (b) dates that health care was provided to a patient;
 - (c) general department of service information (e.g., cardiology, pediatrics);
 - (d) treating physician;
 - (e) outcome information (e.g., patient deceased or had a bad outcome) and
 - (f) health insurance status.
2. All fundraising communications made to an individual (including those made verbally) must contain clear and conspicuous instructions for how the patient can opt-out of receiving such communications in the future. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost. Requiring patients to write a letter to opt out is considered an undue burden and is therefore not acceptable. Examples of acceptable opt-out methods include (1) a toll-free or local telephone number, (2) an email address, (3) a pre-printed, pre-paid postcard and (4) other similar simple, quick and inexpensive opt-out mechanisms. The following language is “sample” opt-out language:
- If you do not want to receive future fundraising requests supporting [UPMC or Name of Specific Campaign], you can call _____ and communicate to us that you do not want to receive fundraising requests. There is no requirement that you agree to accept fundraising communications from us, and we will honor your request not to receive fundraising communications from us after the date we receive your notice.***
3. In the event that a patient does opt-out of receiving information related to fundraising, the opt-out request must be recorded by the respective UPMC development area and the patient shall not receive future fundraising communications from the respective entity.
4. An opt-out decision does not lapse. For example, if a patient opts-out but then makes a donation, that donation does not serve (absent a separate election to opt back in), to automatically add the patient back into the mailing list for fundraising communications.
5. UPMC may not condition treatment or payment on whether a patient has elected to receive fundraising communications.
6. If there are questions on whether a particular scenario related to fundraising requires patient authorization or not, the respective entity’s Fundraising department and/or the Privacy Officer should be contacted.

C. USE & DISCLOSURE OF PHI FOR MARKETING

1. UPMC must have a patient's prior written marketing authorization to use or disclose PHI for marketing communications. Exceptions to this include:
 - a. When the communication occurs during a face to face encounter between UPMC and the patient.
 - b. The communication involves a promotional gift of nominal value provided by UPMC.

D. USE & DISCLOSURE OF PHI FOR RESEARCH PURPOSES

UPMC has determined that it is not necessary to have multiple (i.e., research and health care provider specific) HIPAA Notice of Privacy Practices provided to and signed by the patient-subject. UPMC, in providing services whereby PHI is created due to clinical research activity, has a treatment relationship with the patient. As such, the patient-subject will sign a UPMC Consent to Treatment, Payment and Operations form acknowledging receipt of the UPMC Notice of Privacy practices when they present for services. In accordance with federal regulations and the ethics professional literature, patients involved in Quality Improvement activities are not research subjects. All researchers that in any way use UPMC clinical services in conducting their research, must utilize a HIPAA authorization form [See "HIPAA Privacy Rule Guidance for Researchers" for model language at the [University of Pittsburgh Human Research Protection Office \(Pitt HRPO\) website](#)]. The HIPAA research authorization may be combined with the study informed consent document as is explained below.

All researchers who conduct research at or within a UPMC entity, or request access to PHI held by UPMC for research purposes, or use a UPMC entity to fulfill orders for required services pursuant to a research protocol, shall adhere to these research provisions. This policy, as well as any related procedures, shall be distributed along with instructions to all Institutional Review Boards (IRB), if requested, known to provide services to affected researchers.

All IRBs that approve research protocols involving the use of a UPMC provider entity (existing or newly created PHI) will be expected to support UPMC with its HIPAA compliance initiative. This includes: providing HIPAA compliance training (with the assistance of UPMC); providing guidance to all affected researchers; examining study documentation to ensure HIPAA research authorization language is appropriate; and cooperating with audits that may be conducted by UPMC to assure compliance with UPMC HIPAA policies and procedures related to research.

All researchers who conduct research involving the recording of existing PHI (held by a UPMC entity) or creation of PHI (by a UPMC entity) pursuant to the research protocols must secure and maintain an approved HIPAA research authorization (as specified by UPMC) from patient-subjects upon their enrollment into a research study. [An alternative (de-identification) procedure exists for previously held (existing) PHI – see below]. Obtaining the HIPAA research authorizations shall be in addition to obtaining the written informed consent of patient-subjects using the IRB-approved informed consent document (see noted exception below). All researchers must provide copies of these HIPAA research authorizations to any UPMC provider entity as requested. [Note: The required language of the HIPAA research authorization may be combined with the language in the informed consent document if the researcher so chooses. The researcher is directly responsible for assuring the appropriate combination of the HIPAA information.]

The UPMC template HIPAA research authorization will be provided to the researchers, upon request, for their use in assuring HIPAA compliance. The researcher must customize this template research authorization and explain its content to the patient-subject. Other pertinent requirements regarding the research authorization are as follows:

- the researcher must obtain the patient-subject's signature upon enrolling them into a research study; and, the researcher must maintain the signed research authorization for a period of no less than six years (or longer if required by applicable law or UPMC policy), and must make a copy available to UPMC upon request.
- the researcher must adequately describe how the patient's protected health information will be used or disclosed for future research.

Compound authorizations for conditioned and unconditioned studies are permissible under HIPAA, but must clearly differentiate between the conditioned and unconditioned study components. Additionally, the patient-subject must be given the option to opt-in to the unconditioned study's activities as outlined in the authorization. The researcher must make clear to the patient-subject that their choice not to opt-in will not impact treatment, payment or benefits.

Relative to research studies that involve the collection and analysis of existing PHI held by a UPMC provider entity:

- the researcher must submit the research study for IRB approval prior to its implementation (see UPMC policy HS-PS0497 IRB Approval of Human Research at UPMC and,
- the researcher must secure a HIPAA research authorization from each patient-subject whose PHI they desire access to and must present this authorization to the appropriate UPMC Health Information Management (Medical Records)

department, or area where records are held, in order to access records; or, alternatively,

- the researcher may use the services of an honest broker to obtain the PHI in a de-identified manner. De-identification means that the patient-subjects cannot be identified (by the researcher or others) directly or indirectly through identifiers linked to the patient-subject. De-identification must be done in accordance with HIPAA regulations. The honest broker will de-identify medical record information by automated (e.g., de-ID computer application for electronic/computer stored PHI) and/or manual methods (for paper record PHI). All honest brokers shall be approved in advance by both the IRB of record and the UPMC Privacy Officer. If an honest broker system/service is not part of the UPMC covered entity, they must execute a valid business associate agreement with UPMC to access UPMC- held PHI for de-identification. If an honest broker system/service is to be used to obtain de-identified PHI, this fact must be identified in the study's IRB submission and addressed per the attachment A;
- in certain circumstance(s), a researcher may request a waiver of HIPAA authorization. Pitt HRPO, serving as the UPMC Privacy Board, has the authority to approve waivers within HIPAA requirements.

HIPAA generally permits access by a patient to his/her own medical records with a few limited exceptions. One exception is for research-related PHI. HIPAA permits the researcher to specify in the research authorization any limits they are placing on a patient-subject's access to their own medical records due to their study participation for the duration of the study. However, UPMC has made the following policy decisions relative to patient access to medical records held by UPMC (as a result of fulfilling researcher orders for services):

- Researchers generally may not put any restrictions on PHI that is in the possession of UPMC as a result of currently or previously providing health care services to the patient/research subject;
- A researcher may petition a UPMC provider's Health Information Management (HIM) department manager or the designated medical record contact, on a patient-by-patient basis, to restrict patient/subject access to PHI held by a UPMC provider entity. After consultation with the UPMC Privacy Officer, this restriction may be granted or denied.

HIPAA permits the researcher and UPMC to condition research participation on the patient-subject's signing of a research authorization. The UPMC research authorization will condition research participation (research-related hospital and other provider services) and any consequent need to obtain previously created PHI, on the patient-subject's signing both the research authorization and the IRB-approved informed consent document or the combined document.

If a decisionally-impaired individual is incapable of providing directly the requisite HIPAA authorization/informed consent for research participation, such authorization/consent must be obtained from the individual's authorized representative. If the individual has been declared mentally incapacitated by the court, the respective court documents should be reviewed to determine if legal authority for consent for participation in research is addressed and, if so, to whom such authority is granted. If the court documents do not address proxy consent for participation in research, the individual should be excluded from participation unless the IRB specifically grants a waiver of the informed consent requirement for this individual. In the absence of a declaration of mental incapacity by a court-of-law, who should serve as the authorized representative to consent on behalf of the decisionally-impaired individual should be consistent with existing hospital orders and/or Commonwealth of Pennsylvania rules addressing consent for clinical care of the decisionally-impaired individual. Commonwealth of Pennsylvania regulations specify that proxy consent for clinical care should follow "lines of sanguity". For research involving the evaluation of "emergency" procedures, an exception to the authorization/consent requirement must be approved by the IRB. If applicable, patient-subjects enrolled in the research study under the authorization/consent of their authorized representative shall personally sign the HIPAA research authorization and the IRB-approved informed consent document as soon as they recover the decisional capacity to sign such documents.

HIPAA permits customization of a research authorization to specify in detail that Treatment, Payment and Health Care Operations (TPO) uses/disclosures may be more limited than would be otherwise permissible under the TPO consent document. It will be the policy of UPMC to not permit customization (by a researcher) of the UPMC research authorization to limit TPO PHI (created by a UPMC entity pursuant to research order fulfillment) uses and disclosures by UPMC. If there are extenuating circumstances, the researcher may petition the UPMC Privacy Officer for an exception. If an exception is granted, it will be the researcher's responsibility to clearly communicate to the UPMC entity's director of health information management, or the individual designated by that entity to receive such information, what limitations on uses and disclosures have been placed on an individual patient's PHI created (by the UPMC entity) pursuant to research orders. This communication must include documentation of the Privacy Officer's permission along with a copy of the signed research authorization.

For reviews of PHI preparatory to research (hypothesis/protocol development), HIPAA permits UPMC to make available the PHI to a researcher based solely on the researcher's written representations that no PHI shall be recorded for the purpose of research and/or removed from the provider entity and that the PHI reviewed by the researcher shall be limited to that necessary to prepare a research protocol. UPMC shall permit researchers to review PHI, held by a UPMC entity, for the purpose of preparing a research hypothesis and research protocol. Researcher should use the attachment B for this purpose. The researcher must submit the completed request form to OSPARS@upmc.edu for review. Once

approved, the researcher must submit this signed agreement to the director of the entity's HIM department or an individual designated by the entity to receive such information in order to access the records/PHI.

UPMC, if presented a signed Use and Disclosure of Protected Health Information (PHI) for Research Purposes Pursuant to the HIPAA Privacy Rules Policy applicable to Decedent PHI (see attachment C), may grant access to and permit researchers to record the PHI of deceased individuals, held by a UPMC entity, under the following conditions:

- If the information is de-identified by an honest broker service; or,
- Pursuant to a valid research authorization signed by the administrator or executor of the deceased individual's estate or the person who is listed as next of kin; or,
- Pursuant to a request to access decedent PHI signed by the UPMC Privacy Officer for a research protocol approved by CORID (see UPMC policy HS-RS0004, Research and Clinical Training Involving Decedents) or an IRB. The researcher must attest to the fact that the PHI sought is solely for this research study; access to this PHI is necessary for this research; and that s/he or study staff have verified the death of the individuals whose PHI is sought. Approval for such requests will be limited to circumstances where it is truly impossible to get authorization for access to the PHI.

UPMC recognizes that there are databases containing PHI that reside on PCs and servers in the various locations which the researchers work and see patients. These database files serve a variety of purposes including pure research, pure treatment, or a mixture of both. Databases exclusively used for treatment are not covered by the HIPAA regulations on research. The PHI in these databases shall not be used for research purposes unless such use is compliant with HIPAA and research regulatory requirements as previously stated in this policy.

E. PATIENT RESTRICTIONS

UPMC patients have the right to request restrictions on the use and disclosure of their PHI. To do so, they are to submit a written request to where they had services provided and tell UPMC (1) what information they want limited, (2) whether they want to limit the use, disclosure or both and (3) the person or institution the limits apply to (for example, their spouse). UPMC is not required to, and except in extenuating circumstances, does not agree to requests for restrictions.

If UPMC does agree to a request for restriction, the restriction may be removed if (1) the patient agrees to or requests the termination in writing, (2) the patient orally agrees to the termination and the oral agreement is documented, or (3) UPMC informs the patient in writing that it is terminating its agreement to a

restriction, and if so, such termination will only be effective for PHI created or received after UPMC has informed the patient.

V. RESPONSIBILITY

It shall be the responsibility of each UPMC entity and, with respect to fundraising, of each supporting foundation, to implement processes and procedures to meet the requirements set forth in this policy based on the facilities unique systems and processes.

It shall be the responsibility of the Health Information Management Department to review and approve any restriction, to ensure that the restriction is appropriate and to ensure that the restriction can be honored. The Health Information Management Department shall also be responsible for the removal of a restriction described in section IV.E.

VI. RESEARCH RELATED RESPONSIBILITIES

It shall be the responsibility of researchers that conduct research within UPMC or request access to PHI held by UPMC for research purposes to implement processes and procedures within their work setting to meet the requirements set forth in this policy.

It shall be the responsibility of the Pitt IRB and other external IRBs of record (e.g. central IRBs employed by the UPMC Clinical Trials Office), to implement processes and procedures to meet the requirements set forth in this policy.

It shall be the responsibility of the UPMC HIM department managers or the designated medical record contact, to implement processes and procedures within their work setting to meet the requirements set forth in this policy.

VII. NON-COMPLIANCE

An employee's failure to abide by this policy may result in disciplinary action pursuant to UPMC policy HS-HR0704 entitled "Corrective Action and Discharge". Other non-employee work force members may be sanctioned in accordance with applicable UPMC procedures.

VIII. POLICIES REFERENCED WITHIN THIS POLICY

[HS-IS0217 System Management and Change Control](#)

[HS-IS0204 Authentication and Access Controls](#)

[HS-IS0201 Information Systems Security Policy Administration](#)

[HS-IS0205 Physical Access](#)

[HS-HR0704 Corrective Action and Discharge](#)

[HS-PS0497 IRB Approval of Human Subjects Research at UPMC](#)

[HS-RS0004 Research and Clinical Training Involving Decedents](#)

SIGNED: Linn Swanson
Chief Audit and Compliance Officer

ORIGINAL: April 14, 2003

APPROVALS:

Policy Review Subcommittee: February 11, 2016

Executive Staff: February 29, 2019

PRECEDE: May 1, 2015

SPONSOR: UPMC Office of Patient & Consumer Privacy

*** 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.**

Attachments

Attachment A

SAMPLE AGREEMENT

Use and Disclosure of Protected Health Information (PHI) For Research Purposes

Pursuant to the HIPAA Privacy Rules Policy applicable to living subject PHI.

DATA USE AGREEMENT

This Data Use Agreement (the “Agreement”) is made this ____ day of _____, 20__ by and between UPMC and _____ (“Recipient”).

WHEREAS, 45 CFR 164, Subpart E (titled “Standards for Privacy of Individually Identifiable Health Information” and herein referred to as the “HIPAA Privacy Rule”) allows UPMC to make available for the purposes of research, public health or health care operations a Limited Data Set to Recipient, provided that Recipient agrees to be bound by the terms of this Agreement; and

WHEREAS, Recipient desires for UPMC to make available the Limited Data Set as described below and agrees to be bound by the terms and conditions of this Agreement; and

WHEREAS, UPMC agrees to make available such Limited Data Set, provided that Recipient agrees to abide by the terms and conditions of this Agreement as well as applicable UPMC policies and IRB requirements.

NOW, THEREFORE, in consideration of the mutual covenants and promises hereinafter set forth, the parties hereto agree as follows:

A. DEFINITIONS

For the purposes of this Agreement, terms used herein shall have the same definition as set forth in the HIPAA Privacy Rule.

B. DATA TO BE PROVIDED

The Limited Data Set provided pursuant to this Agreement contains data acquired from [*NAME LOCATION AND/OR SOURCE SYSTEM*] and related to [*IDENTIFY THE TYPE OF DATA AND/OR DATA FIELDS*]. Such data shall be limited to data that is the Minimum Necessary to reasonably accomplish the Authorized Purposes identified in Section (C)(1) of this Agreement.

For the purpose of this Agreement and consistent with the HIPAA Privacy Rule, “Minimum Necessary” is defined as that protected health information that is *“reasonably necessary to achieve the purpose of the disclosure”* and is disclosed to only *“Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties.”*

Consistent with the HIPAA Privacy Rule, in no case will the Limited Data Set include any of the following identifiers:

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

C. PERMITTED USES AND DISCLOSURES

1. Recipient agrees to limit the use and disclosure of the Limited Data Set to the following purposes ("Authorized Purposes"): [ADD PURPOSES]
2. The Recipient shall allow only the following individuals access to the Limited Data Set for the Authorized Purpose and consistent with the assurances and obligations set forth in this Agreement: [ADD LIST OF AUTHORIZED INDIVIDUALS].
3. Recipient acknowledges that such individuals have a need to access the Limited Data set to carry out their duties.

D. ASSURANCES

1. Recipient shall not use or further disclose the Limited Data Set other than as permitted by this Agreement or as otherwise Required By Law.
2. Recipient shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted by this Agreement.
3. Recipient shall report to the UPMC Privacy Officer any use or disclosure of the Limited Data Set not provided for by this Agreement of which Recipient becomes aware.
4. Recipient shall ensure that any agents, including a subcontractor, to whom it provides the Limited Data Set agrees to the same restrictions and conditions that apply to the Limited Data Set Recipient with respect to such information.
5. Recipient shall not re-identify the information or contact the individuals for whose records are contained within the Limited Data Set.

E. BREACH AND TERMINATION

1. In the event that this Agreement is breached by Recipient, UPMC, at its sole discretion, may a) terminate this Agreement upon written notice to Recipient or b) request that Recipient, to the satisfaction of UPMC, take appropriate steps to cure such breach. If Recipient fails to cure such breach to the satisfaction of UPMC or in the time prescribed by UPMC, UPMC may terminate this Agreement upon written notice to Recipient.
2. Should this Agreement be terminated for any reason, including, but not limited to Recipient's decision to cease use of the Limited Data Set data, Recipient agrees to destroy or return all Limited Data Set data provided pursuant to this Agreement (including copies or derivative versions thereof).

F. MISCELLANEOUS

1. Notices

Any notice permitted or required as provided for herein shall be in writing and to the contact and address as noted below or as may be provided by either party to the other in writing from time to time. Notice to UPMC shall be to:

Name: _____

Address: _____

Notice to Recipient shall be to:

Name: _____

Address: _____

2. Governing Law

This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Pennsylvania.

UPMC Recipient

Name (print): _____

Name (print): _____

Title: _____

Title: _____

Signature: _____

Signature: _____

Attachment B

SAMPLE AGREEMENT

Use and Disclosure of Protected Health Information (PHI) For Research Purposes

Pursuant to the HIPAA Privacy Rules Policy applicable to Reviews Preparatory to Research.

HIPAA RESEARCH AGREEMENT – PHI USAGE FOR REVIEWS PREPARATORY TO RESEARCH

This Health Insurance Portability and Accountability Act (HIPAA) Research Agreement (The “HIPAA Agreement”) is made this _____ day of _____, 20__ by and between UPMC and _____ (The Researcher).

HIPAA sets forth a rule (the Privacy Rule) governing the privacy of a patient’s identifiable health information (referred to in the Privacy Rule as protected health information or “PHI”). The Privacy Rule sets forth guidelines intended to preserve the integrity and confidentiality of PHI. The Privacy Rule applies to health plans, health care clearinghouses and health care providers. The Privacy Rule can be found at 45 CFR, Part 164, Subpart E or at <http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm>.

Section 164.512(i) of the Privacy Rule titled “Standard: Uses and Disclosures for Research Purposes” provides that UPMC may disclose a patient’s PHI to the Researcher for reviews preparatory to research based on the following representations from the Researcher, to which Researcher agrees to comply:

- (a) Such use or disclosure is solely for purposes of reviewing the PHI as necessary to prepare a research protocol or for similar purposes preparatory to research (e.g., to design a study or to assess the feasibility of conducting a study).

Describe, below, the purpose(s) of your desired review of PHI:

- (b) The PHI being sought to be disclosed is limited to the minimum necessary to achieve the purpose(s) of the review.

Describe, below, the specific nature of the PHI that you are requesting for review and indicate why each of the data elements being requested is necessary to achieve the purpose(s) of the review:

- (c) The PHI being sought to be disclosed is necessary for the research project.

Address, below, why the PHI that you are requesting for review is necessary in order to prepare a research protocol:

- (d) The Researcher will not remove any PHI from UPMC in the course of the research review.
- (e) The Researcher will comply with IRB requirements for all research studies that result from this review performed preparatory to research.

Researcher:

_____ (Print or type name)
_____ (Signature)

UPMC

_____ (Print or type name)
_____ (Signature)

Attachment C

SAMPLE AGREEMENT

Use and Disclosure of Protected Health Information (PHI) For Research Purposes
Pursuant to the HIPAA Privacy Rules Policy applicable to Decedent PHI.

TO: UPMC Privacy Officer or designee (CORID or Pitt IRB)

FROM: Name of Principal Investigator:

RE: Request to review Decedent Protected Health Information for Research
Name of Research Study:
Pitt IRB # or CTO # if available:

I, _____ and my research study staff would like to review Protected Health Information (PHI) of UPMC 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 UPMC policy, as well as state and federal law, to handle this PHI in a manner that protects the confidentiality of the decedents.

Signature of PI

Date

Reviewed and approved by Research Compliance Officer or designee

Signature of Research Compliance Officer / Designee

Date