

FORM APPROVED COUNTY COUNSEL
 BY: GREGORY P. PRIAMOS
 DATE: 9/25/14

Departmental Concurrence

**SUBMITTAL TO THE BOARD OF SUPERVISORS
 COUNTY OF RIVERSIDE, STATE OF CALIFORNIA**

806



FROM: Riverside County Regional Medical Center

SUBMITTAL DATE:
 September 18, 2014

SUBJECT: Approval of the Participation Agreement with the California Maternal Quality Care Collaborative. Districts: All [\$0]

RECOMMENDED MOTION: That the Board of Supervisors:
 1. Approve and authorize the Chairman to execute the attached Participation and Business Associate Agreement with the California Maternal Quality Care Collaborative (CMQCC).

BACKGROUND:

Summary

Effective January 2013 Riverside County Regional Medical Center joined the CMQCC at Stanford University to provide data as part of a Quality Improvement Collaborative. This focus of this collaborative is to gather data related to high blood pressure during pregnancy. The attached updated agreement has been requested by CMQCC to better define the terms of the obligations of both parties and compliance with HIPAA requirements.

Lowell Johnson
 Lowell Johnson
 Chief Executive Officer

FINANCIAL DATA	Current Fiscal Year:	Next Fiscal Year:	Total Cost:	Ongoing Cost:	POLICY/CONSENT (per Exec. Office)
COST	\$ 0	\$ 0	\$ 0	\$ 0	Consent <input type="checkbox"/> Policy <input checked="" type="checkbox"/>
NET COUNTY COST	\$ 0	\$ 0	\$ 0	\$ 0	

SOURCE OF FUNDS: Enterprise Funds
Budget Adjustment: NO
For Fiscal Year: 2014/2015

C.E.O. RECOMMENDATION: APPROVE

BY: *Debra Cournoyer*
 Debra Cournoyer

County Executive Office Signature

MINUTES OF THE BOARD OF SUPERVISORS

- A-30
- 4/5 Vote
- Positions Added
- Change Order

Prev. Agn. Ref.: 2/26/13 3.55 | District: All | Agenda Number:

3-28

Impact on Residents and Businesses

This service impacts the patients residing in Riverside County receiving care from Riverside County Regional Medical Center (RCRMC).

Contract History and Price Reasonableness

On February 26, 2013, agenda item no. 3.55, the Board approved the CMQCC initial participation fee of \$7000 and the agreement to provide performance metrics data on maternity services provided at RCRMC. CMQCC has no plans to institute additional participation fees for these tools and guidelines. In the event future fees are required, all hospitals will be provided an opportunity to determine if they will continue to participate in this collaborative.

California Maternal Quality Care Collaborative Participation Agreement

This agreement (the "Participation Agreement") is entered into by and between County of Riverside (the "Participant") and The Board of Trustees of the Leland Stanford Junior University, on behalf of the California Maternal Quality Care Collaborative / California Perinatal Quality Care Collaborative within the School of Medicine ("CMQCC" or "the Collaborative"), as of _____ (the "Effective Date").

CMQCC, through its Executive Committee and the Steering Committee of the California Maternal Data Center ("CMDC"), has established a statewide reporting program to collect hospital-level performance data on California maternal and neonatal care.

Recitals

1. As originally contemplated, Stanford University established CMQCC as a voluntary statewide reporting program to collect and report hospital-level performance data on maternal and neonatal care in order to improve care and outcomes for mothers and their newborns in California.
2. Participant desires to participate in the Collaborative and to adhere to the principles outlined below, established by CMQCC, for (i) the development and implementation of performance improvement metrics and strategies for maternity and labor and delivery units in California and for (ii) the education of health care consumers through publication of selected, risk-stratified indicators of Participant level performance.
3. CMQCC and Participant desire to enter into this Participation Agreement setting forth the terms relating to the Participant's participation in the Collaborative.

Agreement

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

1. Collaborative Participants. Hospitals with Labor and Delivery Units in the State of California are eligible to participate in the Collaborative. CMQCC will also permit, on a case-by-case basis, hospitals with Labor and Delivery Units located in other States to participate in the Collaborative. All potential CMQCC participants must enter into a participation agreement substantially the same as this Participation Agreement in order to participate in the Collaborative.
2. Purpose and Goals of the Collaborative. The Participant acknowledges that the purpose of the Collaborative is to improve the quality and outcomes of perinatal health care in California through:
 - a) Development of a responsive, real time, statewide maternal and perinatal data system.
 - b) Taking advantage of existing core state and front-end maternal and perinatal data systems.
 - c) Improvement in the accuracy of the data collected for documenting and reporting on maternal and infant health and the provision of maternity care services.
 - d) Development of a collaborative network of public and private obstetric and neonatal providers, insurers, public health professionals and business groups to support a system for benchmarking and continuous performance improvement activities for perinatal care.

3. Release of Information. The purpose of the Collaborative is to improve the care for and outcomes of California's pregnant women and their newborns. In order to fulfill this purpose, the parties recognize the importance of sharing valuable information generated through the Collaborative publically in accordance with the standards set forth in this Participation Agreement and Attachment B. Public release of specific, risk-stratified indicators of quality of care is contemplated to (i) support quality and performance improvement efforts and (ii) provide usable information to consumers of perinatal health care.
- a) In particular, and for general public health purposes, the parties agree that CMQCC shall be entitled to use, publish and/or publically release aggregate data including but not limited to data sets derived from the Participant Data (as defined in Section 7(a) of this Participation Agreement) which is de-identified such that the information cannot reasonably be used to identify any of Participant's patients. Notwithstanding the foregoing, these specific uses, publications or other public releases may identify participants in the Collaborative, including Participant, but shall not identify in any way any performance or other data shared with CMQCC as the Participant's data.
 - b) The parties also agree that CMQCC shall provide Participant-specific reports, which will include Participant-specific information based upon the Participant Data, confidentially to Participant so that Participant may evaluate certain quality and other indicators for purposes of quality improvement and benchmarking by Participant. Collaborative shall provide additional consultation and/or training regarding performance improvement for Participant and as described further in Section 8(h) of this Participation Agreement.
 - c) In addition to use, publication or other release of certain Collaborative information otherwise permitted by this Participation Agreement, the parties also agree that CMQCC shall have the right, but only with explicit authorization in writing and in advance from Participant, to release Participant-specific information to organizations selected by Participant and as described further in Section 9 below.
 - d) In addition, the parties agree that CMQCC shall be entitled to use, publish and/or publically release select quality indicators based on aggregated data that identify the Participant by name, but only for purposes approved in advance by the CMQCC Executive Committee. These select quality indicators shall be based upon Participant Data that is de-identified such that the information cannot reasonably be used to identify any of Participant's patients. Any quality indicators selected for publication or other public release will be communicated to Participant along with comparative data to guide performance improvement efforts at least six months in advance of any publication or other public release date. CMQCC will notify Participant and Participant's Chief of Obstetrics/Maternal-Fetal Medicine and/or designated Administrator of the planned date of publication or other release of any such Participant-specific quality indicators at least sixty (60) days in advance of any such publication or other release by CMQCC. As provided in Section 4(b) of this Participation Agreement, the Participant may terminate this Participation Agreement at any time upon thirty (30) days' written notice to CMQCC, and as provided in Section 10 of this Participation Agreement, and subject to limited exceptions provided in Section 10, any publication by CMQCC based upon the Participant Data after any termination of this Participation Agreement is prohibited.
 - e) Finally, the parties also agree that CMQCC may, from time to time, allow researchers unaffiliated with CMQCC to apply to use, for research purposes, sets of data, which may be based in part upon the Participant Data, but which data, if released to such unaffiliated researchers, shall be de-identified such that the information cannot reasonably be used to identify any of Participant's patients and also de-identified such that the information cannot reasonably be identified as Participant's data. Any such release of information to researchers unaffiliated with CMQCC shall be subject to prior review and approval by the CMQCC Executive Committee or a panel which the CMQCC Executive Committee creates for the specific purpose of reviewing and approving such requests.

4. Term; Termination.

- a) The initial term of this Participation Agreement (“Initial Term”) shall be for a period of three (3) years beginning on the Effective Date, unless sooner terminated as provided herein. At the end of the Initial Term and each Renewal Term (as hereinafter defined), if any, this Participation Agreement shall be automatically renewed for an additional term of one (1) year (each a “Renewal Term”), unless either of the parties provides written notice of non-renewal not less than thirty (30) days prior to the end of the applicable Initial Term or Renewal Term.
- b) Either party may terminate this Participation Agreement at any time without cause upon thirty (30) days’ written notice to the other party. Either party may terminate this Participation Agreement upon breach by the other party of any material provision of this Participation Agreement, provided such breach continues for five (5) days after receipt by the breaching party of written notice of such breach from the non-breaching party and the non-breaching party has not given written authorization for a longer time to cure such breach. This Participation Agreement may be terminated immediately upon the occurrence of any of the following events:
 - (1) Either party closes or discontinues operations to such an extent that program activities cannot be carried out adequately.
 - (2) Participant loses either its license to operate as a hospital under California law or its Medicare certification.

5. Membership. Should the Participant withdraw from the Collaborative, Participant will not be listed in the next publication of the membership as a member.

6. Fees. CMQCC has received start up funds from multiple sources, which are being managed by its fiscal intermediary, Stanford University. As of the date of execution of this Participation Agreement there are no fees to participate in the CMQCC California Maternal Data Center (“CMDC”). Participation fees may be introduced in future years upon sixty (60) days notice to Participant.

7. Participant Obligations. Participant agrees to:

- a) Collect, concurrently with delivery of care to patients, health care process and outcomes data regarding neonatal and maternal conditions and care processes, and to provide the Collaborative with such data in a timely and accurate manner. Specifically, Participant agrees to disclose the following data elements (“Participant Data”), which constitute a Limited Data Set, to CMQCC:
 - Maternal dates of birth;
 - Infant dates of birth;
 - Dates of admission and discharge;
 - Dates of service (dates of delivery);
 - Zip codes;
 - Sex;
 - Race/ethnicity;
 - Principal language spoken by mothers;
 - Principal procedure codes;
 - Other procedure codes (and dates of service);
 - Principal diagnosis;
 - Present on admission principal diagnosis;
 - Other diagnosis codes present on admission;
 - Applicable diagnosis-related group(s);
 - Information, if any, regarding spontaneous rupture of membranes;
 - Active labor information;

- Prior Uterine Surgery;
 - Notation as to exclusive breastfeeding if applicable;
 - Admission type;
 - Disposition of patient;
 - Type of care, and
 - Other clinical metrics, as may be requested from time to time, so long as such metrics are not individual patient identifiers, as defined below.
- b) Report Participant Data on a quarterly or more frequent basis as requested by CMQCC to the CMQCC data center ("CMQCC Data Center") no later than fifty (50) days after the end of any such reporting period. Participant Data are to be submitted via the CMDC web application as specified in instructions provided by the CMQCC CMDC.
 - c) Provide only Participant Data, as specified above, removing all individual patient identifiers,¹ except for a single hospital-assigned unique patient identifier (e.g. Abstract Record Number, Medical Record Number or Hospital Visit Number) (the "Record Identifier") that will be submitted to the CMDC web application by Participant as part of the Participant Data, but which Record Identifier will be encrypted immediately and, in any event, prior to CMQCC having any access to the Participant Data.
 - d) Disclose the Participant Data and Record Identifiers to CMQCC only in accordance with the terms and conditions of the Business Associate Agreement attached hereto as Attachment A.
 - e) Remain at all times the sole keeper of any key for decrypting coded information accessed by CMQCC, including any Record Identifiers held by Participant but encrypted before any CMQCC access.
 - f) Be solely responsible for decisions with respect to use and disclosure of the Participant Data and Record Identifiers anytime before such Participant Data is under the control of CMQCC and for transmission of any Participant Data to CMQCC including any determination as to whether patient authorization is required for transmission of such Participant Data and Record Identifiers to CMQCC.
 - g) Cooperate with CMQCC in connection with CMQCC's exercise of its audit responsibilities as set forth in Section 8(f) below. Such cooperation by Participant may include at times, and as directed by CMQCC, conducting and reporting on Participant's own periodic self-audits of Participant Data in accordance with audit methodologies developed by CMQCC.
 - h) Designate a contact person for the Collaborative, in writing, who will serve as a liaison between the Participant and CMQCC for quality improvement and/or data collection activities.
 - i) Supply hardware (i.e., computers) for data entry.
 - j) Provide appropriate personnel (e.g., physicians, medical records staff or data managers) for training by CMQCC (either in person or by written materials) for purposes of proper collection and submission of Participant Data to CMQCC.

¹ For purposes of this Participation Agreement, individual patient identifiers are defined as the following identifiers of the individual(s) who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual(s): names; postal address information, other than town or city, State, and zip code; telephone numbers; fax numbers; electronic mail addresses; Social Security Numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

- k) Evaluate Participant personnel responsible for maintenance, collection and submission of Participant Data regarding the coding of data in order to assure a minimum standard of data quality, possibly using form evaluation tests that CMQCC may provide to Participant.
- l) Refrain from using quality indicators selected for publication or other public release by CMQCC, including related comparative data, for the purposes of the Participant's marketing or public relations materials.
- m) Securely handle any Participant Data or Record Identifiers uploaded to and accessed through the CMDC web application in the same manner as Participant would handle any personal health information held by covered entity.

8. CMQCC Obligations. CMQCC agrees to:

- a) Provide a web application through CMDC for uploads of the Participant Data, and data entry for specific data elements, in addition to consultation for data collection to or for Participant. CMQCC may also make available a web browser application upon request that the Participant may use for purposes of (i) removing Social Security Numbers from Participant Data, and (ii) previewing file to confirm removal of all Social Security Numbers, prior to transmitting to CMQCC, as required by Section 7(d), subject to any terms and conditions as may be applicable to such application. Regardless of whether Participant uses the web browser application, Participant warrants that it will ensure all Social Security Numbers have been removed prior to submission to CMQCC, which has no need for such identifiers.
- b) Facilitate Participant's own quality improvement analyses and related activities by providing Participant with data quality reports that (i) compare the data elements included in Participant's Participant Data submissions to standard benchmarks and (ii) highlight outlier status for any category of data elements provided by the Participant.
- c) Use and disclose the Participant Data and Record Identifiers only in accordance with the terms and conditions of the Business Associate Agreement attached hereto as Attachment A.
- d) Only release information publicly in accordance with Sections 3 and 9 of this Participation Agreement.
- e) Facilitate Participant's own quality improvement analyses and related activities via the CMDC web application and provide Participant with Participant-specific performance measures on a monthly, quarterly and/or annual basis including comparison to similar hospital, regional and statewide aggregate data as reasonably available; provided, however, that such comparison data shall be blinded except as to Participant such that no other participants will be identifiable through such reports.
- f) Contingent upon the availability of funding, periodically audit any and all Participant Data received by CMQCC for completeness and accuracy and provide a summary of audit findings to Participant. Such audit may include directing Participant to conduct its own periodic self-audits of Participant Data, developing appropriate self-audit methodologies for Participant, and reviewing Participant's results after conducting such self-audits.
- g) Aggregate the Participant Data into the CMQCC limited data set (the "CMQCC Data Set"), which CMQCC Data Set shall be owned and subject to the exclusive control of CMQCC.
- h) Based upon CMQCC expertise and experience, and without the need to use any Participant Data, provide training and consultation on use of the CMDC web application and the metrics generated by the CMDC web application. Any such consultation or training services shall be provided free of charge to Participant if such consultation or training is supported by grant funding to CMQCC. If no grant

funding supports such consultation or training services, such services shall be rendered by CMQCC in accordance with a mutually agreed upon fee schedule.

- i) As the development of the Collaborative progresses, the CMQCC Executive Committee and the CMDC Steering Committee, with participation of certain designated Participant representatives, will select and package perinatal performance indicators suitable for public release.
- j) Through the CMDC web application, provide benchmarking data based on data aggregated across all participants.

9. Reports to Select Outside Organizations.

- a) The Parties hereby recognize and agree that Participant Data may be useful for purposes of supporting the missions and critical healthcare quality improvement and research, evaluation and accreditation agendas of certain key organizations other than Participant and CMQCC. For this reason, the Parties hereby acknowledge and agree that Participant will be given the opportunity to select organizations to which CMQCC may provide reports based upon the Participant Data; Participant's election(s) of organizations with which CMQCC is permitted to share reports based upon the Participant Data will be made in writing and in advance of any release of any reports based on Participant Data as described in Section 3(d) of this Participation Agreement. To the extent required by HIPAA, CMQCC agrees to enter into a Business Associate Agreement or Data Use Agreement, as applicable, with any of the organizations approved in advance and in writing by Participant. Participant may change its election of organizations with which CMQCC is authorized to share reports based on Participant Data at any time upon ninety (90) days written notice to CMQCC.

10. Publication Prohibited after Termination. Upon termination of this Participation Agreement, whether upon expiration of the term or any earlier termination as permitted hereunder, CMQCC agrees that no publication based upon Participant Data shall occur after said termination date; provided that CMQCC shall not be required to recall publications already existing that are based upon such Participant Data.

11. Contact Person for Reports. Participant requests that all communications and reports relating to Participant Data submitted by Participant should be made to the following individual:

12. Limitation of Liability. Participant understands and agrees that CMQCC shall have no liability for any problems relating to the electronic transmission of data or reports, whether due to problems with CMQCC's server, the Participant's service provider, the Participant's use of a third party to submit data, or otherwise.

13. Compliance with Law. The Parties agree to comply with all applicable federal and state laws including without limitation any applicable laws with respect to use, disclosure, re-use or re-disclosure of individually identifiable health information.

14. Independent Contractors. None of the provisions of this Participation Agreement are intended to create any relationship between the parties other than that of independent entities contracting with each other solely for the purpose of effecting the provisions of this Participation Agreement. Nothing in this Participation Agreement shall constitute or be construed as constituting or intending to create an agency, partnership, joint venture, or employer/employee relationship between CMQCC and the Participant. Neither of the parties, nor any of their respective officers, directors, employees, or agents, shall have the authority to bind

the other or shall be deemed or construed to be the agent, employee or representative of the other. Neither party, nor any of their employees or agents, shall have any claim under this Participation Agreement or otherwise against the other party for workers' compensation or any employee benefits of any kind.

15. Notices. Any notice required or permitted to be given to a party under the provisions of this Participation Agreement shall be deemed given if mailed by certified or registered United States mail, first-class, postage prepaid, or nationally recognized courier service, to the contact and address set forth on the signature page hereof. Either party may, from time to time, change its notice address by written notice to the other party in accordance with the provisions of this Section 15.
16. Severability. If any provision of this Participation Agreement is declared invalid or unenforceable, such provision shall be limited and construed so as to make it enforceable or, if such limitation or construction is not possible, such provision shall be deemed stricken from this Participation Agreement. In such event, all other provisions not stricken from this Participation Agreement shall remain in full force and effect, unless such enforcement would be inconsistent with the purposes of this Participation Agreement.
17. Effect on Prior Agreements. This Participation Agreement supersedes all prior agreements, written or oral, and constitutes the entire Participation Agreement between the Participant and CMQCC regarding the subject matter hereof.
18. Counterparts; Facsimiles. This Participation Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.
19. Miscellaneous. This Participation Agreement shall be binding upon and inure to the benefit of CMQCC, the Participant and their successors and assigns. This Participation Agreement shall be governed by and construed under the laws of the State of California, without giving effect to conflict of laws principles. This Participation Agreement may not be modified except in a written amendment signed by both parties.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have duly executed this Participation Agreement as of the Participation Agreement Effective Date.

PARTICIPANT

Signed: _____
Date: _____
Name: _____
Title: _____
Address: _____
Phone: _____
FAX: _____

**THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY**

Signed: _____
Date: _____
Name: Kathleen Thompson
Title: Dean's Office Representative,
School of Medicine, Stanford University

FORM APPROVED COUNTY COUNCIL
BY: NEAL R. KIPNIS DATE

Handwritten signature in blue ink over the printed name NEAL R. KIPNIS.

READ AND UNDERSTOOD:

Signed: _____
Date: _____
Name: Barbara Murphy, RNC, MSN
Title: Project Director
Address: California Maternal Quality Care
Collaborative (CMQCC)
Medical School Office Building
1265 Welch Road, MS 5415
Stanford, CA 94305 USA
Attn: Allana Moore
Cubicle X109
Phone: (650) 725-6108
FAX: (650) 721-5751

Attachment B

California Maternal Quality Care Collaborative Standards for Confidentiality and Public Release of Member Hospital/Group Level Performance

Purpose and Premise:

The purpose of the Collaborative is to improve the perinatal health and outcomes of all California residents *while avoiding unfair competitive advantage for any provider group or agency or further limiting access to care for isolated or disproportionately high risk populations.* In order to provide the consumers of perinatal health care with useful, accurate information upon which to make health care choices, significant results of quality improvement efforts will be formatted and released under the standards for public reporting/benchmarking as listed below.

Standards for any public release of CMQCC information include:

1. The Collaborative owns the CMQCC Data Set, as described at Section 8.g of the CMQCC Participation Agreement (the "Agreement") and Attachment A, and its California Maternal Data Center Steering Committee, with approval by the CMQCC Executive Committee, sets standards for access and level of release of information within the framework of the Agreement and Attachment A.
2. All hospital/group level data remain blinded and confidential except to the individual hospital/group for its own quality improvement except as such significant performance metrics may be designated for public reporting or performance evaluation in a form to be determined by the CMQCC Executive Committee and its subcommittees.
3. Volume requirements, risk stratification and data quality standards are communicated in writing to each participant. Should Collaborative decide that any hospital/group data are insufficient for adequate risk stratification due to volume or quality of reporting, participant will be notified and may choose either to be excluded from that cycle of public reporting or to be included with appropriate notation.
4. A full quality improvement cycle on any selected indicator for public release will be completed prior to any release. This includes a designated period of baseline measurement, a designated period for quality/performance improvement followed by a designated period for post-improvement measurement.
5. Each participant including at least the Participant's Chief of Obstetrics/Maternal-Fetal Medicine and/or designated Administrator will be notified in writing of CMQCC's intent to release hospital/group performance level information at least sixty (60) days prior to any contemplated release.
6. Any public release must have accompanying narrative outlining the strengths, weaknesses and significance of the reported information.
7. Participant may withdraw from having its hospital/group level information publicly released by the Collaborative up to thirty (30) days prior to any public release of hospital/group level information without penalty. Request to withdraw must be in writing and transmitted by hospital/group official in such a manner as to insure receipt by Collaborative office. Should participant withdraw, hospital/group name will be removed from Collaborative membership list.

Attachment A

Business Associate Agreement

This Business Associate Agreement (the "BA Agreement") by and between _____ ("Covered Entity") and The Board of Trustees of the Leland Stanford Junior University, on behalf of the California Maternal Quality Care Collaborative / California Perinatal Quality Care Collaborative within the School of Medicine, ("Business Associate") is effective as of _____ (the "BA Agreement Effective Date") and is entered into pursuant to Section 7 of the Participation Agreement by and between Covered Entity and Business Associate (the "Participation Agreement"). Business Associate and Covered Entity are sometimes referred to herein individually as a "Party" and, collectively, as the "Parties."

RECITALS

WHEREAS, Covered Entity wishes to disclose certain Participant Data, which constitutes a Limited Data Set, to Business Associate for use by Business Associate in performance of the services under the Participation Agreement;

WHEREAS, Covered Entity wishes to also disclose certain Record Identifiers, which may, when maintained in combination with the Limited Data Set, constitute Protected Health Information, for Business Associate to maintain in encrypted format, but not access; and

WHEREAS, Covered Entity and Business Associate wish to ensure that the Participant Data and Record Identifiers are appropriately safeguarded.

NOW, THEREFORE, Covered Entity and Business Associate agree as follows:

1. General Provisions.

1.1 Definitions; Compliance with Law. All capitalized terms used but not otherwise defined in this BA Agreement shall have the meaning set forth in the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology Economic and Clinical Health Act ("HITECH"), and regulations issued thereunder, including but not limited to the privacy regulations under 45 C.F.R. Parts 160 and 164 Subparts A and E (the "Privacy Regulation"), the security regulations under 45 C.F.R. Parts 160 and 164 Subparts A and C (the "Security Regulation"), and the breach notification regulations under 45 C.F.R. Parts 160 and 164 Subparts A and D (the "Breach Notification Regulation") (collectively referred to herein as "HIPAA"), all as may be amended from time to time, and state privacy law, including but not limited to the Confidentiality of Medical Information Act ("COMIA"), as applicable, and state breach notification laws. The parties agree to comply with all applicable federal and state law, including but not limited to HIPAA and state privacy and breach notification law, as may be amended from time to time.

1.2 Effect. The provisions of this BA Agreement shall control with respect to Protected Health Information Business Associate receives from or on behalf of Covered Entity, and the terms and provisions of this BA Agreement shall supersede any conflicting or inconsistent terms and provisions in the Participation Agreement, including all exhibits or other attachments thereto and all documents incorporated therein by reference, to the extent of such conflict or inconsistency. This BA Agreement shall not modify or supersede any other provision of the Participation Agreement.

2. Business Associate's Obligations.

2.1 Use and Disclosure of Protected Health Information. Pursuant to the Participation Agreement, Business Associate provides services for Covered Entity that involve the use and disclosure of Protected Health Information. To the extent Business Associate is performing one of Covered Entity's obligations under the

Privacy Regulation, Business Associate agrees to comply with the legal requirements that apply to Covered Entity in the performance of such obligation. Except as otherwise specified herein, Business Associate may access, use and disclose Protected Health Information received from or on behalf of Covered Entity ("PHI") as permitted or required to perform functions, activities, or services for or on behalf of Covered Entity under the Participation Agreement and this BA Agreement, and as permitted by or Required by Law, but shall not otherwise use or disclose any PHI. In addition, Business Associate is permitted to use or disclose PHI as set forth below:

2.1.1 Business Associate may use PHI internally for its proper management and administrative services or to carry out its legal responsibilities, and as authorized by the Participation Agreement and this BA Agreement;

2.1.2 Business Associate may disclose PHI to a third party for Business Associate's proper management and administration, provided that the disclosure is Required by Law or Business Associate obtains reasonable assurances from the third party to whom the PHI is to be disclosed that the third party will (i) protect the confidentiality of the PHI, (ii) only use or further disclose PHI as Required by Law or for the purposes for which the PHI was disclosed to the third party, and (iii) notify Covered Entity of any instances of which Business Associate is aware in which the confidentiality of the PHI has been breached;

2.1.3 Business Associate may use PHI to provide Data Aggregation services as defined by HIPAA; and

2.1.4 Business Associate may de-identify PHI, consistent with applicable HIPAA requirements.

2.2 Safeguards. Business Associate shall use reasonable and appropriate safeguards to prevent the use or disclosure of PHI except as otherwise permitted or required by this BA Agreement. In addition, Business Associate shall implement Administrative Safeguards, Physical Safeguards and Technical Safeguards set forth under the Security Regulation that reasonably and appropriately protect the Confidentiality, Integrity and Availability of Electronic PHI that it creates, receives, maintains or transmits on behalf of Covered Entity.

2.3 Mitigation. Business Associate shall take reasonable steps to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of this BA Agreement.

2.4 Third Parties. Except as otherwise permitted by this BA Agreement, Business Associate shall ensure that any agent, including a subcontractor, to whom Business Associate provides PHI received from Covered Entity agrees to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such PHI.

2.5 Reporting Improper Disclosures of PHI.

2.5.1 If Business Associate becomes aware of a use or disclosure of PHI in violation of this BA Agreement by Business Associate or by a third party to which Business Associate disclosed PHI, Business Associate shall report any such use or disclosure to Covered Entity without unreasonable delay.

2.5.2 Business Associate shall report any Security Incident involving electronic PHI of which it becomes aware in the following manner: (a) any actual, successful Security Incident will be reported to Covered Entity in writing without unreasonable delay, and (b) any attempted, unsuccessful Security Incident of which Business Associate becomes aware will be reported to Covered Entity orally or in writing on a reasonable basis, as requested by Covered Entity. If the Security Regulation are amended

to remove the requirement to report unsuccessful attempts at unauthorized access, the requirement hereunder to report such unsuccessful attempts will no longer apply as of the effective date of the amendment.

2.5.3 Business Associate shall, following the discovery of a Breach of Unsecured PHI under the Breach Notification Regulation or a breach of PHI under the applicable breach notification laws, notify the Covered Entity of such Breach or breach without unreasonable delay and in no case later than five (5) calendar days after discovery of the Breach or breach.

2.6 Access to Information. Upon receipt of a written request by Covered Entity for access to PHI about an Individual contained in any Designated Record Set of Covered Entity maintained by Business Associate, if any, Business Associate shall make available to Covered Entity such PHI (for so long as Business Associate maintains such information in the Designated Record Set) as required by 45 C.F.R. §164.524. If Business Associate receives a request for access to PHI directly from an Individual, Business Associate shall forward such request to Covered Entity.

2.7 Availability of PHI for Amendment. Upon receipt of a written request from Covered Entity for the amendment of an Individual's PHI contained in a Designated Record Set of Covered Entity maintained by Business Associate, if any, Business Associate shall provide such information to Covered Entity for amendment and incorporate any such amendments in the PHI (for so long as Business Associate maintains such information in the Designated Record Set) as required by 45 C.F.R. §164.526. If Business Associate receives a request for amendment to PHI directly from an Individual, Business Associate shall forward such request to Covered Entity.

2.8 Accounting of Disclosures. Upon receipt of a written notice by Covered Entity to Business Associate that it has received a request for an accounting of disclosures of PHI (other than disclosures to which an exception to the accounting requirement applies), Business Associate shall make available to Covered Entity such information as is in Business Associate's possession and is required for Covered Entity to make the accounting required by 45 C.F.R. §164.528.

2.9 Availability of Books and Records. Following reasonable advance written notice, Business Associate shall make its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary for purposes of determining Covered Entity's compliance with HIPAA.

3. Termination.

3.1 Termination Upon Breach of Provisions Applicable to PHI. Any other provision of the Participation Agreement notwithstanding, the Participation Agreement and this BA Agreement may be terminated by either party (the "Non-Breaching Party") upon thirty (30) days written notice to the other party (the "Breaching Party") in the event that the Breaching Party breaches any provision contained in this BA Agreement in any material respect and such breach is not cured within such thirty (30) day period. If termination of the Participation Agreement and this BA Agreement is not feasible, the Non-Breaching Party may report the Breaching Party's breach to the Secretary of HHS.

3.2 Return or Destruction of PHI Upon Termination. Upon termination of this BA Agreement, Business Associate shall return or destroy all PHI received from Covered Entity in Business Associate's role as Business Associate or created or received by Business Associate as a Business Associate on behalf of Covered Entity and which Business Associate still maintains as PHI. Notwithstanding the foregoing, to the extent that Business Associate reasonably and in good faith determines that it is not feasible to return or destroy such PHI, the terms and provisions of this BA Agreement shall survive termination of the Participation Agreement and such PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such PHI. Nothing herein shall be intended to impose Business Associate requirements on

Business Associate in its role as a provider of care or any activities that are outside of its role as Business Associate.

4. Obligations of Covered Entity.

4.1 Permissible Requests. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done by Covered Entity.

4.2 Minimum Necessary Information. Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, Covered Entity will provide only the minimum necessary PHI for the accomplishment of Business Associate's purpose.

4.3 Consents/Authorization. Covered Entity represents that, to the extent Covered Entity provides PHI to Business Associate, Covered Entity has obtained the consents, authorizations and/or other forms of legal permission required under HIPAA and other applicable law, if any. Covered Entity shall notify Business Associate of any restrictions to, changes in, or revocation of permission by an individual to use or disclose PHI to the extent that such changes may affect Business Associate's use or disclosure of PHI.

5. Miscellaneous.

5.1 Interpretation. Any ambiguity in this BA Agreement shall be interpreted to permit compliance with HIPAA.

5.2 Effect of Agreement. Except as specifically required to implement the purposes of this BA Agreement, or to the extent inconsistent with this BA Agreement, all other terms of the Participation Agreement shall remain in full force and effect.

5.3 Amendment. The Parties agree to take such action as is necessary to amend this BA Agreement from time to time as is necessary for compliance with the requirements of the HIPAA and any other applicable law.

5.4 State Law. Nothing in this BA Agreement shall be construed to require Business Associate to use or disclose the PHI without a written authorization from an individual who is a subject of the PHI, or written authorization from any other person, where such authorization would be required under state law for such use or disclosure.

5.5 No Third Party Beneficiaries. Nothing express or implied in this BA Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Business Associate, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

5.6 Primacy. To the extent that any provisions of this BA Agreement conflict with the provisions of any other agreement or understanding between the parties, this BA Agreement shall control with respect to the subject matter of this BA Agreement.

5.7 Notices. Any notices to be given under this BA Agreement to a Party shall be made via U.S. Mail or express courier to such Party's address set forth below, and/or via facsimile to the facsimile telephone numbers listed below.

If to Covered Entity, to:

Attention: _____
Facsimile: _____

If to Business Associate, to:

with a copy to:

Stanford University
Office of Audit, Compliance and Privacy
616 Serra Street
Encina Hall - Room 10
Stanford, CA 94305-6212
Attn: David Behinfar, Director of Privacy
Facsimile: (650) 725-0073

Stanford University
Office of the General Counsel
Building 170, Third Floor, Main Quad
P.O. Box 20386
Stanford, CA 94305-2038
Attn: Ann James
Facsimile: (650) 723-4323

Each Party may change its address and that of its representative for notice by giving notice thereof in the manner provided above in this Section 5.7.

5.8 Governing Law. This BA Agreement shall be governed by and construed in accordance with the laws of the State of California, without application of principles of conflicts of laws. The Parties hereto agree that any disputes arising under this contract shall be resolved in the California State courts of Santa Clara County, California, or in the Federal District Court for the Northern District of California sitting in San Francisco, California, and the Parties hereby submit themselves to the personal jurisdiction of said courts.

5.9 Counterparts; Facsimiles. This BA Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have duly executed this BA Agreement as of the BA Agreement Effective Date.

COVERED ENTITY

**THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR UNIVERSITY**

Signed: _____
Date: _____
Name: _____
Title: _____

Signed: _____
Date: _____
Name: Kathleen Thompson
Title: Dean's Office Representative,
School of Medicine, Stanford University

READ AND UNDERSTOOD:

Signed: _____
Date: _____
Name: Barbara Murphy, RNC, MSN
Title: Project Director

FORM APPROVED COUNTY COUNSEL
BY: Neal R. Kipnis DATE 1/26/07