

## RELEASE OF PROTECTED HEALTH INFORMATION (“PHI”) FOR RESEARCH PURPOSES

### PURPOSE

The purpose of this policy is to establish guidelines for the release of Protected Health Information (“PHI”) for research from the UCLA Health System data and document repositories that ensure the privacy of patients as required by the federal Health Insurance Portability and Accountability Act of 1996 (the “Privacy Rule”), the Common Rule (45 Code of Regulations, Part 46), and California law.

### DEFINITIONS

**“Individually-identifiable health information”** is any information that is created or received by a health care provider, that relates to (a) the past, present, or future physical or mental health or condition of an individual; (b) the provision of health care to an individual; or (c) the past, present or future payment for the provision of health care to an individual; and that identifies the individual or, with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**“Protected health information” or “PHI”** is any individually identifiable health information collected or created as a consequence of the provision of health care by a covered entity, in any form (including verbal communications).

**“Research”** means the “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. In general, research differs from treatment in that the end goals of treatment are to benefit the individual being treated, while research is performed for the benefit of obtaining general knowledge.

**“Research-Related Health Information” or “RHI”** The University of California has defined the term research-related health information (RHI) when individually-identifiable information that is used during participation in a research study but that is not part of any medical treatment. When research is associated or derived from a healthcare service event (either related to the provision of care or the payment for such care), then the information may be classified as both RHI and PHI. Research studies that use medical records as a source of personally-identifiable research data are using PHI, and in order to obtain the PHI from a covered health care provider, the provider must comply with all requirements of the IRB and the Privacy Rule.

**“Treatment”** under the Privacy Rule is defined to include all the preventive, diagnostic, therapeutic, rehabilitation, maintenance and palliative care provided to an individual as well as the provision, coordination, management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to the patient; or the referral of a patient for health care from one health care provider to another.

“**Workforce**” means employees, volunteers, and other persons whose conduct, in the performance of their work for UCLA Health System, is under the direct control of UCLA Health System or the Regents of the University of California, whether or not UCLA Health System pays them. The Workforce includes employees, medical staff, and other health care professionals; agency, temporary and registry personnel; and trainees, housestaff, students and interns, regardless of whether they are UCLA trainees or rotating through UCLA Health System facilities from another institution.

## **POLICY**

Research on human subjects is primarily regulated by the Department of Health and Human Services. Most research involving human subjects operates under the Common Rule (codified at 45 Code of Federal Regulations, Part 46) and/or the FDA’s human subject’s protections regulations. Federal regulations require UCLA’s IRBs to review and approve all University-affiliated human subject research, regardless of funding source. (*See: UCLA’s “Investigator’s Manual for the Protection of Human Subjects.”*)

In the course of conducting research, researchers may create, use and/or disclose PHI. The Privacy Rule establishes the conditions under which PHI may be used or disclosed by UCLA Health System for research purposes. Under the Privacy Rule, UCLA Health System is permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances as set forth in the Privacy Rule and as outlined in this policy.

All disclosures of PHI for research at UCLA Health System must be approved by a UCLA Institutional Review Board

UCLA Health System and its researchers shall be required to meet the requirements of the Common Rule, the Privacy Rule and California law.

### **I. Researchers and Individually-Identifiable Health Information Subject to the Privacy Rule**

#### **A. PHI vs. RHI.**

The concept of RHI recognizes that the Privacy Rule applies to those records associated with an individual’s health care, and that, in some instances, health care records may be used or produced in the course of doing research. When RHI and PHI are mixed in a research project, it may become impossible to determine the source and use of a particular item of information or data, thus the researcher should apply the Privacy Rule privacy standards to any project that contains PHI (e.g., clinical trials).

#### **B. Researchers.**

A member of UCLA Health System Workforce may serve dual roles as both a covered provider under the Privacy Rule and a non-covered researcher. A researcher is a

covered health care provider if he or she furnishes services to individuals, including the subjects of research, and transmits any health information in electronic form in connection with a transaction covered by the Privacy Rule. For example, a researcher who conducts a clinical trial that involves the delivery of routine health care, such as an MRI or liver function test, and transmits health information in electronic form to a third party payer for payment, would be a covered health care provider under the Privacy Rule.

In contrast, a research study that does not include a diagnostic or therapeutic intervention and does not acquire health-related facts or PHI from a covered entity, would create information that, if individually identifiable health information, could be classified as RHI.

## II. **General Rule: Authorization Required to Use or Release PHI For Research Purposes**

Except as permitted as set forth in Section III below, UCLA Health System may not release any PHI, in whole or in part, to a researcher for research purposes, without a written authorization from the patient for the use or disclosure of such information.

### A. Authorization Requirements.

The Privacy Rule requires that patient authorization forms meet certain requirements (*see*: Privacy Policy and Procedure No. 9412, "*Authorization to Disclose PHI*"). For example, the authorization must describe the information to be used or disclosed, the purpose of the disclosure, and specify the time period in which the authorization is in effect.

1. An authorization for the use or disclosure of PHI for a specific research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of PHI for research.
2. UCLA Health System may condition the provision of research-related treatment on the provision of an authorization for the use or disclosure of PHI.
3. The statement "end of research study" or similar language is sufficient to describe the expiration event for the authorization to use PHI for research.
4. The statement "none" or similar language is sufficient to describe the expiration event if the authorization is for UCLA Health System to use or disclose PHI for the creation or maintenance of a research database or research repository.

A copy of UCLA Health System's authorization form for research purposes is attached hereto as Appendix 1 and is also available from UCLA's IRB office.

B. Individual May Revoke Authorization.

An individual may revoke his or her authorization for research. In this case, the researcher can continue to use and disclose PHI that was obtained prior to the time an individual revoked his or her authorization, as necessary to maintain the integrity of the research study and to the extent that UCLA Health System and/or the researcher have relied upon the authorization. The reliance exception would not, however, permit UCLA Health System to continue to disclose additional PHI to a researcher for its own research purposes if the information were not already gathered at the time an individual withdraws his or her authorization.

In any event, PHI may be disclosed to the researcher and sponsor for other purposes allowed by law without patient authorization, such as FDA notification of adverse events.

**III. Disclosure of PHI for Research Purposes That Do Not Require an Individual's Authorization**

UCLA Health System may disclose PHI to a researcher without patient authorization as follows:

- A. An IRB or Privacy Board has approved and certified a Waiver of Authorization (See Section IV, below);
- B. An IRB or Privacy Board has approved a research protocol using a Limited Data Set and a Data Use Agreement has been entered into between the researcher and UCLA Health System (*See* Section V below); or
- C. An IRB or Privacy Board has approved a protocol using De-Identified Data (*See*: Section VIII below).

Only the minimum necessary information as approved by the IRB shall be disclosed.

**IV. Waiver of Authorization for Research**

A. Boards with Authority to Waive.

UCLA Health System may use or disclose PHI for research, without an authorization from the individual to whom the PHI pertains, subject to certain approvals. UCLA Health System must obtain approval to waive the authorization, in whole or part, from an IRB established in accordance with federal law.

B. Criteria for Waiver of Individual Authorization.

The IRB or Privacy Board must make a determination that all of the following criteria for waiving individual authorization or altering the requirements of the individual authorization are met:

1. The use or disclosure of PHI must involve no more than minimal risk to the privacy of individuals, based on the presence of the following three elements:
  - a) There is an adequate plan to protect the identifiers from improper use or disclosure;
  - b) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or retention is required by law; and
  - c) There are adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity except as required by law, for authorization oversight of the research project, or for other research as permitted by the Privacy Rule;
2. The research cannot practicably be conducted without the alteration or waiver; and
3. The research cannot be conducted without access to and use of the PHI.

C. Review and Approval Procedures by a UCLA IRB.

The IRB must follow the requirements of the Common Rule for both normal and expedited review. The Common Rule is the rule for the protection of human subjects in research promulgated by the Department of Health and Human Services, and adopted by numerous federal government agencies, including the National Institutes for Health ("NIH") for research funded by those agencies.

Some agencies have requirements that supplement that Common Rule, and IRBs should determine if any additional provisions apply under any particular research contract or grant. Although privately funded drug and device trials are subject to a different regulatory scheme enforced by the FDA, if UCLA Health System seeks to waive individual authorization for drug and device research, it must use the Common Rule and not the FDA rules for waiver under this Privacy Rule provision.

D. Documentation of Approval of the Waiver.

The waiver of approval must be documented as follows:

1. Identification of the IRB and the date the action was taken;
2. A statement that the IRB has determined that the waiver of authorization satisfies the required waiver criteria;
3. A brief description of the PHI for which use or access has been determined to be necessary by the IRB; and
4. A statement that the waiver has been reviewed and approved under either normal or expedited review procedures.

The signature of the Chair or other member designated by the Chair of the IRB.

## V. Use and Disclosure of "Limited Data Sets"

The Privacy Rule permits the use and disclosure of a Limited Data Set in connection with research, public health or health care operations. PHI can be provided for research purposes without patient authorization if it is included in a limited data set, **and a Data Use Agreement has been completed with the Principal Investigator.**

The Limited Data Set may include:

1. Zip Code;
2. Date of birth and date of death, as appropriate;
3. Date(s) of service; and
4. Geographic subdivision (city).

The Limited Data Sets excludes the following 16 elements:

1. Names;
2. Postal address other than town or city, state and 5-digit zip code;
3. Telephone numbers;
4. Fax numbers;
5. Electronic 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 and serial numbers, including license plate numbers;
12. Device identifiers and serial numbers;
13. Web Universal Resource Locators (URL's);
14. Internet protocol (IP) address numbers;

15. Biometric identifiers, including voice and finger prints; and
  16. Full face photographic images and any comparable images.
- A. Must Enter into Data Use Agreement.

The Limited Data Set of PHI can be disclosed only if UCLA Health System enters into a Data Use Agreement with the recipient (researcher) of the Limited Data Set. The Data Use Agreement must do all of the following:

1. Establish the permitted uses and disclosures of the information for research purposes (public health and health care operations are other permitted purposes).
2. Not authorize the recipient to use or further disclose the information in a manner that would violate the privacy regulations if done by the UCLA Health System.
3. Establish who is permitted to use or receive the Limited Data Set.
4. Provide that the recipient will not use or disclose the information other than as permitted by the agreement or as required by law.
5. Require the recipient to use appropriate safeguards to prevent use or disclosure of the information other than as provided by the agreement.
6. Mandate the recipient to report to UCLA Health System any use or disclosure not permitted by the agreement of which the recipient becomes aware.
7. Require the recipient to ensure that any agent or subcontractor of the agent to whom the Limited Data Set is provided agrees to the same restrictions and conditions with respect to the information.
8. Require the recipient not identify the information or contact the individuals to whom it belongs.

A copy of UCLA Health System's Data Use Agreement is attached hereto as Appendix 2.

UCLA Health System will be considered to have itself violated the privacy regulations if it knows of a pattern or practice of the recipient is in violation or material breach of the Data Use Agreement, unless UCLA Health System takes reasonable steps to cure the breach or end the violation, and if unsuccessful, discontinues disclosure and reports the problem to the Secretary of the Department of Health and Human Resources.

## VI. Using De-Identified PHI for Research

Health information that does not identify an individual, and with respect to which there is no reasonable basis to believe that the information can be used to identify the individual, is not considered PHI. As such, UCLA Health System may always use or disclose for research purposes health information that has been de-identified in accordance with the Privacy Rule.

### A. De-Identification Standards.

In order to properly de-identify PHI, UCLA Health System must remove all of the identifiers specified in the Privacy Rule. Except as otherwise required by the IRB, the researcher shall be responsible for de-identifying the PHI in accordance with the following guidelines. The Privacy Rule requires the removal of the following identifiers with respect to the individual, his or her relatives, employers, and household members:

1. Names;
2. Dates of birth, death, admission and discharge (except year);
3. Postal address including city, state and zip code;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URL's);

15. Internet protocol (IP) address numbers;
16. Biometric identifiers, including voice and finger prints,
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic or code

After removing the identifiers, the information **cannot be released** if UCLA Health System has actual knowledge that the information used alone or in combination with other information could identify an individual.

Both California law and the Privacy Rule permit the disclosure of PHI to a third party for the purpose of de-identifying the data, so long as the third party does not further disclose the PHI or manipulate the de-identified data in a way that reveals individually-identifiable medical information.

**B. Obtaining an Expert Opinion of Minimum Risk ("Statistical Waiver").**

As an alternative to de-identification, UCLA Health System may seek an expert opinion that the disclosure of PHI would create minimal risk that the recipient would be able to identify the individual.

1. The expert must be a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable.
2. The expert must apply those principles and methods to determine that the risk is very small that the information could be used, alone or in combination with any other reasonably available information, by an anticipated recipient to identify the individual who is the subject of the information.
3. The expert must document the method and results of the analysis to justify the determination.

**C. UCLA Health System Must Control Re-Identification Codes.**

UCLA Health System can implement a code or key that will let it re-identify de-identified data, but the code or key must not be capable of being translated so as to identify the individual. Only UCLA Health System can use the code to re-identify the information; it may not disclose the code to any other person. For example, UCLA Health System could de-identify information in its data base or

create a limited data set to sell to researchers who want to conduct studies on the existing data, but it cannot provide the researcher with the key or code to re-identify the data for the purpose of contacting individuals either about the results of the study or to participate in new studies.

## VII. PHI May be Used or Disclosed for FDA Monitoring Purposes

UCLA Health System may disclose PHI **without patient authorization** for public health purposes, which includes disclosure to a person who is subject to FDA jurisdiction and who is responsible for quality safety or effectiveness of an FDA-regulated product or activity. Such activities include:

- A. Collecting or reporting adverse events, product defects or biological product deviations;
- B. Tracking FDA-regulated projects;
- C. Enabling product recalls, repairs, replacement or look back; or
- D. Conducting post-marketing surveillance.

## VIII. Disclosures Related To Adverse Events

A researcher may disclose PHI to the IRB, NIH, FDA, and research sponsors and to UCLA Health System or other entity as required by regulations or University policy. The possibility of the disclosure should be included in the terms of the original consent document signed by the research participants, in cases where the requirement for consent/authorization has not been waived by an IRB.

The Privacy Rule-defined "operations activities" of the IRB, such as quality assurance, monitoring, auditing, and reporting of adverse events require the IRB to use PHI in their role as a member of the University. The IRB will notify UCLA Health System of adverse events arising from research studies that involve patient care and have implications for patient safety.

## IX. Research Transition Provisions

- A. Protocols Approved Before April 14, 2003.

For protocols approved prior to April 14, 2003, UCLA Health System may contain to use or disclose PHI for research purposes as follows:

- 1. If a study is active prior to April 14, 2003, the pre-existing consent form approved by the IRB will comply with the authorization requirements for subjects already enrolled in the study.

2. New subjects who enter into the protocol on or after April 14, 2003 must sign an authorization in accordance with the Privacy Rule as an addendum to the consent form. The approved research authorization form (Appendix 1) must be utilized.

**B. New or Modified Protocols After April 14, 2003.**

If patients are enrolled in a new protocol or in a modified protocol on or after April 14, 2003, UCLA Health System may release PHI for research purposes with a valid authorization either as:

1. A separate authorization (which meets the requirements of the Privacy Rule) signed by the patient for the disclosure of PHI for research purposes as an addendum to the consent form; or
2. The Privacy Rule authorization language included in the consent form, with the authorization language in the consent form having a separate signature in addition to the consent form signature.

**X. Transition Provisions: IRB Waivers of Authorization**

For protocols approved prior to April 14, 2003, UCLA Health System may continue to use or disclose PHI for research purposes under a waiver approved by the IRB of informed consent for research in accordance with the Common Rule or the FDA regulations on the protection of human subjects.

If the PHI requested is beyond that originally approved in the IRB waiver of authorization, a new waiver of authorization in accordance with the Common Rule or the FDA regulations on the protection of human subject and the Privacy Rule must be obtained from the IRB.

**XI. Accounting of Disclosures of PHI for Research Purposes**

If requested by an individual whose PHI may have been disclosed for a research protocol, UCLA Health System must provide an accounting of those disclosures provided to a researcher under an IRB Waiver of Authorization.

The Health Information Management Services Department will include the disclosures made for research purposes in a centralized tracking system which shall include patient name(s), medical record number, a description of the PHI disclosed (including time frame of data), the IRB approval number, as well as the researcher's name and contact information. The tracking will also include the purpose of the study and the type of PHI sought and the date(s) of the disclosures.

**XII. Retrospective Research Studies Involving Data Re-Analysis**

When a researcher requests PHI from UCLA Health System or wants to use data already held by the researcher for purposes of retrospective research studies involving data re-

analysis, Health Information Management Services has the responsibility to determine whether the IRB-approved Waiver of Authorization or the patient's original Authorization (e.g., the stated purpose of the research or the authorized PHI) covers subsequent research analyses.

If UCLA Health System determines that previous legal permissions do not cover the re-analysis request, then the researcher must either obtain an IRB-approval for reanalysis using another authorization, waiver of authorization, a Limited Data Set, or deidentified data set.

### **XIII. Research Databases (including Tissue and Organ Banks and Organ Procurement Organizations)**

UCLA Health System may use PHI without patient Authorization for the creation of a research database, provided the IRB or researcher creating the research database provides UCLA Health System with documentation that the IRB has determined that a specified Waiver of Authorization criteria were satisfied. UCLA Health System can use or disclose PHI maintained in the research for future research studies as permitted by the Privacy Rule (i.e., pursuant to an individual's Authorization or an IRB-approved Waiver).

If the data base was created prior to April 14, 2003 without the individual's legal permission or a Waiver of Consent from the IRB, the PHI contained in the database may be only used for research purposes either with individual Authorization or an IRB-approved Waiver after April 14, 2003.

An Organ Procurement Organization may only receive PHI without patient authorization for the purpose of facilitating organ, eye, or tissue donation and transplantation. Research conducted on tissue obtained from a living donor requires an IRB-approved protocol.

### **XIV. Disclosures to Registries**

UCLA Health System must disclose PHI to registries if mandated by the FDA or required or permitted by the Privacy Rule or other State or federal law. UCLA Health System may disclose PHI for research purposes to a registry, including those sponsored by academic and non-profit organizations, if such disclosure is:

- A. Made pursuant to a UCLA IRB-approved Waiver of Authorization; or
- B. Made pursuant to the individual's authorization; or
- C. Consists of a limited data set or de-identified data and disclosure of a limited data set requires a Data Use Agreement to restrict further disclosure or violation of California law.

## **XV. Clinical Laboratories that Participate in Research**

All University of California clinical laboratories are, in the performance of certain functions, subject to the Privacy Rule requirements for disclosing PHI to a researcher for purposes of a University IRB-approved research protocol. In contrast, when the analysis of the data containing PHI is for the purposes of conducting quality assurance, this function is considered part of UCLA Health System’s health care operations and no specific authorization or research approval is required.

## **XVI. Patient’s Right to Access PHI Created in a Research Trial**

PHI created as part of a research protocol and maintained as part of UCLA Health System’s designated record set<sup>a</sup> is accessible to the research participant with the following exception: UCLA Health System may suspend the individual’s right to access the information created or obtained by UCLA Health System for a clinical trial while the clinical trial is in progress, provided the research participant agreed to this denial or access when consenting to participate in the trial. The researcher/health care provider must inform the individual that access will be reinstated at the conclusion of the trial.

## **XVII. Re-disclosure of PHI by Third Parties**

In order to offer research subjects reassurances that their PHI will remain confidential even after disclosure to a third party, UCLA Health System should endeavor to gain assurance from the study sponsor that PHI will not be re-disclosed for purposes other than that for which it was collected or created. When research sponsors will not agree to protect PHI from re-disclosure, the Privacy Rule requires that the research authorization specifically state that confidentiality may be lost when research is disclosed to a third party.

## **PROCEDURE**

### **I. Request to be Submitted by Principal Investigator to Privacy Management Office**

- A. The Principal Investigator requesting the PHI must forward the following documents to Health Information Management Services:
  1. Copy of the Letter of Approval of the Protocol from the IRB; and
  2. The original signed “Request for Release of Patient Identifiable Information from Data Repositories ([Appendix 3](#)) specifying data selection criteria, and preferred format for receipt of data.
- B. The request must also be accompanied by one of the following (otherwise only de-identified data will be provided):

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<sup>a</sup> “Designated record set” includes medical records and billing records about individuals and maintained by UCLA Health System.

1. A copy of the IRB Waiver Approval;
  2. A signed patient authorization; or
  3. A Data Use Agreement (if request is for a Limited Data Set) approved by the IRB (*see*: [Appendix 2](#)).
- C. In some situations, the Limited Data Set or de-identified dataset can only be created from abstracting data from the full medical record. In those situations, a designated member of the workforce may create the dataset provided the following documentation has been provided:
1. Certification of completion of Basic Privacy Rule Training;
  2. Certification of completion of the Research specific Privacy Rule training; or
  3. Completed and signed Confidentiality Agreement ([Appendix 4](#)).

## II. Verification by Health Information Management Services

The request will be reviewed by Health Information Management Services to ensure that the requested data elements complies with the description of PHI for which the IRB has issued the authorization waiver, or complies with the approved data use agreement. Health Information Management Services will track requests.

### A. Authorization Verification

Health Information Management Services shall follow special verification procedures when the research requested is to be released pursuant to a patient authorization. Health Information Management Services shall:

1. Validate the authorization. Expiration date can be indicated as "none" or as "at end of research study";
2. Enter the authorization into the PHI Tracking system and scan the authorization form; and
4. Provide the information as specified on the patient's authorization to the researcher.

## III. Provision of Information to the Researcher

Once verified by the Director of Health Information Management Services or directly by the database owner, Health Information Management Services will coordinate the download of the approved data from the UCLA Health System data repositories with the data repository owner and will provide the information to the Principal Investigator. Aggregate data will be provided electronically or will be downloaded to recordable medium such as a disk or CD. The information will be protected by a password or other approved security measures.

#### **IV. Documenting Disclosures**

The disclosures of the PHI provided under an IRB Waiver approval will be recorded in the UCLA PHI Tracking database by patient, and included in any of the applicable patient's requests for an accounting of disclosures from their Designated Record Set.

#### **FORMS:**

- Appendix 1 – Research Authorization Form
- Appendix 2 – Data Use Agreement
- Appendix 3- Confidentiality Statement Form A - UC
- Appendix 4 – Confidentiality Statement Form B- Non-UC

#### **REFERENCES**

Health Insurance Portability and Accountability Act, 45 CFR 160-164  
California Medical Information Act, California Civil Code Section 56 *et seq.*

#### **REVISION HISTORY**

Approved: April 8, 2003  
Effective Date: April 14, 2003  
Revised Date: April 21 2008

#### **APPROVAL**

HIPAA Committee

Hospital Policy Committee

Carole A. Klove, JD, RN  
Chief Compliance and Privacy Officer

**Appendix 1****Authorization for Release of Personal Health Information and Use of Personally Unidentified Study Data for Research**

**Study Title (or IRB Number if study title may breach subject's privacy):**

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**Sponsor/Funding Agency:** \_\_\_\_\_

**XVII. A. Introduction:**

The federal privacy law called the Health Insurance Portability and Accountability Act (HIPAA) requires you to give your permission for \_\_\_\_\_\* to release your Personal Health Information to the research team and others so that you can participate in this study. This form describes the different ways that the researcher, research team and the research sponsor may use your Personal Health Information for the research study. You must sign this form to participate in the study.

**XIII. B. RELEASE OF PERSONAL HEALTH INFORMATION**

If you agree to participate in this research study and sign this form, you are authorizing \_\_\_\_\_\* to release the following Personal Health Information. Your Personal Health Information contains specific health information about you and information that identifies you. For example, Personal Health Information may include your name, address, phone number and social security number.

**XVIII. C. Description of Your Health Information to be Released (check one or more):**

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Entire Medical Record          | <input type="checkbox"/> Laboratory Reports    | <input type="checkbox"/> Emergency Medicine Center Reports |
| <input type="checkbox"/> Health Care Billing Statements | <input type="checkbox"/> Dental Records        | <input type="checkbox"/> History & Physical Exams          |
| <input type="checkbox"/> Pathology Reports              | <input type="checkbox"/> Operative Reports     | <input type="checkbox"/> Diagnostic Imaging Reports        |
| <input type="checkbox"/> EKG                            | <input type="checkbox"/> Radiology Reports     | <input type="checkbox"/> Consultations                     |
| <input type="checkbox"/> Progress Notes                 | <input type="checkbox"/> Radiologic & MR Scans | <input type="checkbox"/> Outpatient Clinic Records         |
|   | <input type="checkbox"/> Discharge Summary     | <input type="checkbox"/> Psychological Tests               |
| <input type="checkbox"/> Other _____                    |  |  |

**D. \_\_\_\_\_\* May Release Personal Health Information to These People or Organizations for the Following Purposes:**

1. To the researcher and members of the research team for the research purposes described in the attached Informed Consent Form, and to other individuals at UC who oversee the research, including the human research ethics review board;
2. To the Food and Drug Administration (FDA), to the research sponsor or the sponsor's representatives, or to other government agencies in the U.S. and other countries, as required by law to monitor the quality, safety or effectiveness of the study. These organizations and their representatives may see your Personal Health Information, but they may not copy or take it from your medical record unless permitted or required by law;
3. Once your Personal Health Information is released, it may be redisclosed and not protected by HIPAA. Your Personal Health Information may be protected under other state or federal privacy

laws. The research team will protect your information as described in the attached Informed Consent Form and will comply with the requirements of all applicable laws that protect the confidentiality of your Personal Health Information.

#### **XIX. E. Specific Authorizations**

The following information will not be released unless you put **your initials** on the specific line(s).

\_\_\_\_\_ I specifically authorize the release of information pertaining to drug and alcohol abuse, diagnosis or treatment (42 C.F.R. §§2.34 and 2.35).

\_\_\_\_\_ I specifically authorize the release of HIV/AIDS testing information (California Health and Safety Code §120980(g)).

\_\_\_\_\_ I specifically authorize the release of information pertaining to mental health diagnosis or treatment (California Welfare and Institutions Code §§5328, *et seq.*) as follows: \_\_\_\_\_ -

\_\_\_\_\_ I specifically authorize the release of genetic testing information (California Health and Safety Code §124980(j)).

#### **XIV. F. USE AND RELEASE OF PERSONALLY UNIDENTIFIED STUDY DATA**

If you agree to participate in this research study, the research team, the research sponsor and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does **not** include your name, address, telephone or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others in the following ways:

1. To perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, use it to improve the design of future studies, and publish it in scientific journals; or
2. To share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

#### **XX. G. Expiration**

This Authorization to release Personal Health Information will expire at the end of the research study and the conclusion of all required study monitoring. The use of the Personally Unidentified Study Data has no expiration date.

#### **XXI. H. Revoking Authorization**

You can cancel ("revoke") this Authorization at any time. To cancel this Authorization, write to the researcher identified in the attached Informed Consent Form, or ask a member of the research team to give you a form to revoke the Authorization. If you cancel this Authorization, you may not be able to continue to participate in the research study. Also, you may not be eligible for medical treatment related to the research study. You may want to discuss with the research team the effect on your medical treatment of canceling this Authorization. If you cancel the Authorization, information that was collected about you may continue to be used. Also, the sponsor and government agencies may continue to see your medical records to monitor the research that was done before you cancelled the Authorization.

#### **XXII. I. Authorization**

By signing this Authorization you agree that you have been given the opportunity to ask questions and you agree to the release of your Personal Health Information and to the use and release of the Personally Unidentified Study Data as described in this form. If you have questions, you may contact the researcher. You will be given a signed copy of this Authorization.

---

Subject's Name (print)

---

Subject's Signature

Date

*For Minor Subjects or For Adults Incapable Of Giving Consent (where IRB approved):*

---

Legally Authorized Representative's Name (print)

Relationship to the Subject

---

Representative's Signature

Date

***\* Insert the name of the covered entity (the holder of the medical records), e.g., campus, medical center, clinic.***

## Appendix 2 – Data Use Agreement

*[Insert Name and Address of Data Recipient]*

**Re: Data Use Agreement**

Dear \_\_\_\_\_:

The federal Health Insurance Portability and Accountability Act and the regulations promulgated thereunder (collectively referred to as the “Privacy Rule”) permit the use and disclosure by UCLA Health System of certain information that may include Protected Health Information (“PHI”), in connection with research, public health or health care operations.

UCLA desires to disclose or make available to you (“Data Recipient”) certain limited information, some of which may include PHI, for the purposes of research, public health or health care operations in a manner that protects the privacy and security of such information.

This Data Use Agreement (“Agreement”) is required by the Privacy Rule and sets forth the terms and conditions pursuant to which UCLA will disclose PHI contained in a Limited Data Set (“LDS Information”) to you in accordance with and as allowed by the Privacy Rule.

### 1. **Definitions.**

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy Rule.

***1.1 “Limited Data Set” is a data set of Protected Health Information (“PHI”) that excludes the following direct identifiers (as set forth in 45 C.F.R. section §164.514(b)(2)(i)):***

- 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; and
  - q. Any other unique identifying number, characteristic, or code.
- 1.2 “Protected Health Information” or “PHI” means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental 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 (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under the Privacy Rule, including, but not limited to 45 C.F.R. §164.501.

## 2. Use of Limited Data Set Information.

- 2.1 Requested Limited Data Set Information. Data Recipient requests copies of the LDS Information identified in Exhibit A.
- 2.2 Intended Use of LDS Information. Under the Privacy Rule, the use and disclosure of a limited data set in connection with research, public health, or health care operations is permitted without the patient’s written authorization. Data Recipient represents that he or she requires the LDS Information for the purposes described in Exhibit B.
- (a) Research. If the LDS Information is intended to be used for research purposes, the Data Recipient must have had Exhibit B reviewed and approved by the applicable UCLA IRB.
  - (b) Public Health. If the LDS Information is intended to be used for public health purposes, the Data Recipient must have had Exhibit B reviewed and approved by the UCLA Health System Privacy Officer.
  - (c) Health Care Operations. If the LDS Information is to be used for health care operations, the Data Recipient must have had Exhibit B reviewed and approved by the UCLA Health System Privacy Officer.

## 3. Release of Information.

- 3.1 Procedure. Upon confirmation by Health Information Management Services (HIMS) of Data Recipient’s compliance with all UCLA Health System (and if applicable, UCLA IRB) approvals/requirements relating to the release of the LDS Information, HIMS shall either: (a) provide the Limited Data Set to the Data Recipient; or (b) make available the information necessary for the Data Recipient to create the Limited Data Set.
- 3.2 Creation of the Limited Data Set. In accordance with the requirements contained in the Privacy Rule, the Limited Data Set created under this Agreement shall not

include any of the Direct Identifiers identified in Section 1.1 above.

- a. By HIMS. HIMS will create the LDS Information identified in Exhibit A when the data is available in abstracted format from currently existing UCLA databases. In these cases, the UCLA database owner will abstract the LDS Information from the database.
- b. By Data Recipient. If the data is not available in an electronic format, the Data Recipient may create the Limited Data Set from a manual abstraction process from paper records. Data Recipient acknowledges and agrees that neither the Data Recipient nor any person assisting Data Recipient in the abstraction process shall be provided access to PHI unless they have completed all applicable HIPAA training (as evidenced by a HIPAA training certificate); and (2) have signed the Confidentiality Agreement attached hereto as Exhibit C.

#### **4. Responsibilities of Data Recipient.**

- 4.1 Permitted Uses and Disclosures. Data Recipient may use the LDS Information received from UCLA pursuant to the Agreement solely for the purpose identified on Exhibit B. Data Recipient will not use or disclose the LDS Information other than as permitted by this Agreement or as required by law.
- 4.2 No Further Use. Data Recipient is not authorized and shall not use or further disclose the LDS Information other than as permitted under the Agreement or as required by law or regulation.
- 4.3 Safeguards. Data Recipient shall use appropriate administrative, technical and physical safeguards to prevent any use or disclosure of the LDS Information other than as provided for by the Agreement.
- 4.4 Reporting of Disclosures. Data Recipient shall notify the UCLA Health System Privacy Officer (and if the LDS Information is to be used for research purposes, the IRB) in writing within five (5) working days of its discovery of any use or disclosure of the LDS Information not permitted by this Agreement of which Data Recipient, or employees or agents under the supervision of Data Recipient become aware. The Privacy Officer shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.
- 4.5 Redisclosure of Limited Data Set. Data Recipient shall ensure that any person or entity to whom it provides the LDS Information, which may include but is not limited to, research assistants, shall agree with the Data Recipient in writing (by signing the Confidentiality Agreement attached hereto as Exhibit C or when the LDS is provided to a research collaborator or sponsor under a sponsored research agreement, by signing an appropriate agreement negotiated by the Office of Contract and Grant Administration) that the person or entity will hold the LDS

Information confidentially and use or disclose the LDS Information only as required for the purpose it was used or disclosed to the person or entity or as required by law.

Additionally, the person or entity receiving the LDS Information shall notify Data Recipient of any instances of which it is aware in which the confidentiality of the LDS Information has been breached.

- 4.6 No Identification or Contact. Data Recipient agrees that it shall not use the LDS Information in such a way to identify any individual and shall not use any LDS Information to contact any individual(s) to whom the LDS Information relates.
- 4.7 Compliance with Law and UCLA (and if applicable, IRB) Policies and Procedures. Data Recipient shall comply with all applicable federal and state laws and regulations, including the Standards for Electronic Transactions and the Standards for Privacy of Individually Identifiable Health Information 45 CFR Parts 160, 162, and 164, if applicable under the terms and requirements of this Agreement. Data Recipient shall also comply with all applicable UCLA and IRB policies and procedures.
- 4.8 Regulatory Compliance. Data Recipient shall make its internal practices, books and records relating to the use and disclosure of PHI received from UCLA available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining UCLA's compliance with the Privacy Rule.
- 4.9 Inspection of Records. As requested by UCLA, Data Recipient shall cooperate with any request by UCLA to make available to UCLA during normal business hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of UCLA's PHI contained in the LDS for purposes of enabling UCLA to determine Data Recipient's compliance with the terms of this Amendment.

## 5. Term and Termination.

- 5.1 Term. The provisions of this Agreement shall be effective as of the date this Agreement is signed by both parties and Data Recipient's research has been approved by the IRB and shall terminate when all of the Limited Data Set provided by UCLA to Data Recipient is destroyed or returned to UCLA, or, if it is not feasible to return or destroy the Limited Data Set, Data Recipient continues to protect/safeguard such information in accordance with the termination provisions in this section.
- 5.2 Material Breach. A breach by Data Recipient of any material provision of this Amendment, as determined by UCLA, shall constitute a material breach of the Agreement, and shall provide grounds for immediate termination of this

Agreement by UCLA. Any breach of this Agreement will be reported by UCLA to UCLA Health System's Privacy Officer (and if applicable, to the appropriate UCLA IRB) and may also be reported by UCLA to the Secretary of the Department of Health and Human Services.

- 5.3 Effect of Termination. Upon termination of the Agreement for any reason, Data Recipient shall return or, at the option of UCLA, destroy all PHI received from UCLA, or created and received by Data Recipient that Data Recipient still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, Data Recipient shall continue to extend indefinitely the protections of this Amendment to such information, and immediately terminate any further use or disclosure of such PHI.

This Agreement, together with its exhibits, constitutes the entire agreement between us. This Agreement may be amended by UCLA upon notice to you in order to comply with any applicable federal or state laws or regulations.

If the terms and conditions of this Agreement are acceptable to you, please sign a copy of this Agreement in the space below and return a copy to us.

Sincerely,

Carole A. Klove, RN, JD  
Compliance and Privacy Officer

Janet Hoffberg  
Director, Medical Records

**ACCEPTED AND AGREED TO BY:**

**Data Recipient**

\_\_\_\_\_  
(Print Name)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

**EXHIBIT A**

**LIMITED DATA SET INFORMATION**

**EXHIBIT B**  
**INTENDED USE OF LIMITED DATA SET INFORMATION**

*PLEASE COMPLETE EACH SECTION THAT APPLIES:*

\_\_\_ **Research**

Description of Research: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

IRB Approval Number: \_\_\_\_\_

Intended disclosure of LDS Information to third parties (e.g., research assistants, collaborators)?

\_\_\_ Yes \_\_\_ No

If yes, please identify individuals to receive LDS Information:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_ **Public Health Purposes**

Description of Activity: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Intended disclosure of LDS Information to third parties (e.g., research assistants, collaborators)?

\_\_\_ Yes \_\_\_ No

If yes, please identify individuals to receive LDS Information:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_ **Health Care Operations**

Description of Activity: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Intended disclosure of LDS Information to third parties (e.g., research assistants, collaborators)?

\_\_\_ Yes \_\_\_ No

If yes, please identify individuals to receive LDS Information:

\_\_\_\_\_  
\_\_\_\_\_

**Appendix 3****CONFIDENTIALITY AGREEMENT****FORM A – TO USE WITH UC EMPLOYEES**

The federal Health Insurance Portability and Accountability Act ("HIPAA") and its regulations, the California Confidentiality of Medical Information Act and other federal and state laws and regulations were established to protect the confidentiality of medical and personal information, and provide, generally, that patient information may not be disclosed except as permitted or required by law or unless authorized by the patient. These medical privacy laws and regulations apply to all members of the UCLA Health System workforce including faculty, staff, residents, fellows, medical and other health sciences students and volunteers.

In certain circumstances, HIPAA allows members of the University's workforce to use and disclose a limited data set of health information in order to carry out research, public health, or health care operations activities without obtaining the patient or subject's authorization. Likewise, HIPAA allows the workforce member to create that limited data set of health information using the medical record or other PHI so long as the workforce member signs this Confidentiality Agreement and agrees to reasonably safeguard all health information used and disclosed for these purposes.

1. As a member of the UCLA Health System workforce, I understand that I may be working with confidential medical and other sensitive or private information. This information may include, but is not limited to, medical records, personnel information, ledgers, verbal discussions, and electronic communications including e-mail.
2. I understand and acknowledge that HIPAA requires that I obtain training on the requirements of HIPAA and UCLA Health System's policies and procedures relating to protection of confidential patient information, and I agree to obtain all required training before I access, use or disclose any confidential patient information.
3. I acknowledge that it my responsibility to respect the privacy and confidentiality of patient and other confidential information. I will not access, use or disclose patient or other confidential information unless I do so in the course and scope of fulfilling my duties as a member of the UCLA Health System workforce. I understand that I am required to immediately report any information about unauthorized access, use or disclosure of confidential patient information to the UCLA Health System Privacy Officer.
4. I understand and acknowledge that, should I breach any provision of this agreement, I may be subject to civil or criminal liability and disciplinary action consistent with applicable UCLA Health System policies and procedures including those concerning access, use and disclosure of such information and disciplinary policies.
5. I understand that on occasion I may seek access to a limited data set of information for the purposes of research (including the creation of research data bases), public health or

health care operations and may be responsible for creating a limited data set. These activities may be for my own purposes or that of another member of the University's workforce. I may only create a limited data set for research purposes with the approval of the Institutional Review Board ("IRB"). Health care operations may include teaching activities such as undergraduate medical education or providing continuing medical education ("CME") courses. Another use of limited data sets would be to convert existing patient data bases into a data base that may be used for teaching or research purposes in compliance with HIPAA and other laws.

6. A limited data set is created using protected health information and requires that certain individual identifiers including names, all addresses other than town, city, and zip code, and all unique identifying numbers have been removed.
7. I understand that I may not use or further disclose the limited data set for purposes other than for the purposes set forth in the Data Use Agreement. I will use appropriate safeguards to prevent use or disclosure of the information other than as provided for in this agreement. I will report to the UCLA Health System Privacy Officer (and if the LDS Information is to be used for research purposes, the IRB) and any use or disclosure of the information not provided for in this agreement. I will not attempt to identify the information or contact the subjects of the information.

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(Signature)

---

(Print Name)

---

(Date)

**Appendix 4****CONFIDENTIALITY AGREEMENT****FORM B – TO USE WITH NON-UC EMPLOYEES**

This Confidentiality Agreement (“Agreement”) is entered into between The Regents of the University of California, on behalf of its Los Angeles campus, School of Medicine and Medical Center (“UCLA”) and \_\_\_\_\_, and \_\_\_\_\_ individual/corporation (“User”).

The federal Health Insurance Portability and Accountability Act and the regulations promulgated thereunder (collectively referred to as the “Privacy Rule”) permit the use and disclosure by UCLA of certain information that may include Protected Health Information (“PHI”), in connection with research, public health or health care operations provided that: (1) the PHI is de-identified to meet the requirements of a Limited Data Set; (2) the Limited Data Set recipient enters into a Data Use Agreement with UCLA; and (3) the recipient of the Limited Data Set ensures that any person or entity to whom it provides the Information, such as User, agrees in writing that the agent or subcontractor will hold the Information confidentially and use or disclose the Information only as required for the purpose it was used or disclosed to the agent or subcontractor or as required by law.

UCLA and/or its employee(s) (referred to hereafter as “UCLA Workforce Member”) desires to disclose or make available to User certain Protected Health Information that is contained in a Limited Data Set for the purposes of research, public health or health care operations in a manner that protects the privacy and security of such information.

This Agreement sets forth the terms and conditions under which any confidential information may be disclosed by the UCLA Workforce Member to User and protected from disclosure to third parties.

In consideration of the mutual promises made below, the parties agree as follows:

1. Definitions.

***1.1 “Limited Data Set” is a data set of Protected Health Information (“PHI”) that excludes the following direct identifiers (as set forth in 45 C.F.R. section §164.514(b)(2)(i)):***

- 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; and
- p. Full face photographic images and any comparable images; and**
- q. Any other unique identifying number, characteristic, or code.**

- 1.2 "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental 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 (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including, but not limited to 45 CFR Section 164.501. The purpose of this Amendment is to satisfy certain standards and requirements of HIPAA and the HIPAA Regulations, including, but not limited to, Title 45, Section 164.504(e) of the Code of Federal Regulations ("CFR"), as the same may be amended from time to time.

## 2. Responsibilities of User.

- 2.1 Permitted Uses and Disclosures. User may use the LDS Information received from UCLA pursuant to this Agreement solely for the purpose identified on Exhibit A. User will not use or disclose the Information other than as permitted by this Agreement or as required by law.
- 2.2 No Further Use. User is not authorized and shall not use or further disclose the information other than as permitted under this Agreement or as required by law or regulation.
- 2.3 Safeguards. User shall use appropriate administrative, technical and physical safeguards to prevent any use or disclosure of the information other than as provided for by this Agreement.
- 2.4 Reporting of Disclosures. User shall notify the UCLA Health System Privacy Officer (and if the LDS Information is to be used for research purposes, the IRB) in writing within five (5) working days of its discovery of any use or disclosure of the Information not permitted by the Agreement of which User, its employees or agents become aware. The Privacy Officer shall take (i) prompt corrective action to cure any deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations.

- 2.5 Agents. User shall ensure that any person or entity to whom it provides the LDS Information shall agree with the User in writing to be bound by the same restrictions, terms and conditions that apply to User under this Agreement.

Additionally, the agent or subcontractor shall notify User of any instances of which it is aware in which the confidentiality of the LDS Information has been breached.

- 2.6 No Identification or Contact. User agrees that it shall not use the LDS Information in such a way to identify any individual and shall not use any LDS Information to contact any individual(s) to whom the Information relates.
- 2.7 Compliance with Law and UCLA (and if applicable, IRB) Policies and Procedures. User shall comply with all applicable federal and state laws and regulations, including the Standards for Electronic Transactions and the Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160, 162 and 164, if applicable under the terms and requirements of this Agreement. User shall also comply with all applicable UCLA and IRB policies and procedures.
- 2.8 Regulatory Compliance. User shall make its internal practices, books and records relating to the use and disclosure of PHI received from UCLA available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining UCLA's compliance with the Privacy Rule.
- 2.9 Inspection of Records. As requested by UCLA, User shall cooperate with any request by UCLA to make available to UCLA during normal business hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of UCLA's PHI contained in the LDS for purposes of enabling UCLA to determine User's compliance with the terms of this Amendment.

### 3. Term and Termination

- 3.1 Term. The provisions of this Agreement shall be effective as of the date this Agreement is signed by both parties and User's research has been approved by the IRB and shall terminate when all of the Limited Data Set provided by UCLA to User is destroyed or returned to UCLA, or, if it is not feasible to return or destroy the Limited Data Set, User continues to protect/safeguard such information in accordance with the termination provisions in this section.
- 3.2 Material Breach. A breach by User of any material provision of this Amendment, as determined by UCLA, shall constitute a material breach of the Agreement, and shall provide grounds for immediate termination of this Agreement by UCLA. Any breach of this Agreement will be reported by UCLA to UCLA Health System's Privacy Officer (and if applicable, to the appropriate UCLA IRB) and

may also be reported by UCLA to the Secretary of the Department of Health and Human Services.

- 3.3 Effect of Termination. Upon termination of the Agreement for any reason, User shall return or, at the option of UCLA, destroy all PHI received from UCLA, or created and received by User that User still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, User shall continue to extend indefinitely the protections of this Amendment to such information, and immediately terminate any further use or disclosure of such PHI.

4. Indemnification and Insurance.

- 4.1 Indemnification. User agrees to defend at UCLA's election, indemnify, and hold harmless UCLA, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses, (including costs and reasonable attorneys' fees) or claims for injury or damages that are caused by or result from the acts or omissions of User, its officers, agents or employees with respect to the use and disclosure of UCLA's PHI.

- 4.2 Insurance. User, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force, and maintain insurance as follows:

- a. Comprehensive or Commercial Form General Liability Insurance (contractual liability included) with limits as follows:
- |  |         |
|--|---------|
| (1) Each Occurrence  | \$_____ |
| (2) Products/Completed Operations Aggregate                      | \$_____ |
| (3) Personal and Advertising Injury                              | \$_____ |
| (4) General Aggregate (Not applicable to the Comprehensive Form) | \$_____ |

If the above insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement.

- b. Professional Liability Insurance with a limit of dollars (\$) per occurrence. If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement.
- c. Workers' Compensation as required by California State law. It should be expressly understood, however, that the coverage and limits referred to under a., and b. above shall not in any way limit the liability of the User. The User shall furnish the University with certificates of insurance

evidencing compliance with all requirements prior to commencing work under this Agreement. Such certificates shall:

- (1) Provide for thirty (30)-days advance written notice to the University of any modification, change, or cancellation of any of the above insurance coverage.
- (2) Indicate that The Regents of the University of California has been endorsed as an insured under the coverage referred to under a., b., and c.
- (3) Include a provision that the coverage will be primary and will not participate with nor be excess over any valid and collectible insurance or program of self-insurance carried or maintained by the University.

It should be further understood that the provisions under (2) and (3) above shall only apply in proportion to and to the extent of the negligent act or omissions of the User, its officers, agents, or employees.

5. Miscellaneous Provisions.

5.1. No Third Party Beneficiaries. Nothing express or implied in this Amendment is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than UCLA, User and their respective successors or assigns.

5.2. Notice to Secretary. If UCLA knows of a pattern of activity or practice of User that constitutes a material breach or violation of User’s obligation under this Amendment, if the breach or violation continues, and if termination of this Amendment is not feasible, UCLA is required by the HIPAA regulations to report the problem to the Secretary of Health and Human Services.

5.3. Survival. The obligations of User under Sections 2 and 4 of this Agreement shall survive the termination of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement by their duly authorized representatives.

The Regents of the University of California  
on behalf of UCLA Health System  
("UCLA")

\_\_\_\_\_

("User")

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_