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Release of Protected Health Information (“PHI”) for Research Purposes Policy, HS 9440

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:

1. An IRB or Privacy Board has approved and certified a Waiver of Authorization (See Section IV, below);
2. 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
3. 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

1. 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.

2. 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:
 - i. There is an adequate plan to protect the identifiers from improper use or disclosure;
 - ii. 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
 - iii. 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.

3. 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.

4. 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.

1. 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.

2. **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.

3. **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:

1. Collecting or reporting adverse events, product defects or biological product deviations;
2. Tracking FDA-regulated projects;
3. Enabling product recalls, repairs, replacement or look back; or
4. 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**

1. **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.

2. **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:

1. Made pursuant to a UCLA IRB-approved Waiver of Authorization; or
2. Made pursuant to the individual's authorization; or
3. 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 set¹ 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):
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.

1. **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
3. 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.*

APPROVAL

HIPAA Committee
Hospital Policy Committee
Carole A. Klove, JD, RN
Chief Compliance and Privacy Officer

^a “Designated record set” includes medical records and billing records about individuals and maintained by UCLA Health System.

EXHIBIT A

LIMITED DATA SET INFORMATION

Attachments

- 2: [Data Use Agreement](#)
- 1: [Authorization for Release of Personal Health Information and Use of Personally Unidentified Study Data for Research](#)
- B: [Intended Use of Limited Data Set Information](#)
- 4: [Confidentiality Agreement Form B – To Use with Non-UC Employees](#)
- 3: [Confidentiality Agreement Form A – To Use with UC Employees](#)