

**UPMC
POLICY AND PROCEDURE MANUAL**

**POLICY: HS-EC1611
INDEX TITLE: Ethics & Compliance**

SUBJECT: Use and Disclosure of Protected Health Information (PHI) For Research Purposes Pursuant to the HIPAA Privacy Rules
DATE: November 12, 2007

I. POLICY

It is the policy of the University of Pittsburgh Medical Center (UPMC) to comply with the Health Insurance Portability and Accountability Act (HIPAA) rule pertaining to research requirements of its uses and disclosures of PHI and any applicable related state laws that are not preempted by HIPAA. The HIPAA Privacy Regulations can be located at 45 C.F.R. Parts 160 and 164 or at <http://aspe.hhs.gov/admsimp/final/PvcTxt01.htm>. Terms used herein and not otherwise defined shall have the meanings ascribed to them in the Privacy Regulations.

UPMC has determined that it is not necessary to have multiple (i.e., researcher and hospital-specific) HIPAA research authorizations signed by the patient-subject. The hospitals, in providing services whereby individually identifiable medical information (protected health information) is created pursuant to a physician-researchers service order, have a treatment relationship with the patient. As such, the patient will sign a UPMC treatment consent form acknowledging receipt of the Notice of Privacy practices at the UPMC hospital or other provider entity when they present for research-related services. All researchers, that in any way use a UPMC provider entity in conducting their research, must use and customize (specific to each study or each patient) the UPMC-approved template HIPAA research authorization (available from the IRB) as this authorization explains both UPMC and researcher uses and disclosures of patient-subject PHI. The HIPAA research authorization may be combined with the study informed consent document as is explained below.

II. PURPOSE/SCOPE

This policy identifies the requirements when UPMC uses and/or discloses PHI for research purposes. This policy applies to all UPMC entities and locations.

III. REQUIREMENTS

1. All researchers that conduct research at or within a UPMC entity, or request access to “protected health information” (PHI) held by a UPMC entity for research purposes, or use a UPMC entity (i.e., hospital) to fulfill orders for services that are required pursuant to a research protocol, shall adhere to this policy. This policy, as well as any related procedures, shall be distributed along

with instructions to all Institutional Review Boards (IRB's) that are known to provide services to affected researchers.

2. All IRBs that approve research protocols that in any way involve the use of a UPMC provider entity (existing or newly created PHI), will be expected to support UPMC with its HIPAA compliance initiative. Specific support is expected in providing HIPAA compliance training (with the assistance of UPMC), in answering questions, providing guidance to all affected researchers, for examining the study documentation to ensure HIPAA research authorization language is appropriate, and with audits that may be conducted by UPMC to assure IRB and researcher compliance with UPMC HIPAA policies and procedures related to research.
3. All researchers, that conduct research involving the recording of PHI (held by a UPMC entity) or involving the creation of PHI (by a UPMC entity) pursuant to a physician-researcher's orders for provider (e.g. hospital) services, must secure and maintain a 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 number 5 below]. Obtaining the HIPAA research authorizations shall be in addition to (see noted exception below) obtaining the written informed consent of patient-subjects using the IRB-approved informed consent document. All researchers must provide copies of these HIPAA research authorizations to any provider entity within the UPMC 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 IRB will be responsible for examining the study documentation to further assure that the at the HIPAA research authorization language is appropriately incorporated, either as a stand-alone document or combined with the informed consent].
4. The UPMC template HIPAA research authorization will be provided to the researchers for their use in assuring HIPAA compliance. The researcher must customize this template research authorization and explain its content to the patient-subject. The template research authorization form/language will be accompanied by a set of instructions regarding research authorization customization and use he researcher may combine the HIPAA research authorization language with the informed consent document provided that all UPMC-required HIPAA disclosures are made. 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.
5. 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; 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 system/service 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. This honest broker system/service 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 broker systems/services shall be approved in advance by both the IRB of record and UPMC. If an honest broker system/service is not part of the UPMC covered entity (UPP is part of the UPMC covered entity), they must execute a valid business associate agreement with UPMC in order 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;
 - in an extenuating circumstance, a researcher may request a waiver of HIPAA authorization. The request should be submitted to the UPMC Privacy Officer. If appropriate, the UPMC Privacy Officer will review, acknowledge and forward the waiver to the appropriate UPMC IRB-of-Record for consideration;
 - under no circumstances will a UPMC Health Information Management (Medical Records) department/area (where medical records are held) accept a waiver of authorization from an IRB where the UPMC Privacy Officer has not also acknowledged the waiver. If a UPMC medical record department/area manager or staff member is uncertain as to the validity of a waiver of HIPAA authorization, the UPMC Privacy Officer should be consulted before any access to records is granted to the researcher.

6. 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, resulting from 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 are certainly free to present restrictions (in the HIPAA research authorization) related to the patient-subject PHI that they possess;
 - researchers may not generally put any restrictions on PHI that is in the possession of any UPMC provider entity as a result of currently or previously providing hospital or other health care services to the patient/research subject;
 - a researcher may petition a UPMC provider entity's 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; and,
 - if a UPMC-held PHI restriction is granted, the researcher will be permitted to state this restriction in the HIPAA research authorization for that patient, and, the UPMC provider entity HIM manager or designated medical record contact must immediately flag that patient's file as "restricted patient access" so that the HIM/medical record staff know of the restriction.

7. HIPAA permits the researcher and UPMC to condition research participation on the patient-subject's signing of a research authorization. The UPMC research authorization, which shall be used by all researchers where research in any way involves a UPMC provider entity, 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.

8. 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 sanguinity". 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.

9. HIPAA permits customization of a research authorization to specify in detail that 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 researchers 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.
10. For reviews of PHI preparatory to research (hypothesis/protocol work), HIPAA permits UPMC to make available the PHI to a researcher based solely on the researchers 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. UPMC has a template agreement that is available to the researcher (from the IRB or UPMC) for this HIPAA-permitted activity. The researcher must provide requested information and attest/sign and submit this agreement to the director of the entity's health information management department or an individual designated by the entity to receive such information in order to access the records/PHI.
11. UPMC 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,
 - if 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.

12. 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 that are exclusively used for treatment are not covered by the HIPAA regulations that relate to research and/or IRB compliance. The PHI in these databases shall not be used for research purposes unless the use is compliant with all of the HIPAA and IRB requirements as previously stated in this policy.

IV. RESPONSIBILITY

It shall be the responsibility of researchers that conduct research at a UPMC entity, or request access to PHI for research purposes held by a UPMC entity, or use a UPMC entity (i.e., hospital) to fulfill orders for hospital (or other) services that are required pursuant to a research protocol, collectively the “affected researchers”, 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 IRB, that provide services to affected researchers pursuant to this policy, 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 UPMC provider entity’s HIM department manager or the designated medical record contact, that provide services to affected researchers pursuant to this policy, to implement processes and procedures within their work setting to meet the requirements set forth in this policy

V. 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.

SIGNED: Tom Nigra
Chief Compliance Officer

ORIGINAL: April 14, 2003

REVIEW MONTH: April

Policy Review Subcommittee: October 11, 2007

Executive Staff: November 12, 2007 (formerly HS-RS0001)

PRECEDE: September 8, 2006

SPONSOR: UPMC HIPAA Program Office

Attachments

SAMPLE FORM

Attachment A - Use and Disclosure of Protected Health Information (PHI) For Research Purposes Pursuant to the HIPAA Privacy Rules Policy

HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT (HIPAA)

RESEARCH AUTHORIZATION

AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES

(Division, Department, School, or Center Letterhead)

**University of Pittsburgh
Institutional Review Board
IRB Number:**

TITLE:

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATORS:

SOURCE OF SUPPORT:

Why is my additional authorization being requested?

You have previously given your consent to participate in the above-named research study. The purpose of this additional form is to provide you with specific information regarding the use and disclosure of your identifiable medical information for the purpose of this research study. While much of this information was provided to you previously, recently enacted laws focused on the privacy of medical information require that this information be addressed in a certain manner. Through the use of this additional form, we are seeking your authorization (consent) for the use and disclosure of your identifiable medical information for the purpose of this research study as per the requirements addressed in these recently enacted laws.

What uses of my identifiable medical information will this research study involve?

[Include if the research study involves the collection of the subjects' current or future identifiable medical information]:

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning *[specify the nature of the data that will be recorded]*. This information will be used for the purpose of *[specify the purpose of the research use of the current and/or future identifiable medical information]*.

[Include if the research study will involve the generation of information (e.g., diagnostic information, laboratory information, treatment or adverse event information that will appear or be placed in the subjects' medical records]:

This research study will result in identifiable information which will be placed into your medical records held at *[specify the name of the applicable institution or physician's office]*. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes *[specify the type research data which may or will be recorded in the subject's medical record]*.

Who will have access to my identifiable medical information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization form and their research staff, the following individuals will or may have access to your identifiable medical information related to your participation in this research study:

[Include routinely]:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical information for the purpose of monitoring the appropriate conduct of this research study.

[Include if an external sponsor of the research study will have access to the subjects identifiable medical information for study monitoring or data analysis purposes]:

Authorized representatives of the sponsor of this research study, *[specify name of sponsor and/or contract research organization]*, will review and/or obtain your identifiable medical information for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. *[Include if applicable - "Authorized representatives of the study sponsor may also be present during your participation in certain research procedures."]* While the study sponsor understands the importance of maintaining the confidentiality of your identifiable medical information, UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor.

The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable medical information related to your participation in the study.

[Include if the research study involves an evaluation of any article (e.g., drug, device, electronic product, food additive) regulated by the U.S. Food and Drug Administration]:

Authorized representatives of the U.S. Food and Drug Administration may review and/or obtain your identifiable medical information for the purpose of monitoring the accuracy of the research data. While the U.S. Food and Drug Administration understands the importance of maintaining the confidentiality of your identifiable medical information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the U.S. Food and Drug Administration.

[Include if the research study (or any aspect of the research study) will involve the utilization of hospital or health care services (e.g., laboratory tests, diagnostic procedures); hospital or health provider care of the patient-subject; or hospital or health provider billing activities]:

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable medical information for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

[Include if applicable]:

[Identify any other individuals who may or will have access to the participant's identifiable medical information and the purpose of such access.]

Include routinely:

In unusual cases, the investigators may be required to release your identifiable research information in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

May I have access to my medical information resulting from participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document which you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider unless otherwise specifically stated below.

[Include if you intend to restrict patient-subject access to medical information generated as a result of the patient's-subject's participation in the research study]:

[Specify any restrictions on the patient's-subject's access to medical information generated as a result of research participation. Indicate that such access will be granted at the end of the research study. Note that the UPMC does not generally permit investigators to include restrictions on patient-subject access to medical record information held by UPMC or affiliated health care providers. The principal investigator must petition the Privacy Officer, UPMC, on a study-specific basis, if s/he wishes to restrict respective patient-subject access to their own medical record information. If the Privacy Officer, UPMC, grants such restrictions, it will be the principal investigator's responsibility to clearly communicate to the involved UPMC hospital(s) or affiliated health care providers the restrictions that have been granted. This communication must include documentation of the Privacy Officer's permission along with a copy of this signed consent form/authorization.]

May I refuse to provide my authorization for the use of my identifiable medical information for the purpose of this research study?

Your authorization to use and disclose your identifiable medical information for the purpose of this research study is completely voluntary. However, if you do not provide your written authorization for the use and disclosure of your identifiable medical information, you will not be allowed to participate or continue to participate in the research study.

Whether or not you provide your authorization for the research use and disclosure of your medical information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Whether or not you provide this written authorization will have no affect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my authorization for the use of my identifiable medical information for the purpose of this research study?

You may withdraw, at any time, your authorization for the use and disclosure of your identifiable medical information for the purpose of this research study. However, if you withdraw your authorization for the use and disclosure of your identifiable medical record information, you will also be withdrawn from further participation in this research study. Any identifiable medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your authorization you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed above.

Your decision to withdraw your authorization for the research use and disclosure of your medical information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Your decision to withdraw this authorization will have no affect on your current or future relationship with the University of Pittsburgh.

For how long will the investigators be permitted to use my identifiable medical record information?

The investigators may continue to use and disclose your identifiable medical information for the purposes described above for an indefinite period of time.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my identifiable medical information. Such future questions will be answered by the investigators listed on the first page of this form.

Any questions I have about my rights associated with the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

By signing this form, I agree to allow the use and disclosure of my medical information for the purposes described above. A copy of this authorization form will be given to me.

Participant's Signature

Date

[If applicable]: For adults (age \geq 18 years old) determined to be decisionally impaired and thus unable to provide direct authorization, incorporate the following standard statements and signature lines:

Participant's Name (Print)

The above-named individual is unable to provide direct authorization for study participation because _____.

Therefore, by signing this form, I give permission for the use and disclosure of his/her medical information for the purpose of this research study.

Representative's Name (Print)

Representative's Relationship to Participant

Representative's Signature

Date

[If applicable]: Incorporate the following statements if the potential patient-subject is capable of exercising some judgement concerning the use of his/her medical information for the purpose of the research.

VERIFICATION OF EXPLANATION

I certify that I have explained the nature and purpose of the research use and disclosure of the above-named individual's medical information in appropriate language. He/she has had an opportunity to discuss this with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to allow the use and disclosure of his/her medical information for the purpose of this research study.

Investigator's Signature

Date

[If applicable]: For research studies wherein the nature of the subject population is such that an individual may not be capable of initially providing direct authorization for the research use of his/her medical information but may recover adequate decision-making capability for direct authorization at a later time, also incorporate the following standard statements and signature lines:

AUTHORIZATION FOR THE CONTINUED RESEARCH USE OF MEDICAL INFORMATION

I understand that I am currently participating in a research study. I further understand that authorization for the research use and disclosure of my medical information was initially obtained from my authorized representative as a result of my inability to provide direct authorization at the time that this initial authorization was requested. I have now recovered to the point where it is felt that I am able to provide direct authorization for the continued use and disclosure of my medical information for the purpose of this research study.

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my continued participation in this research study, I am encouraged to ask additional questions I may have about the research use and disclosure of my identifiable medical information. Such future questions will be answered by the investigators listed on the first page of this form. Any questions I have about my rights associated with the research use and disclosure of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

By signing this form, I agree to allow the continued use and disclosure of my medical information for the purposes described above. A copy of this authorization form will be given to me.

Participant's Signature

Date

[If applicable]: For children (age 0-17 years), incorporate the following standard statements and signature lines:

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to directly authorize the research use and disclosure of his/her medical information. Therefore, by signing this form, I give my authorization for the use and disclosure of his/her medical information for the purpose of this research study.

Parent's or Guardian's Name (Print)

Relationship to Participant (Child)

Parent's or Guardian's Signature

Date

SAMPLE AGREEMENT

Attachment B - - Use and Disclosure of Protected Health Information (PHI) For Research Purposes Pursuant to the HIPAA Privacy Rules Policy

DATA USE AGREEMENT

This Data Use Agreement (the "Agreement") is made this _____ day of _____, 200_ by and between UPMC/University of Pittsburgh Medical Center ("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/University of Pittsburgh Medical Center Recipient

Name (print): _____

Name (print): _____

Title: _____

Title: _____

Signature: _____

Signature: _____

SAMPLE AGREEMENT

Attachment C - Use and Disclosure of Protected Health Information (PHI) For Research Purposes Pursuant to the HIPAA Privacy Rules Policy

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 _____, 200__ by and between UPMC/University of Pittsburgh Medical Center (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/admsimp/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/University of Pittsburgh Medical Center

(Print or type name)

(Signature)