PENN Medicine:
University of Pennsylvania Health System &
University of Pennsylvania School of Medicine

HIPAA Policy & Procedure for Research

PRIVACY & CONFIDENTIALITY
Policy Number: RA-CMP-001
Date Approved: May 26, 2004

I. PURPOSE

To implement privacy protections required by the Health Insurance Portability and Accountability Act ("HIPAA") privacy regulations (the "Privacy Rule") for research uses and disclosures of Protected Health Information created or received by the University of Pennsylvania Health System and the School of Medicine ("UPHS/SOM").

II. POLICY STATEMENT

The University of Pennsylvania Health System and the School of Medicine ("UPHS / SOM") uses and discloses protected health information in research in a manner that respects patient privacy in accordance with the privacy regulations (the "Privacy Rule") promulgated under the Health Insurance Portability and Accountability Act ("HIPAA") and other applicable laws.

III. WHO SHOULD KNOW THIS POLICY?

- Faculty, Staff, Students & Trainees of the University of Pennsylvania School of Medicine
- Workforce members of the University of Pennsylvania Health System
- "Authorized members of the University of Pennsylvania" (see Definitions Section in Part V. of this policy)
- Trustees of the University of Pennsylvania and PENN Medicine

IV. PROCEDURES

RESPONSIBLE PERSON / DEPT	PROCEDURE
ALL	**I. PERMISSIBLE USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH:**
	General Rule:

SUPERSEDES: NONE – New Policy	ISSUED BY: 7/19/04 Dean, School of Medicine & EVP of the University of PA for UPHS — Date

UPHS / SOM may use and disclose PHI for research purposes under any of the following circumstances:

A. With an authorization on the UPHS / SOM HIPAA Research Authorization Form signed by the individual.

B. Where the Institutional Review Board has waived the HIPAA authorization requirement, pursuant to Paragraph I.B below.

C. Where UPHS / SOM is using or disclosing only data contained in a limited data set and UPHS / SOM has entered into a data use agreement with the recipient as described in Paragraph I.C below.

D. Where UPHS / SOM is using or disclosing only "de-identified data" as defined in Paragraph I.D below.

UPHS/SOM RESEARCHERS & STUDY STAFF

A. Uses & Disclosures of PHI Under Authorization

UPHS / SOM may use or disclose PHI for research purposes in accordance with the terms of a valid authorization signed by the individual or their personal representative. The authorization may be a separate document (see Attached Authorization Template) or combined in an IRB approved Informed Consent Document. The authorization must include the following:

a. Description of the PHI collected as part of the study
b. Who may use or disclose the information
c. Who may receive the information
d. Purpose of each use or disclosure
e. Expiration date or event
f. Right to revoke authorization in writing
g. Reference to the Notice of Privacy Practices (see Attached)
h. A statement that re-disclosures of the health information are no longer protected by HIPAA
i. Signature of individual and date (if signed by a personal representative, a description of the authority to act for the individual)

UPHS/SOM RESEARCHERS & STUDY STAFF

B. Uses & Disclosures of PHI Under IRB Waiver of HIPAA Authorization:

UPHS / SOM may use or disclose PHI for research purposes without patient authorization if UPHS / SOM obtains an IRB approved waiver of authorization, subject to accounting described below. Please refer to the attached form "HIPAA Waiver".

Where UPHS / SOM is using or disclosing PHI for research purposes pursuant to this Paragraph, UPHS / SOM must satisfy requirements regarding a patient's right to an accounting under UPHS / SOM's Accounting Policy. [see Section IV. Accounting for Disclosures]

UPHS/SOM RESEARCHERS / STUDY STAFF

C. Use of a Limited Data Set for Research Purposes:

1. UPHS / SOM may use or disclose PHI contained in a limited data set for research purposes provided that such use or disclosure is conducted as part of an IRB approved protocol.

2. UPHS / SOM may use or disclose data contained in a "limited data set" for research purposes, without obtaining individual authorization, provided that UPHS / SOM enters into a data use agreement with the recipient of the limited data set signed on behalf of the Trustees of the University of Pennsylvania by the UPenn Office of Research Services.

3. A "limited data set" excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

   a. Names;
   b. Postal address information, other than town or city, State, and zip code;
   c. Telephone numbers;
   d. Fax numbers;
   e. Electronic mail addresses;
   f. Social Security numbers;
   g. Medical record numbers;
   h. Health plan beneficiary numbers;
   i. Account numbers;
   j. Certificate / license numbers;
   k. Vehicle identifiers and serial numbers, including license plate numbers;
   l. Device identifiers and serial numbers;
   m. Web Universal Resource Locators (URLs);
   n. Internet Protocol (IP) address numbers;
   o. Biometric identifiers, including finger and voice prints;
   p. Full face photographic images and any comparable images.

4. A data use agreement between UPHS / SOM and the recipient must be in the form of the "UPHS / SOM HIPAA Data Use Agreement" (see Attached Form).

5. If any individual at UPHS / SOM becomes aware of a pattern of activity or practice of the limited data set recipient that constitutes a material breach or violation of a UPHS / SOM HIPAA Data Use Agreement, such individual must immediately report to the UPHS and SOM Privacy Officer for appropriate next steps under HIPAA.

6. UPHS / SOM may assign a code or other means of record identification to allow information de-identified under this Paragraph to be re-identified by the covered entity provided that:

   a. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

   b. UPHS / SOM does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

7. If "limited data set" information is disclosed pursuant to a HIPAA Waiver there is no Accounting requirement (please refer to section IV of this document for complete discussion of our Accounting obligations in the research context).

UPHS/SOM RESEARCHERS / STUDY STAFF

D. Use of De-identified Data for Research Purposes:

1. UPHS / SOM may use or disclose de-identified data for research purposes provided that such use or disclosure is conducted as part of an IRB approved protocol that received an exemption from IRB review (see attached IRB Claim of Exemption of IRB Review).

2. Data that is "de-identified" under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization.

3. Data is "de-identified" under HIPAA if:

   a. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, applying such principles and methods,

determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information and documents the methods and results of the analysis that justify such determination; **OR**

b. The following identifiers of the individual or of relatives, employers, or household members of the individual are removed (provided that UPHS / SOM does not have actual knowledge that the information can be used alone or in combination with other information to identify an individual who is a subject of the information):

i. Names,

ii. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

a. the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

b. the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

iii. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge data, date of death; and all ages over 89 (and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older);

iv. Telephone numbers;

v. Fax numbers;

vi. Electronic mail addresses;

vii. Social security numbers;

viii. Medical record numbers;

ix. Health plan beneficiary numbers;

x. Account numbers;

xi. Certificate/license numbers;

xii. Vehicle identifiers and serial numbers, including license plate numbers;

xiii. Device identifiers and serial numbers;

xiv. Web Universal Resource Locators (URLs);

xv. Internet Protocol (IP) address numbers;

xvi. Biometric identifiers, including finger and voice prints;

xvii. Full face photographic images and any comparable images; and

xviii. Any other unique identifying number, characteristic, or code, except as permitted by the re-identification section set forth in Paragraph I.D.3 below.

4. UPHS / SOM may assign a code or other means of record identification to allow information de-identified under this Paragraph to be re-identified by the covered entity provided that:

a. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

b. UPHS / SOM does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

5. If "de-identified" information is disclosed, regardless of whether the IRB has issued a HIPAA Waiver of Authorization there is no Accounting requirement (please refer to section IV of this document for complete discussion of our Accounting obligations in the research context).

II. SPECIAL RULES FOR CERTAIN RESEARCH SITUATIONS.

A. Special Rules on Reviews Preparatory to Research for Protocol Preparation:

UPHS / SOM may use (ie. share only among UPHS/SOM workforce members) PHI for research purposes provided that the researcher represents that:

1. Use of such PHI is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;

2. No PHI will be removed from UPHS / SOM by the researcher in the course of review; and

3. PHI being sought is necessary for the research purposes.

The Principal Investigator must document all of the above and keep a copy of this in the study records (see attached Sample Letter documenting the need to review PHI in order to prepare a protocol).

Researchers outside of UPHS/SOM may NOT obtain PHI in order to prepare a research protocol without first obtaining an IRB Waiver of Authorization as described in section I.B. Anyone within UPHS/SOM sharing PHI with an outside research for the purpose of preparing a protocol must obtain documented proof that the UPenn IRB has approved the Waiver of Authorization. After obtaining proof of the Waiver, the UPHS/SOM individual that provides PHI to the outside researcher will be responsible for accounting for all disclosures made to the outside researcher as described in section IV of this document.

B. Special Rules on Recruitment for Research Studies:

Healthcare Providers within UPHS / SOM may directly contact patients of UPHS / SOM for IRB approved research for studies conducted under a HIPAA Authorization and/or IRB Waiver of HIPAA Authorization for (Please refer to sections I.A & I.B of this document) recruitment purposes. However, to recruit subjects for participation in a research study using PHI, the following contact methods in descending order of preference are:

1. By a physician or other Health Care Professional who has taken care of a patient.

2. By the UPENN School of Medicine using a cover letter agreed

upon by a Physician who has taken care of the patient using script approved by the UPENN IRB.

3. By the researcher. Direct recruitment by a researcher who has not taken care of the patient will require specific UPENN IRB approval and will only be allowed when both of the other two alternatives are impractical.

Researchers who are not within UPHS / SOM may contact patients of UPHS / SOM only pursuant to an IRB Waiver of HIPAA Authorization, as described above (See section I.B) and in accordance with the contact procedures detailed above. In such cases, to the extent that UPHS / SOM is disclosing PHI to an individual outside of UPHS / SOM (e.g. a Contract Research Organization or Sponsor or another School at Penn such as the Dental School or School of Nursing), the HIPAA accounting rule applies. See [Accounting Section of this policy Section IV of this Document]

C. Special Rules on Decedents:

UPHS / SOM may use or disclose a decedent's PHI for research purposes, without authorization, if the researcher:

1. Represents that the use or disclosure sought is solely for research on the PHI of decedents;

2. Documents, at UPHS / SOM's request, the death of such individual; and

3. Represents that the PHI for which use or disclosure is sought is necessary for research purposes.

The Principal Investigator must document all of the above and keep a copy of this in the study records (see attached Sample Letter documenting the need to access PHI of a decedent for research purposes).

D. Special Rules for Research Commenced Prior to HIPAA Compliance Date:

UPHS / SOM may use or disclose for research PHI that it created or received at any time, provided that there is no agreed-to restriction and

UPHS / SOM has obtained, prior to April 14, 2003:

1. An authorization, consent or other express legal permission to use or disclose PHI for the research; or

2. The informed consent of the individual to participate in the research; or

3. As to research subject to the Common Rule (and subject to any agreed restrictions), an IRB waiver of informed consent obtained in accordance with the then applicable provisions of the Common Rule as adopted by the relevant agency (a list of such provisions is set forth in Section 164.532(c)(3) of the Privacy Rule). A covered entity must obtain a HIPAA-compliant authorization if the covered entity obtains informed consent from an individual participating in such research after April 14, 2003.

If for safety reasons a patient who signed an informed consent form prior to April 14th, 2003 is re-consented - the new consent must contain the HIPAA authorization language or a separate HIPAA Authorization Form (see section I.A).

E. Special Rules for Research Databases and Tissue Repositories / Banks that Contain PHI:

After April 14, 2003 the following procedures must be followed in order to establish and access research databases and tissue repositories that contain PHI:

1. To include PHI in a research database or tissue repository the research subject must sign a HIPAA Authorization as described in section I.A of this document.

2. To access the database or tissue repository to perform research - the Principal Investigator (PI) or researcher performing the research must contact the IRB and obtain a Waiver of HIPAA Authorization prior to conducting the research as described in section I.B of this document. However, the PI or researcher may review information contained in the database or tissue repository in order to prepare the protocol for submission to the IRB as described in section II.A above.

III. PATIENT ACCESS TO PHI.

UPHS / SOM grants patients the right to access, inspect, and copy certain PHI maintained by UPHS / SOM. *See* Access Policy of appropriate UPHS entity. As described in such Access Policy, the right to access may be suspended during a clinical trial, provided that the patient has agreed to the denial of access when consenting to participate in the clinical trial and UPHS/SOM has informed the individual at what point the right of access would be reinstated. UPHS / SOM should consult the terms of any research authorization or informed consent signed by patients/research subjects to determine the extent to which access to PHI may be denied during a clinical trial.

IV. ACCOUNTING FOR DISCLOSURES

Patients have the right to receive an accounting of certain disclosures made of their protected health information (PHI). It is the policy of UPHS /SOM to grant that right in accordance with the HIPAA privacy regulations and applicable law.

The accounting must include certain disclosures (but not uses) of the requesting patient's PHI made by UPHS/SOM and business associates during the period requested by the patient up to six years prior to the request but in no event earlier than April 14, 2003.

1. In order to provide patients with an accounting of disclosures of their PHI as required under the HIPAA privacy regulations, PI's or research staff must record all applicable disclosures of PHI as required. This accounting must include:

    a. The date (or range of dates) of disclosure;
    b. The name of the entity or person to whom the information was disclosed;
    c. If available, the address of the entity or person to whom the information was disclosed;
    d. A brief description of the PHI disclosed; and
    e. A brief statement explaining the purpose for the disclosure or, in lieu of this statement, a copy of the written request for disclosure that caused the disclosure, if applicable.

2. Business Associates: The accounting must include all

disclosures made to business associates involved in research. Please refer to section V of the document for more information on Business Associates. All applicable disclosures made by the Business Associate must also be tracked and reported. UPHS/SOM standard Business Associate contract addendum requires that the Business Associate notify UPHS/SOM of any reportable disclosures.

3. If, during the period covered by the accounting, UPHS/SOM has made multiple disclosures of a patient's PHI to the same person or entity for the same purpose, UPHS/SOM may provide the following information in lieu of listing each individual disclosure:

    a. For the first disclosure, all of the information listed in 1, above;
    b. The date of the last disclosure; and
    c. The frequency, periodicity, or number of disclosures made during the time period.

V. **BUSINESS ASSOCIATES**

A Business Associate is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, UPHS/SOM. In cases where a Business Associate relationship exists, HIPAA requires that certain contract language be included in agreements with the individual or entity (see Business Associate Contact Addendum Attached).

A Business Associate agreement is required only where a person or entity outside of UPHS/SOM who receives PHI and is conducting a "covered" function or activity on behalf of a covered entity. Research, is not a "covered" function or activity, so outside researchers who receive PHI in accordance with the policies and procedures specified in this document DO NOT require Business Associate language.

This exception to the business associate agreement requirement does not, however, cover all disclosures made in the general context of research, but rather covers only disclosures made by a covered entity to a researcher for research purposes. Certain disclosures, therefore, even if made solely in the general context of research, will nonetheless require a business associate agreement between UPHS/SOM and the

entity or individual receiving the information if the recipient of the information is using or disclosing the information to perform a function or activity regulated by the Rule.

The central question is whether or not the disclosure of PHI is to a researcher for research purposes? If the anserwer to this question is yes, the Business Assocociate language is NOT required.

If the recipient of the PHI merely performing a function on behalf of the UPHS/SOM researcher or research project then Business Associate language will be required.

Example 1: In a multi-site clinical trial where UHS/SOM serves as the primary data coordinating site, other sites (e.g. a site at another academic medical center) who are subcontractors on the clinical trial and report the data from the clinical trial back to UPHS/SOM are NOT Business Associates. The other sites are involved in the conduct of the research, interpretation and collection of the data and are therefore researchers. For the purpose of this trial they are considered key part of the research team and are not merely performing an activity on our behalf.

Example 2: In a research project to conduct a survey to gather health information from volunteers, a company is engaged to perform random-digit dialing, conduct a survey provided by the UPHS/SOM researcher and report the results back to the researcher. In this example the entity IS A BUSINESS ASSOCIATE and the agreement with that entity would require Business Associate language. The entity is performing a service on our behalf and is not considered part of the research team because they are adding no intellectual input into the design or conduct of the research. They are merely providing support to carry out a part of the research project without any real input into the research design.

Example 3: A Contract Research Organization (CRO) – or other such entity or individual - is contracted by UPHS/SOM in an Investigator-initiated clinical trial to provide quality assurance and auditing for a clinical trial being conducted at UPHS/SOM. In this case, the entity IS A BUSINESS ASSOCIATE and the agreement with the entity would require Business Associate language. The CRO is performing a service on our behalf and is not part of the research team in carrying out the project or by adding intellectual input into the design and conduct of the research. The CRO is merely checking the quality of the data that has been gathered and assessing regulatory compliance.

For assistance in determining whether an entity is a Business Associate in the research context, please contact the Office of Research Integrity & Compliance at (215) 573-8800.

V. DEFINITIONS

"Authorized Members of the University of Pennsylvania" Includes the University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs, the University of Pennsylvania Office of Human Research (the office which monitors research studies) and other authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access PHI in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.)

"**Business Associate**" is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity.

"De-identified Data" Data is "de-identified" under HIPAA if all 18 elements of individually identifiable information are removed from the data set. These 18 elements are listed in Section I.D.3 of this policy. Data that is "de-identified" under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization.

"Disclosure" means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside of UPHS / SOM.

"Limited Data Set" " A limited data set can be any collection of paper records or electronic databases containing PHI that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual. See section I.C.3 for a list of direct identifiers.

"Protected Health Information" or "PHI" means information that is created or received by UPHS and the School of Medicine; and relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present, or future payment for the provision of health care to a patient; and that identifies the patient or for which there is a reasonable basis to believe the information can be used to identify the patient. PHI includes information of persons living or deceased.

The following components of a patient's information also are considered PHI: a) names; b) street address, city, county, precinct, zip code; c) dates directly related to a patient, including birth date, admission date, discharge date, and date of death; d) telephone numbers, fax numbers, and electronic mail addresses; e) Social Security numbers; f) medical record numbers; g) health plan beneficiary numbers; h) account numbers; i) certificate/license numbers; j) vehicle identifiers and serial numbers, including license plate

numbers; k) device identifiers and serial numbers; l) Web Universal Resource Locators (URLs); m) biometric identifiers, including finger and voice prints; n) full face photographic images and any comparable images; and o) any other unique identifying number, characteristic, or code.

"**Research**" means a systematic investigation designed to develop or contribute to generalizable knowledge, including research development, testing, and evaluation.

"Use" means to share, employ, apply, utilize, examine, or analyze PHI within UPHS / SOM.

"**UPHS**" includes The Hospital of the University of Pennsylvania, Pennsylvania Hospital, Presbyterian Medical Center, Wissahickon Hospice, and the Clinical Care Associates, Clinical Health Care Associates.

VI. CONTACTS

School of Medicine Privacy Officer – Research Issues
James Moran
215-573-8800
jmoran@mail.med.upenn.edu

UPHS Chief Privacy Officer – Patient Care Issues
Russell Opland
215-615-0643
oplandr@uphs.upenn.edu

University Chief Privacy Officer
Lauren Steinfeld
215-573-3348
laurenst@pobox.upenn.edu

VII. ATTACHMENTS

Attachment 1: Authorization Language Template
Attachment 2: Data Use Agreement
Attachment 3: UPHS / SOM Notice of Privacy Practices

SUPERSEDES: NONE – New Policy	ISSUED BY: 7/19/04 Dean, School of Medicine & EVP of the University of PA for UPHS — Date

Attachment 4: HIPAA Waiver: Request for IRB Wavier of Authorization / Consent to Review Documents, Records or Data Sources Containing Identifiable, Protected Health Information (PHI) for Research Purposes
Attachment 5: Sample Letter Documenting Reviews Prep.
Attachment 6: Sample Letter on Decedents
Attachment 7: Business Associate Contact Addendum

SUPERSEDES: NONE – New Policy	ISSUED BY: 7/19/04 Dean, School of Medicine & EVP of the University of PA for UPHS Date

ATTACHMENT 1:

University Of Pennsylvania
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: *<<Insert Title of the Research Study>>*

Principal Investigator: *<<Insert the Name of the Primary Investigator>>*
<<Insert Address>>
<<Insert Phone Numbers>>

***Co-Investigators:** *<<Insert the Names of the Co-investigators>>*
<<Insert Phone Numbers>>

You have agreed to participate in the study mentioned above and have signed a separate informed consent that explained the procedures of the study and the confidentiality of your personal health information. This authorization form gives more detailed information about how your health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study.

What personal health information is collected and used in this study, and might also be shared (disclosed)?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study: ***[Modify this list as appropriate- delete or add items as necessary]***:

- Name
- Address
- Telephone number
- Family medical history
- Allergies
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- List all other tests and procedures that will be performed in the study ***[these tests and procedures should be fully described in the existing ICF along with the associated risks and discomforts of the tests and procedures]***

- *[List any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites]*

Why is your personal health information being used?

Your personal contact information is important for the University of Pennsylvania Health System and School of Medicine research team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following *[Modify this list as appropriate- delete or add items as necessary. For EACH LISTING include a brief description of WHY they will receive the information {the examples below are suggestions only}.]*:

- Other collaborating academic research center(s) *[list all academic centers including those at the University of Pennsylvania that may not be within the health system or its associated support offices. This would include collaborators at Wharton, School of Nursing etc. and their roles in project {who are working with the investigators in studying the economic impact of this treatment}]*
- Research data coordinating office and/or their representative: *[name that group or company [who will be responsible for collecting results and findings from all the centers}]*
- Research data management office and/or their representative: *[name that group or company]*
- Pharmaceutical Company and/or their representative: *[name that group or company {who will use the results for submissions to the Food and Drug Administration}]*
- Government agency and/or their representative: *[name that agency { who need to confirm the accuracy of the results submitted to the government or using government funds}]*
- Contract Research Organization: : *[name that company {whose job is to review and correct any mistakes before the results are given to the sponsor or government}]*
- Others: *[name the other group and why they will receive the results]*

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations.

[Depending on how personal health information will be handled for a specific study, the following notes some example language that might also be included (if applicable):]

- In all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.
- In records and information disclosed outside of the University of Pennsylvania Health System and School of Medicine, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of Pennsylvania Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests and procedures done solely for this research study and not as part of your regular care ***[will or will not]*** be included in your medical record.

Will you be able to access your records?

You will be able to request access to your medical record when the study is completed.

[If applicable, for the majority of blinded studies or other studies where access <u>will</u> be denied:]

During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

[If applicable, for open label studies and other studies for which access <u>will not</u> be denied:]

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your

permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

[ONLY USE THE FOLLOWING PARAGRAPH IF APPLICABLE]
If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that all information that could identify you is removed from these specimens.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

By signing this document you are permitting the University of Pennsylvania Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Subject's Name **[print]**	Subject's Signature	Date

Person obtaining authorization **[print]**	Person obtaining authorization Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person's authority to serve as the subject's authorized representative.

_____

ATTACHMENT 2:

REVISED 2/26/03

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM &
UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE

DATA USE AGREEMENT

This Data Use Agreement ("Agreement") is made and entered into as of this _____ day of _____, 20__ by and between the University of Pennsylvania Health System (UPHS) and the University of Pennsylvania School of Medicine (SOM) ("Covered Entity") and _____ ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which Covered Entity will Disclose certain Protected Health Information (PHI) to the Data Recipient as described below (insert a meaningful description of the data set):

_____

_____

_____

2. Except as otherwise specified herein, Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described in the research application. The title of the research project has been provided below:

_____

_____

3. In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include:

_____ _____

_____ _____

_____ _____

4. Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.

5. Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.

6. Data Recipient agrees to report to the Covered Entity any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor, within ten (10) days of its discovery.

7. Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.

8. Data Recipient agrees not to identify the information contained in the Limited Data Set or contact the individual.

9. Data Recipient will indemnify, defend and hold harmless Covered Entity and any of covered Entity's affiliates, and their respective trustees, officers, directors, employees and agents ("Indemnitees") from and against any claim, cause of action, liability, damage, cost or expense (including without limitation, reasonable attorney's fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Limited Data Set or any other breach of this Agreement by Data Recipient or any subcontractor, agent or person under Data Recipient's control.

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM AND UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE	**DATA RECIPIENT**
_____	_____
Name:_____	Name:_____
Title: _____	Title:_____

ATTACHMENT 3:

UPHS / SOM Notice of Privacy Practices

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully. You will be asked to acknowledge that you have received our notice of privacy practices.

We understand that information about you and your health is very personal and therefore, we will strive to protect your privacy as required by law. We will only use and disclose your personal health information as allowed by applicable law.

We are committed to excellence in the provision of state-of-the-art health care services through the practice of patient care, education, and research. Therefore, as described below, your health information will be used to provide you care and may be used to educate health care professionals and for research. We train our staff and workforce to be sensitive about privacy and to respect the confidentiality of your personal health information.

We are required by law to maintain the privacy of our patients' personal health information and to provide you with notice of our legal duties and privacy practices with respect to your personal health information. We are required to abide by the terms of this Notice of Privacy Practices so long as it remains in effect. We reserve the right to change the terms of this Notice of Privacy Practices as necessary and to make the new Notice of Privacy Practices effective for all personal health information maintained by us. You may receive a copy of any revised notice at any of our hospitals or doctors' offices, or a copy may be obtained by mailing a request to the UPHS Privacy Office, 3rd floor, 3550 Market Street, Philadelphia PA 19104-3329.

The terms of this Notice of Privacy Practices apply to the following entities owned and operated by and affiliated with the Trustees of the University of Pennsylvania operating as a clinically integrated health care arrangement: the University of Pennsylvania Health System and its subsidiaries, including but not limited to the Hospital of the University of Pennsylvania, Pennsylvania Hospital, the University of Pennsylvania Medical Center - Presbyterian, Phoenixville Hospital, the Clinical Practices of the University of Pennsylvania, Clinical Care Associates, Penn Medicine at Radnor, Penn Medicine at Limerick, Penn Center for Rehabilitation and Care, Penn Home Infusion Therapy, Wissahickon Hospice, Penn Care at Home, Presbyterian Personal Care Residence, Inc., Presbyterian Anesthesiology Foundation, and Presbyterian Multi-Specialty Group Practice Foundation; the University of Pennsylvania School of Medicine, and the physicians, licensed professionals, employees, volunteers, and trainees seeing and treating patients at each of these care settings. All of these entities and persons listed will share personal health information of patients as necessary to carry out treatment, payment, and health care operations as permitted by law. This Notice of Privacy Practices does not apply when visiting a non-CPUP or non-CCA physician in their private medical office.

USES AND DISCLOSURES OF YOUR PERSONAL HEALTH INFORMATION
The following categories detail the various ways in which we may use or disclose your personal health information. For each category of uses or disclosures we will give you illustrative examples. It should be noted that while not every use or disclosure will be listed, each of the ways we are permitted to use or disclose information will fall into one of the following categories.

Your Authorization. Except as outlined below, we will not use or disclose your personal health information for any purpose unless you have signed a form authorizing the use or disclosure. This form will describe what information will be disclosed, to whom, for what purpose, and when. You have the right to revoke that authorization in writing, except to the extent we have already relied upon it.

Uses and Disclosures for Treatment. We will make uses and disclosures of your personal health information as necessary for your treatment. For instance, doctors, nurses, and other professionals involved in your care will use information in your medical record and information that you provide about your symptoms and reactions to plan a course of treatment for you that may include procedures, medications, tests, etc. We may also disclose your personal health information to institutions and individuals outside the University of Pennsylvania Health System and the University of Pennsylvania School of Medicine that are or will be providing treatment to you.

Uses and Disclosures for Payment. We will make uses and disclosures of your personal health information as necessary for payment purposes. For instance, we may forward information regarding your medical procedures and treatment to your insurance company to arrange payment for the services provided to you or we may use your information to prepare a bill to send to you or to the person responsible for your payment.

Uses and Disclosures for Health Care Operations. We will use and disclose your personal health information as necessary, and as permitted by law, for health care operations. This is necessary to run the University of Pennsylvania Health System and the University of Pennsylvania School of Medicine and to ensure that our patients receive high quality care and that our health care professionals receive superior training. For example, we may use your personal health information in order to conduct an

evaluation of the treatment and services we provide, or to review the performance of our staff. And, for education and training purposes, your health information may also be disclosed to doctors, nurses, technicians, medical students, residents, fellows and others.

Our Facility Directory. We use information to maintain a directory function listing your name, room number, general condition and, if you wish, your religious affiliation. Unless you choose to have your information excluded from this directory, the information, excluding your religious affiliation, will be disclosed to anyone who requests it by asking for you by name. This information, including your religious affiliation, may also be provided to members of the clergy, even if they don't ask for you by name. Please let our staff know when you check in or register if you would like to have your information excluded from this directory function.

Persons Involved In Your Care. Unless you object, we may in our professional judgment disclose to a member of your family, a close friend, or any other person you identify, your personal health information to facilitate that person's involvement in caring for you or in payment for that care. We may use or disclose personal health information to assist in notifying a family member, personal representative or any other person that is responsible for your care of your location and general condition. Finally, we may also disclose limited personal health information to a public or private entity that is authorized to assist in disaster relief efforts in order for that entity to locate a family member or other persons that may be involved in some aspect of caring for you.

Fundraising. We may contact you, at times in coordination with your physician, to donate to a fundraising effort on our behalf. If we contact you for fundraising purposes, you will be provided with the opportunity to opt out of receiving any future solicitations.

Appointments and Services. We may use your personal health information to remind you about appointments or to follow up on your visit.

Health Products and Services. We may from time to time use your personal health information to communicate with you about treatment alternatives and other health-related benefits and services that may be of interest to you.

Research. We may use and disclose your personal health information as permitted or required by law, for research, subject to your explicit authorization, and/or oversight by the University of Pennsylvania Institutional Review Boards, committees charged with protecting the privacy rights and safety of human subject research, or similar committee. In all cases where your specific authorization has not been obtained, your privacy will be protected by confidentiality requirements evaluated by such committee. This is necessary to investigate cutting-edge health care through improved treatments, medications and outcomes research. For example, you may be approached by your physician to ask if you would be interested in participating in a clinical trial of a new drug for your condition. Or, your health information may be used with the approval of the committee charged with protecting the rights of research subjects, described above, to conduct outcomes research to see if a particular procedure is effective.

Business Associates. Certain aspects and components of our services are performed through contracts with outside persons or organizations, such as auditing, accreditation, legal services, etc. At times it may be necessary for us to provide certain of your personal health information to one or more of these outside persons or organizations who assist us with our payment/billing activities and health care operations. In such cases, we require these business associates to appropriately safeguard the privacy of your information.

Other Uses and Disclosures. We are permitted or required by law to make certain other uses and disclosures of your personal health information without your consent or authorization. Subject to conditions specified by law:

- We may release your personal health information for any purpose required by law;
- We may release your personal health information for public health activities, such as required reporting of disease, injury, and birth and death, and for required public health investigations;
- We may release your personal health information to certain governmental agencies if we suspect child abuse or neglect; we may also release your personal health information to certain governmental agencies if we believe you to be a victim of abuse, neglect, or domestic violence;
- We may release your personal health information to entities regulated by the Food and Drug Administration if necessary to report adverse events, product defects, or to participate in product recalls;
- We may release your personal health information to your employer when we have provided health care to you at the request of your employer for purposes related to occupational health and safety; in most cases you will receive notice that information is disclosed to your employer;
- We may release your personal health information if required by law to a government oversight agency conducting audits, investigations, inspections and related oversight functions;

- We may use or disclose your personal health information in emergency circumstances, such as to prevent a serious and imminent threat to a person or the public;
- We may release your personal health information if required to do so by a court or administrative order, subpoena or discovery request; in most cases you will have notice of such release;
- We may release your personal health information to law enforcement officials to identify or locate suspects, fugitives or witnesses, or victims of crime, or for other allowable law enforcement purposes;
- We may release your personal health information to coroners, medical examiners, and/or funeral directors;
- We may release your personal health information if necessary to arrange an organ or tissue donation from you or a transplant for you;
- We may release your personal health information if you are a member of the military for activities set out by certain military command authorities as required by armed forces services; we may also release your personal health information if necessary for national security, intelligence, or protective services activities; and
- We may release your personal health information if necessary for purposes related to your workers' compensation benefits.

Confidentiality of Alcohol and Drug Abuse Patient Records, HIV-Related Information, and Mental Health Records. The confidentiality of alcohol and drug abuse patient records, HIV-related information, and mental health records maintained by us is specifically protected by state and/or Federal law and regulations. Generally, we may not disclose such information unless you consent in writing, the disclosure is allowed by a court order, or in limited and regulated other circumstances.

RIGHTS THAT YOU HAVE

Access to Your Personal Health Information. Generally, you have the right to access, inspect, and/or copy personal health information that we maintain about you. Unless you are currently a patient in our hospital or during a scheduled appointment with a clinician, requests for access must be made in writing and be signed by you or your representative. We will charge you for a copy of your medical records in accordance with a schedule of fees established by applicable state law. You may obtain an access request form from the doctor's office or Medical Records department of the hospital you visited.

Amendments to Your Personal Health Information. You have the right to request that personal health information that we maintain about you be amended or corrected. We are not obligated to make all requested amendments but will give each request careful consideration. All amendment requests, in order to be considered by us, must be in writing, signed by you or your representative, and must state the reasons for the amendment/correction request. If an amendment or correction you request is made by us, we may also notify others who work with us and have copies of the uncorrected record if we believe that such notification is necessary. Please note that even if we accept your request, we may not delete any information already documented in your medical record. You may obtain an amendment request form from the doctor's office or Medical Records department of the hospital you visited.

Accounting for Disclosures of Your Personal Health Information. You have the right to receive an accounting of certain disclosures made by us of your personal health information after April 14, 2003 except for disclosures made for purposes of treatment, payment, and healthcare operations or for certain other limited exceptions. Requests must be made in writing and signed by you or your representative. Accounting request forms are available from the doctor's office or Guest Services department of the hospital you visited. The first accounting in any 12-month period is free; you will be charged a fee of $20 for each subsequent accounting you request within a 12-month period.

Restrictions on Use and Disclosure of Your Personal Health Information. You have the right to request restrictions on certain of our uses and disclosures of your personal health information for treatment, payment, or health care operations. For example, you may request that we do not share your health information with a certain family member. A restriction request form can be obtained from the doctor's office or Guest Services department of the hospital you visited. We are not required to agree to your restriction request but will attempt to accommodate reasonable requests when appropriate and we retain the right to terminate an agreed-to restriction if we believe such termination is appropriate. In the event we have terminated an agreed upon restriction, we will notify you of such termination.

Confidential Communications. You have the right to request communications regarding your personal health information from us by alternative means or at alternative locations and we will accommodate reasonable requests by you. You must request such confidential communication in writing to each department to which you would like the request to apply.

Paper Copy of Notice. As a patient you retain the right to obtain a paper copy of this Notice of Privacy Practices, even if you have requested such copy by e-mail or other electronic means. You may also print this web page or download a copy (requires free Adobe Acrobat Reader).

ADDITIONAL INFORMATION

Complaints. If you believe your privacy rights have been violated, you may file a complaint in writing with the doctor's office or Guest Services department of the hospital you visited. You may also file a complaint with the Secretary of the U.S. Department of Health and Human Services in Washington D.C. All complaints must be made in writing and in no way will affect the quality of care you receive from us.

For further information. If you have questions or need further assistance regarding this Notice of Privacy Practices, you may contact us in writing at UPHS Privacy Office, 3rd floor, 3550 Market Street, Philadelphia, PA 19104-3329, or by telephone at (215) 615-0638, or by e-mail at privacy@uphs.upenn.edu.

Effective Date. This Notice of Privacy Practices is effective April 14, 2003.

ATTACHMENT 4: IRB Request for Waiver of HIPAA Authorization

Grant #		**Responsible Org.**
Project Title		
Principal Investigator	Name Title Address	Phone email 8 digit PennCard ID#
Primary Contact (if not Principal Investigators)	Name Title Address	Phone email 8 digit PennCard ID#
IRB USE ONLY	**This project meets the IRB criteria for waiver of authorization:** ☐ **Yes** ☐ **No** _____ Printed name: authorized IRB signatory _____ _____ Authorized IRB signature Date	

VIII. REQUIRED INFORMATION

The information **must** include a specific description of the procedure(s) and health information collected/used (e.g. surveys, record reviews, etc.), involving the human subjects in sufficient detail to demonstrate to the IRB reviewer that the research project/protocol meets the requirements for waiver of authorization and prospective informed consent. The information can be provided on this form or included as a separate addendum keeping the numbered heading scheme of this form.

If you are only collecting or using – *and <u>not</u> disclosing:*

- *<u>Indirect identifiers</u>* (listed in the right hand column of the table noted below), the risk is considered minimal risk to privacy. If you disclose information containing indirect identifiers under a data use agreement then the disclosure is also deemed minimal risk by the IRB.
- *<u>Direct identifiers</u>* (listed in the left hand column of the table noted below), then you must provide a rationale for the collection and use of these identifiers. The following issues must be addressed if applicable: How will the collected data be kept secure? Will the direct identifiers be kept separate from the collected health information and separately secured? These are addressed in the numbered items below.

If you are collecting or using – *and <u>will be</u>* disclosing:

- *<u>Direct identifiers</u>*, the risk to privacy may be greater than minimal and full IRB review is required. In this circumstance you will need to describe additional privacy protections in question # 8 below, in order to demonstrate to the IRB that the research will qualify as less than minimal risk.

Please provide the following information:

1. The objective (hypothesis) of the research project and a brief background for the study. If this is a new IRB submission please submit an **IRB cover sheet**, two copies of the protocol summary and full protocol. If this is a request to amend a protocol, provide a copy of the amended protocol and IRB number.

2. The rationale for the use of the selected subject population, record set, archives or material and sources of information.

3. Describe the reasons why the research could not be practicably carried out without the waiver of authorization or consent to collect and/or use the protected health information.

4. Provide a rationale as to why the research described in the research protocol could not be practicably conducted without access to the health information.

5. The specific type of data to be collected and used and why this is considered the minimum necessary to conduct the analysis. (Must be specific and include a copy of a data collection sheet(s).) ***Please complete the attached table: "Identifiable Information."***

6. Does the recorded data contain either a direct identifier or a link to allow the re-identification of the individual?[1] ☐ Yes ☐ No

   If yes describe the procedures to protect the confidentiality and security of this linking data set and specific plans as to the time point at which the linking data set will be destroyed.

   If the linking set will not be destroyed provide written assurance that access to the identifiable data for future research will not be done without prior IRB approval.

7. During the conduct of the research what is your plan to protect the identifiers from improper use and disclosure?

8. If you intend to disclose information containing direct identifiers listed below in the "Identifiable Information" table (left column), the risk to privacy may be greater than minimal and full IRB review is required. Please provide the Committee a rationale as to why the disclosure of the protected health information with these direct identifiers, is thought to involve no more than minimal risk to the rights, welfare and/or privacy of the individuals. Fully describe any additional privacy protections that will be put in place in order to protect the privacy of the individuals. Please submit an original and 19 copies of this form.

[1] The code or other means of record identification should not be derived from or related to information about the research subject and should not otherwise permit re-identification of the subject.

Please complete the following checklist related to specific identifiers of the research subject or of relatives, employers, or household members of the research subject to be collected, used or disclosed.

Direct Identifiers		Identifiable Information	Indirect Identifiers (Limited Data Set)	
Used/ Collected (check if yes)	**Disclosed** (check if yes)		**Used/ Collected** (check if yes)	**Disclosed** (check if yes)
☐	☐	Names		
☐	☐	Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code.		
		City/Town, State and Zip Code *(Note: for the records to be considered de-identified only the first three digits of the zip code can be used[2])*	☐	☐
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)	☐	☐
		Ages less than 90, and "90 and above" for those over 90.	☐	☐
☐	☐	Telephone numbers, including fax		
☐	☐	Electronic mail addresses		
☐	☐	Social security numbers		
☐	☐	Medical record numbers		
☐	☐	Health plan beneficiary numbers, or any other account numbers		
☐	☐	Certificate/license numbers, & vehicle identifiers and serial numbers, including license plate numbers,		
☐	☐	Implanted device identifiers and serial numbers		
☐	☐	Web Universal Resource Locators (URLs)		
☐	☐	Internet Protocol (IP) address numbers		
☐	☐	Biometric identifiers, including finger and voice prints or any audio recordings		
☐	☐	Full face photographic images and any comparable image, including video recordings		
☐ None of the Direct Identifiers noted above will be collected			☐ None of the Indirect Identifiers noted above will be collected	

[2] The first three digits of the zip code may be used as long as the population in that region is greater than 20,000. If the geographic unit is less than 20,000 only state may be used.

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this request for Waiver of HIPAA Authorization is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research project/protocol. I agree to comply with all UPenn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Permitting performance of the project only by qualified personnel according to the research project/protocol.
- Maintaining of a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least three years following termination of the project unless otherwise necessary to protect subject confidentiality as described in the project/protocol.
- Acquiring the necessary review by the UPenn IRB if substantial changes are made in the research project/protocol or if any change is made which may result in the research no longer meeting the criteria for waiver.
- Maintaining as secure any protected health information collected for this research project/protocol, and not sharing access to such information with any individual without prior review and approval of the IRB and/or privacy officer unless such subset has been created to exclude all identifiable demographic information as defined in this document, or unless additional data use agreements have been obtained for distribution of limited data sets.
- Forbidding attempts to re-identify the subjects from the data collected under this waiver, and attempts to contact the subjects or their family members.

I have completed the required educational program on ethical principles and regulatory requirements in human subjects research and HIPAA as necessary prior to initiating the research.

_____ _____

Signature: Principal Investigator noted above Date

FACULTY SPONSOR'S ASSURANCE

(Only for projects where the Principal Investigator is a student, resident, fellow, or Collaborating Investigator outside of the Covered Entity, e.g. Wharton PI.)

By my signature as sponsor on this research application, I certify that the student or investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved project/protocol. In addition,

I agree to meet with the principal investigator on a regular basis to review study progress.

Should problems arise during the course of the study, I agree to be available, personally, to supervise the the student or fellow or provide assistance to the Collaborator.

I assure that the student, resident, fellow or Collaborating Investigator will complete all required educational programs on ethical principles and regulatory requirements in human subjects research as required.

If I will be unavailable, as when on sabbatical, leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Office of Regulatory Affairs by letter of such arrangements.

_____

Printed Name: Faculty Sponsor

_____ _____

Signature: Faculty Sponsor Date

*The faculty sponsor must be a member of the standing UPenn faculty. The faculty sponsor is considered the responsible party for legal and ethical performance of the project.

DEPARTMENT HEAD SIGNATURE

(Only if the Principal Investigator is Faculty)

As department head, I acknowledge that this research is in keeping with the standards set by our department and I assure that the principal investigator will meet all departmental or school requirements for review and approval of this research prior to initiation.

_____

Printed Name: Department/Unit Head

_____ _____

Signature: Department/Unit Head Date

Definitions

"De-identified Data" Data that is "de-identified" under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization. Data is "de-identified" under HIPAA if the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

- ***Names***
- ***All geographic subdivisions smaller than a State***, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (a) the geographical unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people: and(b) the initial three digits of a zip code for all such geographic units containing 20,000 of fewer people is changed to 000.
- ***All elements of dates (except year)*** for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or order.

- ***Telephone numbers***
- ***Fax numbers***
- ***Electronic mail addresses***
- ***Social security numbers***
- ***Medical record numbers***
- ***Health plan beneficiary numbers***
- ***Account numbers***
- ***Certificate/license numbers***
- ***Vehicle identifiers and serial #s (e.g. license plate #'s)***
- ***Device identifiers and serial numbers***
- ***Web Universal Resources (URLs)***
- ***Internet Protocol (IP) address numbers***
- ***Biometric identifiers, including finger and voice prints***
- ***Full face photographic images and any comparable images***

Any other unique identifying number, characteristic, or code, except that a code may be assigned to allow information de-identified by removal of all above information to be re-identified provided that: (a) the code is not derived from or related to the information from and the individual and is not otherwise capable of being translated so as to identify the individual; and, (b) the code is not used for any other purpose nor disclosed to any outside entity

"Disclosure" means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside of UPHS / SOM or other covered entity.

"Limited data set" Members of a covered entity may use or disclose data contained in a "limited data set" for research purposes, without obtaining individual authorization, provided that UPHS / SOM enters into a data use agreement with the recipient of the limited data set signed on behalf of the Trustees of the University of Pennsylvania by the UPenn Office of Research Services. A "limited data set" excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- ***Names***
- ***Postal address information, other than town or city, State, and zip code***
- ***Telephone numbers***
- ***Fax numbers***
- ***Electronic mail addresses***
- ***Social security numbers***
- ***Medical record #'s & Health* plan beneficiary #'s**
- ***Account numbers***
- ***Certificate/license numbers***
- ***Vehicle identifiers/ serial #'s (e.g. license plate #'s)***
- ***Implanted device identifiers and serial numbers***
- ***Web Universal Resource Locators (URLs)***
- ***Internet Protocol (IP) address numbers***
- ***Biometric identifier including finger and voice prints***
- ***Full face photo images and any comparable image***

"Protected Health Information (PHI)" Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse: and (2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Use" means to collect, share, employ, apply, utilize, examine, or analyze PHI within UPHS / SOM.

ATTACHMENT 5:

Sample Letter Documenting Reviews in Preparation for Research
–to be on Official UPenn SOM or UPHS letterhead-

To: Russ Opland, UPHS Privacy Officer
From: [Insert Name of Principal Investigator]
Date: [Insert Date]
Re: Request to Review Protected Health Information to Develop a Research Protocol

I, _____ (name of Principal Investigator) and/or my study staff would like to review UPHS/SOM records containing Protected Health Information in order to prepare a research protocol. The use of such PHI is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.

I understand and agree that no Protected Health Information will be removed from UPHS / SOM in the course of review; and the Protected Health Information being sought is necessary to develop the research protocol.

In the course of this review the following general description of the records sought is found below:

_____

_____

_____

P.I. Signature: _____ Date: _____

ATTACHMENT 6:

Sample Letter Documenting Request to Review Decedent Health Information for Research
–to be on Official UPenn SOM or UPHS letterhead-

To: Russ Opland, UPHS Privacy Officer
From: [Insert Name of Principal Investigator]
Date: [Insert Date]
Re: Request to Review Decedent Protected Health Information for Research

I, _____ (name of Principal Investigator) and/or my study staff would like to review UPHS/SOM records containing Protected Health Information of decedents for research purposes. The use of such PHI is sought solely for research on the Protected Health Information of decedents and that I able to provide evidence to UPHS/SOM that the Protected Health Information is only obtained from decedents and will provide the death certificate if it is requested by UPHS/SOM.

The following general description of the records sought is found below:

_____

_____

_____

P.I. Signature: _____ Date: _____

ATTACHMENT 6:

UPHS/SOM BUSINESS ASSOCIATE ADDENDUM

This Addendum is made and entered into as of _____, 200__ ("Effective Date"), by and between _____("Business Associate") and **The Trustees of the University of Pennsylvania as owner and operator of the University of Pennsylvania Health System,** a Pennsylvania non-profit corporation having its principal place of business at 21 Penn Tower, 3400 Spruce Street, Philadelphia, Pennsylvania 19104-4385 ("UPHS") and the **University of Pennsylvania School of Medicine** (SOM). For purposes of this Addendum, UPHS refers to the component(s) of UPHS which has/have entered into the underlying Agreement with Business Associate as the same is described below.

For good and valuable consideration the sufficiency of which is hereby acknowledged, the parties intending to be legally bound agree as follows:

1. This Addendum amends and adds to the terms and conditions of a certain agreement (including any Purchase Orders issued by UPHS/SOM) entered into with Business Associate, titled _____; dated _____ or; that relates to the provision of _____ services ("Agreement"). **[Must complete at least one.]** All other terms, provisions and obligations of Business Associate and UPHS as set forth in the Agreement shall remain in full force and effect.

2. This Addendum applies only to the extent that Business Associate is receiving from or on behalf of UPHS/SOM Protected Health Information ("PHI") as the same is defined in the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), 45 CFR Part 160 and 164.

3. Obligations and Activities of Business Associate

With regard to its use and disclosure of PHI, Business Associate agrees to:

(a) not use or further disclose PHI other than as permitted or required by the Agreement, by this Addendum or as required by law as defined in 45 CFR 164.501.

(b) use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement or Addendum.

(c) report to UPHS/SOM any use or disclosure of PHI not provided for by this Agreement or Addendum of which it becomes aware.

(d) ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of UPHS/SOM agrees to the same restrictions and conditions that apply through this Addendum to Business Associate with respect to such information.

(e) provide access in a manner designated by UPHS/SOM, within twenty (20) days of receiving a request from UPHS/SOM, to PHI in a designated record set, as defined under HIPAA, to UPHS/SOM or, as directed by UPHS/SOM, to an Individual, as defined under HIPAA, in order to meet the requirements under 45 CFR 164.524.

(f) make any amendment(s) to PHI in a designated record set that UPHS/SOM directs or agrees to pursuant to 45 CFR 164.526 at the request of UPHS/SOM or an Individual, within thirty (30) days of receiving such request and in a manner designated by UPHS/SOM.

(g) make internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of UPHS/SOM available to UPHS/SOM, or at the request of UPHS/SOM to the Secretary of the U.S. Department of Health and Human Services, in a time and manner designated by UPHS/SOM or the

Secretary, for purposes of the Secretary determining UPHS/SOM' compliance with HIPAA. Business Associate shall immediately notify UPHS/SOM upon receipt by Business Associate of any such request, and shall provide UPHS/SOM with copies of any such materials.

(h) document disclosures of PHI and information related to such disclosures as would be required for UPHS/SOM to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(i) provide to UPHS/SOM or an Individual in a manner designated by UPHS/SOM, within thirty (30) days of receiving a request from UPHS/SOM, information collected in accordance with this Addendum, to permit UPHS/SOM to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(j) upon termination or expiration of the Agreement, return or destroy all PHI received from UPHS/SOM or created or received by Business Associate on behalf of UPHS/SOM, and retain no copies of PHI in any form whatsoever, except if such return or destruction is infeasible in which case Business Associate agrees to extend all protections of this Addendum to Business Associate's use and disclosure of any retained PHI and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the PHI infeasible. To the extent that returning or destroying the PHI is infeasible, Business Associate shall provide UPHS/SOM notification of the conditions that make such return or destruction infeasible.

4. Permitted Uses and Disclosures by Business Associate

Except as otherwise limited in this Addendum, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, UPHS/SOM as specified in the Agreement, provided that such use or disclosure would not violate HIPAA if done by UPHS/SOM. In using and disclosing PHI, Business Associate shall make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended use or disclosure.

5. Obligations of UPHS/SOM

(a) UPHS/SOM shall provide Business Associate upon request with the notice of privacy practices that UPHS/SOM produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(b) UPHS/SOM shall provide Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if UPHS/SOM knows that such changes affect Business Associate's permitted or required uses and disclosures.

(c) UPHS/SOM shall notify Business Associate of any restriction to the use or disclosure of PHI that UPHS/SOM has agreed to in accordance with 45 CFR 164.522, to the extent such restriction may affect Business Associate's use of disclosure of PHI.

(d) UPHS/SOM shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done by UPHS/SOM.

6. Termination and Amendment

Without limiting the rights and remedies of UPHS/SOM set forth elsewhere in the Agreement, this Addendum or available under applicable law, UPHS/SOM may promptly terminate the Agreement without penalty or recourse to UPHS/SOM if UPHS/SOM determines that Business Associate has violated a material term of the provisions of this Addendum. Business Associate agrees that the Agreement may be amended from time to time by UPHS/SOM if and to the extent required by the provisions of HIPAA and regulations promulgated thereunder, in order to assure that the Agreement is consistent therewith.

7. Miscellaneous

(a) Survival. The respective rights and obligations of Business Associate under this Addendum shall survive the termination of the Agreement.

(b) Interpretation. Any ambiguity in this Addendum shall be resolved in favor of a meaning that permits the parties to comply with HIPAA.

(c) Governing Law. This Addendum shall be governed by the laws of the Commonwealth of Pennsylvania, without reference to it choice of law rules.

IN WITNESS WHEREOF, the parties have each caused this Addendum to be executed by their duly-authorized officers on the day and year first above-written.

The Trustees of the University of Pennsylvania
As owner and operator of the
University of Pennsylvania Health System

By: _____

Title: _____

Date: _____

_____ [Business Associate]

By: _____

Title: _____

Date: _____