

UCLA Health System Data Use Agreement

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; Initials
- 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 authorized IRB as determined by the UCLA Health System Chief Privacy Officer.
- (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 Chief 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 Chief Privacy Officer.

3. Release of Information.

- 3.1 Procedure. Upon confirmation by the UCLA Health System Health Information Management Services-Release of Information Department ("HIMS-RIO") of Data Recipient's compliance with all UCLA Health System (and if applicable, UCLA authorized IRB as determined by the UCLA Health System Chief Privacy Officer) approvals/requirements relating to the release of the LDS Information, the HIMS-RIO 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-RIO. The HIMS-RIO 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 Chief 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 Chief 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.

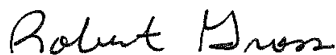
- 5.1 Term. The provisions of this Agreement shall be effective as of the date this Agreement is signed by both parties and Data Recipient's research has been approved by the IRB and shall terminate when all of the Limited Data Set provided by UCLA to Data Recipient is destroyed or returned to UCLA, 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 Chief Privacy Officer (and if applicable, to the appropriate UCLA authorized IRB as determined by the UCLA Health System's Chief Privacy Officer) 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,



Chief Privacy Officer

ACCEPTED AND AGREED TO BY:

Data Recipient

(Print Name)

(Signature)

(Home Institution)

(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: _____

Name of Approving IRB: _____

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:

EXHIBIT C

CONFIDENTIALITY AGREEMENT

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 _____, an _____ 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; Initials
- 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 Chief 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 Chief 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 Chief Privacy Officer (and if applicable, to the appropriate UCLA authorized IRB as determined by the UCLA Health System Chief Privacy Officer) 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")

