REQUEST FOR PROPOSAL

HEMOPHILIA TREATMENT CENTER
REPLACEMENT FACTOR SALES PROGRAM PROVIDER

RFP # 1409HSC-BC

DATE MAILED:  SEPTEMBER 29, 2014
Buyer Contact:  Bill Corbett
Tel #: (916) 734-5951
Fax #: (916) 734-0346
E-mail: william.corbett@ucdmc.ucdavis.edu

DUE DATE:

NOVEMBER 5, 2014
By: 3:00 PM, Pacific Time

Return Response to:

(In person, by mail, email or by courier)
RFP # 1409HSC-BC

Purchasing Department
University of California, Davis, Health System
4800 2nd Avenue, Suite 3010
Sacramento, CA 95817

The University of California Davis, Medical Center web address for downloading this document and any updates until the submittal due date is:
http://www.ucdmc.ucdavis.edu/matmgt/
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### Deviations from specifications:
Any deviation from the specifications shall be identified and fully described. The right is reserved to accept or reject quotations on each item separately, or as a whole, and to waive any irregularities in the quotation; irregularities may, however, render the quotation non-responsive.

### Public disclosure:
Responses to Become Public Records:
All materials submitted in response to this solicitation become a matter of public record and shall be regarded as public record.

### Designation of Confidential Information:
The Regents will recognize as confidential only those elements in each response, which are trade secrets as that term is defined in the law of California and which are clearly marked as ‘TRADE SECRET,’ ‘CONFIDENTIAL,’ or ‘PROPRIETARY.’ Vague designations and blanket statements regarding entire pages or documents are insufficient and shall not bind The Regents to protect the designated matter from disclosure.

The California Public Records Act limits The Regents’ ability to withhold prequalification and bid data to trade secrets or records, the disclosure of which is exempt or prohibited pursuant to federal or state law. If a submittal contains any trade secrets that a Contractor does not want disclosed to the public or used by The Regents for any purpose other than evaluation of the Contractor’s eligibility, each sheet of such information must be marked with the designation “Confidential.” The Regents will notify the submitter of data so classified of any request to inspect such data so that the submitter will have an opportunity to establish that such information is exempt from inspection in any proceeding to compel inspection.

### The Regents Not Liable for Required Disclosure:
The Regents shall not in any way be liable or responsible for the disclosure of any records if they are not plainly marked ‘TRADE SECRET,’ CONFIDENTIAL,’ or ‘PROPRIETARY,’ or if disclosure is required by law or by an order of the court.
I. INTRODUCTION

The University of California, Davis Health System (UCDHS) provides the organizational framework that enables the University of California Davis to fulfill teaching, research, patient-care and public service missions. It consists of the School of Medicine (UCDSOM), the UC Davis Medical Center (UCDMC), the UC Davis Medical Group and several specific centers such as the UC Davis Cancer Center, the UC Davis Children’s Hospital and the UC Davis M.I.N.D. Institute. Together they deliver primary, secondary and tertiary care throughout inland Northern California. The UC Davis Medical Group, the health system’s physician network, includes over 500 physicians and 150 areas of medical specialty geographically dispersed in 25 locations.

UCDMC is one of five teaching hospitals operated by The Regents of the University of California. UCDMC is a 619-bed, fully accredited hospital which serves as the main clinical education site for the UCD School of Medicine. Prior to its acquisition by The Regents in 1973, the hospital was owned and operated by Sacramento County and served as the primary provider of health care to Sacramento’s medically indigent population.

UCDMC is the sole Level 1 trauma center serving the Sacramento-Sierra area and the primary tertiary care referral center for a 32-county area of more than five million residents. Each year UCDMC admits approximately 32,000 inpatients, while its 150-plus clinics log more than 828,000 outpatient and emergency visits.

The UCDHS School of Medicine operates the UC Davis Hemophilia Treatment Center (HTC). The HTC is comprised of both pediatric and adult patients and is currently serving approximately 42 patients with varying severities. The HTC outpatient program provides patients with the option of acquiring their needed pharmaceutical products and supplies from the HTC.

Over the past year approximately 2 million factor units were dispensed to HTC patients; however the HTC program makes no guarantees for any specific volume. The HTC operates its 340B Drug Program in compliance with the office of Health and Human Services, Health Resources and Services Administration (HRSA) 340B Drug Pricing program.

UCDHS is seeking responses from qualified vendors meeting the criteria below and as further detailed in this RFP:

Be or own and operate a pharmacy legally licensed dispensing pharmacy in the state of California able to operate in full compliance with all state and federal laws including, but not limited to the guidelines specified in 10272. Federal Register/Vol. 75, No. 43. Able to demonstrate their experience providing comprehensive 340B pharmacy services to a hemophilia program in similar size a scope as the UCDHS HTC. The provider must be able to provide services to California state patients (i.e. Medi-Cal).

At a minimum the selected vendor(s) shall provide the following services:

Obtain authorization from third party payers, ordering and receiving pharmaceutical products, tracking, safeguarding and full accounting of inventory.
Order Processing – Bidder must be able to accept and process orders between 8:00 a.m. and 5:00 p.m., PST daily excluding weekends and holidays.

Maintain a robust system to provide all required reports on behalf of and to the HTC.

Billing and collecting from patient third party payers.

II. DESIRED SERVICES AND EXPECTATIONS

The purpose of this request for proposal is to solicit information from prospective qualified pharmacies (Bidders) interested in providing specialized pharmaceutical, administrative, billing and accounting services to assist UCDHS in managing the distribution of replacement factor to patients participating in the HTC’s 340B program. The agreement is expected to commence on February 1, 2015 and shall continue for a two year period, with an option for three additional 1 year renewals. Prices are fixed for the initial two year contract period.

It is a MANDATORY requirement that Bidders provide a complete narrative with answers to all statements listed in section IX, the Tier 1 and Tier 2 questions. The narrative response must reference each corresponding section and item number in the order of questions provided on the list. Bidder must be able to meet all requirement identified as “Mandatory.” Any Bidder not meeting a Mandatory requirement will be considered unqualified and eliminated from further consideration.

III. QUESTION AND ANSWER PERIOD

If you have questions or require clarification of various aspects of the RFP, submit them to UCDHS, Bill Corbett via plain text email no later than October 6, 2014 by 3 PM. Individual questions will not be answered directly to submitter. All questions submitted shall be responded to as an addendum to the RFP. The addendum will be emailed to each potential Bidder of record and posted on the UCDHS Purchasing web site at: http://www.ucdmc.ucdavis.edu/matmgt/. The identity of the submitter of any particular question will not be disclosed. Inquiries and questions regarding this RFP will not be entertained after the October 6, 2014 date. Answers to Bidder questions will be posted by October 17, 2014.
IV. ADDENDUM OR SUPPLEMENT TO REQUEST FOR PROPOSAL

UCDHS may modify the RFP prior to the RFP due date, by issuance of amendments sent by email, facsimile, overnight courier or certified mail with return receipt requested to all Bidders who receive a copy of this RFP from UCDHS. Amendments will be clearly marked as such. Each amendment will be numbered consecutively and will become part of this RFP. Any Bidder who fails to receive such amendments shall not be relieved of any obligation under this quotation as submitted. SPECIFICATIONS OR RFP REQUIREMENTS MAY BE REVISED ONLY THROUGH WRITTEN NOTICE OF ADDENDUM ISSUED BY BILL CORBETT, UNIVERSITY OF CALIFORNIA DAVIS HEALTH SYSTEM, PURCHASING DEPARTMENT. CHANGES BY ANY OTHER INDIVIDUAL ARE NOT AUTHORIZED.

V. BASIC OF AWARD/RFP TERMS

The award will be determined by a lowest cost per quality point basis using the criteria shown below. Quality points will be awarded for factors other than cost. Quality points, the number being predetermined by UCDHS, will be awarded by category dependent upon the relative importance of each category.

Proposals will be evaluated using a two-tier evaluation. Bidder responses shall initially be evaluated for factors listed in Tier 1 Prequalification Requirements. To be eligible to advance to the second tier, Tier 2 Technical Qualification, a Bidder must receive at least seventy (70%) of the available Tier 1 quality points and meet the Mandatory requirements. Those Bidders receiving less than (seventy) 70% of the total quality points in the Tier 1 evaluation or unable to meet Mandatory requirements shall be eliminated from further consideration.

To determine the lowest cost per quality point, each Bidder’s cost as outlined in the Cost Proposal will be divided by the total quality points awarded to that particular Bidder’s response for Tier 2 Technical Qualifications and, if necessary, oral presentations. UCDHS reserves the right to only invite Bidders who have scored in the top three ranking to participate in oral presentations. Responses may be evaluated by more than one person. If evaluated by two or more individuals, an average of all the quality points awarded per category will be used.

The Bidder with the lowest cost per quality point shall be given the opportunity to enter into negotiations with UCDHS, if the cost is within the project funding allotment and Bidder’s proposal is in compliance with all terms and conditions expressed within the RFP document. If UCDHS and Bidder are unable to come to satisfactory terms, UCDHS reserves its right to pursue other alternatives, including, but not limited to, awarding the opportunity to negotiate with the next lowest cost per quality point Bidder.

UCDHS reserves the right to award separate contracts to multiple Bidders if in the best interest of UCDHS. UCDHS reserves the right to select partial solutions from the Bidder’s offering. If multiple contracts are awarded, an order preference will be provided to Bidders with the lowest overall cost proposal.
Responses that are incomplete in that there has been failure to respond in all of the requested areas may be disqualified. UCDHS reserves the right to set the criteria for and make this determination independently in each case.

UCDHS reserves the right to accept, reject or waive any irregularities in any proposal. UCDHS reserves the right to reject all responses received in response to this request.

The award of this RFP is contingent upon funding availability.

UCDMC reserves the right to disqualify any Bidder for cause including, but not limited to, the following:

- Misrepresentation and/or omission of facts in the Bidder’s submittal, or in any other communication from Bidder in connection with this submittal request.

- Submission of a proposal deviating from an acceptable range of credible proposals or quotes, which places the Bidder excessively high or excessively low and indicates an unrealistic appraisal of the costs of agreement performance, and which may indicate a lack of understanding of agreement requirements, and which the respondent cannot substantiate, indicating an inability to perform as specified.

- A lack of quality references. UCDHS will be the sole judge of whether a Bidder has the prior experience required for this service needed by the UCDHS HTC.

UCDHS reserves the sole right to determine whether a proposal is responsive and to select a proposal which best serves the interest of the UCDHS. UCDHS also reserves the right to reject all proposals and, if in the best interest of UCDHS, award a contract from any proposal. UCDHS reserves the right to award separate agreements to multiple vendors if in the best interest of UCDHS. UCDHS reserves the right to select partial solutions from the Bidder’s offering. If multiple agreements are awarded, an order preference will be provided to bidders with the lowest overall cost proposal.

Unless otherwise stated, the Bidder’s proposal will be considered valid for a period of six (6) months from the bid due date.

UCHDS is not liable for any cost incurred by Bidders prior to the issuance of an agreement, contract or purchase order

VI. REQUIRED SUBMITTALS

Copies of Proposals

The Bidder is required to submit one (1) signed original, five (5) hard copies of their proposal to include all pages of the RFP and narrative. **Responses must be received no later than 3:00 P.M**
(PST) on, or before November 5, 2014. Responses must be submitted in person, by U.S. Mail, email, or express delivery. Request for Proposal responses should be submitted with the words Hemophilia Treatment Center clearly marked on the outside, referencing the Request for Proposal number (RFP 1409HSC-BC) located on the cover page. Submit responses to:

(In person or by courier)
RFP # 1409HSC-BC
Purchasing Department
University of California, Davis, Health System
4800 2nd Avenue, Suite 3010
Sacramento, CA 95817

VII. TERMS AND CONDITIONS

The terms and conditions for the resulting agreement are stated in this RFP and its Exhibits. Proposed changes and/or modifications to the terms and conditions are not invited and may cause the Bidder’s proposal to be rejected.

The final agreement will be issued by the University of California Davis Health System Contracts office, The Independent Contractor Agreement, (Exhibit A), contains the basic agreement language and upon award and shall incorporate this RFP and the Bidder’s response. To facilitate the project schedule, insurance requirements as outlined in the Exhibit A, must accompany your response. Failure to comply with this requirement may result in cancellation of any agreement resulting from this Request for Proposal.

University of California, Davis Health System, HIPAA Business Associate Amendment, (Exhibit B), is a requirement of any resulting agreement.

The Bidder has prime agreement responsibility; subcontractors may be used, but the prime contractor must accept full responsibility for the subcontractor’s performance. All subcontractors must be identified by the contractor, and the contractor must describe the type of contractual arrangement with all subcontractors. The prime contractor shall be responsible for meeting all terms and conditions of the agreement. UCDHS reserves the right to approve/disapprove all subcontractors.

The contractor, and any subcontractors performing work hereunder, shall maintain accounts, records, documents and other evidence (“Records”) detailing all elements of their costs and supporting all charges made by them under any agreement. These records shall be retained by the contractor and subcontractor for a period of three years from the date of the expirations of any resulting agreement. The system of accounts employed by the contractor and the subcontractors hereunder shall be satisfactory to the University, shall be in accordance with generally accepted accounting principles consistently applied, and shall be subject to inspection and audit by the University and any of its duly authorized representatives at all reasonable times and places.
The Bidder may not distribute any announcement or news release relating to this RFP or the services described herein without written approval by the University of California Davis Health System. Any materials to be provided to regulatory agencies, other entities, or to the public shall be submitted to UCDHS for review and distribution unless otherwise directed by a UCDHS technical representative.

Patient Solicitation – The Bidder hereby agrees not to solicit UC Davis patients during the agreement period or after termination of this contract. The UC Davis HTC staff will coordinate and communicate patient requirements to the contractor. All orders for products to be dispensed will be placed by the contractor on behalf of the UC Davis HTC.

Under the agreement the Contract pharmacy will dispense factor only in the following circumstances:

a) Upon presentation of a prescription bearing the UC Davis heading, the patient’s name, a designation that the patient is 340B eligible for this service and the signature of a legally qualified health care provider affiliated with the UC Davis HTC

Or

b) Upon receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health provider affiliated with the HTC who states that the prescription is for a 340B eligible patient. The HTC will provide a list of all qualified health care providers and will update the list of providers to reflect any changes.

VIII. GENERAL INFORMATION / CERTIFICATION

The bidder shall not maintain or provide racially segregated facilities for employees at any establishment under the bidder’s control. The bidder agrees to adhere to the requirements set forth in Executive Orders 11246 and 11375, and with respect to activities occurring in the State of California, to the California Fair employment and Housing Act Government Code section 2900 et seq.). Expressly, the Bidder shall not discriminate against any employee or applicant for employment because of race, color, religion, sex, national origin, ancestry, medical condition, marital status, age, physical and mental handicap in regard to any position for which the employee or applicant for employment is qualified, or because he or she is a disabled veteran or veteran of the Vietnam era. The Bidder shall further specifically undertake an outreach effort in regards with the hiring, promotion and treatment of minority group persons, women, the handicapped, and disabled veterans and veterans of the Vietnam era. The Bidder shall communicate this policy in both English and Spanish to all people as concerned within its company, with outside recruiting services and the minority community at large. The Bidder shall provide the University on request a breakdown of it labor force by groups, specifying the above characteristics within job categories, and shall discuss with the University its policies and practices relating to its programs.
A) Please complete the vendor contact information requested below:

Company Name ____________________________________________________________

Federal Employer Identification # ___________________________________________

Contact Person/Title ______________________________________________________

Address __________________________________________________________________
________________________________________________________________________

Telephone __________________________ Fax ________________________________

E-mail Address __________________________________________________________

I certify that I am authorized to sign on behalf of the organization I represent for this offer, and agree to all terms and conditions described herein.

_________________________ ________________________________
Date Telephone Number Authorized Signature / Title

________________________________________________________________________
Email Address

IX. PREQUALIFICATION, TECHNICAL QUALIFICATION, COST PROPOSAL

TIER 1 – PRE QUALIFICATION REQUIREMENTS

1. State name, title of principals and total number of employees.

2. Provide year firm’s founding.

3. Provide ownership of company and subsidiary information, if applicable.

4. Provide the address and a general description of your business including, dispensing, storage, and refrigeration capacity.

5. Provide any information that may be a considered a conflict of interest, including but not limited to; identify by name any University position any University officer, faculty member, or other employee who holds a position of director, officer, partner, trustee, manager, or employee in the Bidder’s organization, as well as the name of any near relatives who are employed by the University and any employees or relatives volunteering at University.
6. State total dollar amount of work performed for University in the last twelve months, if any.

7. Attach an organizational chart. Indicate any areas where subcontractors are used and identify such subcontractors (company or individual name).

8. Provide a listing of licensed support staff that will be able to support the resulting agreement. Please indicate the general level of experience the staff has in administering a comprehensive Hemophilia 340B Program. Will you designate a representative who will be the primary contact for UC Davis?

9. Please provide a copy of your pharmaceutical license authorizing you to perform these duties in the State of California. It is a Mandatory requirement that Bidder own or operate a dispensing pharmacy licensed in the State of California.

10. It is a Mandatory requirement that Bidder is able to provide 340B drug services to State of California covered patients, (Medi-Cal). Please state your compliance with this requirement.

11. Does your pharmacy have a licensed pharmacist that is able to dispense 340B drugs and ancillary supplies?

12. State your ability to provide all additional ancillary supplies and non-factor medication as outline in Exhibit C.

13. Provide a description of your experience managing a 340B program.

14. References – The University requires that your references be from academic environments, medical centers over 500 beds, or a designated Hemophilia treatment center with at least 20-30 patients at an individual institution. References must clearly show date(s) of experience, name of customer(s) receiving similar products/services. For each reference, Please provide a name, a title, telephone number, and email address of each of the following:
   a. Physician in charge
   b. Hemophilia Nurse Coordinator
   c. Individual responsible for supervising the 340B Pharmacy

   Furnishing incorrect and/or incomplete reference information may lead to a bidder’s elimination from consideration of award. The decision to eliminate bidder from consideration for award for poor reference checks or for incorrect and/or incomplete reference information shall be at the sole discretion of UCDHS and shall not be subject to appeal.

15. Has your firm had their services terminated by a client in the last 4 years? If so, explain the circumstances of why that business was ended.
16. Exclusion - The Bidder certifies that neither the Bidder, nor its shareholders, members, directors, officers, agents, employees or members of its workforce have been excluded or served a notice of exclusion or have been served with a notice of proposed exclusion, or have committed any acts which are cause for exclusion, from participation in, or had any sanctions, or civil or criminal penalties imposed under, any federal or state healthcare program, including but not limited to Medicare or Medicaid, or have been convicted, under federal or state law (including without limitation a plea of nolo contendere or participation in a first offender deterred adjudication or other arrangement whereby a judgment of conviction has been withheld), of a criminal offense related to (a) the neglect or abuse of a patient, (b) the delivery of an item or service, including the performance of management or administrative services related to the delivery of an item or service, under a federal or state healthcare program, (c) fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in any program operated by or financed in whole or in part by an federal, state or local government agency, (d) the unlawful, manufacture, distribution, prescription or dispensing of a controlled substance or (e) interference with or obstruction of any investigation into any criminal offense described in (a) through (d) above. Each Party further agrees to notify the other Party immediately after the Party becomes aware that any of the foregoing representation and warranties may be inaccurate or may become incorrect.

Bidder acknowledges and agrees:
Notification Requirements-Bidder shall notify UCDHS immediately in the event that (1) Bidder is convicted of a criminal offense related to health care and/or related to the provision of services paid for by Medicare, Medicaid, or another federal health care program; or (2) Bidder is excluded from participation in any federal health care program, including Medicare and Medicaid.

Termination-UCDHS may terminate any resulting Agreement immediately in the event that (1) Bidder is convicted of a criminal offense related to health care and/or related to the provision of services paid for by Medicare, Medicaid or another federal health care program; or (2) Bidder is excluded from participation in any federal health care program, including Medicare and Medicaid.
TIER 2 – TECHNICAL QUALIFICATION

1. Please give a detailed description of your pharmacy’s service philosophy, program and ability to provide the HTC with services described in the RFP. In addition, please provide a complete step-by-step description of your process (patient identification, authorization, ordering, and storage processes ensuring HTC 340B inventory is separate from other inventory, dispensing, billing and collections).

2. Describe any features of your 340B Drug program that distinguish your program from others providing the same or similar services.

3. Describe the process you use to verify insurance coverage and authorization for eligible 340B patients.

4. Describe and provide samples of your status and management reports. Can the reports be customized to meet specific client needs?

5. Describe what information would be available to UCDHS via an on-line web site?

6. Describe your process and the business criteria used for accepting and releasing patient orders to minimize risk.

7. Describe your capability to assist clients with understanding laws and other legal questions related to operating a compliant 340B program.

8. UCDHS would expect billing collections to be no less than 95% of the total bill in the 30 to 45 day range. Describe your process for obtaining prior authorization and issuing billing to payers. Describe your electronic billing capabilities. What are your actual collection percentage and your average amount of days to receive payment?

9. Describe your process for claims follow-up and unpaid billings.

10. What are your expectations of your clients?

11. Describe your technological capabilities for discovery. Do you have access to “EDEX” through DWC?

12. Infectious waste disposal shall be available to all patients as a component of the service fee. Please describe your mechanism for retrieval of used contaminated items.

13. Describe any value added services (e.g. nursing support for in home infusion training or other support services).
COST PROPOSAL

UCDHS is requiring qualified Bidder to submit their proposed cost of services as a flat **cost per unit of factor** rate. The cost per unit of factor shall be all-inclusive (services, ancillary supplies, shipping, infectious waste disposal services for HTC patients, etc).

Pharmaceutical Distribution $___________ Per unit of Factor

Billing $___________ Per unit of Factor

Do you offer a combined rate for pharmaceutical distribution and billing? If so, please provide cost:
Combined rate $___________ Per unit of Factor

Please include any additional cost for providing the services or any valued added service addressed in the Request for Proposal. **Any charges not included in the Cost Proposal will not be accepted and may be cause for cancellation.**

Are the prices you have quoted herein the lowest offered to any federal, state or municipal, similar institution account? Yes ______________. If no, please explain:
Exhibit A

INDEPENDENT CONTRACTOR AGREEMENT

This Agreement is made and entered into in Sacramento, California, by and between THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, a California Constitutional Corporation, on behalf of its University of California Davis Health System ("University") and XXXXX ("Independent Contractor").

The parties agree as follows:

1. The Independent Contractor shall perform the following services to the best of their ability:

If such services are not performed to the sole satisfaction of University, University may terminate this Agreement immediately upon written notification to Independent Contractor.

2. The above-described Services shall be provided at the following day, time, and location.

3. The Independent Contractor shall be paid $________ less state and federal taxes including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661—18677, if applicable. No other payment will be made in advance of work performed except as otherwise specified in this Agreement. Final payment will be withheld pending completion of the work. Invoices may be submitted to:

If applicable, any reimbursement for travel and per diem shall be in accordance with established University rates and policies (http://manuals.ucdavis.edu/ppm/contents.htm#300).

4. Independent Contractor shall provide, at his/her own expense, all equipment, materials, and related services as are necessary to perform as described above.

5. This Agreement may be terminated by either party upon thirty (30) working days' notice to the other.

6. If this Agreement is terminated at any time during the Agreement period and Independent Contractor has satisfactorily completed any of the covenants contained in this Agreement in the time or manner specified, the Independent Contractor will be compensated for all completed services rendered up to and including the last day of service. University reserves the right to determine what shall be deemed completed Services.

7. Both parties agree that in the performance of this Agreement the Independent Contractor will not be an agent or employee of University, and will not be covered by University's Worker's Compensation Insurance or Unemployment Insurance, is not eligible to participate in University’s retirement programs, nor is entitled to any other University benefits.

8. Independent Contractor hereby assigns all right, title and interest, including copyright, to any copyrightable work(s) developed under this Agreement to the University in perpetuity and agrees to execute or produce any and all documents necessary to allow University to register copyright for such works.

9. Independent Contractor shall defend, indemnify and hold University, its officers, employees and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys’ fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorneys’ fees, or claims for injuries or damages are caused
by or result from the negligent or intentional acts or omissions of Independent Contractor, its officers, agents or employees.

University shall defend, indemnify and hold Independent Contractor, its officers, employees and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys’ fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorneys’ fees, or claims for injuries or damages are caused by or result from the negligent or intentional acts or omissions of University, its officers, agents or employees.

10. Insurance Requirements. Independent Contractor warrants he/she shall maintain during the term hereof policies of insurance with minimum coverage as follows:

a. General Liability: Comprehensive or Commercial Form (Minimum Limits)
   1) Each Occurrence $1,000,000
   2) Products, Completed Operations Aggregate $2,000,000
   3) Personal and Advertising Injury $1,000,000
   4) General Aggregate (BI, PD)* $2,000,000

   * (not applicable to comprehensive form)

b. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than $1,000,000 per occurrence.

The above coverage must name The Regents of the University of California as an additional insured. This provision shall apply in proportion to and to the extent of the negligent acts or omissions of the non-University party and any person or persons under the non-University party's direct supervision and control.

c. Workers’ Compensation as required under California State Law.

Check on Professional Liability Insurance

If any insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

11. All notices, requests, or other communications required under this Agreement shall be in writing and shall be delivered to the respective parties by personal delivery; by deposit in the United States Postal Service as certified or registered mail, postage prepaid, return receipt requested; or by a reputable overnight delivery service such as Federal Express. Notices shall be deemed delivered on the date of personal delivery, on the date indicated on the United States Postal Service return receipt, or on the date indicated by express mail receipt, as applicable. Notices shall be addressed to the parties at the addresses set forth below:

**UNIVERSITY:**
Health System Contracts
Sherman Building, Room 2300
2315 Stockton Boulevard
Sacramento, CA 95817

**INDEPENDENT CONTRACTOR:**

Either party may change its address by written notice to the other during the term.

12. This Agreement shall be construed in accordance with the laws of the State of California.

13. To the extent required by applicable law, Independent Contractor shall make available, upon written request from University, the Secretary of Health and Human Services, the Comptroller General of the United States, or any other duly authorized agent or representative, this Agreement and Independent
Contractor’s books, documents and records. Independent Contractor shall preserve and make available such books, documents and records for a period of four (4) years after the end of the term of this Agreement. If Independent Contractor is requested to disclose books, documents or records pursuant to this Section for any purpose, Independent Contractor shall notify University of the nature and scope of such request, and Independent Contractor shall make available, upon written request of University, all such books, documents or records. If Independent Contractor carries out any of the duties of this Agreement through a subcontract with a related organization (“Subcontractor”), with a value or cost of Ten Thousand Dollars ($10,000) or more over a twelve (12) month period, such subcontract shall contain a clause to the effect that until the expiration of four (4) years after the end of the term of such subcontract, the related organization shall make available, upon written request from the Secretary of Health and Human Services, or upon request by the University, Comptroller General of the United States, or any other duly authorized agent or representatives, the subcontract and Subcontractor’s books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

14. Independent Contractor warrants that he/she/it is not excluded from participation in any governmental sponsored program, including, without limitation, the Medicare, Medicaid, or Champus programs (http://exclusions.oig.hhs.gov/search.html) and the Federal Procurement and Nonprocurement Programs (http://epls.arnet.gov/PrivacyActProvisionsEPLS.html). This Agreement shall be subject to immediate termination in the event that Independent Contractor is excluded from participation in any federal healthcare or procurement program.

15. During the performance of this Agreement, Independent Contractor and any and all of its subcontractors shall not unlawfully discriminate against any employee or applicant for employment because of race, religion, color, national origin, ancestry, physical handicap, mental condition, marital status, age, sex, or sexual orientation. Independent Contractor and any and all subcontractors shall ensure that the evaluation and treatment of their employees and applicants for employment are free of such discrimination. Independent Contractor and any and all subcontractors shall comply with the provisions of the Fair Employment and Housing Act (Government Code, Section 12900 et seq.) and the applicable regulations promulgated thereunder (California Administrative Code, Title 2, Section 7285.0 et seq.). The applicable regulations of the Fair Employment and Housing Commission, implementing Government Code, Section 12990, set forth in Chapter 5, Division 4, Title 2 of the California Administrative Code are incorporated into this Agreement by reference and made apart hereof as if set forth in full. Independent Contractor and any and all subcontractors shall give written notice of their obligations under this clause to labor organizations with which they have a collective bargaining or other agreement.

16. No form of the University name shall be used in promotional materials, signs, announcements or other forms of communication or advertising originated by Independent Contractor unless express written permission for such use has been obtained in advance.

17. Each party shall use their best efforts to keep confidential any information provided by the other party and marked “Confidential Information” or any oral information conveyed and followed by a written communication within thirty (30) days that said information shall be considered Confidential Information. Neither of the parties shall have an obligation to preserve the confidential or proprietary nature of any Confidential Information which:

1. was already known to the party free of any obligation to keep it confidential at the time of its disclosure by the disclosing party as evidenced by written records prepared prior to such disclosure; or
2. is or becomes publicly known through no wrongful act of the party to which the Confidential Information was disclosed; or
3. is rightfully received from a third person having no direct or indirect secrecy or confidentiality obligation with respect to such Confidential Information; or
4. is independently developed by an employee, agent or contractor of the party, not associated with the Services and who did not have any direct or indirect access to the Confidential Information; or
5. is approved for release by written authorization of the disclosing party.
6. Disclosure is required by law.

Notwithstanding the above, Independent Contractor understands that University is a public institution and that any information received by University from Independent Contractor will be subject to the California Public Records Act (California Government Code Sections 6250 et seq.).

18. Independent Contractor shall comply with the Health Insurance Portability and Accountability Act of 1996, (“HIPAA”) and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable laws and regulations as further outlined in Exhibit B, attached hereto and made a part hereof.

19. No party to this Agreement may assign this Agreement, assign rights under this Agreement, or delegate duties under this Agreement without prior written consent of the other party hereto. Except as specifically provided in this Agreement, any attempted assignment or delegation of a party’s rights, claims, privileges, duties or obligations hereunder shall be null and void.

20. This Agreement contains all the terms agreed upon by both parties and supersedes all prior written or oral agreements with respect to the subject matter herein. This Agreement may not be amended except in writing and signed by both parties.

INDEPENDENT CONTRACTOR                     THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By_______________________________________  By_______________________________________

Name:_______________________________________  Annie Wong, Director

Title:_______________________________________  Health System Contracts

Date__________________________  Date__________________________

Taxpayer ID #20-8928932

Pursuant to the Federal Privacy Act of 1974, you are hereby notified that disclosure of your social security number is required pursuant to Sections 6011 and 6051 of Subtitle F of the Internal Revenue Code and pursuant to Regulation 4, Section 404, 1256, Code of Federal Regulations, under Section 218, Title II of the Social Security Act, as amended. The social security number is used to verify your identity. The principal uses of the number shall be to report payments and income taxes withheld to Federal and State governments.
This HIPAA Business Associate Agreement ("BA AGREEMENT") supplements and is made a part of any and all agreements entered into by and between The Regents of the University of California, a California corporation ("UNIVERSITY"), on behalf of its University of California Davis Health System and ____________________________ ("BUSINESS ASSOCIATE") and is effective as of __________________ (“Effective Date”). UNIVERSITY has designated all of its HIPAA health care components as a single component of its hybrid entity and therefore this agreement is binding on all other health care components of the UNIVERSITY.

RECITALS

A. UNIVERSITY and BUSINESS ASSOCIATE desire to protect the privacy and provide for the security of Protected Health Information (as that term is defined herein) used by or disclosed to BUSINESS ASSOCIATE in compliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the regulations promulgated thereunder by the U.S. Department of Health and Human Services (45 CFR Parts 160, 162 and 164, the "HIPAA Regulations"), the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"), California Health and Safety Code §1280.15, California Civil Code §§1798.82 and 1798.29, and other applicable laws and regulations. The purpose of this BA AGREEMENT is to satisfy certain standards and requirements of HIPAA, the HIPAA Regulations, including 45 CFR § 164.504(e), and the HITECH Act, including Subtitle D, part 1, as they may be amended from time to time.

B. BUSINESS ASSOCIATE provides services to UNIVERSITY, or performs or assists in the performance of UNIVERSITY activities or functions, involving the use or disclosure of Protected Health Information in the course of such service or assistance.

C. UNIVERSITY wishes to disclose to BUSINESS ASSOCIATE certain information, some of which may constitute Protected Health Information or Medical Information (herein collectively referred to as “PHI”).

Therefore, intending to be legally bound hereby, the parties agree as follows:

1. EFFECT OF AGREEMENT. This BA AGREEMENT amends, supplements and is made a part of any and all agreements between UNIVERSITY and BUSINESS ASSOCIATE, regardless of whether the agreement(s) shall have been entered into before or after the Effective Date of this BA AGREEMENT. To the extent that the terms of the agreement(s) are inconsistent with the terms of this BA AGREEMENT, the terms of this BA AGREEMENT shall control.

2. DEFINITIONS.
2.1 “Breach” means the unauthorized acquisition, access, use, or disclosure of PHI that compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information, and shall have the meaning given to such term under HIPAA and the HIPAA regulations, including 45 CFR §164.402, as well as California Civil Code §§ 1798.29 and 1798.82.

2.2 “Electronic Health Record” means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff, and shall have the meaning given to such term under the HITECH Act, including Section 13400(5).

2.3 “Electronic PHI” means PHI that is transmitted by or maintained in electronic media and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR § 160.103. For the purposes of this BA AGREEMENT, Electronic PHI includes all computerized data, as defined in California Civil Code §§ 1798.29 and 1798.82.

2.4 "Information System" means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR § 164.304.

2.5 “Medical Information” means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient’s medical history, mental or physical condition, or treatment and shall have the meaning given to such term under California Civil Code § 56.05.

2.6 “Protected Health Information” ("PHI") means any information, including Electronic PHI, 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 § 160.103. For the purposes of this BA AGREEMENT, PHI includes all medical information and health insurance information as defined in California Civil Code §§ 56.05 and 1798.82.

2.7 “Secretary” means the Secretary, Department of Health and Human Services, or his or her designee.

2.8 "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an Information System, and shall have the meaning given to such term
under HIPAA and the HIPAA Regulations, including 45 CFR § 164.304.

2.9 “Unsecured PHI” means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of an Encryption or Destruction technology or methodology specified by the Secretary in guidance issued under Section 13402(h)(2) of the HITECH Act on the Health and Human Services Web site, as such guidance may be revised from time to time, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR § 164.402.

2.9.1 “Encryption” means a technology or methodology that utilizes an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key, and such confidential process or key that might enable decryption has not been breached, and shall have the meaning given to such term under HIPAA and HIPAA Regulations, including 45 CFR § 164.304.

2.9.2 “Destruction” means the use of a technology or methodology by which the media on which the PHI is stored or recorded has been shredded, destroyed, cleared, or purged, as appropriate, such that the PHI cannot be read, retrieved, or otherwise reconstructed. Redaction is inadequate for the purposes of destruction.

3. RESPONSIBILITIES OF BUSINESS ASSOCIATE.

3.1 Permitted Uses and Disclosures of PHI. BUSINESS ASSOCIATE may use, access, and/or disclose PHI received by BUSINESS ASSOCIATE solely for the purpose of performing a function or activity for or on behalf of the University. To the extent the BUSINESS ASSOCIATE carries out one or more of UNIVERSITY’s obligation(s) under Subpart E of 45 CFR Part 164, BUSINESS ASSOCIATE must comply with the requirements of Subpart E that apply to the UNIVERSITY in the performance of such obligation(s).

3.1.1 Minimum Necessary. With respect to the use, access, or disclosure of PHI by BUSINESS ASSOCIATE as permitted under section 3.1, BUSINESS ASSOCIATE shall limit such use access, or disclosure, to the extent practicable, to the minimum necessary to accomplish the intended purpose of such use, access, or disclosure. BUSINESS ASSOCIATE shall determine what constitutes the minimum necessary to accomplish the intended purpose in accordance with HIPAA, HIPAA Regulations and any applicable guidance issued by the Secretary.

3.1.2 Documentation of Disclosures. With respect to any disclosures of PHI by BUSINESS ASSOCIATE as permitted under section 3.1, BUSINESS ASSOCIATE shall document such disclosures including, but not limited to, the date of the disclosure, the name and, if known, the address of the recipient of the disclosure, a brief description of the PHI disclosed, and the purpose of the disclosure.

3.1.3 Modification of PHI. Except as permitted under section 3.10.2 below, BUSINESS ASSOCIATE shall not modify any existing data to which it is granted access
other than to correct errors, or derive new data from such existing data. BUSINESS ASSOCIATE shall record any modification of data and retain such record for a period of seven (7) years.

3.1.4 Electronic Transaction Standards. Where applicable, BUSINESS ASSOCIATE shall adhere to the transaction standards as specified in 45 CFR §§ Parts 160 and 162.

3.2 Other Permitted Uses and Disclosures of PHI. BUSINESS ASSOCIATE may, if necessary and only to the extent necessary, use PHI (i) for the proper management and administration of BUSINESS ASSOCIATE’s business, (ii) to provide data aggregation services relating to the health care operations of UNIVERSITY, or (iii) to carry out BUSINESS ASSOCIATE’s legal responsibilities, subject to the limitation in section 3.3, below. BUSINESS ASSOCIATE shall obtain reasonable assurances from the person to whom the PHI is being disclosed that, as required under this BA AGREEMENT, the PHI will be held confidentially and used or further disclosed only as required by law for the purpose for which it was disclosed. BUSINESS ASSOCIATE shall require that any Breaches or Security Incidents be immediately reported to BUSINESS ASSOCIATE. BUSINESS ASSOCIATE shall then report the Breach or Security Incident to UNIVERSITY in accordance with section 3.7.

3.3 Nondisclosure of PHI. BUSINESS ASSOCIATE is not authorized and shall not use or further disclose UNIVERSITY’s PHI other than as permitted or required under any agreement it has with University, including this BA AGREEMENT, or as required by law or regulation.

3.3.1 Disclosures Required by Law. In the event BUSINESS ASSOCIATE is required by law to disclose PHI, BUSINESS ASSOCIATE shall promptly notify UNIVERSITY of such requirement. BUSINESS ASSOCIATE shall give UNIVERSITY sufficient opportunity to oppose such disclosure or take other appropriate action before BUSINESS ASSOCIATE discloses the PHI.

3.3.2 Legal Process. In the event BUSINESS ASSOCIATE is served with legal process or a request from a governmental agency that may potentially require the disclosure of PHI, BUSINESS ASSOCIATE shall promptly, and in any case within two (2) business days of its receipt of such legal process or request, notify UNIVERSITY. BUSINESS ASSOCIATE shall not disclose the PHI without UNIVERSITY’S consent unless pursuant to a valid and specific court order or to comply with a requirement for review of documents by a governmental regulatory agency under its statutory or regulatory authority to regulate the activities of either party.

3.4 Prohibition on Sale of PHI for Remuneration. Subject to the limitations set forth in Section 13405(d)(2) of the HITECH Act, BUSINESS ASSOCIATE shall not directly or indirectly receive remuneration in exchange for any of UNIVERSITY’s PHI unless BUSINESS ASSOCIATE first obtains authorization from UNIVERSITY. UNIVERSITY shall not grant such authorization unless the subject of the PHI has granted UNIVERSITY a valid authorization that includes a specification of whether the PHI can be further exchanged for remuneration by the entity receiving the individual’s
3.5 Security Standards. BUSINESS ASSOCIATE shall take appropriate security measures (i) to protect the confidentiality, integrity and availability of UNIVERSITY's Electronic PHI information that it creates, receives, maintains, or transmits on behalf of the UNIVERSITY and (ii) to prevent any use or disclosure of UNIVERSITY's PHI other than as provided by the Agreement and this BA AGREEMENT. Appropriate security measures include the implementation of the administrative, physical and technical safeguards specified in the HIPAA Security Rule (the Standards for Security of Electronic Protected Health Information at 45 CFR Parts 160, 162, and 164).

3.6 Security Documentation. BUSINESS ASSOCIATE shall maintain the policies and procedures implemented to comply with section 3.5 in written form (paper or electronic). If an action, activity or assessment is required to be documented, BUSINESS ASSOCIATE shall maintain a written record (paper or electronic) of the action, activity, or assessment, shall retain the documentation for six (6) years from the date of its creation or the date when it last was in effect, whichever is later, make documentation available to those persons responsible for implementing the procedures to which the documentation pertains, and review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the PHI.

3.7 Notification of Breaches and Security Incidents. BUSINESS ASSOCIATE shall notify UNIVERSITY in writing as soon as possible, but in no event more than two (2) business days, after BUSINESS ASSOCIATE becomes aware of any Breach of or Security Incident involving UNIVERSITY's PHI. BUSINESS ASSOCIATE shall be deemed to be aware of any Breach or Security Incident as of the first day on which such Breach or Security Incident is known or reasonably should have been known to its officers, employees, agents or subcontractors. BUSINESS ASSOCIATE shall identify as soon as practicable each individual whose unsecured PHI has been, or is reasonably believed by BUSINESS ASSOCIATE to have been, accessed, acquired, or disclosed during such Breach or Security Incident. BUSINESS ASSOCIATE shall cooperate in good faith with UNIVERSITY in the investigation of any Breach or Security Incident.

3.8 Prompt Corrective Actions. In addition to the notification requirements in section 3.7 above, and with prior notice to the UNIVERSITY, BUSINESS ASSOCIATE shall take (i) prompt corrective action to remedy any Breach or Security Incident, (ii) mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by BUSINESS ASSOCIATE, and (iii) take any other action required by applicable federal and state laws and regulations pertaining to such Breach or Security Incident.

3.8.1 Notification of Corrective Action and Provision of Policies. BUSINESS ASSOCIATE will provide written notice to UNIVERSITY as soon as possible but no later than twenty (20) calendar days after discovery of the Breach or Security Incident of (i) the actions taken by BUSINESS ASSOCIATE to mitigate any harmful effect of such Breach or Security Incident and (ii) the corrective action BUSINESS ASSOCIATE has taken or shall take to prevent future similar Breaches or Security Incidents. Upon UNIVERSITY's request, BUSINESS ASSOCIATE will also provide to
UNIVERSITY a copy of BUSINESS ASSOCIATE’s policies and procedures that pertain to the Breach or Security Incident involving UNIVERSITY’s PHI, including procedures for curing any material breach of this BA AGREEMENT.

3.8.2 Lost or Indecipherable Transmissions. BUSINESS ASSOCIATE agrees to make reasonable efforts to trace lost or translate indecipherable transmissions. BUSINESS ASSOCIATE shall bear all costs associated with the recreation of incomplete, lost or indecipherable transmissions if such loss is the result of an act or omission of BUSINESS ASSOCIATE.

3.9 RIGHTS and RESPONSIBILITIES of UNIVERSITY.

3.9.1 Right of UNIVERSITY to Accounting or Audit. Within fifteen (15) calendar days of UNIVERSITY’s request, BUSINESS ASSOCIATE shall provide, at BUSINESS ASSOCIATE’s expense, an audit or written accounting of the uses and disclosures of UNIVERSITY’s PHI made by BUSINESS ASSOCIATE and its Agents, if: (i) UNIVERSITY receives credible information that there has been a Breach or Security Incident involving UNIVERSITY’s PHI, or (ii) if UNIVERSITY determines that the written notice provided in section 3.8.1 does not provide sufficient assurances that the Breach or Security Incident involving UNIVERSITY’s PHI has been remedied.

3.9.2 UNIVERSITY’s Right to Terminate. If BUSINESS ASSOCIATE fails to provide the accounting or audit in a timely manner, or if UNIVERSITY is not satisfied that the corrective action is sufficient to reasonably prevent similar Breaches or Security Incidents in the future, UNIVERSITY may terminate its applicable agreements with BA in accordance with section 5, below.

3.9.3 Costs Related to Inappropriate Use, Access or Disclosure of PHI. If BUSINESS ASSOCIATE fails to adhere to any of the privacy, confidentiality, and/or data security provisions set forth in this BA AGREEMENT or any other agreement it has with UNIVERSITY or if there is a Security Incident or Breach of PHI in BUSINESS ASSOCIATE’s possession and, as a result, PHI or any other confidential information is unlawfully accessed, used or disclosed, BUSINESS ASSOCIATE agrees to pay and reimburse UNIVERSITY for any and all costs, direct or indirect, incurred by UNIVERSITY associated with any Security Incident or Breach notification obligations. BUSINESS ASSOCIATE also agrees to pay for any and all fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting if it fails to notify the UNIVERSITY of the Breach or Security Incident as required by this BA AGREEMENT.

3.9.4 Regulatory Compliance. BUSINESS ASSOCIATE shall make its internal practices, books and records relating to the use, disclosure or security of PHI received from UNIVERSITY (or created or received by BUSINESS ASSOCIATE on behalf of UNIVERSITY) available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining UNIVERSITY’s and/or BUSINESS ASSOCIATE’s compliance with federal/state privacy and security laws and regulations.
3.9.5 Inspection of Records. Within thirty (30) calendar days after UNIVERSITY’s written request, BUSINESS ASSOCIATE shall make available to UNIVERSITY and its authorized agents, during normal business hours, all facilities, systems, procedures, records, books, agreements, policies and procedures relating to the use and/or disclosure of UNIVERSITY's PHI for purposes of enabling UNIVERSITY to determine BUSINESS ASSOCIATE’s compliance with federal/state privacy and security laws and regulations.

3.10 Rights of Individuals.

3.10.1 Individual's Right to Request Restrictions of PHI. BUSINESS ASSOCIATE shall notify UNIVERSITY in writing within five (5) business days after receipt of any request by individuals or their representatives to restrict the use and disclosure of the PHI BUSINESS ASSOCIATE maintains for or on behalf of UNIVERSITY. Upon written notice from UNIVERSITY that it agrees to comply with the requested restrictions, BUSINESS ASSOCIATE agrees to comply with any instructions to modify, delete or otherwise restrict the use and disclosure of PHI it maintains for or on behalf of UNIVERSITY.

3.10.2 Individual's Request for Amendment of PHI. BUSINESS ASSOCIATE shall inform UNIVERSITY within five (5) business days after receipt of any request by or on behalf of the subject of the PHI to amend the PHI that BUSINESS ASSOCIATE maintains for or on behalf of UNIVERSITY. BUSINESS ASSOCIATE shall, within twenty (20) calendar days after receipt of a written request, make the subject's PHI available to UNIVERSITY as may be required to fulfill UNIVERSITY’s obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR § 164.526. BUSINESS ASSOCIATE shall, as directed by UNIVERSITY, incorporate any amendments to UNIVERSITY's PHI into copies of such PHI maintained by BUSINESS ASSOCIATE.

3.10.3 Individual's Request for an Accounting of Disclosures of PHI. BUSINESS ASSOCIATE shall document all disclosures of PHI and, within twenty (20) calendar days after receipt of a written request, make available to UNIVERSITY, and, if authorized in writing by UNIVERSITY, to the subject of the PHI, such information maintained by BUSINESS ASSOCIATE or its agents as may be required to fulfill UNIVERSITY’s obligations to provide an accounting for disclosures of UNIVERSITY's PHI pursuant to HIPAA, the HIPAA Regulations, including, but not limited to, 45 CFR § 164.528, and the HITECH Act, including, but not limited to Section 13405(c).

3.10.4 Electronic Health Records. If BUSINESS ASSOCIATE, on behalf of UNIVERSITY, uses or maintains Electronic Health Records with respect to PHI, UNIVERSITY may provide an individual, upon the individual's request, with the name and contact information of BUSINESS ASSOCIATE so that the individual may make a direct request to BUSINESS ASSOCIATE for an accounting of disclosures made by BUSINESS ASSOCIATE during the three (3) years prior to the date on which the accounting is requested or as otherwise provided under the HITECH Act Section 13405(c)(4)(A) or Section 13405(c)(4)(B).
3.10.5 Access to PHI by the Individual. If UNIVERSITY determines that an individual's PHI is held solely by BUSINESS ASSOCIATE or if BUSINESS ASSOCIATE is acting on behalf of UNIVERSITY to provide access to or a copy of an individual's PHI, BUSINESS ASSOCIATE shall, within five (5) calendar days after receipt of a written request, make available to UNIVERSITY, and, if authorized in writing by UNIVERSITY, to the subject of the PHI, such information as may be required to fulfill UNIVERSITY’s obligations to provide access to or provide a copy of the PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR § 164.524.

3.10.6 Access to Certain Information in Electronic Format. If BUSINESS ASSOCIATE uses or maintains Electronic Health Records with respect to PHI on behalf of UNIVERSITY, BUSINESS ASSOCIATE shall, upon request of UNIVERSITY, provide UNIVERSITY with the requested Electronic Health Record in an electronic format.

3.11 Compliance with Law. In connection with all matters related to this BA AGREEMENT, BUSINESS ASSOCIATE shall comply with all applicable federal and state laws and regulations, including, but not limited to, HIPAA, the HIPAA Regulations, 45 CFR §§ Parts 160, 162 and 164, and the HITECH Act, Subtitle D, part 1, California Civil Code §1798.29 and California Health and Safety Code §1280.15, as they may be amended from time to time.

4. BUSINESS ASSOCIATE’S AGENTS. Other than as expressly authorized herein, BUSINESS ASSOCIATE will provide UNIVERSITY's PHI only to persons or entities, including subcontractors, that have an agency relationship to BUSINESS ASSOCIATE and that have been approved in advance by UNIVERSITY (“Agents”). BUSINESS ASSOCIATE will provide PHI to Agents solely for the purposes of carrying out the Agreement.

4.1 BUSINESS ASSOCIATE shall require such Agents to agree to the same restrictions and conditions that are imposed on BUSINESS ASSOCIATE by this BA AGREEMENT, and to provide written assurance of such agreement, including, but not limited to, sections 3.5 (“Security Standards”), 3.6 (“Security Documentation”) and 3.7 (“Notification of Breaches and Security Incidents).

5. TERMINATION AND OTHER REMEDIES.

5.1 Material Breach. A breach by either party of any material provision of this BA AGREEMENT shall constitute a material breach of the agreement(s) between UNIVERSITY and BUSINESS ASSOCIATE. Either party, upon written notice to the other party describing the breach, may take any of the following actions:

5.1.1 Terminate all applicable agreements, including this BA AGREEMENT, immediately if the other party has breached a material term of this BA AGREEMENT.

5.1.2 Terminate the applicable agreement(s), including this BA AGREEMENT, unless the other party, within five (5) business days, provides a plan to cure the breach and, within fifteen (15) business days, cures the breach;
5.1.3 In the case of a material breach of the BA AGREEMENT, if termination is not feasible, upon the non-breaching party’s request, the breaching party shall:

(a) at its expense, provide a third-party review of the outcome of any plan implemented under section 5.1.2. to cure the breach;

(b) at its expense, submit to a plan of monitoring and reporting to demonstrate compliance with the BA AGREEMENT.

5.2 Effect of Termination - Return or Destruction of PHI held by BUSINESS ASSOCIATE or BUSINESS ASSOCIATE's Agents. Upon termination, expiration or other conclusion of the BA AGREEMENT for any reason, BUSINESS ASSOCIATE shall return or, at the option of UNIVERSITY, provide for the Destruction of all PHI received from UNIVERSITY, or created and received by BUSINESS ASSOCIATE on behalf of UNIVERSITY in connection with the BA AGREEMENT, that BUSINESS ASSOCIATE or its Agents still maintains in any form, and shall retain no copies of such PHI. Within thirty (30) calendar days after the termination of this BA AGREEMENT, BUSINESS ASSOCIATE shall both complete such return or Destruction and certify in writing to UNIVERSITY that such return or Destruction has been completed.

5.3 Return or Destruction Not Feasible. If BUSINESS ASSOCIATE represents to UNIVERSITY that return or Destruction of UNIVERSITY’s PHI is not feasible, BUSINESS ASSOCIATE must provide UNIVERSITY with a written statement of the reason that return or Destruction by BUSINESS ASSOCIATE or its Agents is not feasible. If UNIVERSITY determines that return or Destruction is not feasible, this BA AGREEMENT shall remain in full force and effect and shall be applicable to any and all of UNIVERSITY’s PHI held by BUSINESS ASSOCIATE or its Agents.

5.4 Other Remedies. Notwithstanding the foregoing rights to terminate the Agreement, UNIVERSITY shall have such other remedies as are reasonably available at law or equity, including injunctive relief.

5.5 Civil and Criminal Penalties. BUSINESS ASSOCIATE understands and agrees that it is subject to civil or criminal penalties applicable to BUSINESS ASSOCIATE for unauthorized use, access or disclosure of PHI in accordance with the HIPAA Regulations and the HITECH Act.

6. CHANGES TO THIS BA AGREEMENT.

6.1 Compliance with Law. The parties acknowledge that state and federal laws and regulations relating to electronic data security and privacy are rapidly evolving and that additional obligations and responsibilities may be imposed on BUSINESS ASSOCIATE to ensure compliance with the new laws and regulations. The parties specifically agree to comply with all applicable laws and regulations and take such action as may be necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations, the HITECH Act, and other applicable state and federal laws.
and regulations relating to the security or confidentiality of PHI, without need to amend or modify this BA AGREEMENT.

7. INSURANCE AND INDEMNIFICATION.

7.1 Insurance. In addition to any general and/or professional liability insurance coverage required of BUSINESS ASSOCIATE under the Agreement, BUSINESS ASSOCIATE agrees to obtain and maintain, at its sole expense, liability insurance on an occurrence basis, covering any and all claims, liabilities, demands, damages, losses, costs and expenses arising from a breach of the security, privacy, or confidentiality obligations of BUSINESS ASSOCIATE, its officers, employees, agents and subcontractors, under this BA AGREEMENT. Such insurance coverage shall be maintained for the term of the Agreement, and a copy of such policy or a certificate evidencing the policy shall be provided to UNIVERSITY at UNIVERSITY’s request.

7.2 Indemnification by BUSINESS ASSOCIATE. BUSINESS ASSOCIATE agrees to defend, indemnify, and hold harmless UNIVERSITY, its officers, employees and agents from and against any and all claims, liabilities, demands, damages, losses, costs and expenses (including reasonable attorneys’ fees), or claims for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent such claims, liabilities, demands, damages, losses, costs and expenses (including costs and reasonable attorneys’ fees), or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of BUSINESS ASSOCIATE, its officers, employees or agents.

7.3 Indemnification by UNIVERSITY. UNIVERSITY agrees to defend indemnify, and hold harmless BUSINESS ASSOCIATE, its officers, agents and employees from and against any and all claims, liabilities, demands, damages, losses, costs and expenses (including reasonable attorneys’ fees), or claims for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent such claims, liabilities, demands, damages, losses, costs and expenses (including reasonable attorneys’ fees), or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of UNIVERSITY, its officers, employees or agents.

8. MISCELLANEOUS PROVISIONS.

8.1 Assistance in Litigation or Administrative Proceedings. BUSINESS ASSOCIATE shall make itself, and any employees or agents assisting BUSINESS ASSOCIATE in the performance of its obligations under this BA AGREEMENT, available to UNIVERSITY at no cost to UNIVERSITY to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings against UNIVERSITY, its directors, officers, agents or employees based upon claimed violation of HIPAA, the HIPAA Regulations or other laws relating to security and privacy.

8.2 Independent Contractor. BUSINESS ASSOCIATE is an independent contractor and nothing in this BA AGREEMENT is intended to create or imply an agency or employment relationship between UNIVERSITY and BUSINESS
8.3 No Third-Party Beneficiaries. Nothing express or implied in this BA AGREEMENT is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than UNIVERSITY, BUSINESS ASSOCIATE and its respective agents, successors or assigns.

8.4 Number. Where the context admits, words in the plural include the singular, and the singular includes the plural.

8.5 Survival. The obligations of BUSINESS ASSOCIATE under Sections 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 5.2, 5.3, 5.5, 7.2, 7.3, and 8.1 of this BA AGREEMENT shall survive the termination of any agreement between UNIVERSITY and BUSINESS ASSOCIATE.

8.6 Notices. Any notices to be given to either party shall be made via U.S. Mail or express courier to the address given below and/or via facsimile to the facsimile telephone numbers listed below.
If to BUSINESS ASSOCIATE, to: With a copy (which shall not constitute notice) to:

___________________________ _______________________________  ______________________________
___________________________ _______________________________  ______________________________
___________________________ _______________________________  ______________________________
Attention: __________________ Attention: ______________________
Fax: ______________________ Fax: __________________________

If to UNIVERSITY, to: With a copy (which shall not constitute notice) to:

Health System Contracts  ______________________________
Sherman Building, Suite 2300 ______________________________
University of California Davis Health System  ______________________________
2315 Stockton Boulevard ______________________________
Sacramento, CA  95817 ______________________________
Attention: Director Attention: ______________________
Fax: 916-734-3520 Fax: __________________________

Each party may change its address and that of its representative for notice by giving notice in the manner provided above.
IN WITNESS WHEREOF, the parties hereto have duly executed this BA AGREEMENT.

The Regents of the University of California on behalf of its University of California
Davis Health System

[Name of BUSINESS ASSOCIATE]

___________________________________ ______________________________
Signature Signature

Annie Wong ______________________________
Printed Name Printed Name

Director, UC Davis Health System Contracts
Title

___________________________________ ______________________________
Date Date
Ancillary Infusion Supplies (including but not limited to, the following)

Ace bandages - various sizes
Alcohol wipes
Adhesive tape remover pads
Alcohol swab sticks
Band-Aids - “stretch”
Betadine wipes
Betadine swab sticks
Butterfly infusion sets - various sizes/brands
Central line dressing change kits
Chux
Opsite 3000 dressings
Other central line supplies as needed
Cath No-activated
Exam gloves - variety of sizes
Sterile gloves - variety of sizes
Factor packers
2 x 2 gauze pads
4 x 4 gauze pads
Hep-lock solution for injection
Huber needles - variety of sizes
Injection caps
Normal saline for injection
Normal saline wipes
Paper tape - variety of sizes
3-way stopcocks
Straight needles - variety of sizes
Syringes - variety of sizes/brands
Tegaderm dressings
Tourniquets
Transfer needles
NON-FACTOR MEDICATIONS PRESCRIBED BY THE UC DAVIS HEMOPHILIA PROGRAM
(PLEASE NOTE THAT THE DRUGS NAMED ARE EXAMPLES OF COMMONLY PRESCRIBED MEDICATIONS
THE LIST IS NOT EXCLUSIVE)

PEDIATRIC and ADULT

Amicar syrup and tablets *
Stimate nasal spray *
Desmopressin Acetate for Injection

Analgesics
Tylenol with codeine
NORCO/Lortabs
EMLA cream

Non-steroidal anti-inflammatory drugs
Trilisate
Celebrex
Motrin

Antibiotics
Amoxicillin
Ceclo\nSeprla
Acyclovir
Dapsone
Neosporin ophalmic ointment

HIV Medications
Abacavir
D4T
Epivir
Ritonavir
Saquinavir
Sustiva
Tenofovir
Viracept
Viramimmune

GI Medications
Propranolol
Prilosec
Lomotil

Hepatitis C Medications
Pegylated Interferon
Ribavirin

* These items must be kept in stock as they are used to treat bleeding episodes and often need to be dispensed for next day delivery.